FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **268143-5 (S)** **Related reports:** 268143-1; 268143-2; 268143-3; 268143-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	--	WAES0810USA00861	06-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Gluteous maxima	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Guillain-Barre syndrome

Symptom Text: Information has been received form a nurse practitioner, she knew a pediatric nurse that reported a female who on an unspecified date was vaccinated with GARDASIL vaccine and 24 hours after receiving vaccine the patient experienced Guillain-Barre Syndrome and was hospitalized. No other information reported. Additional information has been requested

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **276540-2 (S)** **Related reports:** 276540-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-Mar-2007	02-Apr-2007	13	05-May-2009	11-May-2009	CO		11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Blood culture negative, Blood pressure decreased, Fatigue, Hyperthermia, Intensive care, Laboratory test normal, Myalgia, Pyrexia, Sepsis, Toxic shock syndrome

Symptom Text: Shortly after the second GARDASIL shot in the series at the end of March 2007, my daughter became mysteriously ill, with very severe muscle pains and fever on 4/2/2007. On 4/4/2007, the condition worsened. She was brought to the ER where her blood pressure dropped drastically and symptoms intensified. She was airlifted to another hospital, nearly died, and spent a week in the ICU. For the next year, she was fatigued and overheated very easily. The physicians never came up with a definitive diagnosis. They suspected toxic shock syndrome, septicemia or some other infection, but no infection site was located, and all blood cultures and other tests were negative. Her illness remains a total mystery. My wife and I suspect that it could have been an immunologic reaction to the GARDASIL vaccine, and what we have learned since then seems to support this.

Other Meds:

Lab Data: I would have to request from MD.

History: None.

Prex Illness:

Prex Vax Illns:

Vaers Id: **277352-2 (S)** **Related reports:** 277352-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
50.0	F	21-Feb-2007	03-Apr-2007	41	27-May-2008	29-May-2008	MI		29-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0243U	0	Left arm	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Facial palsy, Guillain-Barre syndrome, Inappropriate schedule of drug administration, Miller Fisher syndrome, Nerve injury, Neurological symptom, Paraesthesia, Visual disturbance

Symptom Text: Facial tingling started 4/1/07. Total bilateral facial paralysis of sudden onset. Diagnosis: Guillain-Barre syndrome (GBS) Miller Fisher facial variant. Multiple related facial, cranial nerves, vision, whole body, etc. Impairments & symptoms.

Other Meds: MINOCIN

Lab Data: MRI's, EMG's, Spinal Taps (2), Blood work and labs, etc.

History: None; Prior fully treated Lyme disease

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **277622-2** **Related reports:** 277622-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Apr-2007	17-Apr-2007	10	17-Sep-2008	21-Oct-2008	--	WAES0808USA04045	22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abasia, Arthralgia, Influenza like illness, Joint swelling, Muscular weakness, Pain

Symptom Text: Information has been received from a physician and a registered nurse (RN) concerning a 17 year old female who on 31-JAN-2007, 07-APR-2007 and 07-AUG-2007 was vaccinated with a 0.5 ml first, second and third doses of GARDASIL vaccine (yeast) (lot #655617/1447F, 657617/0384U and 658222/0927U), respectively. The RN reported that a week and one half after the second dose, on approximately 17-APR-2007 the patient developed flu like symptoms with body ache. Following the third dose of GGARDASIL vaccine (yeast), the patient developed joint swelling and pain with muscle weakness that started in November of 2007. The symptoms got progressively worse to the joint where the patient could not walk. The patient consulted an infectious disease specialist, various testing were performed but the results were negative. The joint swelling and pain with muscle weakness was continued to present. The patient presently was "better" as far as the joint pain, but still had mild joint pain and muscle weakness. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **279595-2 (S)** **Related reports:** 279595-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	01-Nov-2006		14-Jul-2008	15-Jul-2008	CT	WAES0807USA00756	16-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anxiety, Central nervous system lesion, Paraesthesia, Pharyngolaryngeal pain, Syncope, Vertigo, Vomiting

Symptom Text: Information has been received from a physician concerning a 17 year old female with asthma who was vaccinated with GARDASIL. In November 2006, the patient experienced paraethesias of the left thumb, left hand and right forearm and was hospitalized. On an unspecified date the patient experienced anxiety and sore throat. On 14-MAY-2007 the patient experienced syncope, paresthesias of the left hand, right fingers and right toes and vomiting. The patient sought unspecified medical attention. On 15-MAY-2007 head computed tomography showed possible low attenuation of the region of the left occipital lobe. This may represent a chronic area of old infarction. Recommend magnetic resonance imaging (MRI) to further evaluate. On 15-MAY-2007, the brain MRI showed multiple periventricular white matter lesions, tube which demonstrated enhancement following contrast administration. Findings may be related to an active demyelinating process such as multiple sclerosis versus a post viral acute disseminated encephalomyelitis. Correlation with cerebrospinal fluid was recommended. On 18-MAY-2007 cerebrospinal fluid (CSF) cytopathology performed for a history indicating vertigo, was negative for malignant cells. There was rare clusters of small lymphocytes. Enterovirus shell viral culture indicated no virus was detected. On 18-MAY-2007 complete blood count with differential was within normal limits except for mean corpuscular hemoglobin (MCH) was 31.5 and granulocytes were 71.9. Antinuclear antibody screen, rheumatoid factor, sedimentation rate, component C3 test and component C4 test were within normal limits. A complement total CH50 was 64, Lyme AB screen with reflex western blot showed no detectable antibody, serum IGG was high at 1656 and a miscellaneous fatty acid profile was within normal limits. Serum Borrelia burgdorferi IgM Western blot antibody and serum Borrelia burgdorferi IgG Western blot antibody tests did not detect antibodies. CSF Myelin Basic Protein was negative. However, the oligoclonal IGG bands showed that the pat

Other Meds: Unknown

Lab Data: magnetic resonance, 05/19/07, abnormal; spinal X-ray, 05/19/07, abnormal; chest X-ray, 05/19/07, abnormal; magnetic resonance, 05/15/07, abnormal; diagnostic laboratory, 05/06/08, neuromyelitis optica autoantibody, IgG test: Negative; diagn

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **281400-2** **Related reports:** 281400-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-May-2007	04-May-2007	1	23-May-2008	01-Jul-2008	MI	WAES0706USA00299	01-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	76220388U	0	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	61221309F	1	Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site discomfort, Injection site swelling, Injection site urticaria

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female (previously reported as male) who on 03-MAY-2007 was vaccinated SC with a second dose of varicella virus vaccine live (Oka/Merck) (Lot#656122/1309F). Additional suspect vaccination included an IM first dose of Gardasil (Lot# 657622/0388U). Subsequently the patient developed a raised welt, swelling and discomfort at the injection site which was the size of a softball. Unspecified medical attention was sought. Subsequently, the patient recovered. No further information was provided. There was no product quality complaint involved. Additional information is not expected. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **282372-2 (D)** **Related reports:** 282372-1; 282372-3; 282372-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		21-Jul-2008	22-Jul-2008	CA	WAES0807USA03098	31-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: SERIOUS, DIED, LIFE THREATENING, PERMANENT DISABILITY

MedDRA PT Death, Unresponsive to stimuli

Symptom Text: Information has been received from a medical assistant concerning a 22 year old female with no known medical history and no known allergies who was vaccinated with GARDASIL. Subsequently the patient experienced an unexplainable death. The mother of the patient found her daughter unresponsive and dead in her bed. It was noted that this death was reported to VAERS and the death was not caused by GARDASIL. It is unknown if medical attention was sought. The medical assistant considered the death to be disabling and life-threatening. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **283952-2** **Related reports:** 283952-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-May-2007	08-May-2007	0	23-May-2008	01-Jul-2008	NY	WAES0705USA02671	01-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	SANOFI PASTEUR	NULL	0	Right arm	Subcutaneously	
	VARCEL	MERCK & CO. INC.	0169U	1	Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	188U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site reaction, Injection site swelling, Pain in extremity

Symptom Text: Information has been received from a healthcare employee concerning an 18 year old female who on 08-MAY-2007 was vaccinated with VARIVAX (Lot # 656078/0169U). Concomitant vaccine therapy administered at the same time included a first dose of GARDASIL. On 08-MAY-2007 the patient developed a local injection site reaction in the arm with swelling and redness. Symptoms resolved without any treatment. No other information was available at the time of this report. Unspecified medical attention was sought. No product quality complaint was sought. Additional information has been requested. Follow-up information received from a certified medical assistant stated that on 08-MAY-2007, the patient was vaccinated with a second subcutaneous dose of VARIVAX in the upper left arm. A first intramuscular dose of GARDASIL (Lot # 657006/0188U) was given in the left deltoid. A first subcutaneous dose of MENOMUNE (Lot # U2278AA) was given in the upper right arm on 08-MAY-2007. The patient stated that her arms hurt the day of injection, 08-MAY-2007 and then redness and swelling appeared on 09-MAY-2007 which lasted until 13-MAY-2007. The patient was seen on 11-MAY-2007 and the redness was approximately a quarter size. Subsequently, the patient recovered.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

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Vaers Id: **284013-2** **Related reports:** 284013-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Jun-2007	28-Jun-2007	3	23-May-2008	01-Jul-2008	NY	WAES0707USA04854	01-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0644U	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Induration, Tenderness

Symptom Text: Information has been received from a health professional concerning a 14 year old female student with no medical history or allergies, who on 25-JUN-2007 at 13:12, was vaccinated with her second SC dose of varicella virus vaccine live (Oka/Merck) (lot# 657783/0644U) in the right arm. Concomitant vaccination administered that day at 13:12 included a first IM dose of Gardasil vaccine (MDS) (lot# 658094/0524U) in the left arm. There was no illness at the time of vaccination. On 28-JUN-2007, at 14:59 the patient developed a 4-5 cm diameter area of the right arm that was red, hard, and slightly tender for 2 days, with induration 2 cm within, over the right tricep. No medical attention was sought. No labs or diagnostic studies were performed. The patient was reassured and advised to apply an ice pack and take Motrin. Subsequently the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **284274-2 (S)** **Related reports:** 284274-1; 284274-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Jul-2007	03-Jul-2007	0	11-Feb-2009	16-Feb-2009	AZ		16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0181U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Dyspnoea, Erythema nodosum, Headache, Immediate post-injection reaction, Loss of consciousness, Mass, Neurological examination normal, Pyrexia

Symptom Text: Pt had immediate reaction to the shot which was reported by the office at that time. The patient was seen in the Emergency room a week later with fevers and shortness of breath. She developed lumps on her legs and she was diagsnosed with erythema nodosum at that time. The patient continues to have neurologic issues with passing out, headaches, shortness of breath. The lumps on her legs are resolved. Pt has had neurologic workup which was unremarkable.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **284274-3 (S)** **Related reports:** 284274-1; 284274-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Sep-2008	01-Oct-2008	30	18-Mar-2009	19-Mar-2009	--	WAES0903USA01837	30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Amnesia, Apnoea, Cough, Dizziness, Dyspnoea, Gaze palsy, Headache, Hypoaesthesia, Loss of consciousness, Malaise, Migraine, Orthostatic hypotension, Posture abnormal, Presyncope, Syncope, Vision blurred

Symptom Text: Information has been received from a consumer concerning his 14 year old granddaughter with a history of migraine who in September 2008, was vaccinated with a dose of GARDASIL. In October 2008 (on an unspecified time after vaccination), the patient experienced abdominal pain and headaches. Her symptoms had been getting more pronounced and more frequent. Since December 2008, the patient had spent more time out of school than in school. On approximately 18-FEB-2009 ("three weeks ago") the patient was doing homework and was feeling well. Then she began to look unwell and laid down on the couch. As her grandparents watched, the patient's body started to "draw up", her hands became claws, and she developed numbness in her legs and hands. Then she developed extreme shortness of breath and coughing. Her head rolled back, her eyes crossed, she passed out and stopped breathing. Paramedics were called and she was taken to a hospital. This was about the seventh time the patient had gone to the ER in the last two months. Oxygen was given in the ambulance. By the time she reached the hospital the patient was responding. After this episode the patient lost her memory for a week and only recognized a few people. The patient was later released from the ER. In the last 2.5 months the patient had spent two nights in the hospital. While at a children's hospital for testing, the patient fainted and was admitted for testing for one week. The patient had had migraines lasting as long as a month. Numerous MRIs and CAT scans were performed. On 10-MAR-2009 (" Last night") the patient went to the ER. All tests had come up with no diagnosis. Unknown medications had not worked. At the time of reporting, the adverse events persisted. Additional information has been requested. 4/10/09-records received for DOT 9/7/08-consult for evaluation of syncope. Initial syncopal episode 1-2 years ago however this past week epxperienced 3-4 episodes with 1st episode ocurring 9/3/08 when running for about half an hour and started feeling dizzy and passed

Other Meds: Unknown

Lab Data: Unknown 4/10/09-records received-CBC normal, electrolytes normal, normal LFTs, potassium low 2.9. TSH normal. EKG normal sinus rhythm with sinus bradycardia. Echocardiogram normal. CT of head normal.

History: Migraine 4/10/09-records received-PMH: GI history of reflux. Cardiac history of syncope.

Prex Illness:

Prex Vax Illns:

Vaers Id: **286091-2** **Related reports:** 286091-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	26-Feb-2007	27-Feb-2007	1	23-May-2008	01-Jul-2008	CO	WAES0708USA00434	01-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0187U	0	Left leg	Unknown	
	VARCEL	MERCK & CO. INC.	1308F	1	Right leg	Unknown	
	HEPA	MERCK & CO. INC.	1280F	0	Left leg	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Tenderness

Symptom Text: Information has been received from a health professional concerning an 11 year old female, who on 26-FEB-2007 was vaccinated with a second dose of varicella virus vaccine live (Oka/Merck) (lot# 656081/1308F) in the right thigh. Concomitant vaccinations administered that day included the first dose of Gardasil vaccine(MSD) (lot # 656049/0187U) in the left thigh and the first dose of hepatitis A virus vaccine inactivated (MSD) (lot#656071/1280F) in the left thigh. On 27-FEB-2007, the patient experienced 2' X 2' spot that was solid, red, swollen and tender. Unspecified medical attention was sought. Subsequently, the patient recovered. No product quality complaint was involved. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **286297-2** **Related reports:** 286297-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Jul-2007	Unknown		23-May-2008	23-Jun-2008	CO	WAES0708USA00539	24-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0600U	1	Left leg	Unknown	
	HPV4	MERCK & CO. INC.	0524U	0	Right leg	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site pain, Injection site pruritus, Injection site swelling, Injection site vesicles

Symptom Text: Information has been received from a physician concerning a 12 year old female who on 21-JUL-2007 was vaccinated in the left thigh with the second dose of varicella virus vaccine live (Oka/Merck) (Lot #657456/0600U). Concomitant therapy included the first dose of Gardasil (Lot #658094/0524U) in the right thigh. Subsequently, the patient experienced injection site redness, injection site tenderness in the left thigh that was hard, blistery and itchy. The area was swollen in a 6" X 8" area. Subsequently, the patient recovered in 6 days. Zyrtec was given. No further information is available.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **287383-2** **Related reports:** 287383-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Jul-2008	21-Jul-2008	--	WAES0807USA01414	21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Fear of death, Loss of consciousness

Symptom Text: Information has been received from the news media which reported that a female patient who on an unknown date was vaccinated with GARDASIL. The patient passed out and had a seizure after vaccination with GARDASIL. After the patient's seizure, she did not want to go to bed because she thought that she wasn't going to be able to wake up. Upon internal review, the patient's seizure was considered an other important medical event. No additional information is expected.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **290331-3 (S)** **Related reports:** 290331-1; 290331-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	05-Jun-2007	05-Jun-2007	0	20-Jun-2008	23-Jun-2008	--	WAES0806USA01379	23-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0263U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Fibromyalgia, Injection site induration, Injection site warmth, Lymphadenopathy, Muscle contractions involuntary, Muscle spasms, Night sweats, Rash, Rhabdomyolysis, Trismus, Vision blurred

Symptom Text: Information has been received from the mother of a 24 year old female consumer with allergy to CELEXA and allergy to metals who on 05-JUN-2007 was vaccinated with the first dose of GARDASIL (lot #655849/0263U), 0.5 mL IM in the arm. Concomitant therapy included VALIUM, baclofen, prednisone, TORISEL, "dizanidine HCl" [therapy unspecified], PERCOCET, oxycodone, PRILOSEC, estradiol, ZOLOFT, ALLEGRA, albuterol and "birth control pills" (unspecified). On 05-JUN-2007 after getting her first 0.5 mL dose of GARDASIL, the patient's arm was "warm and hard for a couple of weeks" and the patient recovered from this event. On approximately 19-JUN-2007, a couple of weeks after the first vaccination, the patient's clavicular lymph node swelled up. The swelling was almost gone when the patient received the second dose of GARDASIL (Lot #658100/0525U) on 08-AUG-2007. On 09-AUG-2007, after the second dose, every lymph node in the patient's body swelled up. She could not open her mouth and could not relax her muscles. The patient was admitted to the hospital for 3 days, her serum creatine kinase level went up to 500 and she was diagnosed with rhabdomyolysis. The patient had muscle missing on the bottom of her right foot and she had symptoms of fibromyalgia. She had muscle contractures and spasms and had rashes on top of the spasms. The patient developed hormonal problems, did not have her period for 6 months and was having night sweats. The patient's left eye was "out of focus" and the muscles were "jumping around in her left eye." She had a magnetic resonance imaging (MRI), blood work and an eye test performed which results were not reported. At the time of reporting, the patient was recovering from the events while on therapy (unspecified). No product quality complaint was involved. Additional information has been requested.

Other Meds: [therapy unspecified]; PERCOCET; albuterol; baclofen; VALIUM; estradiol; ALLEGRA; hormonal contraceptives; PRILOSEC; oxycodone; prednisone; ZOLOFT; TORISEL

Lab Data: magnetic resonance, 08/09/07, results not reported; ophthalmological exam, 08/09/07, results not reported; hematology, 08/09/07, results not reported; serum creatine kinase, 08/09/07, 500, went up to 500

History:

Prex Illness: Drug hypersensitivity; Allergy to metals

Prex Vax Illns:

Vaers Id: **291286-2 (S)** **Related reports:** 291286-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Jul-2007	12-Jul-2007	1	31-Aug-2008	01-Sep-2008	AZ		02-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0525U	1	Left arm	Unknown	
MNQ	SANOFI PASTEUR	U2326AA	0	Left arm	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Chills, Cough, Dyspepsia, Fatigue, Gastrooesophageal reflux disease, Inflammation, Migraine, Oesophagitis, Pain, Pyrexia, Screaming

Symptom Text: Adverse reaction to the HPV (Gardasil) vaccine. This is a summary of what we have been through for over a year. Patient was 14 at the time of her first vaccination (first vaccine 7/11/07, second vaccine 9/12/07). She was just the average teenager enjoying herself and having fun with her friends. She works hard and really struggles to do well in school and is in honors classes. She is a real achiever. She also has dreams for her future and goals that are very important to her. We did not know that July 11th, 2007 would be the day that would change our lives. This is what our family's life has been like. When the Gardasil adverse reaction started July 12th, 2007, we started logging it to see if there was a pattern and there was no pattern. The migraine headaches went on for months and she would just scream. It was so hard because we did not know what to do. She has been in and out of the hospital and emergency rooms, several dozen doctor appointments (over 50 doctors), dozens of trips for blood work. She has been on approximately 70+ different types of medicine including Demerol to stop the pain. They have checked for anemic, valley fever, thyroid problems, allergies, asthma, sinus infections, chest x-rays, MRI, CT scans, eyes checked, EEG, EKG, upper GI, endoscopy (upper scope), heavy metal poisoning, arthritis/inflammation, checked her white blood cells, etc. She has had migraine headaches that were every day and were so bad that she would scream. She said that it felt like someone was stabbing her in the head with a knife. Her heart burn made her curl up on the floor in severe pain, she has an inflamed esophagus which was a result of chronic coughing. She missed approximately 50 days of school. We have been seeing a neurologist that specializes in migraine headaches (1st appt. 11/8/2007). We are also seeing a naturopathic doctor (1st appt. 6/2/2008) because the doctors in the medical profession do not know what to do other than give her more drugs. We are still dealing with ice pick migraine heada

Other Meds:

Lab Data: Dates Tests 07/11/07, 09/12/07 Gardasil vaccine 08/17/07 MRI - Brain 08/28/07 Labs 09/06/07 EKG 09/17/07 MRI - Hip (right/left) 09/26/07 Ophthalmology - Eye appointment 10/17/07 Ultrasound - pelvic area 11/02/07 Labs: Valley

History: cats, pollen, seasonal allergies

Prex Illness: No illnesses at time of HPV vaccination.

Prex Vax Illns:

Vaers Id: **291867-2** **Related reports:** 291867-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-Sep-2007	27-Sep-2007	0	23-May-2008	03-Jul-2008	DE	WAES0709USA04578	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2491AA		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2062AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0960F	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1184U	0	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site, Erythema, Immediate post-injection reaction, Incorrect route of drug administration, Pruritus

Symptom Text: Initial and follow up information has been received from a health professional concerning a 13 year old female who on 27-SEP-2007, at 10:07, was vaccinated with a first dose of 0.2 mL of varicella virus vaccine live (Oka/Merck) (Lot # 65843/1184U) intradermally into the left forearm, followed later by the remaining dose of 0.3 mL subcutaneously into the left arm (Lot # 658431/1184U). Concomitant vaccine therapy that same day, at 10:07, included , a first dose of Gardasil intramuscularly into the right arm (Lot # 654535/0960F), a first dose of Adacel, intramuscularly into the left arm (Lot # C2491AA), and a first does of Menactra intramuscularly into the right arm (Lot # U2062AA). The patient was initially given 0.2 mL into the left forearm as an intradermal shot. The patient was later given the remaining 0.3 mL subcutaneously into the left upper arm. There was an immediate localized skin erythema and itching at the left forearm. This event was reported as a nursing error, and not product confusion. Unspecified medical attention was sought at the office. There was no product quality complaint. At the time of reporting the patient had recovered on an undisclosed date. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **298821-2** **Related reports:** 298821-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		19-May-2008	11-Jun-2008	MD	WAES0804USA03666	11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Discomfort, Erythema, Oedema peripheral, Skin discolouration

Symptom Text: Information has been received from a mother concerning her 19 year old daughter who was vaccinated with a second dose of GARDASIL about 4 months ago. There was no concomitant medication. Subsequently the day following the second dose of GARDASIL the patient's hands became swollen, red and purple colored and uncomfortable. Medical attention was sought. The patient recovered from these adverse events about 24 hours after the AE (also reported as 48 hours after vaccination). No other information was available. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **301628-3** **Related reports:** 301628-1; 301628-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	31-Dec-2007	31-Dec-2007	0	16-Jun-2008	10-Jul-2008	MI	WAES0804USA02611	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Inappropriate schedule of drug administration, Syncope

Symptom Text: Initial and follow up information has been received from a registered nurse concerning a 20 year old white female student with no known allergies (previously reported as 17 year old) who on 31-DEC-2007 (previously reported as on ??-JUN-2007) at 11:00 AM was vaccinated intramuscularly into right deltoid with a 0.5 mL first dose of GARDASIL (Lot # unknown) and in April 2008 was vaccinated intramuscularly with a 0.5 mL second dose of GARDASIL. Concomitant therapy included ESTROSTEP. In follow up report from the doctor's office it was reported that the patient had syncope five minutes after (about 11:05 AM) she got her first injection. She fell off the examination table and hit her head on the floor. She went to the emergency room and a head computed axial tomography (CT scan) was done with negative result. It was reported that on 31-DEC-2007 patient recovered. Additional information is not expected.

Other Meds: ESTROSTEP

Lab Data: Head computed axial, 12/31/07, normal.

History:

Prex Illness: Contraception

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **305431-2 (S)** **Related reports:** 305431-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jan-2007	07-Jun-2007	156	15-Sep-2008	22-Sep-2008	AZ		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Gait disturbance, Hypoaesthesia, Lymphomatoid papulosis, Pain, Skin lesion

Symptom Text: June 2007 - left lower leg becomes numb, sharp shooting pains insensitive to hot or cold, unable to walk long distances. June 2007 - lesions all over body - multiplying quickly. 1-3-08 Clinic diagnosis: Lymphomatoid Papulosis.

Other Meds:

Lab Data: Numerous nerve tests, biopsies, MRI's (3), cat scans, blood work

History: None

Prex Illness: None

Prex Vax Illns: ~HPV (Gardasil)~2~17~In Patient

Vaers Id: **305606-3 (D)** **Related reports:** 305606-1; 305606-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	01-Apr-2008		02-Jun-2008	03-Jun-2008	--	WAES0805USA04734	04-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a physician concerning a "17 year old" female who on an unspecified date was vaccinated with GARDASIL. In April 2008, approximately 6 weeks ago the patient died. The physician reported that one of the patient's mother did not want to agree to the vaccine because her friend's daughter died after receiving it. The 17 year old patient was found dead on the floor by her mother. The autopsy was performed and the outcome was unspecified. The physician only has information on the patient that refused the vaccine. No further information was provided. The reporter felt that the event was disabling and life threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **305701-2** **Related reports:** 305701-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Jan-2008	28-Jan-2008	0	19-May-2008	12-Jun-2008	--	WAES0804USA00802	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2771AA	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2405AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0928U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Information has been received on request from the FDA under the act regarding a 15 year old female with no previous illnesses, who on 28-JAN-2008 was vaccinated IM in the left arm with a first dose of GARDASIL (Lot# 658554/0928U). Concomitant therapy included ADACEL (Lot# C2771AA) administered in the right arm, and MENACTRA (Lot# U2405AA) administered in the left arm. On 28-JAN-2008 GARDASIL was misadministered. It was documented on the patient's immunization record by the office assistant for the patient to receive GARDASIL and MENACTRA when the patient's parent had requested MENACTRA and ADACEL. The ADACEL was administered later. The parent was upset over the administration of GARDASIL. No laboratory diagnostics were performed. At the time of the report, the outcome of the patient was unknown. The VAERS ID# is 305701. Additional information is not available.

Other Meds:

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **305703-2** **Related reports:** 305703-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Feb-2008	20-Feb-2008	0	19-May-2008	11-Jun-2008	--	WAES0804USA00801	11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bradycardia, Nausea, Pallor, Syncope

Symptom Text: Information has been received on request from the FDA under the act regarding a 16 year old female with a history of seizure with local anesthesia at the dentist office, who on 20-FEB-2008 was vaccinated in the left deltoid with a second dose of GARDASIL (Lot# 659180/1758U). There were no concomitant medications. On 20-FEB-2008 post vaccination the patient walked immediately to the check out counter and became pale, nauseous, and had a syncopal episode in which she became bradycardic. The patient was treated with an adult EPIPEN, BENADRYL 50mg, and oxygen. The patient was then sent to the emergency room via EMS. The patient's glucose was 94 and pulse oximetry was 100%. At the time of the report, the outcome of the patient was unknown. The VAERS ID# is 305703. Additional information is not available.

Other Meds: None

Lab Data: pulse oximetry, 02/20/2008, 100%; blood glucose, 02/20/2008, 94

History: Convulsion

Prex Illness:

Prex Vax Illns:

Vaers Id: **306843-2** **Related reports:** 306843-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	03-Mar-2008	03-Mar-2008	0	19-May-2008	11-Jun-2008	PA	WAES0804USA05253	11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0171U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Genital swelling, Vaginal swelling

Symptom Text: Information has been received from a nurse concerning her 20 year old daughter with no medical history and no known drug reactions or allergies who on 03-MAR-2008 was vaccinated IM with the first 0.5 ml dose of GARDASIL (Lot # 655620/0171U). There was no concomitant medication. On 03-MAR-2008 the patient experienced swelling of the vagina and labia. The patient began to experience the swelling two hours after receiving the vaccination. The swelling was reduced with the administration of BENADRYL. The patient recovered 05-MAR-2008. Patient did not seek medical attention. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **306868-2 (S)** **Related reports:** 306868-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Sep-2007	20-Dec-2007	86	14-May-2008	15-May-2008	--	WAES0804USA05009	15-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2382BA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0524U	0	Unknown	Intramuscular	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abasia, Asthenia, Back pain, Blood product transfusion, Dysphonia, Endotracheal intubation, Eyelid ptosis, Fall, Gait disturbance, Gastrointestinal tube insertion, Gastrooesophageal reflux disease, Grip strength decreased, Guillain-Barre syndrome, Hypoaesthesia, Hypoaesthesia oral, Intensive care, Mechanical ventilation, Myalgia, Pain in jaw, Paraesthesia, Paraesthesia oral, Pharyngitis, Plasmapheresis, Rash pruritic, Tracheitis, Weight decreased, Wheelchair user

Symptom Text: Information has been received on request from the FDA under the Freedom of Information Act concerning a 15 year old female with asthma, allergic rhinitis, nickel dermatitis and a history of a fractured toe who on 25-SEP-2007 was vaccinated intramuscularly into the left arm with the first dose of GARDASIL (Lot # 658094/0524U). Concomitant therapy included MENACTRA (Lot U2382BA), ADVAIR, albuterol, CLARITIN and TRIAMCINOLON COMPOSITUM. On 20-DEC-2007, prior to admission, the patient presented with a several day history of numbness and tingling in her extremities, with progressive weakness. Symptoms began six days prior to admission with right fifth digit numbness. Four days prior to admission she felt increasing pharyngitis and numbness and tingling in lips. Three days prior to admission she felt increasing generalized weakness. Two days prior to admission the patient was increasingly hoarse. On the day of admission the patient demonstrated a wide based gait, and was holding onto the wall to walk. She fell in the bath tub and was unable to get up. She had decreased grip strength. She also had a ten pound weight loss one week prior to admission. Some of her symptoms also included acid reflux, global myalgias, jaw pain, and back pain. She had a pruritic rash on her frame. Diagnostic testing performed included an electromyography on 27-DEC-2007 indicating the medial ulnar motor response was very low in amplitude and mildly long in distal latency. A repeat electromyography was performed on 04-JAN-2008 revealed no response obtainable in the median or ulnar motor nerves, and the peroneal motor study showed low amplitude response and MIL. Treatment required admission to the intensive care unit, prolonged period of intubation and ventilator support, plasmapheresis, intravenous immunoglobulin, physical and occupational therapy and nasogastric tube feeding. She also had developed bilateral ptosis and tracheitis. she was diagnosed with Guillain-Barre syndrome on 17-JAN-2008. She was transferred to a rehabilitation unit and re

Other Meds: albuterol 2 puff; TRIAMCINOLON COMPOSITUM; ADVAIR 1 puff; CLARITIN

Lab Data: electromyography 12/27/07 - median ulnar motor response very low amplitude and mildly long distal latency; electromyography 01/04/08 - no response obtainable in median or ulnar motor nerves, peroneal motor study showed low amplitude

History: Fractured toe

Prex Illness: Asthma; Rhinitis allergic; Dermatitis

Prex Vax Illns:

Vaers Id: **307606-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Dec-2007	08-Dec-2007	1	17-Mar-2008	10-Apr-2008	MO	WAES0802USA03368	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning her daughter, an 18 year old with a history of tonsillectomy, and heavy periods which cause anaemia. On 07-DEC-2007, the patient was vaccinated with her first dose of Gardasil. On 08-DEC-2007 the patient experienced fine rash on legs. On 08-Feb-2008, the patient received her second dose of Gardasil. Concomitant therapy included ZYRTEC-D and hormonal contraceptives (unspecified). On 09-FEB-2008 the patient experienced fine rash on legs. The patient's fine rash on legs persisted. The patient sought unspecified medical treatment and unspecified lab diagnostics were performed. The report states the therapy was discontinued on 08-Feb-2008. Additional information has been requested. On 14-FEB-2008 the patient was diagnosed with eczema on her legs and stomach. Follow up information indicated the patient recovered on an unknown date. Additional information has been requested.

Other Meds: ZYRTEC-D; hormonal contraceptives

Lab Data: [procedure unspecified]

History: Tonsillectomy; Heavy periods; Anaemia

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **307607-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Dec-2007	15-Dec-2007	11	17-Mar-2008	10-Apr-2008	AR	WAES0802USA03371	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Fatigue, Heart rate increased

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter, with an allergy to pollen and a history of tonsillectomy, who on 04-OCT-2007 and 04-Dec-2007 was vaccinated with her first and second doses, respectively of Gardasil (lot #s not reported). "Sometime later in December 2007", the patient began to have breathing problems (NOS), sometimes accompanied by a rapid heart beat. Also, it was reported that she has been much more fatigued than usual. It was reported that periodically, some of these episodes have been very severe and temporarily incapacitate her. Usually, the breathing problems last for one or two minutes and then they dissipate. The patient's breathing problems and fatigue persisted. Unspecified medical attention was sought. A CAT scan endoscopy and echocardiogram are schedule to be done in March, 2008. Additional information has been requested. Follow-up information was received from the physician and nurse who reported that the patient was an active dancer who developed shortness of breath after dancing. She was referred for an allergy and asthma evaluation as well as a cardiac evaluation. Her allergy and asthma tests as well as echocariogram were negative, and she was ruled out as having cardiac, asthma or allergy problems. On an unspecified date she was diagnosed with excercise induce reactive airways disease and bronchospasm. The doctor stated that the rapid heart beat and breathing problems (shortness of breath) were symptoms of this. These events (as well as the fatigue) were considered non-serious. At the time of this report the patient still continued to occasionally have this breathing related reaction after she danced but was reported as stable. The physician also reported that on 18-FEB-2008, the patient was evaluated for joint pain and achey muscles (also considered non-serious). The patient was diagnosed with arthralgia and bronchospasm. All lab work including CBC, ANA, ESR and others were within normal limits (labs not provided). On 26-FEB-2008, the patient was

Other Meds: Unknown

Lab Data: allergy test, negative; echocardiography, negative; complete blood cell, within limits; serum ANA, within limits; erythrocyte, within limits;

History: Tonsillectomy

Prex Illness: Pollen allergy

Prex Vax Illns:

Vaers Id: **309588-3** **Related reports:** 309588-1; 309588-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	31-Mar-2008	02-Apr-2008	2	01-May-2008	05-May-2008	OH		05-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2844AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1486U	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cellulitis, Injection site erythema, Injection site induration, Limb discomfort

Symptom Text: Saw patient 4 days following immunization. Local induration, erythema 4" around vaccine site. C/O arm discomfort. Treated as cellulitis with Duricef since Benadryl for allergic reaction was not effective in decreasing symptoms.

Other Meds:

Lab Data:

History: PCN, Bactrim, Biaxin

Prex Illness: No

Prex Vax Illns:

Vaers Id: **310262-2 (D)** **Related reports:** 310262-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Apr-2008	Unknown		12-Apr-2009	13-Apr-2009	NC		13-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	1	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death, Injection site pain

Symptom Text: Patient only complained of pain at the injection sight, died three days after vaccinated.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: Death~HPV (Gardasil)~1~0~Patient

Vaers Id: **310432-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	10-Mar-2008	12-Apr-2008	33	16-Apr-2008	15-May-2008	FL	WAES0803USA01425	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oedema peripheral, Pain in extremity

Symptom Text: Information has been received from a physician concerning a female who in approximately February 2008, was vaccinated with the first dose of GARDASIL (lot# not provided). The same night following vaccination, the patient went to the Emergency Room with a swollen and painful arm. No further information was provided. Additional information has been requested. Additional information received from D-form (07/APR-2008). For the reporter, the patient received her first dose of GARDASIL and within 48 hours experienced pain, swelling and redness of arm, resulting in an ER visit. The patient was treated with oral steroids. Subsequently, the patient recovered from the pain, swelling and redness of her arm. The reporter did not see the patient during the acute reaction, but was informed after recovery. There is no additional information. Additional information received from D-form (29-APR-2008). The patient is an otherwise healthy 11-year-old female with a history of chicken pox disease as a younger child. On 19-MAR-2008 the patient was vaccinated in the left arm with the first dose of GARDASIL (lot# 657621/0387U). On 12-APR-2008 the patient developed Herpes Zoster on the skin of her left back/side/chest. The patient twice sought unspecified medical attention in the physician's office. VALTREX was initiated on 18-APR-2008. The patient is currently recovering. The physician is not sure if the Herpes Zoster was related to GARDASIL vaccine. Additional information is not expected.

Other Meds: Unknown

Lab Data:

History: Chickenpox

Prex Illness:

Prex Vax Illns:

Vaers Id: **310439-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	19-Feb-2008	19-Feb-2008	0	16-Apr-2008	15-May-2008	PA	WAES0803USA01610	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Pain in extremity, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 21 year old female who on 28-NOV-2007 was vaccinated intramuscularly in the left arm with her first dose of GARDASIL (lot # 658556/1060U). Concomitant therapy included hormonal contraceptives (unspecified). On 19-FEB-2008 the patient was vaccinated intramuscularly in the left arm with her second dose of GARDASIL (lot# not reported). While in the office, the patient experienced soreness down her arm to her fingers and intermittent numbness in her hand all in the left arm. The patient used ibuprofen (MOTRIN) intermittently and was offered physical therapy, but declined. The patient recovered after 6 weeks. The patient sought medical attention in the office. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **310445-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	11-Mar-2008	11-Mar-2008	0	16-Apr-2008	15-May-2008	WI	WAES0803USA01762	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Fall, Gaze palsy, Musculoskeletal stiffness

Symptom Text: Information has been received from medical assistant concerning a 13 year old female patient who on 11-MAR-2008 was vaccinated IM with a 0.5 ml first dose of GARDASIL (lot# 655604/0052X). Concomitant therapy included MENACTRA. On 11-MAR-2008, after receiving the dose the patient was waiting on the table when 30 seconds later she landed backward on the table in which her eyes rolled back, she stiffened and jerked for 3 seconds. Patient stayed extra 15 minutes then went home. The patient was recovered. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **310447-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		16-Apr-2008	14-May-2008	IL	WAES0803USA01766	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Urticaria

Symptom Text: Information has been received from a health professional concerning a 21 year old female patient who on an unspecified date was vaccinated with a 0.5 ml second dose of Gardasil (lot# not provided). Subsequently the patient experienced mild hives. No respiratory problems. The patient did not have any AE symptoms with the first vaccination. Unknown medical attention was sought. At an unspecified date the patient's hives faded without further incident. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **310448-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Apr-2008	15-May-2008	--	WAES0803USA01782	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, No reaction on previous exposure to drug

Symptom Text: Information has been received from a health professional concerning a female who was vaccinated with the second dose of GARDASIL (lot# not reported). Subsequently the patient experienced dizziness and nausea one month after receiving the second dose. The patient sought unspecified medical attention. The patient did not have any side effects after receiving the first dose. Additional information received 28-MAR-2008. The nurse called to state that the practice does not have any further information regarding the case and they do not want to receive any further letters. Additional information is not expected. Additional information received from memo (01-APR-2008): Nurse states, "No further information." Additional information is not expected.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **310450-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Feb-2008	01-Feb-2008	0	16-Apr-2008	15-May-2008	PA	WAES0803USA01790	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer through the Merck pregnancy registry concerning a 16 year old female who on 01-FEB-2008 was vaccinated with the third dose of GARDASIL (lot# not reported). Concomitant suspect therapy included VARIVAX (Oka/MSD) (MSD) (lot# not reported). Other concomitant medication included VENTILAN (albuterol) and prenatal vitamins. Per the reporter, the patient found out that she was pregnant about a week after receiving the third dose. Before she was known to be pregnant, the patient had a pap smear that was irregular, so a biopsy of the cervix was performed. Per the reporter, "I don't know if this made her more fertile. Also, before her pregnancy, when she received her first dose, she experienced an irregular menstrual cycle." The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: VENTILAN(ALBUTEROL); vitamins (unspecified)

Lab Data: cervical smear, irregular; cervix biopsy; diagnostic laboratory; beta-human chorionic , positive;

History: Asthma

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **310457-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		16-Apr-2008	14-May-2008	OR	WAES0803USA01851	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a health professional concerning a 20 year old female who was vaccinated on an unspecified date with Gardasil (lot# not reported) and felt lightheaded. The patient recovered after sitting in the office for few minutes. Additional information has been requested. This is in follow-up to report(s) previously submitted on 4/14/2008. Information has been received from a health professional concerning a 20 year old female who was vaccinated in 2007 with her first dose of GARDASIL (lot# not reported) and felt lightheaded. The patient recovered after sitting in the office for a few minutes. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **310460-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	16-Jan-2008	16-Jan-2008	0	16-Apr-2008	15-May-2008	NJ	WAES0803USA01921	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discomfort, Nasopharyngitis, Throat irritation

Symptom Text: Information has been received from a physician concerning a 25 year old female with a history of cardiac murmur who in January 2008, was vaccinated with her first dose of GARDASIL (lot number unspecified). Concomitant therapy included fexofenadine hydrochloride (ALLEGRA) and hormonal contraceptives (unspecified). In January 2008, after receiving the vaccine, the patient experienced uncomfortable feeling on the injection site. On 10-Mar-2008, the patient experienced scratchy throat and cold after a flight. Patient still has the cold and scratchy throat. Additional information has been requested. Follow up information received from the physician indicated the patient never mentioned the adverse events. During the patient's visit in March 2008, the patient did not report any of those experiences with second injection.

Other Meds: ALLEGRA; hormonal contraceptives

Lab Data: Unknown

History: Cardiac murmur

Prex Illness:

Prex Vax Illns:

Vaers Id: **310567-2 (S)** **Related reports:** 310567-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Apr-2008	12-Apr-2008	4	27-Mar-2009	30-Mar-2009	IL		30-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Abdominal distension, Abdominal pain, Activities of daily living impaired, Arthralgia, Fatigue, Joint swelling, Nausea, Rash, Serum sickness, Urticaria

Symptom Text: Patient was given the second injection of the Gardasil vaccine on 4/8/08 by her pediatrician. It was the only injection she received. A few days later she experienced severe joint pain and swelling plus skin hives/rashes. Her pediatrician put her on 60 mg of Prednisone for 3 days. When the symptoms worsened, we were sent to hospital on 4/23/08. Patient was diagnosed with Serum Sickness from the Gardasil vaccine. We started seeing Dr. in Rheumatology on 6/12/08. Dr. prescribed pulse IV Solumedrol administered by a home care nurse along with the oral steroids. Patient experienced a reoccurrence of symptoms on 8/15/08 and 9/3/08. With each reoccurrence she was unable to walk, with joint and abdominal swelling and pain. Methotraxate and Enbrel were prescribed along with the oral and IV steroids. Patient relapsed again and was admitted to hospital for testing on 10/15/08. When no new diagnosis or treatment came out of three days of inpatient examination, we sought a second opinion with Dr. in Pediatric Rheumatology. She stopped the Enbrel and Methotraxate and started reducing the steroids. Patient also saw Dr. in Gastroenterology for her constant nausea. Testing has been inconclusive. Patient experienced another reoccurrence of symptoms in February and March of 2009. Patient began physical therapy on 3/14/09 to help with the joint pain. Patient missed 30 days of school her first semester of senior year, and has already missed 10 days of her second semester due to this illness. Patient takes 10 pills every morning and 6 every evening, along with other medication as needed. She continues to experience consistent fatigue and nausea along with intermittent joint pain and skin hives/rashes.

Other Meds: None

Lab Data: Blood Tests, CT Scan, Bone Scan, Upper Endoscopy, TB Test, Colonoscopy - all inconclusive

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **310614-3** **Related reports:** 310614-1; 310614-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Feb-2008	13-Feb-2008	2	09-Jun-2008	16-Jun-2008	CA		19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2380BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0388U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Arthralgia, Back pain, Crying, Dizziness, Eye movement disorder, Eye pain, Fall, Fatigue, Headache, Musculoskeletal chest pain, Neck pain, Pain in extremity, Paraesthesia, Sensory disturbance, Syncope

Symptom Text: she didn't have any problems at first except the pain in her arm .I didn't put the two together until later .. dizzy, fainting,headache most of the time,tingling in arms legs now a constant pain in legs and ribs,she says a popping feeling in her blood veins where her arms bend,neck pain, tired,her eyes have pain and will flutter and look up . fainting it just happens and she falls so hard just drops seven times in one day ,she doesn't move anything for about two minutes no matter what, when she comes through she is crying and cant lift her head up,Stormy say's her head fills empty and heavy sometimes every joint in her body hurts even the arch of her feet hurt and her spine hurts, Stormy has chronic stomach pain .the pain between her ribs is an ache pain sometimes its a stabbing pain.The fainting or passing out is at least one time every day we believe the most in one day was eight times but really we lost count. pain behind her knees is often. been to the clinic and 5 different er's nobody knows what to do,they all say something different,

Other Meds: loestrin 24fe

Lab Data: all test were negative

History: none

Prex Illness:

Prex Vax Illns:

Vaers Id: **310700-2** **Related reports:** 310700-1; 310700-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	21-Feb-2008	28-Feb-2008	7	16-May-2008	23-May-2008	WA		23-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Joint swelling, Musculoskeletal stiffness

Symptom Text: Approximately 1 week after receiving vaccine, pt developed ankle swelling, arthritic joint pain, & morning stiffness, lasting 1-5 weeks. Pt saw rheumatologist on 3/11/08 & was given MEDROL + a diuretic. After starting meds, sx went away in 6 days. Per Dr., sx could have been coincidental + unrelated to GARDASIL. Pt also took ibuprofen for sx per RN/Dr. office 5/16/08.

Other Meds: unknown

Lab Data: Bloodwork was completed, unknown results.

History: NKDA, dyslipidemia, borderline HTN, anxiety, migraine headaches

Prex Illness:

Prex Vax Illns:

Vaers Id: **310700-3** **Related reports:** 310700-1; 310700-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	U	21-Feb-2008	28-Feb-2008	7	16-Jun-2008	10-Jul-2008	WA	WAES0805USA03666	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Oedema peripheral

Symptom Text: Information has been received from a physician concerning a 23 year old, 67.5 inch, 168 pound female dental hygienist with no pertinent medical history or allergies, who on 21-FEB-2008 was vaccinated with the first dose of GARDASIL (lot # 657006/0188U), expiration date 21-NOV-2009, IM to the left deltoid. It was reported that within 1 week of receiving the GARDASIL, the patient began developing severe knee pain and lower extremities swelling. The patient sought medical attention and was treated with ibuprofen (manufacturer not specified), over the counter 400 mg up to three times a day. On 05-MAR-2008, the patient saw the physician for obvious edema and knee effusion. Laboratory tests were ordered and a c-reactive protein (CRP) was noted to be 24.6, BSR was 65, and Antistreptolysin O Ab was high at 248.6. The patient was treated with MEDROL DOSE PAK, and DYAZIDE over 1 week. The symptoms resolved on approximately 12-MAR-2008. A follow-up visit to a rheumatologist found no other likely causes for the symptoms except for GARDASIL. Additional information has been requested.

Other Meds: ZOLOFT

Lab Data: diagnostic laboratory, BSR 65; serum C-reactive, 24.6; serum antistreptolysin, 03/05/08, 248.6

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **310717-2** **Related reports:** 310717-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		17-Jul-2008	18-Aug-2008	AZ	WAES0806USA08927	18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician and an office manager concerning an approximately 18 year old female who on an unspecified date was vaccinated intramuscularly with a first 0.5 ml dose of GARDASIL (Lot #660391/0063X). After receiving GARDASIL the patient fainted. At the time of the report, it was unknown if the patient had recovered from the event. Unspecified medical attention was sought. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **310979-2** **Related reports:** 310979-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Mar-2008	17-Mar-2008	0	08-Jul-2008	10-Jul-2008	CA		04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Disturbance in attention, Dizziness, Fatigue, Feeling abnormal, Genital rash, Influenza like illness, Injection site pain, Malaise, Nausea, Vulvovaginal pruritus

Symptom Text: General feeling unwell, soreness at injection site, feeling 'funny', dizzyness, tiredness on injection day. Following day sent home from school early, couldn't concentrate, tired, general feeling unwell, nausous, flu like. Called doctors office. Next day symptoms worse, scratching, vaginal itching and vaginal rash worsening from previous evening. Returned to doctors office for check of symptoms. Doctor called another doctor from office for second opinion. Was prescribed Triamcinolone acetonide cream usp, 0.1%, topical use.

Other Meds: Takes multi-vitamins

Lab Data:

History: Allergy to Penicillin, latex, nickel

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **311424-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		01-May-2008	02-May-2008	GA		02-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Started losing patches of hair after 2nd injection.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 311439-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-May-2008	01-May-2008	0	01-May-2008	05-May-2008	OH		05-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Body temperature increased

Symptom Text: Temperature per patient 99.2 - patient took Tylenol. Weakness - no treatment done.

Other Meds: None

Lab Data: None known

History: Migraines, Endometriosis

Prex Illness: None

Prex Vax Illns:

Vaers Id: **311440-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Apr-2008	29-Apr-2008	0	01-May-2008	05-May-2008	TN		05-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	19674	0	Left arm	Intramuscular	
	TTOX	SANOFI PASTEUR	U1993BA	5	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash pruritic

Symptom Text: 4 hours after vaccines administered developed pruritic rash on thighs and upper (L) chest. Treated next day with Benadryl. Depo Medrol 40mg and Decadron 4mg.

Other Meds:

Lab Data: None

History: Seasonal Allergies

Prex Illness: None

Prex Vax Illns:

Vaers Id: **311442-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	21-Apr-2008	21-Apr-2008	0	01-May-2008	02-May-2008	OH		02-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Dizziness, Headache, Hyperventilation

Symptom Text: 1 hrs after receiving Gardasil pt felt weak, dizzy, hyperventilated. Pt felt dizzy & weak with a headache for 5 days post injection. Pt went to pediatrician had blood tests-all were WNL. Pt has fully recovered. Pt. also complained of joints aching.

Other Meds:

Lab Data:

History: none

Prex Illness: no

Prex Vax Illns:

Vaers Id: 311455-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	15-Oct-2007	15-Oct-2007	0	02-May-2008	05-May-2008	--	WAES0710USA03731	05-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a 23 year old female who on 15-OCT-2007 was vaccinated with her first dose of Gardasil. On 18-OCT-2007 the patient found out she was pregnant. On 22-APR-2008, it was reported by the patient, that on approximately 01-NOV-2007, reported as "about two weeks after calling," that she had lost the baby. She reported that the miscarriage was early in her pregnancy and she was doing fine. Upon internal review, spontaneous abortion was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **311456-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Mar-2008	28-Mar-2008	0	02-May-2008	05-May-2008	OH	WAES0804USA00974	05-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lip swelling, Rash maculo-papular

Symptom Text: Initial and follow-up information has been received from a physician concerning an 18 year old female with a urinary tract infection at the time of vaccination and no allergies or drug reactions who on 28-MAR-2008 was vaccinated with a first dose of GARDASIL (lot# 659182/1757U) injection in the left arm at 10:00 AM. Concomitant therapy included BACTRIM for the urinary tract infection. After receiving the vaccine in the office and on the way home the patient developed diffuse rash. On 29-MAR-2008 the patient was seen by the physician and saw the patient at that time had markedly swollen lips and she had a diffuse maculopapular rash all over. Subsequently, on an unspecified date the patient recovered from the rash and swollen lips. No further information was provided. The reporter felt that maculopapular rash and swollen lips were considered to be an other medical event. Additional information has been requested.

Other Meds: Bactrim

Lab Data: Unknown

History: None

Prex Illness: Urinary tract infection

Prex Vax Illns:

Vaers Id: 311457-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	09-Apr-2008	09-Apr-2008	0	02-May-2008	05-May-2008	TX	WAES0804USA05085	05-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a medical assistant concerning a 19 year old female, who on 09-APR-2008 was vaccinated with a 0.5mL first dose of Gardasil. Subsequently, the patient was pregnant. It was reported that the office did not conduct a pregnancy test prior to the vaccination. The patient called the office to report that she experienced a miscarriage on 21-APR-2008. The patient went to see the physician. A total serum human chorionic gonadotropin test was performed and did not show that the patient was pregnant. On 09-APR-2008 the patient experienced received first dose while pregnant. At the time of the report, the outcome of the patient was unknown. Upon internal review miscarriage was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: total serum human, did not show patient was pregnant

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 311458-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		02-May-2008	05-May-2008	FR	WAES0804USA05385	05-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Encephalitis

Symptom Text: Information has been received from a paediatrician concerning an approximate 12 year old female with a history of non-medicated rheumatism who on an unspecified date was vaccinated with GARDASIL (lot#, injection route and site not reported). Subsequently, on an unspecified date 1.5 weeks post-vaccination the patient experienced cerebellitis and was hospitalized. The outcome was not reported. Additional information is not expected. Other business partners included are: E2008-03718.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Rheumatism

Prex Vax Illns:

Vaers Id: 311459-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Mar-2007	01-Mar-2008	338	02-May-2008	05-May-2008	FR	WAES0804USA05386	05-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0902F	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Herpes zoster, Immunodeficiency common variable, Sepsis syndrome, Streptococcal infection

Symptom Text: Information has been received from a health authority, concerning a 16 year old female patient, and recurrent infections with transaminases increased (since 2005), who on 29-MAR-2007 was vaccinated with the first dose, which was well tolerated (lot # 654884/0902F; batch NE24240); on 07-MAY-2007 was vaccinated with the second dose, which was well tolerated (lot # 655671/1024F; batch NE63230); and on 06-DEC-2007 was vaccinated with the third dose in the upper arm, of Gardasil (lot # 0251U; batch NF56480). In January 2008, the patient developed streptococcal infection with sepsis syndrome and herpes zoster. In March 2008, the patient was diagnosed with a common variable immunodeficiency, with decreased IgG and IgG 1. She was hospitalized (date and duration not reported. Common variable immunodeficiency was considered to be immediately life threatening. The reporter (not specified), considered a relation to the vaccine doubtful, as the patient showed recurrent infections with increased transaminases, which occurred for the first time in 2005. Other business partner numbers include: E2008-03745; reference # PEI2008004690.

Other Meds: Unknown

Lab Data: serum immunoglobulin G test, 01Mar08, decreased; serum antiendomysial antibodies test, 01Mar08, IgG 1 decreased

History: No reaction on previous exposure to vaccine; Infection; Transaminases increased

Prex Illness:

Prex Vax Illns:

Vaers Id: 311460-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Jan-2008	09-Jan-2008	8	02-May-2008	05-May-2008	FR	WAES0804USA05691	05-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0483U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Information has been received from a pediatrician concerning a 13 year old female, who in January 2008, was vaccinated with a second dose of GARDASIL (Lot# 0483U; Batch# NG20160). Nine days post vaccination the patient experienced a facial palsy. The patient recovered completely within three months. It was reported that the first vaccination with GARDASIL was well tolerated. Other business partner numbers included: E2008-03798. Additional information is not expected. The file is closed.

Other Meds: Unknown

Lab Data: Unknown

History: No reaction on previous exposure to vaccine.

Prex Illness:

Prex Vax Illns:

Vaers Id: 311519-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Feb-2008	05-Feb-2008	0	02-May-2008	05-May-2008	CT		05-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Vomiting

Symptom Text: Abdominal pain and vomiting starting the evening of vaccination, resolved the next day. Patient refused subsequent doses of vaccine.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 311523-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Jan-2008	14-Feb-2008	21	03-May-2008	05-May-2008	FL		06-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Chest pain, Dizziness, Dyspnoea, Inflammation, Nasopharyngitis, Paraesthesia, Vision blurred

Symptom Text: two weeks after the vaccine for Gardasil I had a cold that lasted a month and a half. Than on 3/20/08 I went to the emergency room because of chest pains shortness of breath dizziness tingling in arms and legs blurred vision. They diagnosed me as having an anxiety attack and they prescribed Xanax. Which I ended up taking to much due to the chest pains i was having I than ended up in the er the next day. After that i went to my doctor for a follow up and saw (P.A) who prescribed cough suppresant and zithromax that I took for 5 days and she told me to go see a cardiologist and a psychiatrist. So then I saw Dr. (Cardiologist) he ran test. He then said my heart was inflammed and gave me trial moblic i had to take for 3 days along with Zantac. I still continued with the chest pains and tingling in arms and legs with the shortness of breath. He then did a 2D echo and had me take a stronger dose of moblic and then had a CT of my chest because he thought I had a pulmonary emboli. Then he gave me motrin 800 mg every 8Hrs as needed for chest pains. I still get the chest pains constantly. Yesterday I started with the shortness of breath and tingling in my arms and legs, the dizziness and blurred vision. I will be calling the cardiologist again on Monday 05/05/08 to see what else I need to do. At that time I will be letting him know that I did recieve the Gardasil injection in January 24,2008, since I had forgotten to tell him. I did not think it was important at the time, but now I am wondering if this is a side effect of Gardasil.I have no problems prior to recieving the shot.

Other Meds: Birth control pills Loestrin 24 Fe

Lab Data: CT of the chest ,Blood work, ECG, 2D Echo

History: shoulder pain no medications taken or prescribed.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **311545-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-May-2008	01-May-2008	0	02-May-2008	05-May-2008	CA		05-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB171AA	2	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1446U	1	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2541AA	1	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1662U	2	Left arm	Subcutaneously	
TD	SANOFI PASTEUR	U1991CA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Rash, Swelling

Symptom Text: 5/1/08 (L) arm rash right after Varicella vaccine administered SQ. 5/2/08 TC to parent. Pt still has rash and slight redness and swelling. Pt told to apply cold compress and come back if worsens/does not improve.

Other Meds:

Lab Data:

History: Allergic to -cillins.

Prex Illness: No

Prex Vax Illns:

Vaers Id: **311564-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	05-Dec-2007	05-Dec-2007	0	05-May-2008	06-May-2008	--	WAES0712USA08442	06-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a 21 year old female consumer that is also the patient, who has no pertinent medical history, drug reaction/allergies or concomitant medication usage. On 05-DEC-2007, the consumer was vaccinated (route and site not reported) with the 1st dose of GARDASIL (lot# not reported). The consumer found out she was pregnant after receiving the 1st dose of GARDASIL. The consumer reported that she was 6 weeks pregnant. The patient did receive unspecified medical attention. No lab diagnostic test were performed. Follow up from the consumer indicated that she had a miscarriage on 31-JAN-2008. She added that "everything is OK now," and added that she had no problems since then. Upon internal review, had a miscarriage was considered to be serious as an other important medical event. No additional information is expected.

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 11/8/2007)

Prex Vax Illns:

Vaers Id: 311565-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-Oct-2007	01-Nov-2007	20	05-May-2008	06-May-2008	FR	WAES0803USA04697	06-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Folliculitis, Lymphadenopathy, Skin lesion, Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning an 18 year old female patient with no medical history reported, who on 12-OCT-2007 was vaccinated intramuscularly into the deltoid with the first dose of Gardasil. On an unspecified date in November 2007, the patient developed bilateral lymphadenopathies of the right groin which resolved one month later. The patient also experienced syncope in November 2007, with "immediate" cessation. This event was considered not serious by the reporter. On 04-JAN-2008, the patient was vaccinated intramuscularly into the deltoid with a second dose of Gardasil. In approximately February 2008 "about a month ago", the patient developed lymphadenopathy at several unspecified sites. It was reported that one of the adenopathies (size 3x2 cm) persisted at the right groin and was associated with exudate. For the events following the second dose of Gardasil, folliculitis was not ruled out and dermatologic examination results were expected. The patient received corrective treatment with unspecified antibiotics that did not solve the problem. The physician consequently ruled out infection. The outcome was currently reduced to what looked more like a skin lesion (the size of an almond) than as an adenopathy. It was reported that the patient did not experience syncope after the second dose of Gardasil. Lymphadenopathy, folliculitis and skin lesion were considered to be other important medical events. Other business partner numbers included: E200802858, E200802742 and RA0152008. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **311566-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		05-May-2008	06-May-2008	--	WAES0804USA04729	06-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Encephalitis

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL. It was reported by the physician, that a daughter of a friend, developed encephalitis after a dose of GARDASIL. The physician could not provide any additional information. At the time of this report the patient's outcome was unknown. No product quality complaint was involved. Upon internal review, encephalitis was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 311567-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	20-Apr-2008		05-May-2008	06-May-2008	FR	WAES0804USA05667	06-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diarrhoea, Drug exposure during pregnancy, Peripheral vascular disorder, Vomiting

Symptom Text: Information has been received from a physician concerning her 17 year old daughter who in March 2008, was vaccinated with a third dose of Gardasil. On 20-APR-2008 the patient was admitted to the hospital with severe vomiting, diarrhea and circulatory disorder. The physician of the hospital was contacted by phone on 22-APR-2008 and reported that the symptoms resolved after 1 and a half days. It was reported that the patient was in her fourth month of pregnancy. It was also reported that the first and second vaccination were well tolerated. Other business partner numbers include: E200803769. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 01Jan08)

Prex Vax Illns:

Vaers Id: **311568-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Mar-2008	06-Mar-2008	0	05-May-2008	06-May-2008	FR	WAES0804USA05671	06-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hypoaesthesia, Injection site pain, Muscular weakness

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 06-MAR-2008 was vaccinated IM in the deltoid muscle with the third dose of GARDASIL (Lot# not reported). Dates and lot #s of previous two vaccinations of GARDASIL were not reported. There were no concomitant medications reported. On 06-MAR-2008 about 10 minutes post vaccination the patient experienced injection site pain and numbness "starting from below the injection site and spreading down to the hand". In the course she additionally developed weakness of the hand. It was reported that the injection site pain resolved after one day and the numbness and weakness were ongoing. It was reported that on 22-APR-2008 the patient was admitted to the hospital for diagnostics. The physician reported that the first two doses of the vaccine were well tolerated. Other business partner numbers include E2008-03768. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **311569-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	01-Feb-2008		05-May-2008	06-May-2008	FR	WAES0804USA05706	06-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated

Symptom Text: Information has been received from a health professional concerning a 14 year old female with Crohn's disease since 08-OCT-2003, and a father who also suffers from the same disease, who in February 2008 the patient was vaccinated IM in the deltoid with a second dose of Gardasil. Concomitant therapies included IMURAN 50mg 2x daily, and mesalamine 500mg 3x daily. Subsequently, the patient experienced a reactivation of Crohn's disease. Since 24-MAR-2008 the patient was treated with PREDNOSOLON 20 and 40mg for the reactivation. The patient had a blood test on 04JAN-2008 and 26-MAR-2008 in the laboratory section. At the time of the report, the outcome of the patient was unknown. Other company numbers included: E2008-03891. Additional information is not available.

Other Meds: IMURAN (AZATHIOPRINE), Unk - Unk; mesalamine, Unk - Unk

Lab Data: diagnostic laboratory test, 04Jan08, blood test-increase for the blood platelets, VS, and CRP; diagnostic laboratory test, 04Jan08, VS= 49; diagnostic laboratory test, 26Mar08, blood test-increase for the blood platelets, VS, and CRP; diagn

History:

Prex Illness: Regional enteritis

Prex Vax Illns:

Vaers Id: **311580-2 (S)** **Related reports:** 311580-1; 311580-3; 311580-4; 311580-5

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	14-Mar-2008	Unknown		13-May-2008	14-May-2008	--	WAES0805USA00428	21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Unknown	Intramuscular	HPV4

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Autoimmune disorder, Back pain, Haemolytic anaemia, Malaise, Pharyngolaryngeal pain, Pyrexia, Vomiting projectile

Symptom Text: Initial and follow up information has been received from a pediatrician and a consumer concerning his 19 year old daughter with an allergy to a medicine for acne that caused her to projectile vomit who on 23-NOV-2007, around Thanksgiving, was vaccinated with a first dose of GARDASIL (Lot# 658488/0930U). It was reported that she got sick and did nothing the next day. On 14-MAR-2008, the patient was vaccinated IM with a second 0.5 ml dose of GARDASIL (Lot# 659962/1740U). On 17-MAR-2008 three days after receiving the vaccine, the patient developed a fever that wouldn't go away. She tested positive for hemolytic anemia and was hospitalized. On 18-MAR-2008, four days after receiving the second dose the patient had complained of a sore throat, stomach and back ache and a fever up to 104 degrees. She had been in the hospital for the past week. Laboratory diagnostic studies performed was reported as "every test they could do". On 21-MAR-2008, the patient had a mononucleosis spot test and it was negative. The patient went back to college and her symptoms worsened. The patient was admitted to the hospital (dates unknown). She was then transferred to a different hospital. It was reported that the patient had 105 vials of blood drawn and the diagnosis of hemolytic anemia seemed to point to an autoimmune response from the second dose of GARDASIL. The patient was discharged from the hospital (hospitalization dates unknown) and it was reported that the patient remains on steroid therapy. At the time of this report, the patient had not recovered. It was also reported that the patient had to drop out of college. The reporting physician was consulting with an infectious disease specialist to confirm the cause of the diagnosis. No product quality complaint was involved. Additional information has been requested.

Other Meds:

Lab Data: Diagnostic laboratory - see narrative; Epstein-Barr virus 03/21/08 - negative.

History: Vomiting projectile

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **311580-3 (S)** **Related reports:** 311580-1; 311580-2; 311580-4; 311580-5

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	14-Mar-2008	31-Mar-2008	17	21-May-2008	22-May-2008	--	WAES0805USA02305	21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Right arm	Intramuscular	HPV4

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Anaemia, Anorexia, Back pain, Chills, Chromaturia, Cytomegalovirus infection, Dyspnoea, Epstein-Barr virus infection, Inflammation, Liver disorder, Lymphadenopathy, Nausea, Pain, Pharyngolaryngeal pain, Pyrexia, Spleen disorder, Viral infection, Vomiting, Weight decreased

Symptom Text: Initial and follow up information has been received from a Registered Nurse (R.N) and by telephone concerning a 19 year old female patient who on 23-NOV-2007 was vaccinated into the left arm with a first dose 0.5 mL of GARDASIL (lot # 658488/0930U) and on 14-MAR-2008 she was vaccinated IM in the right arm with a second dose 0.5 mL of GARDASIL (lot # 659962/1740U) at another office. On 31-MAR-2008, the patient went to a college health clinic with fever, chills, sore throat body aches, nausea, "mono-like symptoms". She had laboratory work done and was diagnosed with Viral syndrome and anemia. Her laboratory work indicated low white blood cell (WBC) count and red blood cell count (RBC). It was reported that she had vomiting, no appetite, inflamed liver and spleen, dark urine, shortness of breath and fever. She also had pain in lower back and abdominal area. The patient had unspecified laboratory work and was referred to infectious disease. After ten days of unconfirmed diagnosis, the patient was hospitalized. On an unknown date the patient was discharged from the hospital. The patient was driven back home and was seen by a cardiologist who noted she was in "good condition". She saw another infectious disease specialist again. This time the patient was admitted to the hospital from 24-APR-2008 to 01-MAY-2008 for fever. The patient had bone marrow and other unspecified laboratory tests done. Some enlarged lymph nodes were detected in pelvis and small bowel. Her hemoglobin was 7.9 and "1.7". She was treated with PREDNISONE 60 mg and at the time of this report was on PREDNISONE 40 mg daily. She tested positive for Epstein-Barr virus (EPV) reported as "EPV" and cytomegalovirus (CMV). Patient's parvo virus, west nile virus/IGM needed to be retested. She lost 17 lb and had to withdraw from college with only one credit to complete. It was noted that the patient had difficulty with everyday activities. The patient's outcome was unknown. The patient's EBV and CMV were considered to be disabling as the patient had to withdraw

Other Meds: Unknown

Lab Data: diagnostic laboratory, 04/24?/08, other blood tests; hemoglobin, 04/24/08, 7.9; hemoglobin, 04/24/08, "1.7"; WBC count, 03/31/08, Low; bone marrow basophilic, 04/24?/08, positive; serum West Nile virus, 04/24?/08, No result reported; serum

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **311580-4 (S)** **Related reports:** 311580-1; 311580-2; 311580-3; 311580-5

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	14-Mar-2008	14-Mar-2008	0	13-May-2008	14-May-2008	GA	WAES0805USA00532	21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Autoimmune disorder, Lymphadenopathy, Pyrexia

Symptom Text: Information has been received from a Registered Nurse (R.N.) concerning a 19 year old female patient with sulfonamide allergy who on 14-MAR-2008 was vaccinated with a dose of Gardasil. The nurse stated that the patient did not receive the Gardasil at her office and it was unknown which dose in the series of the vaccine was given. The nurse reported that the patient developed a fever of 102 to 103 degrees F after she received the Gardasil vaccine which has started for the past month (start date was not specified). The fever came and went almost every day, but did not last the whole day. The patient was hospitalized on 24-APR-2008 in relation to the fever and was discharged on 01-MAY-2008. During her hospitalization it was determined that she had a low white blood cell count and might have a possible auto immune disease. Serum antinuclear antibodies test (ANA) screen was done. Results not provided. A computerized Axial Tomographic (CAT) scan indicated that the patient had enlarged lymph nodes in abdominal cavity, small bowel, and in upper pelvis. She had unspecified blood and laboratory tests done. It was reported that patient was improving and was on steroid therapy. No other information available at the time of this report. Additional information has been requested.

Other Meds: Unknown

Lab Data: computed axial 04/24/08 enlarged lymph nodes; diagnostic laboratory 04/24/08; serum ANA 04/24/08 Possible auto immune disease; body temp 03/??/08 102 F for the past one month; body temp 03/??/08 103 F for the past one month; WBC count 04/24

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **311601-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	02-May-2008	02-May-2008	0	05-May-2008	06-May-2008	MI		06-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient had a procedure done in office. 40 minutes passed and GARDASIL given. 2-3 minutes later patient fainted, fell to floor. BP: 120/62. Recovered 2-3 minutes.

Other Meds: Yaz - (BCP)

Lab Data:

History: NKDA

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **311632-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-Apr-2008	29-Apr-2008	1	05-May-2008	06-May-2008	PA		18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Adnexa uteri pain, Arthralgia, Micturition urgency, Ovulation pain, Pelvic pain, Polyuria, Vaginal discharge

Symptom Text: beginning on the afternoon after the 2nd Gardasil shot, pelvic and stomach pain, joint pain, vaginal discharge with fishy odor, slight bloody discharge 6/9/08-records received for DOS 4/28-5/08/08-received vaccination #2 on 4/28/08-on 5/3/08 C/O middleschmertz pain few days ago. Extremely bad cervical pain, blood tinged fishy odor. 5/5/08 episodic pain since second vaccination. C/O positive urine urgency, polyuria. Pain intermittent. Pelvic exam normal. Impression likely middleschmertz vs. ovarian cyst.

Other Meds: none other than stinging nettle for allergies

Lab Data: n/a

History: seasonal allergies

Prex Illness: none

Prex Vax Illns:

Vaers Id: **311637-1** **Related reports:** 311637-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	M	24-Apr-2008	24-Apr-2008	0	05-May-2008	06-May-2008	TX		06-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache

Symptom Text: Patient complained of headache and dizziness for approximately 14 hours after receiving the vaccine. Patient was observed for 4 hours in the emergency department that evening, but no intervention except ibuprofen was given. Symptoms resolved subsequently.

Other Meds: Kaletra, Didanosine, Sustiva

Lab Data: None

History: HIV, asthma

Prex Illness: None

Prex Vax Illns:

Vaers Id: **311637-2** **Related reports:** 311637-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	M	24-Apr-2008	24-Apr-2008	0	07-May-2008	08-May-2008	TX		15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache

Symptom Text: Patient complained of headache and dizziness for approximately 14 hours after receiving the vaccine. Patient was observed for 4 hours in the emergency department that evening, but no intervention except ibuprofen was given. Symptoms resolved subsequently.

Other Meds: Kaletra, Didanosine, Sustiva

Lab Data: None

History: HIV, asthma

Prex Illness: None

Prex Vax Illns:

Vaers Id: 311641-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	10-Apr-2008	11-Apr-2008	1	05-May-2008	06-May-2008	CA		02-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0930U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Femoral pulse abnormal, Gait disturbance, Groin pain, Oedema peripheral, Pain in extremity, Pallor, Peripheral coldness, Skin discolouration, Tenderness, Weight bearing difficulty

Symptom Text: The morning after her injection she woke up complaining of upper right leg pain, near the groin area where the leg bends. No fever or reddness.Two days later the pain extended down to the knee, and by a week and a half later the pain extended down to the foot. She was also experiencing swelling of the leg and blanching of the skin accompanied by her leg getting cold to touch. Her right leg is painful to touch and she can not tolerate weight bearing. After a day at school the leg is very painful and swollen.So far nothing seems to help, heat, ice, elavating the leg,or vicodin. So she takes extra strength tylenol for the pain. 5/28/2008 MR received from PCP for 2 OVs dated 4/29/08 and 5/02/08 with DX: R leg pain and R leg pain now with absent femoral pulse. Pt presented with c/o of R leg pain which began 1 day s/p HPV vax. Initially started in the groin, then moved distally to the thigh and knee, and now to the ankle over the course of several weeks. Pt was unable to walk for several days but is ambulating with crutches. Pt reports occasional swelling and purplish skin discoloration. PE (+) for pain and tenderness to touch and with hip and ankle flexion and. extension. RTO 3 days later with worsening pain and now coldness of the R lower extremity as well as the purple color. PE (+) for purple discoloration and cool to touch especially in the calf area. No palpable femoral pulse. Concern for acute arterial obstruction. DDx spinal nerve impingement, bony abnormality, RSD.

Other Meds: None

Lab Data: On 4/25 she went to her PMD. On 4/29 she had an xray and ultrasound. These test were negative. On 5/6/08 she is getting a bone scan. Labs and Diagnostics: Venous duplex studies (-). X-ray of hip, knee, and ankle (-). Arterial duplex

History: Denies any

Prex Illness: Denies any

Prex Vax Illns:

Vaers Id: 311643-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-Aug-2007	22-Aug-2007	0	06-May-2008	06-May-2008	AZ		12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Chest pain, Depression, Diarrhoea, Fibromyalgia, Head injury, Headache, Loss of consciousness, Migraine, Muscle contractions involuntary, Self injurious behaviour, Syncope, Tenderness, Tremor, Vaccine positive rechallenge, Vomiting

Symptom Text: After she received 1st injection she kept complaining of her knees, joints aching, fainting and migrine. Then the 2nd injection she really started complaining. Now she was just recently diagnoised with fibromyligia because she aches so bad. She has been hospitalized many of times after injections with migrines and aching joints. I refused the 3rd injection 06/17/2008 MR received for 7 ER visits. Seen 8/8/07 and 10/23/07 r/t pre-existing platelet aggregation defect. Seen 10/28/2007 with dx chest pain. Reproduceble tenderness on exam. Seen 11/20/2007 with dx vomiting and diarrhea. Pt had passed out day prior and hit head. Seen 12/10/2007 with dx Headache Seen 12/22/2007 with dx tremors. Tongue fasiculations noted on exam. Seen 1/14/2008 with R hand fx after hitting a wall. Dx: Danger to self. Depression.

Other Meds:

Lab Data: fibromylagia tons of lab testing have been done but a negative results. Labs and Diagnostics: CXR (-). Platelets 84. EKG WNL. Head CT WNL.

History: Anxiety/Post Tramadic Stress Disorder, Idiopathic Thrombocythemia, Hypotension biventricle diastolic dysfunction. PMH: PTSD, SVT, ITP, migraines, chronic immunodeficiency syndrome.

Prex Illness: none this was her well check

Prex Vax Illns:

Vaers Id: 311646-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-May-2008	Unknown		05-May-2008	06-May-2008	--		06-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness

Symptom Text: After receiving injection pt. walked out of room and started feeling dizzy and passed out on the floor. Pt. eyes were open and pt. was alert. Pt states felt very lightheaded. Went into room and laid on the table s/p check. Pt. remained on table x 30 min. Discharged in stable condition.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 311647-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	30-May-2007	Unknown		05-May-2008	07-May-2008	MO		07-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	0	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea, Pain, Vaccine positive rechallenge, Vomiting

Symptom Text: Pt received Gardasil on 5-30-07 and 8-13-07. States both times felt nauseated, vomited, ached all over body, had bad H/A. When asked why pt did not reveal S&S on 2nd dose, pt stated "she wanted to tough it out". Refused 3rd shot.

Other Meds: Evra patches

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **311652-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	01-May-2008	03-May-2008	2	05-May-2008	06-May-2008	VT		06-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B019AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1768U	1	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	1448U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Inappropriate schedule of drug administration, Local reaction, Pain in extremity, Skin warm

Symptom Text: c/o R arm hurt on 5/2/08 & then on 5/3/08 arm redness & warmth developed. 7 1/2" L x 6" W redness & warmth R upper arm. Able to lift arm overhead & strong hand squeezage. Dx: Local reaction to shot, allergic vrs. cellulitis. TC to mom 5/5/08 & she did begin Keflex 500mg TID x5 days due to increased redness below elbow. Taking as prescribed.

Other Meds: Lexapro 5mg daily

Lab Data:

History:

Prex Illness:

Prex Vax Illns: ~Varicella (Varivax)~2~6~In Sibling

Vaers Id: 311687-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Oct-2007	01-Nov-2007	26	06-May-2008	07-May-2008	IA	WAES0804USA02237	07-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	1	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Cough, Disturbance in attention, Fatigue, Headache, Hypersomnia, Lethargy, Lymphadenopathy, Malaise, Pharyngitis, Pharyngitis streptococcal, Pharyngolaryngeal pain, Pneumonia, Sinusitis, Somnolence, Stomach discomfort, Tonsillitis, Viral infection, Vomiting

Symptom Text: Initial and follow up information has been received from a physician and a registered nurse, concerning a 15 year old Caucasian female patient with allergies to penicillin, cefadroxil monohydrate (DURACEF) and cefalexin (KEFLEX), who on 23-JUL-2007 was vaccinated with her first dose of GARDASIL (lot# 658094/0524U). On 08-OCT-2007 the patient was vaccinated with her second dose of GARDASIL (lot# 658558/1061U). Concomitant therapy referred to use of an albuterol inhaler, and a nebulizer with prednisone. On 12-NOV-2007, the patient visited the physician with complaints of sore throat, enlarged cervical nodes, slight cough and headache, and was diagnosed with pharyngitis, with onset noted as 05-NOV-2007. Treatment included azithromycin (Z-PAK). On 05-JAN-2008, she visited the office again with sore throat, upset stomach, headache, lethargic and sleeping more than normal. She was again diagnosed with pharyngitis, and with fatigue and lethargy. A strep test and mononucleosis test were negative. Treatment was to watch and repeat testing, if not better by the end of the week. The patient was having trouble staying awake to do her school work, and was feeling ill. On 10-JAN-2008, visited the office with complaints of feeling tired all the time, abdominal pain and headache; she was diagnosed with a viral systemic illness. Treatment include eating healthy, and gradually increasing physical activity. On 16-JAN-2008, she visited the office with a sore throat, cough and headache, tired easily, but she was afebrile. She reported taking ibuprofen prn. Her tonsils were enlarged and exudative and she was diagnosed with acute tonsillitis and lymphadenopathy. A strep and mono test were negative; white blood count (WBC) was 8,000 with left shift. Treatment included cefprozil (CEFZIL) for 10 days. On 17-JAN-2008, however, the strep culture had grown positive group A beta strep. On 28-JAN-2008, the patient still had a sore, swollen throat and headache, but no fever, visited the office, and was diagnosed with streptoco

Other Meds: Albuterol; Prednisone

Lab Data: diagnostic laboratory 03/28/08 normal limits; serum Epstein-Barr negative; Streptococcus oralis 01/18/08 negative; Streptococcus group A 01/18/08 positive; WBC count 01/16/08 8000 shift to left; serum TSH 03/28/08 normal; serum C-reactive 0

History: Adverse drug reaction

Prex Illness: Drug hypersensitivity; Penicillin allergy; Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: 311689-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-Oct-2007	04-Feb-2008	119	06-May-2008	07-May-2008	IA	WAES0804USA02241	07-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Acute sinusitis, Balance disorder, Dizziness, Fatigue, Headache, Hypotension, Lethargy, Nasal congestion, Oral intake reduced, Pharyngitis, Pharyngolaryngeal pain, Sinus headache, Somnolence, Vertigo, Viral infection, Weight decreased

Symptom Text: Initial and follow-up information has been received from a physician concerning a 12 year old female, who on 23-JUL-2007 was vaccinated with her first dose of Gardasil (lot# 658094/0524U). Concomitant vaccination included Tdap (Lot# AC5213018A13). On 08-OCT-2007 the patient was vaccinated with her second dose of Gardasil (lot# 658558/1061U). On 04-FEB-2008 the patient was seen in the office and complained of a sore throat, headache, and stomach ache. The patient was diagnosed with acute pharyngitis. The physician believed the pharyngitis to probably be viral, but would follow culture to 48hours. The strep ID was negative. The patient was given information on how to treat and what to watch for. On 18-FEB-2008 the patient was seen at the office with complaints of dizziness/vertigo, severe headache, and felt "off balance." The patient was diagnosed with fatigue, lethargy, and a headache. The patient also experienced weight loss. The patient's head, ears, eyes, nose, and throat (HEENT) was within normal limits, complete blood count (CBC) was normal, serum Epstein-Barr virus antibody test was negative, and blood pressure was 106/60. The patient appeared to be recovering from viral illness. The physician discussed low blood pressure with the patient. The patient was reminded to stand up slow, eat a healthy diet and to call if signs and symptoms worsened or did not improve. On 25-FEB-2008 the patient was seen in the office with complaints of headache, dizziness, and a decrease in oral intake with a 6-10 pound weight loss over the week. The patient's mother reported that the patient has been sleepy during the week. The patient experienced nasal congestion, and mild pain over frontal sinuses. The patient was diagnosed with headache and acute sinusitis. The patient was prescribed ZITHROMAX TRI-PAK. It was reported that the headache was gone. The patient was advised to take antibiotic with chocolate milk or a meal to help with the upset stomach and to continue the ZITHROMAX TRI-PAK and call with any oth

Other Meds: albuterol

Lab Data: diagnostic laboratory, results unknown; diagnostic laboratory, 02/18/08, head, ears, eyes, nose, throat (HEENT)-within normal limits; blood pressure, 02/18/08, 106/6; serum Epstein-Barr, 02/18/08, negative; body weight measurement, lost 6-1

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 311690-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Feb-2008	10-Mar-2008	21	06-May-2008	07-May-2008	FR	WAES0804USA05694	07-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dermatitis

Symptom Text: Information has been received from a health authority concerning a 15 year old female who on 18-FEB-2008 was vaccinated with a third dose of Gardasil. On 10-MAR-2008 the patient experienced dermatitis on both thighs. Based on a biopsy done on an unspecified date, the diagnosis of interface dermatitis was established. It was reported that livedo racemosa was ruled out. The patient was admitted to the hospital. At the time of this report, the symptoms were ongoing. It was also reported that the first and second vaccination were well tolerated. Other business partner numbers include: E200803917 and PEI2008005289. No further information is available.

Other Meds: Unknown

Lab Data: biopsy interface dermatitis

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: 311691-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	09-Apr-2008	09-Apr-2008	0	06-May-2008	07-May-2008	FR	WAES0804USA05709	07-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Gluteous maxima	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site, Inappropriate schedule of drug administration, Injection site pain, Malaise, Multiple sclerosis relapse, Paraesthesia

Symptom Text: Information has been received from a health professional concerning his 29 year old wife with multiple sclerosis (diagnosed in 2007 with demyelinating disease) and papilloma viral infection (detected 6 months after giving birth, HPV positive on 2 Pap tests third and fourth were negative, results of the fifth pending) and a history of pregnancy (at age 26 normal labor) and malaise who on 09-APR-2008 was vaccinated into the buttock with a first dose of Gardasil. Concomitant therapy included interferon. On 09-APR-2008 the patient experienced intense pain during administration. On 10-APR-2008 one day post vaccination, the patient started with malaise, a tingling sensation on the left side of her face and around the eye area. The patient went to the neurologist. According to the neurologist the patient had multiple sclerosis relapse. She was treated with three doses of corticosteroids administered on 14-APR-2008, 15-APR-2008, and on 16-APR-2008. The neurologist did not establish the vaccine as the cause of the MS relapse, but there was a slight risk. Multiple sclerosis relapse and intense pain during administration were considered to be other important medical events. No further information is available.

Other Meds: interferon (unspecified), Unk - Unk

Lab Data: Unknown

History: Pregnancy; Malaise

Prex Illness: Multiple sclerosis; Papilloma viral infection

Prex Vax Illns:

Vaers Id: 311692-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		06-May-2008	07-May-2008	FR	WAES0804USA06198	07-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Injection site reaction, Pyrexia, Throat irritation

Symptom Text: Information has been received from a gyneacologist concerning a 16 year old female who already felt unwell for three days prior to the vaccination, who, on an unspecified date, was vaccinated with a dose of Gardasil. The lot#, injection route, and injection site were not reported. The following night the patient experienced severe fever and was hospitalised. The patient showed a mild injection site reaction and complained about a raspy throat. A blood sample was taken and only showed slightly increased inflammatory values (not otherwise specified). The patient recovered and was discharged from the hospital one day later. The treating physician in the hospital considered no causal relation to the vaccine but an intercurrent infection. Additional information is not available.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test blood sample - showed slightly increased inflammatory values (not otherwise specified).

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 311693-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	20-Dec-2007	20-Dec-2007	0	06-May-2008	07-May-2008	FR	WAES0805NZL00001	07-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0444F	0	Left arm	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Chronic fatigue syndrome, Cold sweat, Condition aggravated, Feeling hot, Hyperhidrosis, Inappropriate schedule of drug administration, Insomnia, Panic attack

Symptom Text: Information has been received from a physician via CSL as part of a business agreement concerning a 29 year old female with chronic fatigue syndrome following a head injury (1998), nontoxic multi-nodular goitre and irritable bowel syndrome who uses alternative practitioners. On 20-DEC-2007 the patient was vaccinated in her left deltoid with the first dose of Gardasil (Lot # 654672/0444F, Batch # NE09880). There was no concomitant medication. It was reported that for 4 days the patient was okay and then for two and a half months the patient experienced hot and cold sweats, insomnia, panic attacks and exacerbation of chronic fatigue syndrome which are gradually settling (also reported as not yet recovered in the same report). The patient was not treated for the adverse events. The reporter felt that hot and cold sweats, insomnia, panic attacks and exacerbation of chronic fatigue syndrome were unlikely to be related to therapy with Gardasil. Hot and cold sweats, insomnia, panic attacks and exacerbation of chronic fatigue syndrome were considered to be disabling in the patient's opinion. Additional information is not expected.

Other Meds: None

Lab Data: Unknown

History: Head injury

Prex Illness: Chronic fatigue syndrome; Nontoxic nodular goitre; Irritable bowel syndrome

Prex Vax Illns:

Vaers Id: 311707-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Apr-2008	30-Apr-2008	0	06-May-2008	07-May-2008	CA		07-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1267U	1	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2552AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1268U	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye movement disorder, Muscle twitching, Pallor, Syncope vasovagal

Symptom Text: After patient received her 3 injections, she became pale and started slumping over. As mom and RN were helping her lay down they noticed her eyes deviating to the right and twitching of her mouth for no more than 15 seconds. She woke up right away and was appropriated. Vasovagal syncope.

Other Meds: tobramycin 0.3% eye drops-pres. 4/30/0

Lab Data: none

History: none

Prex Illness: stye

Prex Vax Illns:

Vaers Id: 311708-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-May-2008	01-May-2008	0	06-May-2008	07-May-2008	NV		07-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B021AA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2552AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1967U	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Head injury, Headache, Loss of consciousness, Memory impairment, Skin laceration, Syncope, Syncope vasovagal

Symptom Text: Pt held in room for 10 mins after imm's for routine waiting period after imm's. Felt fine and was released. Pt did well until 15 min after receiving imm's. Pt was out in waiting room with mother. She felt light headed and dizzy then fainted. Reportedly fell forward and hit front of head on counter then fell back and hit occiput on tile floor. LOC for approx 10 sec. No sz activity. Immediately awake and talking. Does not remember fall but remembers events immediately prior and after. GCS 15. Pupils equal and reactive. no vomiting. Vital taken and able to stand and walk with help to exam room after 5 minutes. Occiput noted boggy with 1 cm lac. No crepitis noted. Pressure dressing applied. Able to take sips of water and ate orange slices. Neuro intact. Mild occipital headache. Two ASA Free Exedrine given for headache. Pt talking, VSS, memory intact except for the fall. GCS 15. Sent to ER via parent's vehicle at 5:10. Mother says now that pt has not eaten today.

Other Meds: None

Lab Data: ER visit

History:

Prex Illness: on menses

Prex Vax Illns:

Vaers Id: 311752-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Apr-2008	01-May-2008	1	06-May-2008	07-May-2008	MO		08-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	19676	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	19774	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site rash

Symptom Text: rash at injection site -red, raised, 3 inches long by 2 inches wide at injection site on left upper arm.

Other Meds: none

Lab Data: none

History: Alleges allergic reaction to Pediazole, history of asthma and allergic rhinitis.

Prex Illness: sore throat - rapid strep screen negative and low threshold of risk for group A beta-hemolytic Streptococcus

Prex Vax Illns: none~ ()~NULL~~In Patient

Vaers Id: **311753-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	28-Apr-2008	28-Apr-2008	0	06-May-2008	07-May-2008	CA		08-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2888AA	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB222AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1758U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Injection site warmth, Oedema peripheral

Symptom Text: Returned to clinic four days post vaccination with right upper arm swollen and erythematous. Site warm to touch. Onset was evening of vaccination. Denies other symptoms: no fever, other rashes,no shortness of breath. States feels feel. Treated with Ice to site and benadryl.

Other Meds:

Lab Data:

History:

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **311757-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	05-May-2008	06-May-2008	1	06-May-2008	07-May-2008	WA		08-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0133X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2546AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Induration

Symptom Text: 4 inch area of induration appeared in r arm. Skin or arm was not affected (no redness, warmth or drainage).

Other Meds: na

Lab Data: N/A

History: na

Prex Illness: na

Prex Vax Illns:

Vaers Id: 311764-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	24-Mar-2008	24-Mar-2008	0	06-May-2008	07-May-2008	NC		08-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Urticaria

Symptom Text: Patient and her mother reported "itchy hives" down right arm that began the evening of the admission and resolved within 24 hours. Patient took Benadryl. (Shot was given in right deltoid).

Other Meds: Crestar; Biotin; Ovcan 35 (FEMCAN)

Lab Data:

History: Iodine allergy; hyperlipidemia; asthma; seasonal allergies.

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: 311782-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Dec-2006	Unknown		07-May-2008	08-May-2008	--	WAES0709USA01102	08-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Delayed delivery, Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received from Pregnancy Registry for Gardasil from a Nurse Practitioner (N.P.) and with a follow up telephone call concerning a 18 year old (previously reported as 20 year old) female patient with abnormal PAP test. She was obese and was a smoker who had cervical condyloma and "SAA". It was reported that patient was vaccinated around December, 2006 with a first dose of Gardasil. On 05-FEB-2007 she was vaccinated with the second dose of Gardasil (lot # 654510/0962F). Concomitant therapy included "birth control patch", Tylenol as needed for headache and she was treated with prenatal vitamins for pregnancy. The reporter reported that patient received her first injection and was pregnant. She had routine obstetrics labs done. No further information was available. In follow up it was reported that her last menstrual period (LMP) was on 03-JUN-2007 and expected delivery date was 09-MAR-2008. There was no information about delivery or outcome of the delivery. In follow up information from the doctor's office it was reported that on 27-SEP-2007 routine serum maternal alpha-fetoprotein test was done. Patient had ultrasound on 25-JUL-2007, 22-AUG-2007, 10-OCT-2007 and in 09-JAN-2008 for confirmation dates and screening of pregnancy. On 22-AUG-2007 pregnancy associated plasma protein test and on 27-SEP-2007 maternal serum alphafeto protein (MSAFP) was done. No information for the results are available. It was reported that on 13-MAR-2008 at 40.4/7 weeks from LMP patient delivered a female normal baby by cesarean section delivery. The indication for C/S delivery was not reported at this time. The baby weighed 8 lb 12 oz and her apgar score was 8.9. No complication was reported with the baby. Upon internal review patient's failure to progress (delayed delivery and) required a cesesaren section delivery. The event was determined to be an other important medical event. Additional information has been requested.

Other Meds: Tylenol; Vitamins (unspecified)

Lab Data: ultrasound 07/26/07 confirmation, dates, screening; ultrasound 08/22/07 confirmation, dates, screening; ultrasound 10/10/07 confirmation, dates, screening; ultrasound 01/09/08; laboratory test Routine OB labs; serum alpha-fetoprotein 09/27/

History: Papanicolaou smear abnormal; Condyloma

Prex Illness: Pregnancy NOS (LMP = 6/3/2007); Headache; Smoker; Obesity

Prex Vax Illns:

Vaers Id: 311783-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	12-Jun-2007	12-Jun-2007	0	07-May-2008	08-May-2008	SD	WAES0706USA03109	08-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Breech presentation, Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner, for the Pregnancy Registry for Gardasil, concerning a 25 year old female with a history of one previous pregnancy and a miscarriage and a history of childhood epilepsy who on 12-JUN-2007 was vaccinated with a first dose of Gardasil (Lot # 657868/0523U) 0.5 mL IM. Concomitant medications included prenatal vitamins daily (unspecified) as a supplement and ZANTAC daily for reflux. The patient received her first dose of Gardasil IM and since found out that she is pregnant. The nurse practitioner mentioned the pregnancy is normal to date. Medical attention was sought. No additional information is available. The last menstrual period (LMP) was 16-MAY-2007 and the estimated time of delivery is 07-FEB-2008. Follow-up information was received. Medical history and dates of LMP and estimated date of delivery was updated. Follow-up information was received from the physician's office. On 10-SEP-2007 there was a quad screen performed and was within normal limits. On 30-JAN-2008 the patient had a normal healthy baby girl weighing 8 pounds 1 ounce. The apgar score was 9/9. The patient was 38 and 6/7 weeks from LMP. During labor/delivery the baby was in a frank breech presentation and c-section was done. Upon internal review c-section for breech presentation was considered to be an other medical event. Additional information is not expected.

Other Meds: ZANTAC; vitamins [unspecified]

Lab Data: diagnostic laboratory 09/10/07 quad screen-within normal limits

History: Epilepsy

Prex Illness: Pregnancy NOS (LMP = 5/16/2007); Oesophageal acid reflux

Prex Vax Illns:

Vaers Id: 311784-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Jan-2008	07-Apr-2008	70	07-May-2008	08-May-2008	FR	WAES0804USA06200	08-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diplopia, Gait disturbance, Mycoplasma infection, Ophthalmoplegia

Symptom Text: Information has been received from a pediatrician concerning a 17 year old female patient who on 28-JAN-2008 was vaccinated with a first dose of Gardasil and on 27-MAR-2008 was vaccinated IM into the upper arm with a second dose of Gardasil (batch # NG20180, lot # 0510U). On 07-APR-2008 she developed ophthalmoplegia and diplopia followed by gait disturbance on same day. The patient was hospitalised on 13-APR-2008. Internuclear ophthalmoplegia and suspicion of multiple sclerosis was diagnosed. Cerebral spinal fluid (CSF) shoed: three oligoclonal bands (a control was sent to a reference laboratory, result not yet available), normal cell count, albumin ratio pathologically increased, slight barrier disorder and no borreliosis. Cranial magnetic resonance imaging (MRI) revealed multiple inflammatory lesions (mesencephal) and periventricular), spinal MRI was normal. Auditory evoked potential (AEP), somatosensory evoked potential (SEP), Visual evoked potential (VEP) and nerve conduction were normal as well as electroconvulsive therapy (ECT) test. Ophthalmological examination, visus of right eye was 0.8 and left eye was 0.7. Serology test revealed a seroactive infection with Mycoplasma pneumoniae. The patient was treated with URBASON one gram per day for three days. The patient improved during the stay in the hospital. The patient was discharged on 21-APR-2008. Further therapy with physiotherapy and adaptation of glasses was planned. The reporter assessed the relation to the vaccine as possible. The other business partner number included: E200803914. The file is closed. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 13Mar08, Cranial MRI revealed multiple inflammatory lesions (mesencephal); auditory evoked potential, 13Mar08, Normal; ophthalmological exam, 13Mar08, 0.8, Visus of right eye; ophthalmological exam, 13Mar08, 0.7,

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 311785-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Jan-2008	22-Jan-2008	1	07-May-2008	08-May-2008	--	WAES0804USA06209	21-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Anorexia, Anxiety, Condition aggravated, Depression, Fear, Insomnia, Menstruation irregular, Nausea, Self esteem decreased, Suicidal ideation, Temporal lobe epilepsy, Thinking abnormal, Weight decreased

Symptom Text: Information has been received from a physician and a consumer concerning a 14 year old female patient with temporal lobe epilepsy (also reported as mild by the mother) who on 21-JAN-2008 was vaccinated with a first dose of GARDASIL. Concomitant therapy included carbamazepine (CARBATROL). The reporter reported that her daughter developed "irrational thoughts and fears that developed into suicidal thoughts." Her grades in school went down and she developed low self esteem. She also experienced "real bad stomach pain" for a month. She was "sick to her stomach and could not eat". Her weight went from 109 pounds to 96 pounds because she was not eating. She had electroencephalography (EEG), blood work (not specified what test), hepatic function tests (Liver test) and pancreatic test done. No results reported for the tests. The reporter indicated that because of these events her daughter will not complete the GARDASIL series. The patient's outcome reported to be recovering. In follow up telephone call the physician (neurologist) stated that the patient had temporal lobe epilepsy and it could result in the patient being more prone to depression and anxiety. He also indicated that the patient might have received the first and second injection of GARDASIL in the late luteal phase of her menstrual cycle which could have resulted in exacerbating mood changes associated with the menstrual cycle and "epileptiform activity". He stated that it was hard to confirm that GARDASIL exacerbated the patient's condition. Upon internal review suicidal thoughts was determined to be an other important medical event. Additional information has been requested. 5/19/08-records received for neurology consultation visits 2/7/08-Impression:History of epilepsy since 15 months of age with symptoms and MRI findings suggestive of complex partial seizures including some with secondary generalization in early childhood. History of recurrent seizures when off of medications as well as MRI findings of mesiotemporal sclerosis, will require antiseizure

Other Meds: CARBATROL

Lab Data: Unknown 5/19/08-records received-EEG normal. MRI findings of mesiotemporal sclerosis, MRI findings suggestive of complex partial seizures

History: 5/19/08-records received-History of epilepsy since 15 months of age with symptoms and MRI findings suggestive of complex partial seizures including some with secondary generalization in early childhood. History of recurrent seizures when off of medications as well as MRI findings of mesiotemporal sclerosis, will require antiseizure medications indefinitely. Had been seizure free fo

Prex Illness: Temporal lobe epilepsy

Prex Vax Illns:

Vaers Id: 311786-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	06-Apr-2007	25-Apr-2008	385	07-May-2008	08-May-2008	FR	WAES0804USA06287	08-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0088U	0	Unknown	Unknown	

Seriousness: LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Type 1 diabetes mellitus, Vision blurred, Weight decreased

Symptom Text: Information has been received from a physician and a medical assistant concerning a 12 year old female patient who on 06-APR-2007 was vaccinated IM with a first dose of Gardasil (lot #655324/0088U) and on 02-AUG-2007 she was was vaccinated with a second dose of Gardasil (lot # 657622/0388U). On 16-JAN-2008 she was was vaccinated her third dose of Gardasil (lot # 657868/0523U). No concomitant therapy was reported. The physician reported that the patient developed diabetes Type 1 after receiving three doses of Gardasil. She was examined in the hospital on 25-APR-2008 and on 28-APR-2008. She was not admitted to the hospital on either occasion. The patient was started on insulin. No further information was provided. The patient's outcome was not recovered. In follow up telephone call the medical assistant reported that the patient began experiencing rapid weight loss and blurry vision (dates not reported). She was diagnosed with Type 1 diabetes. The physician considered patient starting on insulin to be life threatening and disabling and an important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: serum glucose, 25Apr08, 386 mg/dL

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **311787-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	25-Apr-2008	25-Apr-2008	0	07-May-2008	08-May-2008	--	WAES0804USA06460	08-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Blindness transient, Nausea

Symptom Text: Information has been received from a 22 year old female patient who is allergic to amoxicillin and had human papilloma viral infection. On 25-APR-2008 she was vaccinated with a first dose of Gardasil. She reported that approximately twenty minutes after vaccination she began to feel nauseous. In addition, her vision was adversely affected. She began to see black dots and then "everything went black" and she had a temporary total loss of vision for ten to fifteen seconds. She reported that she laid down for ten minutes and she seemed fine after that. The only other symptom she had been experiencing was abdominal cramping as of 26-APR-2008. She had a colposcopy of the cervix on the same day she received the injection. The patient reported to be recovering. Upon internal review temporary total loss of vision was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: colposcopy, 04/25/08, colposcopy of the vagina

History:

Prex Illness: Penicillin allergy; Papilloma viral infection

Prex Vax Illns:

Vaers Id: 311788-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	23-Feb-2008	Unknown		07-May-2008	08-May-2008	FR	WAES0804USA06506	08-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1201U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Erythema, Local reaction, Malaise, Pain, Swelling

Symptom Text: Information has been received from a general practitioner concerning a 21 year old female who on 23-FEB-2008 was vaccinated with a first dose of Gardasil (Lot# 1201U); Batch# NG41880). After the vaccination but on an unspecified date the patient experienced a sensation of malaise and a local reaction with erythema, pain and swelling. The patient was hospitalized on an unspecified date. The reporter was not the physician who vaccinated the patient. At the time of this report, the patient's outcome was not specified. Other company numbers included: E200804034. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 311798-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	29-Apr-2008	01-May-2008	2	07-May-2008	15-May-2008	NC		15-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	175711	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site pain, Injection site warmth

Symptom Text: Pt returned to the clinic 48 hours post-vaccine with 2.5 x 3 cm area of red, hot, very tender induration with 3x4 cm surrounding erythema, LUE at injection site

Other Meds: Daytrana 10 mg

Lab Data:

History: Drug allergies to Septra; Duricef band aids

Prex Illness: None

Prex Vax Illns:

Vaers Id: 311800-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	25-Mar-2008	25-Mar-2008	0	07-May-2008	16-May-2008	FL		03-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pruritus, Rash

Symptom Text: Was contacted by pt's mother afternoon of injection who informed office that pt had called her during her lunch hour and reported a rash on her thigh and some nausea. Pt was contacted. Denied use of new soap, detergent, fragrances, contact with chemicals, etc. On 3/26 pt was contacted again she stated rash went away on 3/25 but reappeared on 3/26/08, arms were itching but no rash presented. Pt stated she did not use the Benadryl 25 mg or 1% Hydrocortisone cream. Was told to contact office if no improvement.

Other Meds: NuvaRing, Kelp, MUI

Lab Data:

History: KNDA codeine causes vomiting

Prex Illness:

Prex Vax Illns:

Vaers Id: 311820-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-May-2008	06-May-2008	0	07-May-2008	08-May-2008	MI		08-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB249AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1968U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Dizziness, Heart rate, Hyperhidrosis, Pallor

Symptom Text: 6:45 pm Received two injections today. Within 1 minute, complained of feeling dizzy. Had not eaten since morning. Color slightly pale, slightly diaphoretic. Reclined in reclining chair, given a sucker and juice to sip. VS checked at 6:50 and 6:55 pm (BP 108/76 p.92,BP 106/76 p.88). At 6:55 pm color was pink, skin warm and dry, "felt better". Assisted to sitting position. Tolerated well. 7 pm Ambulated to lobby with assistance, tol. well. Discharged with Mom.

Other Meds: unknown

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: 311825-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	28-Apr-2008	29-Apr-2008	1	07-May-2008	13-May-2008	MD		14-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
DTAP	SANOFI PASTEUR	C2937BA		Left arm	Intramuscular	YF
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB208AA	1	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1757U	2	Left arm	Intramuscular	
TYP	BERNA BIOTECH, LTD	7352216		Unknown	By Mouth	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Lip swelling, Periorbital oedema, Urticaria

Symptom Text: Came to facility for travel consult 4/15/08; Went to Travel clinic 4/17 for Yellow Fever, Came to facility 4/29/08 had started Oral Typhoid 4/28/08 c/o right periorbital edema, no hives, no SOB. Advised to continue Oral Typhoid. Came to facility 5/5 c/o of Left peri-orbital edema, hives on right arm and left hip, with lip swelling. Denied SOB,wheezing, difficulty swallowing. Received 50 mg of IM benadryl, Epi-Pen, and started tappering dose of prednisone at 60 mg.Advised not to take last dose of Typhoid. Returned to facility 5/6 symptoms resolved

Other Meds: oral contraception

Lab Data:

History: PCN; peaches

Prex Illness: none

Prex Vax Illns:

Vaers Id: **311852-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	22-Mar-2007	22-Mar-2007	0	08-May-2008	09-May-2008	NY	WAES0703USA05313	09-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0012U		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, via the Merck pregnancy registry, concerning a 25 year old female patient who on 22-MAR-2007 was vaccinated with a dose, 0.5ml, IM, of GARDASIL (Lot # 655503/0012U). The physician stated that on 24-MAR-2007, the patient had a positive pregnancy test (over the counter), and added that the patient was pregnant at the time of vaccination. The LMP date was 25-FEB-2007, with an estimated date of delivery of 02-DEC-2007. Follow up information from a nurse at the physician's office, indicated that on 12-DEC-2007, the patient delivered a "normal and healthy baby girl," via a C-section. Attempts for a vaginal delivery included PITOCIN, and "resulted in spontaneous decreases on the baby's heart rate." The infant weighed 8 lb 6 oz, with an Apgar score of 9/9. No further information was reported. Upon internal review, "resulted in decrease in the baby's heart rate" (led to a C-section) was determined to be serious as an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: cesarean section, 12/12/07; beta-human chorionic, 03/24/07, positive

History:

Prex Illness: Pregnancy NOS (LMP = 2/25/2007)

Prex Vax Illns:

Vaers Id: **311853-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	04-Jun-2007	04-Jun-2007	0	08-May-2008	09-May-2008	AZ	WAES0707USA03114	09-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Haemorrhage

Symptom Text: Initial and follow-up information has been received from a physician concerning a 26 year old female with no medical history, who on 04-JUN-2007 was vaccinated with a first dose of GARDASIL. There was no concomitant medication. The patient was pregnant. The pregnancy was confirmed by a pregnancy test. At the time of the report, the patient was 8 weeks pregnant and her outcome was unknown. The patient's last menstrual period was 20-MAY-2007 and her estimated delivery date was 27-FEB-2008. The patient had one previous pregnancy and one full term delivery. No product quality complaint was involved. Follow-up information indicated that on 07-AUG-2007 the patient went to the emergency room due to bleeding. The patient experienced a spontaneous abortion. Upon internal review spontaneous abortion was considered to be an other important medical event. Additional information is not expected.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 5/20/2007)

Prex Vax Illns:

Vaers Id: **311854-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		08-May-2008	09-May-2008	NJ	WAES0804USA03665	09-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician concerning an 18 year old female with no pertinent medical history or drug reactions/allergies who on an unspecified date was vaccinated with a third dose of Gardasil. Subsequently the patient may have been pregnant when she received the third dose of Gardasil. The doses of Gardasil were administered at another physician's office. Unspecified medical attention was sought. On an unspecified date the patient had a positive beta-human chorionic gonadotropin test (unspecified). The patient's LMP date was 13-FEB-2008. The patient's estimated date of delivery is 19-NOV-2008. Follow-up information was received from the physician's office. On an unspecified date the patient had terminated her pregnancy. The patient's outcome was unknown. Upon internal review abortion induced is considered to be an other medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 2/13/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **311855-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	19-Sep-2007		08-May-2008	09-May-2008	FR	WAES0805AUS00014	09-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0138U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chest pain, Gait disturbance, Muscle spasms, Musculoskeletal stiffness, No reaction on previous exposure to drug, Palpitations, Pyrexia

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 15 year old female who had no reaction to the first two doses of GARDASIL. The patient was vaccinated with the third dose of GARDASIL (Lot No. 655742/0188U, Batch No. J0799, Expiry date 07-AUG-2009). On 19-SEP-2007 the patient experienced pyrexia, chest pain, gait disturbance, muscle spasms, musculoskeletal stiffness and palpitations and was hospitalised. It was described that the patient experienced fever, spasms in her arms and legs - could not walk properly, neck stiffness, chest pain and racing heart rate. At the time of reporting on 08-OCT-2007, the outcome of pyrexia, chest pain, gait disturbance, muscle spasms, musculoskeletal stiffness and palpitations were unknown. The agency considered that pyrexia, chest pain, gait disturbance, muscle spasms, musculoskeletal stiffness and palpitations were possibly related to therapy with GARDASIL. The original reporting source was not provided. Subsequently the patient's experience was reported in an article, 25-JAN-2008. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 311856-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	31-Jul-2007		08-May-2008	09-May-2008	FR	WAES0805AUS00015	09-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0491U		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Injection site reaction, Injection site swelling, Rash erythematous

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 26 year old female who was vaccinated with GARDASIL (Lot No. 657870/0491U, Batch No. J1973, Expiry date 11-FEB-2010). On 31-JUL-2007 the patient experienced injection site reaction and rash erythematous. It was described that the patient experienced swollen injection site and raised erythematous rash on arms and torso. At the time of reporting on 30-OCT-2007, the patient had recovered from injection site reaction and rash erythematous. The agency considered that injection site reaction and rash erythematous were possibly related to therapy with GARDASIL. The original reporting source was not provided. Injection site reaction and rash erythematous were considered to be disabling by the agency. Subsequently the patient's experience was reported in an article 25-JAN-2008. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 311857-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	27-Sep-2007	29-Sep-2007	2	08-May-2008	09-May-2008	FR	WAES0805AUS00050	09-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Acidosis, Ascites, Hypocalcaemia, Pancreatitis, Pyrexia, Rash generalised

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 26 year old female who on 27-SEP-2007 was vaccinated with GARDASIL. Concomitant therapy included doxycycline hyclate, PHENERGAN TABLETS/SUPPOSITORIES) and ZANTAC. On 29-SEP-2007 the patient experienced rash generalised, abdominal pain upper (described as right upper quadrant epigastric pain), blood amylase increased, lipase increased, pancreatitis and pyrexia and was hospitalized, CT scan revealed pancreatitis and intraabdominal fluid. On 03-OCT-2007, the patient's calcium was low (hypocalcemia) while pH was 7.25 (acidosis). Abdominal x-ray was abnormal. CT scan of the abdomen revealed a grossly oedematous pancreas and ascites. Blood and urine culture were negative. The patient's GGT was 49, ALT (SGPT) was 27 and the AST (SGOT) was 45. White blood cell count was 10.3 while the haemoglobin was 91%. Other laboratory investigations such as VRE, adenovirus CMV, EBV, HSV, mumps, varicella zoster and toxoplasma screens were all negative. At the time of reporting on 19-OCT-2007 the patient's rash generalised and abdominal pain upper and blood amylase increased and lipase increased and pancreatitis and pyrexia persisted. The agency considered that rash generalised, abdominal pain upper, blood amylase increased, lipase increased, pancreatitis and pyrexia were possibly related to therapy with GARDASIL. The original reporting source was not provided. Subsequently the patient's experience was reported in an article, 25-JAN-2008. Additional information is not expected.

Other Meds: doxycycline hyclate, Unk - Unk; promethazine HCl, Unk - Unk; ranitidine HCl, Unk - Unk

Lab Data: abdominal X-ray, 03Oct07, abnormal; computed axial tomography, 03Oct07, grossly; computed axial tomography, pancreatitis; Epstein-Barr virus antibodies, 03Oct07, negative; WBC count, 03Oct07, 10.3; adenovirus PCR, 03Oct07, negative; arteria

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **311858-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		08-May-2008	09-May-2008	PA	WAES0805USA00174	09-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Gait disturbance, Paralysis

Symptom Text: Information has been received from a nurse within the doctor's office concerning a female patient who was vaccinated with a second dose of GARDASIL. The nurse reported that she heard from her aunt that a patient received the GARDASIL injection and experienced paralysis and could not even cut her own dinner after the injection was administered. The patient had to walk with a cane and also went to physical therapy. She did not receive the vaccine at the reporting nurse's office. No further information was known. The paralysis was considered to be disabling. Additional information is not available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **311859-1 (S)** **Related reports:** 311859-2; 311859-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Mar-2008	15-Apr-2008	26	08-May-2008	09-May-2008	NJ	WAES0805USA00463	23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Fatigue, Hyperreflexia, Immunisation reaction, Impaired driving ability, Muscle disorder, Myalgia, Pain in extremity

Symptom Text: Information has been received from a physician concerning an approximate 17 year old female who in April 2007 ("within the past 2-3 weeks") was vaccinated with a first dose of Gardasil 0.5 mL IM. In April 2007, "couple of weeks" later the patient developed "muscular problems to the point where she couldn't drive". Unspecified medical attention was sought. At the time of reporting it was unknown if the patient had recovered. When asked if it was a significant disability/incapacity, "she said that she thinks it was because the patient could not drive a car". Additional information has been requested. 8/19/08 To be linked to 311859 and 316857. 8/21/2008 Neurology consults received dated 5/2/2008 and 5/27/2008 with Assessment: Myalgias-began 3 weeks after the Gardasil shot and has continued for 3 weeks. Not weak; doubt Guillain-Barre syndrome. PCP refered pt with sx of fatigue, pain upon pulling legs and need to use handrail to pull self climbing stairs, also affects the joints. PCP ? latent virus, restless legs, or rxn to Gardasil (most likely). PE WNL except 4+ DTRs in the lower extremities.

Other Meds: Unknown

Lab Data: Unknown. Labs and Diagnostics included in report: CBC WNL. ESR 19. ANA (-). CH50 91n. C3 115.8n. C4 26.3n. EBV c/w past infection (Capsid Ag IgG 7.01, Nuclear Ab IgG 16.99.) Labs and Diagnostics: MRI brain WNL- no eveidence of demyel

History: Unknown. PMH: none

Prex Illness:

Prex Vax Illns:

Vaers Id: **311859-2** **Related reports:** 311859-1; 311859-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		19-Jun-2008	18-Aug-2008	NJ	WAES0805USA00440	18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Guillain-Barre syndrome, Limb discomfort

Symptom Text: Information has been received from the physician concerning a 17 year old female who was vaccinated with a first dose of GARDASIL. Three weeks to the day of the vaccination, the patient came into the office for a follow up visit with discomfort of leg muscles. It was reported by the physician that this might be sensory variant GUILLAIN BARRE. The patient was being treated on a outpatient basis and with over the counter ADVIL as need but no prescriptions. At the time of this report, the patient had not recovered. No product quality complaint was involved. Upon internal review, GUILLAIN-BARRE was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **311859-3** **Related reports:** 311859-1; 311859-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Mar-2008	14-Apr-2008	25	01-Aug-2008	11-Aug-2008	NJ		29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Muscular weakness, Myalgia, Neurological examination

Symptom Text: Joint pain. "Sore muscles", weakness of large, lower muscle groups - pain hips, knees. Saw by neurologist and I.D.

Other Meds:

Lab Data: WBC, 4.5-11.0 thous, 8.02; RBC, 3.9-5.0 mills, 4.58; HGB, 12.0-15.0 gm%, 13.9; HCT, 35-44 %, 39.4; MCV, 79.0-96.0, 85.9; MCH, 26.0-32.0, 30.4; MCHC, 32.5-36.0, 35.3; PLTS, 150-400 thou, 318; MPV, 6.2-9.1 fL, 7.1; RDW, 12-15, 12.5 manual dif

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 311860-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	Unknown	27-Oct-2007		08-May-2008	09-May-2008	--	WAES0805USA00477	09-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a 27 year old female with an allergic reaction to antibiotics who on 13-MAR-2007 was vaccinated with a first dose of GARDASIL. On an unspecified date the patient was vaccinated with a second and third dose of GARDASIL. There was no concomitant medication. It was reported that the patient had three shots of GARDASIL and experienced a seizure disorder during sleep on 27-OCT-2007, 10-NOV-2007, 01-JAN-2008, 31-JAN-2008, 23-FEB-2008 and 03-APR-2008. Unspecified medical attention was sought. The patient had a computed axial tomography, diagnostic laboratory tests, electroencephalography and a magnetic resonance imaging performed. The results were unknown. At the time of reporting the patient had not recovered. Upon internal review the event seizure disorder was considered to be an other medical event. No additional information is available.

Other Meds: None

Lab Data: computed axial, no results reported; diagnostic laboratory, no results reported; electroencephalography, no results reported; magnetic resonance, no results reported

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: 311861-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		08-May-2008	09-May-2008	MI	WAES0805USA00516	09-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Muscular weakness, Nerve injury, Pain in extremity, Physiotherapy

Symptom Text: Information has been received from a physician concerning an 18 or 19 year old female who in March 2007, was vaccinated with a first dose of Gardasil IM. In March 2007 the patient experienced nerve impact in her shoulder blade. The patient went through physical therapy to repair the nerve damage. The patient was unable to play softball because of the weakness and pain in her arm. The patient could not fully use her arm. At the time of reporting the patient was recovering. The reporter considered the events to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **311867-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Mar-2008	19-Apr-2008	44	08-May-2008	16-May-2008	NC		16-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Palpitations, Paraesthesia, Syncope

Symptom Text: Onset 4-19-08 - X2 episodes of fainting, SOB, palpitations facial & extremity tingling, X1 syncopal episode 5-2-08 with same symptoms -> seen at ER.

Other Meds: None

Lab Data: CMP, CBC, BH, EKG, spirometry, cardiology & neurology referrals

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 311876-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	30-Apr-2008	30-Apr-2008	0	08-May-2008	16-May-2008	ME		16-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0967U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Body temperature increased, Headache, Nausea, Vomiting, Wheezing

Symptom Text: Gardasil inj given at 8:30am on 4/30/08. Pt started feeling nauseous. By evening pt felt weak, wheezing, vomiting until 5am, temp 104 degrees, & HA.

Other Meds:

Lab Data:

History: Flagyl/Imitrex

Prex Illness: joint pain/diarrhea

Prex Vax Illns:

Vaers Id: **311901-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-May-2008	Unknown		08-May-2008	13-May-2008	TX		13-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB216AA	2	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0067X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2546AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B020AA	5	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1917U	1	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cellulitis, Injection site erythema, Injection site warmth

Symptom Text: redness and warmth at injection site after shots given on 05/05/2008. Seen in ER and treated with antibiotics for cellutitis per parent by phone call 05/08/2008 1:30 pm.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **311910-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-May-2008	02-May-2008	1	09-May-2008	13-May-2008	--		13-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Herpes zoster

Symptom Text: RASH ACROSS CHEST DIAGNOSED AS SHINGLES; ONSET OF RASH ONE DAY AFTER HPV #2.

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **311927-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Jul-2007	Unknown		09-May-2008	12-May-2008	OH	WAES0708USA00682	12-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	09270	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse and through a Pregnancy Registry concerning a 17 year old female with no pertinent medical history who on 30-JUL-2007 was vaccinated intramuscularly with the third, 0.5 mL dose of GARDASIL (Lot # "09270"). There was no concomitant medication. It was reported that the patient became pregnant sometime before she received her third dose of the vaccine series. No other symptoms were noted. The patient sought unspecified medical attention. On 01-AUG-2007, the patient had a pregnancy test which was positive with an estimated date of delivery approximately in Jan 2008. No other information was available. Follow-up information was received. The patient had electively terminated her pregnancy on an unspecified date. Upon internal review abortion induced is considered to be an other important medical event. Additional information is not expected.

Other Meds: None

Lab Data: beta-chorionic 08/01/07 positive

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 311928-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	03-Aug-2007	01-Sep-2007	29	09-May-2008	12-May-2008	CA	WAES0710USA05590	12-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received as part of a pregnancy registry from a mother concerning her 18 year old daughter with a drug hypersensitivity to acetaminophen (+) hydrocodone bitartrate (VICODIN) that makes her sick to her stomach and "ovarian problems" that prevent her from menstruating with a history of ovarian cysts and ovarian endometriosis who on 03-AUG-2007 was vaccinated with the first dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). In approximately September 2007, the patient became pregnant. On 05-OCT-2007 the patient received her second dose of GARDASIL. No adverse event was reported. No laboratory studies were performed. As of 25-OCT-2007 the patient was 7 weeks pregnant and her estimated date of delivery is 12-JUN-2008. As of 25-OCT-2007, the patient had not sought medical attention. Follow-up information was received. On an unspecified date the patient had an abortion; elective termination. Upon internal review abortion; elective termination is considered to be an other medical event. Additional information is not expected.

Other Meds: Hormonal contraceptives

Lab Data: None

History: Ovarian cyst; Endometriosis of ovary; Upset stomach

Prex Illness: Pregnancy NOS (LMP = 9/6/2007); Drug hypersensitivity; Ovarian disorder

Prex Vax Illns:

Vaers Id: 311929-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Jul-2007	01-Aug-2007	23	09-May-2008	12-May-2008	--	WAES0804USA05570	12-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received from a mother and 18 year old daughter who on 05-MAY-2007 was vaccinated with her first dose of Gardasil (Lot #, site and route not reported). On 09-JUL-2007 the patient was vaccinated with her second dose of Gardasil (Lot #, site and route not reported). "Sometime in August 2007", the patient missed her period and conducted a home urine pregnancy test which was positive. The patient also reported that she also had a pregnancy blood test which was positive (not further specified). In "January 2008", the patient delivered her baby. The patient was hospitalized for delivery of the baby which she had by cesarean section. No further information was provided. The patient did not report any adverse reaction. It was reported that there were "no complications for the mother or the baby". Additional information has been requested.

Other Meds: Unknown

Lab Data: urine beta-human, 08/??/07, positive; serum beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 311930-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	24-Sep-2007	24-Sep-2007	0	09-May-2008	12-May-2008	FR	WAES0805AUS00038	12-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0491U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia, Vaccine positive rechallenge

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 26 year old female who on 24-SEP-2007, was vaccinated with the second dose of GARDASIL (Lot # 657870/0491U, Batch # J2138, Expiry date 11-FEB-2010). On 24-SEP-2007, after vaccination, the patient experienced hypoaesthesia and paraesthesia which was described as pins and needles and numbness in vaccinated arm, feeling spread across back of her neck and down other arm and into her leg and was hospitalized. It was also reported that the patient had the same reaction after the first dose of GARDASIL. The agency considered that the same reactions were certainly related to therapy with Gardasil. At the time of reporting on 19-OCT-2007, the had patient recovered from the hypoaesthesia and paraesthesia. The agency considered the hypoaesthesia and paraesthesia were certainly related to therapy with GARDASIL. The original reporting source was not provided. Subsequently the patient's experience was reported in an article. Additional information is not expected. A copy of the published article is attached as further documentation of the patient's experience.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **311931-1 (S)** **Related reports:** 311931-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	09-Jan-2008	01-Feb-2008	23	09-May-2008	12-May-2008	--	WAES0805USA00064	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	1	Right arm	Intramuscular	HPV4

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Cerebellar artery occlusion, Cerebrovascular accident, Demyelination, Diplopia, Dizziness, Dysstasia, Gait disturbance, Paraesthesia, Pyrexia, Sinus tachycardia, Vitamin B12 deficiency, Vomiting, Wallenberg syndrome, Weight increased

Symptom Text: Information has been received from a consumer concerning her 20 year old daughter with allergy to azithromycin (ZITHROMAX) who on 09-NOV-2007 was vaccinated with the first dose of GARDASIL, 0.5 mL, (injection form) (Lot # not reported). On 09-JAN-2008, the patient was vaccinated with the second dose of GARDASIL, 0.5 mL, (injection form) (Lot # not reported). Concomitant therapy included drospirenone (+) ethinyl estradiol (YAZ). On 01-FEB-2008, after getting the second dose of GARDASIL, the patient experienced a stroke and was hospitalized. The patient stayed in the hospital for one week. At the time of this report, the patient was recovering from the event. The causality of the event was not reported. No product quality complaint was involved. Additional information has been requested. 6/3/08 Reviewed hospital medical records for 2/4-2/8/2008. FINAL DX: small right CVA; vitamin B12 deficiency; sinus tachycardia; Wallenberg syndrome. Records reveal patient experienced dizziness, left sided numbness, diplopia, fever & vomiting x 2 days. Developed sinus tachycardia & anxiety controlled w/meds. Cardio & neuro consults done. Improved left face & arm paresthesias but left thigh & lower leg paresthesias persisted at d/c to home. Difficulty getting OOB & walking. To have outpatient PT/OT as well as f/u w/neuro & cardio. 9/5/08 Reviewed heme, neuro & rheum consultant medical records of 3/10-5/30/2008. FINAL DX: CVA, lateral medullary syndrome (Wallenberg's) related to the occlusion of the posterior inferior cerebellar artery. Records reveal patient experienced recent CVA, 20# weight gain since CVA.

Other Meds: YAZ

Lab Data: LABS: CT brain WNL. MRI & MRA WNL. Repeat MRI abnormal w/possible focal demyelination. Carotid duplex WNL. Echocardiogram WNL. TEE WNL. Vit B12 194 (L). Influenza A&B neg. ECG w/sinus tachycardia. ANA (H). MRA of neck WNL.

History: PMH: Hashimoto's thyroiditis at age 7, hypothyroidism; pneumonia at age 9; vascular gum irregularity; irregular periods; MVA 4 yrs ago;anxiety. Allergy: zithromax, hives. On Yasmin contraceptive & minocycline for acne. Family hx: heart disease, Hashimotos disease & goiter.

Prex Illness: Contraception; Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **311931-2 (S)** **Related reports:** 311931-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-May-2008	01-May-2008	0	04-Jun-2008	06-Jun-2008	--	WAES0805USA04728	13-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Cerebrovascular accident, Contraception

Symptom Text: Information has been received from a physician concerning a 20 year old female with a history of an unspecified blood disorder, who on an unspecified date was vaccinated with the first dose of GARDASIL, in the first week of May 2008, the patient was vaccinated with the second dose of GARDASIL lot # not provided. Concomitant therapy included hormonal contraceptives (unspecified). It was reported by a physician that the patient experienced a cerebrovascular accident, (CVA), three weeks after receiving her second dose of GARDASIL. The patient was admitted to the hospital on an unspecified date, and has since been released. At the time of reporting, the patient was recovering. The physician had discontinued therapy with GARDASIL. The reporter felt that the event was life-threatening. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data:

History: Blood disorder

Prex Illness:

Prex Vax Illns:

Vaers Id: **311932-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Aug-2007	16-Aug-2007	0	09-May-2008	12-May-2008	FR	WAES0805USA00839	12-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Meconium in amniotic fluid

Symptom Text: Information has been received from a gynecologist, concerning a 16 year old female patient, who was in the 11th week of gestation when on 16-AUG-2007 she was vaccinated with the first dose, and in the 19th week of gestation on 22-OCT-2007, when vaccinated with the second dose of Gardasil (lot #'s, route and site not reported). Concomitant suspect therapy on 16-AUG-2007, included a dose of Vaqta (manufacturer not specified). At the end of October, 2007, the pregnancy was established, at the 20th gestation week, with reported date of LMP on 09-JUN-2007 (estimated date of delivery 15-MAR-2008). After a regular course of pregnancy, the patient gave birth, via cesarean section because of green amniotic fluid, to a healthy child on 15-MAR-2008 (gender and birth weight not reported). The Apgar Index was 8/10/10. The post natal examination of the infant showed no pathologies. This case is closed. Other business partners include: E2008-03804.

Other Meds: Unknown

Lab Data: cesarean section, 15Mar08, because of green amniotic fluid; Apgar score, 15Mar08, 8/10/10

History:

Prex Illness: Pregnancy NOS (LMP = 09Jun07)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **311933-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Oct-2007	14-Apr-2008	189	09-May-2008	12-May-2008	FR	WAES0805USA00840	12-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0251U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chills, Nausea, Pain, Peripheral vascular disorder, Pruritus generalised, Pyrexia

Symptom Text: Information has been received from a gynecologist, concerning a 16 year old female patient who on 08-OCT-2007 was vaccinated IM with the first dose (lot #0251U; batch NF56480; well tolerated), and on 10-DEC-2007, vaccinated IM with the second dose (lot #0276U; batch NF58550; well tolerated), and on 14-APR-2008 vaccinated IM with the third dose (lot # 1068U; batch NH06410) of GARDASIL. On 14-APR-2008 after vaccination, the patient complained about chills, nausea, and pain concerning the whole body. After treatment with paracetamol, twice, the patient developed a fever of up to 39 degrees C. The patient was admitted to the hospital on 15-APR-2008 because of generalized pain and a peripheral circulatory disorder. On 15-APR-2008 and 16-APR-2008, the patient's C-reactive protein (CRP) was increased (values 7.5 and 9.4, respectively - units not specified). On 16-APR-2008, leukocytes were decreased at 3,200, and thrombocytes were decreased at 105,000 (units not specified). Under medication with unspecified infusion and ibuprofen, she recovered on 17-APR-2008, and was discharged from the hospital. On 21-APR-2008, there were no abnormal lab findings. Other business partner numbers include: E2008-03964. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory test 21Apr08 no abnormal findings; body temp 14Apr08 39 degrees C; serum C-reactive protein 15Apr08 7.5 increased; WBC count 16Apr08 3,200 decreased; platelet count 16Apr08 105,000 decreased; serum C-reactive protein 1

History: No reaction on previous exposure to vaccine

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **311934-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		09-May-2008	12-May-2008	FR	WAES0805USA00842	12-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Disseminated intravascular coagulation, Influenza like illness

Symptom Text: Information has been received from a physician, concerning an adolescent female patient, with a history of no reaction on previous exposure to vaccine doses 1 and 2 (dates not specified), who on an unknown date was vaccinated with the third dose of Gardasil (lot #, site and route not specified). Subsequently the patient experienced flu-like symptoms and in the course developed disseminated intravascular coagulation. She was admitted to the hospital and recovered within an unspecified time (details not reported). No further information was available. Other business partner numbers include: E2008-03969.

Other Meds: Unknown

Lab Data: Unknown

History: No reaction on previous exposure to vaccine

Prex Illness:

Prex Vax Illns:

Vaers Id: **311935-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		09-May-2008	12-May-2008	FR	WAES0805USA00844	12-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nervous system disorder, Neurological symptom

Symptom Text: Information has been received from a health authority (reference number PE12008005421) and a physician concerning an approximately 16 year old adolescent female patient who in 2007 was vaccinated with a first, second and a third dose of Gardasil (Lot #, administration routes, sites and dates not reported). The physician reported that the patient experienced recurrent headache and focal neurological symptoms. Multiple lesions in central nervous system (CNS) of unknown origin were detected. Latencies not reported. Symptoms were on going at the time of this reporting. The events "headache recurrent, Neurological disorder not otherwise specified (NOS) and Central nervous system disorder NOS" were considered to be other important medical events. The other business partner number includes: E200804020. Additional information is not available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **311968-2** **Related reports:** 311968-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		19-May-2008	11-Jun-2008	WV	WAES0804USA06163	11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Neuropathy peripheral, Paraesthesia, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician, concerning a 14 year old female patient, who on an unknown date was vaccinated with the first dose of GARDASIL, and subsequently developed tingling and numbness in her arm. Following the vaccination with the second dose (date not specified), the patient again developed numbness and tingling in her arm, as well as peripheral neuropathy. Following the vaccination with the third dose (date not specified), she again developed peripheral neuropathy. The physician sent her to a neurologist (details not provided). At the time of this report, the patient had not recovered from peripheral neuropathy. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **311992-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-May-2008	09-May-2008	1	09-May-2008	13-May-2008	IN		13-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2541AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2775AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1967U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Nausea, Pyrexia, Rash macular, Vomiting

Symptom Text: red splotchy rash, nausea/vomiting, headache, dizziness, fever. OTC Benadryl, topical hydrocortisone cream for rash; continue to follow closely.

Other Meds: NONE

Lab Data:

History:

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312017-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-May-2008	09-May-2008	2	09-May-2008	16-May-2008	MI		16-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	14460U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pruritus, Rash erythematous, Vomiting

Symptom Text: After receiving HPV #3, child got navel pierced. The next day she had nausea, vomiting, light-headedness, dizziness. Stayed home from school. Today (5/9/08) noticed a few white spots on her feet-turned to red, spread to legs, hands & arms. Took Benadryl 5/8/08 for "cold or sinus infection". Reports itching with rash. Advised to see a doctor - clinic info given.

Other Meds: Benadryl for "cold or sinus inf"

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 312018-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	22-Apr-2008	22-Apr-2008	0	09-May-2008	19-May-2008	VA		19-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Dehydration, Headache, Nausea, Pyrexia, Vomiting

Symptom Text: Within few hours of vaccine, client called with complaint of fever to 101, seen in ER within about 8 hrs, was vomiting, had headache, cough (history of asthma). Was treated for dehydration with IV Tordol for headache, Zofran for nausea, cough medicine, on bedrest for 2 days.

Other Meds: No

Lab Data: No access

History: Asthma, Allergies self reported pollen, dust, chlorine, bee stings

Prex Illness: No

Prex Vax Illns:

Vaers Id: 312019-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-May-2008	09-May-2008	0	09-May-2008	19-May-2008	PA		19-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	42621AA	0	Left arm	Unknown	
HPV4	MERCK & CO. INC.	1740U	0	Left arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB207DA	0	Right arm	Unknown	
VARCEL	MERCK & CO. INC.	1998U	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope following vaccines. Pt lying down on table - BP 100/68, HR = 72. Pt did not eat or drink before coming to office; gave soda, pretzels - waited for 20 min - resolved, discharged to home.

Other Meds:

Lab Data:

History: Headaches

Prex Illness: No

Prex Vax Illns:

Vaers Id: **312064-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	17-Sep-2007		12-May-2008	13-May-2008	FL	WAES0710USA06122	13-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for Gardasil concerning a female (demographics not provided) who on an unspecified date was vaccinated with her first dose of Gardasil (Lot# not reported). There was no concomitant medication. The patient reported to the physician that she found out she was pregnant (method of confirmation and date of the confirmation of the pregnancy were not provided) after she received her first dose of Gardasil. On an unspecified date the patient reported to the physician that she was about 6 weeks pregnant. Actual date of her last menstrual period was not reported. It was reported that the patient sought unspecified medical treatment. No additional information was provided. Follow up information received from the physician's office stated that the patient terminated her pregnancy on 31-OCT-2007. Additional details regarding the elective termination were not provided. Upon internal review, the elective termination was consider an other medical event. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 9/17/2007)

Prex Vax Illns:

Vaers Id: **312065-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-May-2007	18-Sep-2007	123	12-May-2008	13-May-2008	FR	WAES0805AUS00032	13-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Idiopathic thrombocytopenic purpura, Menorrhagia, Thrombocytopenia

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 16 year old female who on 18-MAY-2007, 15-JUN-2007 and 15-SEP-2007 was vaccinated with the first, second and the third dose of Gardasil. On 18-SEP-2007 the patient experienced thrombocytopenia and menorrhagia. It was described that the patient had a "severe ITP, platelet count 4 and life threatening menorrhagia". On 21-SEP-2007, the patient recovered from thrombocytopenia and menorrhagia. The agency considered that thrombocytopenia and menorrhagia were possibly related to therapy with Gardasil. Thrombocytopenia and menorrhagia were considered to be immediately life-threatening. The original reporting source was not provided. Subsequently the patient's experience was reported in an article. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312066-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	Unknown	25-Jul-2007		12-May-2008	13-May-2008	FR	WAES0805AUS00033	13-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Optic neuritis, Retinopathy, Scotoma, Vision blurred

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing and Public Case Details form concerning a 24 year old female who was vaccinated with Gardasil (date not provided). On 25-JUL-2007 the patient experienced blurred vision, optic neuritis and scotoma, described as "blurred vision, left greater than right, associated with scotoma. Diagnosis-acute macular neuroretinopathy (AMN)". At the time of reporting to the agency on 15-OCT-2007, the outcome of blurred vision, optic neuritis and scotoma was unknown. The agency considered that blurred vision, optic neuritis and scotoma was unknown. The agency considered that blurred vision, optic neuritis and scotoma were possible related to therapy with Gardasil. The original reporting source was not provided. Blurred vision, optic neuritis and scotoma were considered to be disabling. Subsequently, the patient's adverse experiences were also reported in an foreign article. Additional information is not expected.

Other Meds: Unknown

Lab Data: serum albumin Nil details

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312067-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	08-Oct-2007	08-Oct-2007	0	12-May-2008	13-May-2008	FR	WAES0805AUS00034	13-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Clonus, Hyperreflexia, Hypertonia, Muscular weakness

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 25 year old female who on 08-OCT-2007 was vaccinated with Gardasil. Concomitant therapy included venlafaxine HCl. On 08-OCT-2007, after vaccination, the patient experienced hyperreflexia, clonus, hypertonia and muscle weakness and was hospitalised. It was described that the patient experienced bilateral upper and lower limb hyperreflexia, clonus, high tone and bilateral lower limb weakness. At the time of reporting on 25-OCT-2007, the patient's hyperreflexia and clonus and hypertonia and muscle weakness persisted. The agency considered that hyperreflexia, clonus, hypertonia and muscle weakness were possibly related to therapy with Gardasil. The original reporting source was not provided. Subsequently the patient's experience was reported in an foreign article. Additional information is not expected.

Other Meds: venlafaxine HCl, Unk - Unk

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312068-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	25-Apr-2007	05-May-2007	10	12-May-2008	13-May-2008	FR	WAES0805AUS00037	13-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Polyarthritis

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 13 year old female who on 25-APR-2007 was vaccinated with Gardasil. On 05-MAY-2007 the patient experienced polyarthritis and antinuclear antibody positive and was hospitalised. It was described that the child experienced bilateral upper limbs polyarthritis involving wrists, MCP joints and PP joints. The onset of symptoms were initially on her left side 10 days post Gardasil. The patient was found to have positive antinuclear antibody. All other investigations were found to be NAD (no abnormalities detected). At the time of reporting on 17-OCT-2007, the patient's polyarthritis and antinuclear antibody positive persisted. The agency considered that polyarthritis and antinuclear antibody positive were possibly related to therapy with Gardasil. The original reporting source was not provided. Subsequently the patient's experience was reported in an foreign article. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312069-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	26-Sep-2007	26-Sep-2007	0	12-May-2008	13-May-2008	FR	WAES0805AUS00039	13-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0734U		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Amnesia, Feeling abnormal, Hypotonia, Malaise, Nausea, Pulse pressure decreased, Syncope, Unresponsive to stimuli

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing and Public Case Details form, concerning an 18 year old female who on 26-SEP-2007 was vaccinated intramuscularly with GARDASIL, Batch No. J2926, expiry date 13-MAR-2010, Lot No. 658214/0734U). Subsequently, on 26-SEP-2007 the patient experienced nausea, amnesia, feeling abnormal, hypotonia, syncope and was unresponsive to stimuli, described as "patient reported feeling ill and collapsed. Suppine and unresponsive to verbal stimuli for 30 minutes, pulse faint, floppy, nauseated and spaced out. The patient had no memory of the event". The patient was admitted to the Accident and Emergency department of hospital and was treated with oxygen and IV fluids. Results of laboratory investigations showed serum glucose of 5.3 mmol/L and an electrocardiogram (ECG) was normal. At the time of reporting to the agency on 17-OCT-2007 the patient had recovered from nausea, amnesia, feeling abnormal, hypotonia, syncope and being unresponsive to stimuli. The agency considered that nausea, amnesia, feeling abnormal, hypotonia, syncope and being unresponsive to stimuli were possibly related to therapy with GARDASIL. The original reporting source was not provided. Subsequently, the patient's adverse experiences were reported in an article. Additional information is not expected.

Other Meds: Unknown

Lab Data: electrocardiogram, 26?Sep07, 5.3 mmol/L; serum glucose, 26?Sep07, 5.3 mmol/L

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312070-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		12-May-2008	13-May-2008	VA	WAES0805USA00035	13-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a female (age not reported) who on an unspecified date was vaccinated with the first dose of Gardasil without incident. On an unspecified date, the patient was vaccinated with the second dose of Gardasil. After the second dose (date unspecified), the patient experienced possible seizures. Unspecified medical attention was sought. Subsequently on an unspecified date, the patient recovered from possible seizures. No product quality complaint was involved. Upon internal review, possible seizures was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312071-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Oct-2007	Unknown		12-May-2008	13-May-2008	FR	WAES0805USA01091	13-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0278U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Type 1 diabetes mellitus

Symptom Text: Information has been received from a gynecologist concerning a 14 year old female who on 16-OCT-2007 was vaccinated IM into the upper arm with a first dose of Gardasil (batch# NF56940; Lot# 0278U). Subsequently, on an unspecified date, the patient was diagnosed with type I diabetes mellitus. She was treated with insulin. Outcome was not reported. The physician felt that the patient's type I diabetes mellitus was an other important medical event. No further information is available. Other business partner numbers included E2008-04087.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312072-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	16-Jul-2007	16-Jul-2007	0	12-May-2008	13-May-2008	TX	WAES0708USA01488	13-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Initial and follow up information has been received through the Merck Pregnancy Registry from a registered nurse concerning a 25 year old female with a history of a spontaneous abortion at five weeks from her last menstrual period and malignant melanoma at age 19, with a dysplastic nervous system, and an allergy to penicillin and an allergic reaction to CECLOR, who on 16-MAY-2007 was vaccinated IM in the left deltoid with a 0.5 ml first dose of Gardasil (lot # 657736/0389U). On 16-JUL-2007 the patient was vaccinated IM in the right deltoid with a 0.5 ml second dose of Gardasil (lot # 658100/0525U). There was no concomitant medication. Subsequently the patient became pregnant. Unspecified medical attention was sought. On 03-AUG-2007 the patient had a positive beta-human chorionic gonadotropin test (unspecified). Her last menstrual period was 27-JUN-2007. The estimated date of delivery was 03-APR-2008. It was reported that the patient had one previous pregnancy and one spontaneous abortion at 5 weeks. At the time of the report, the outcome of the patient was unknown. Follow-up information indicated that 39 weeks from her last menstrual period on 27-MAR-2008 the patient gave birth to a male infant. The infant weighed 7 pounds 6 ounces, was 19.5 inches long, and had an Apgar score of 8/9. It was reported that the infant was normal, with no complications or abnormalities. The infant did develop a minimal cleft lip. Other medications used during the pregnancy were ZITHROMAX for a urinary tract infection, prenatal vitamins, and GYNAZOLE for candida. The reporter considered the minimal cleft lip to be a congenital anomaly. Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic, 08/03/07, posit

History: Malignant melanoma; Abortion spontaneous

Prex Illness: Pregnancy NOS (LMP = 6/27/2007); Nervous system disorder; Allergic reaction to antibiotics; Penicillin allergy

Prex Vax Illns:

Vaers Id: **312073-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		12-May-2008	13-May-2008	FL	WAES0804USA03171	13-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness transient, Dizziness

Symptom Text: Information has been received from a physician concerning a female patient with no known drug allergies and no previous medical history who on an unspecified date was vaccinated at another physicians office with her first dose of GARDASIL (lot #unknown, site and route not reported). There was no concomitant medication. The patient reported to the physician that 3.5 post vaccination, she "felt lightheaded for 5 minutes, experienced dizziness, could not see, and everything turned black for a few seconds. Five minutes after the 1st lightheaded spell went away, it happened again and lasted for 5 minutes." The patient did not seek medical attention. It was reported that on an unspecified date the patient was considered to have recovered from the events. The physician reported that the patient plans to continue further doses of the vaccination. No additional information was reported. Upon internal review, vision loss was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **312074-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	28-Aug-2007		12-May-2008	13-May-2008	FR	WAES0805AUS00053	13-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Neuropathy peripheral, Sensory disturbance

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 16 year old female who was vaccinated with GARDASIL. On 28-AUG-2007 the patient experienced neuropathy peripheral and was hospitalised. It was described that approximately 4 weeks after the second dose of GARDASIL, the patient developed bilateral ascending sensory loss in her lower limbs. The examination of the patient revealed a low in sensation to all modalities lower legs to knees. The patient had normal jerks and downgoing plantar reflexes. At the time of reporting on 15-OCT-2007, the patient's neuropathy peripheral persisted. The agency considered that neuropathy peripheral was possibly related to therapy with GARDASIL. The original reporting source was not provided. Subsequently, the patient's experience was reported in an article. Additional information is not expected. A copy of a published literature article is attached as further documentation of the patient's experience.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312075-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	15-Jul-2007	18-Sep-2007	65	12-May-2008	13-May-2008	FR	WAES0805AUS00064	13-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Pancreatitis

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 24 year old female who on 15-JUL-2007 was vaccinated with GARDASIL. On 18-SEP-2007 the patient developed pancreatitis and was hospitalized. Laboratory investigations included calcium which was 2.63 H mmol/L (normal range: 2.10-2.60) and lipase which was 711H U/L (normal range: 13-60). At the time of reporting on 19-OCT-2007, the patient's pancreatitis persisted. The agency considered that pancreatitis was possibly related to therapy with GARDASIL. The original reporting source was not provided. Subsequently the patient's experience was reported in an article, 25-JAN-2008. Additional information is not expected. A copy of the published article is attached as further documentation of the patient's experience.

Other Meds: Unknown

Lab Data: Serum calcium 18Sep07 2.63 H mmol/L Normal Range: 2.10 - 2.60; serum lipase test 18Sep07 711 H U/L Normal Range: 13 - 60

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312076-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	11-Aug-2007	01-Sep-2007	21	12-May-2008	13-May-2008	HI	WAES0805USA00654	13-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0929U	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness transient, Dizziness, Headache, Migraine, Sinusitis

Symptom Text: Information has been received from a physician concerning a 24 year old female with a history of eating disorder, no illness at the time of vaccination who on 29-JAN-2007 was vaccinated with a first dose of GARDASIL (lot # 655617/1447F) in the left deltoid at 3:15 PM. On 25-APR-2007 the patient was vaccinated with a second dose of GARDASIL (lot # 657617/0384U) in the right deltoid at 8:30 AM. On 11-AUG-2007 the patient was vaccinated with a third dose of GARDASIL (lot #658282/0929U) in the left deltoid at 11:10 AM. Concomitant therapy included YAZ. In September 2007, the patient experienced migraine headaches, once a month with loss of vision for 30 minutes followed by 2 to 4 days of headaches and dizziness. The patient has seen the neurologist. The patient had sinusitis at the onset of symptoms in September 2007 which cleared up in 2 months with antibiotics (therapy unspecified). Upon internal review loss of vision is considered to be an Other Medical Event. Additional information has been requested.

Other Meds: YAZ

Lab Data:

History:

Prex Illness: Eating disorder

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312077-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	03-Mar-2008	03-Mar-2008	0	12-May-2008	13-May-2008	FR	WAES0805USA01283	13-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Back pain, Headache, Hyperhidrosis, Myalgia, Nausea

Symptom Text: Information has been received from a physician concerning an 18 year old female with a history of Mycoplasma and Chlamydial infection in October 2007 who on unspecified dates was vaccinated with a first and second dose of Gardasil. On 03-MAR-2008, the patient was vaccinated with the third dose of Gardasil (lot and batch numbers not reported). In March 2008, three weeks after vaccination, the patient developed significant joint and muscle pain in the whole body. She also experienced cephalgia, nausea, lumbar pain, and significant sweating. No cutaneous signs were observed. Complete work-up was performed; the results were normal. The events were reported as severe. At the time of reporting, the patient had not recovered. The events were reported as Other Important Medical Events. Other business partner numbers included: E2008-04197. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Mycoplasma infection; Chlamydial infection

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312093-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-May-2008	01-May-2008	0	12-May-2008	19-May-2008	NY		19-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2545AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1522U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Dizziness, Heart rate normal, Malaise, Vomiting

Symptom Text: 10 minutes after pt received vaccines she reported feeling "sick" & "light-headed". She put head down & elevated her feet. BP 80/40 pulse 64. Vomited at 3pm. Felt better then & BP went back up to 90/60 at 310pm. Pulse 64. Wanted to leave by 320pm. Mother was with her. She reports patient reacts this way when she is anxious.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **312116-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-May-2008	06-May-2008	0	12-May-2008	16-May-2008	NC		20-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAV8242AA	2	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1487U	3	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Give 3rd dose of Hep A and 4th dose of Gardisil. Last facility in record dated 3/31 showed student due for both. Asked if she had received any "shots"/immunizations anywhere else - replied "no" so I gave both. When I went to facility, discovered she had been given both doses at HD 4/3! Incident report done, patient checked X3. Supervising MD notified 5/6

Other Meds: none

Lab Data: none

History: Bronchitis 4/15/08

Prex Illness: none

Prex Vax Illns:

Vaers Id: **312133-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Apr-2008	09-Apr-2008	1	12-May-2008	13-May-2008	FR	WAES0804USA06004	13-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	IPV	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Disorientation, Global amnesia, Malaise, Syncope vasovagal

Symptom Text: Information has been received from a general practitioner concerning a 16 year old female, who on 08-APR-2008 was vaccinated with a second dose of GARDASIL and a dose of IPOL. The day after the vaccination the patient experienced a vasovagal malaise, and a transient global amnesia with a loss of memory and temporospatial disorientation. The patient fully recovered in 3 to 4 hours. The patient went to the hospital to perform a global check-up. A neurological examination, magnetic resonance imaging (MRI), and encephalogram were normal. Upon internal review vasovagal reaction, transient global amnesia, and temporospatial disorientation were considered to be other important medical events. Other business partner numbers included: E200803850. Additional information is not available.

Other Meds: Unknown

Lab Data: diagnostic laboratory test Comment: global check-up; neurological examination Comment: normal; magnetic resonance imaging Comment: normal; electroencephalography Comment: normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312136-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-May-2008	09-May-2008	0	12-May-2008	21-May-2008	NC		30-Mar-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1448U	0	Left arm	Subcutaneously	
TD	SANOFI PASTEUR	U1963CA	2	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1977U	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect route of drug administration

Symptom Text: No adverse event - vaccine given SC instead of IM (HPV - Gardasil). When the nurse gave the vaccine- she drew back blood after hitting a vein. No treatment needed- Nurse placed needle in sharps box & administered a new vaccine.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312158-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	20-Mar-2007	17-Apr-2007	28	13-May-2008	14-May-2008	--	WAES0704USA00316	14-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0263U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Ruptured ectopic pregnancy

Symptom Text: Initial and follow up information has been received from a health professional concerning a 25 year old female with hypertension and protein in urine who on 20-MAR-2007 was vaccinated with Gardasil (lot#655849/0263U). There was no concomitant medication. The nurse reported that the patient was pregnant. The patient's last menstrual period was 27-FEB-2007 with an expected delivery date of 04-DEC-2007. In follow up telephone call to the doctor's office the Licensed Practical Nurse (L.P.N.) reported that the patient was still pregnant with a due date of 06-JUN-2008 and she mentioned that "everything was on track with patient's pregnancy, looked like a big baby." She mentioned that patient continued to have problems with her hypertension and protein in urine which existed before her pregnancy. When the reporter was called back to clarify/confirm patient's information she reviewed her chart and reported that patient had a ruptured ectopic pregnancy on 17-APR-2007. No other information regarding the last menstrual period (LMP) dates were provided. It was confirmed that the patient had not received any additional doses of the vaccine since the March 2007 dose. Upon internal review ruptured ectopic pregnancy was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 2/27/2007); Hypertension; Protein urine present

Prex Vax Illns:

Vaers Id: 312159-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		13-May-2008	14-May-2008	FR	WAES0805AUS00051	14-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	28101		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Genital ulceration

Symptom Text: Information was obtained on requested by the Company from the agency via a Public Case Detail Form and Case Line Listing concerning a 17 year old single female with one sexual partner, with no history of HSV infection who was vaccinated with GARDASIL. Subsequently after vaccination with GARDASIL, the patient developed genital ulceration which was described as severe deep genital ulcers on labia and perineum 2 weeks after vaccination with GARDASIL. In June 2007, 2 HSV PCR swabs done were negative. Serology was negative at 6 weeks. At the time of reporting on 17-OCT-2007 the patient had recovered from the genital ulceration. The agency considered that genital ulceration was possibly related to therapy with GARDASIL. Genital ulceration was considered to be disabling by the agency. The original reporting source was not provided. Subsequently the patient's experience was reported to an article, 25-JAN-2008, page 6. Additional information is not expected.

Other Meds: Unknown

Lab Data: HSV type 1 and/or 2 identification PCR ??Jun07 Comment: negative; HSV type 1 and/or 2 identification PCR ??Jun07 Comment: negative; clinical serology test Comment: negative at 6 weeks

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312161-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Apr-2008	Unknown		13-May-2008	14-May-2008	FR	WAES0805USA01090	14-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 13 year old female, who in April 2008, was vaccinated with a second dose of GARDASIL. Subsequently, exact onset not reported, the patient experienced severe abdominal cramps and was admitted to the hospital. All examinations (not specified) showed normal results. The patient was treated with infusions and omeprazole. The patient recovered within an unspecified time. It was reported that after the patient was vaccinated with the first dose of GARDASIL she experienced slight abdominal cramps. Other business partner numbers included: E200804082. Additional information is not available.

Other Meds: Unknown

Lab Data: diagnostic laboratory test Comment: not specified-normal results

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312180-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-May-2008	05-May-2008	0	13-May-2008	21-May-2008	TX		22-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Syncope vasovagal

Symptom Text: Pt received HPV vaccine #3. Pt appeared to have a reaction. Doctor notified. Pt developed a vasovagal, fainting. Confan applied to pt. Pt was put in lying position and v/s monitored. Pt left clinic ambulating.

Other Meds: N/A

Lab Data: N/A

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: 312182-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-May-2008	01-May-2008	0	13-May-2008	20-May-2008	ME		20-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Hyperhidrosis, Immediate post-injection reaction, Pallor, Presyncope

Symptom Text: Pt given vaccine - within several minutes pt was pale, weak, near fainting, diaphoretic. Helped to bed & kept til pt was able to walk on her own 30-40 minutes later.

Other Meds: None

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 312202-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	07-May-2008	08-May-2008	1	13-May-2008	21-May-2008	FL		21-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2541AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Headache, Pain, Pharyngolaryngeal pain, Pyrexia

Symptom Text: Headache, chills, fever (102.6) "achy", slight sore throat developed on 5/8/08 after receiving both immunizations on 5/7/08 here in office.

Other Meds: Concerta 36mg

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312226-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Apr-2008	28-Apr-2008	0	13-May-2008	20-May-2008	FL		20-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope, Vomiting

Symptom Text: Patient was seen in office for sinus infection and allergies. Patient was administered GARDASIL and when patient left the office, she vomited and had a syncope episode. Mom took her to ER under direction of office. Vomited again.

Other Meds:

Lab Data: CBC; CT; EKG

History:

Prex Illness: sinus infection, allergies

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312263-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Apr-2008	30-Apr-2008	2	13-May-2008	20-May-2008	MI		20-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2844AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2619AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Throat irritation

Symptom Text: Vaccine given on 4/28/08 at 3:45pm. A couple days later, she developed a dry, non-productive cough. No fever. States, "It feels like something is stuck in my throat."

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 312294-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	19-Mar-2007	19-May-2007	61	14-May-2008	15-May-2008	PA	WAES0709USA00587	15-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0955F	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received through the Pregnancy registry concerning a 19 year old female patient, who on 19-MAY-2007 was vaccinated with a second dose of Gardasil. It was reported that the patient was 20 weeks pregnant. The patients last menstrual period was 16-APR-2007 and her estimated delivery date was 21-JAN-2008. The patient sought unspecified medical attention. At the time of the report, the outcome of the patient was unknown. Follow up information was received on 24-MAR-2008 and 02-APR-2008. The patient delivered a baby boy on 28-JAN-2008 (weeks from LMP-40). The baby was born with pneumonia. He weighed 9 lbs. 2 oz. The baby's pediatrician was called on 02-APR-2008. The nurse confirmed the patient had well visits and was seen multiple times during the month of February for pneumonia and what looked like abdominal pain. A request for Medical Records was faxed to the nurse to obtain the baby's records. Follow up information received in the form of physician's notes, indicated that on 28-JAN-2008, the infant first had a "vacuum attempt without success and positive meconium." The physician noted the infant was status post "C-section for failure to progress," and added that the mother was group B strep positive. After birth, the infant had an increased respiratory rate and "was on oxyhood overnight." The chest X-ray revealed right lower lobe pneumonia. Treatment in the hospital included IV ampicillin and gentamycin, and the infant "continued to do well with respiratory rate decreasing and 99% spO2 room air, feeding well." The infant was discharged on 02-FEB-2008 ("two days ago"). On 04-FEB-2008, the infant was seen in follow up at the physician's office, and was "improving clinically" the physician's assessment was pneumonia due to streptococcus, group B. Mild facial jaundice was documented. He was also diagnosed with diaper rash-candida, also noted as etoxicum rash; nystatin was prescribed, with follow up in 2 days. The infant was continued on AUGMENTIN. On 06-FEB-2008, the infant was seen by the physician

Other Meds: vitamins (unspecified) 10 mg

Lab Data: chest X-ray 01/28/08 right lower lobe pneumonia; cesarean section 01/28/08; respiratory rate 01/18/08 increased; vaginal Streptococcus positive

History:

Prex Illness: Pregnancy NOS (LMP = 4/16/2007); Group B betahaemolytic streptococcal positive

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312302-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-May-2008	07-May-2008	1	14-May-2008	23-May-2008	AZ		30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Flushing, Lung neoplasm, Neck pain, Non-cardiac chest pain, Poor peripheral circulation, Tenderness

Symptom Text: Vaccine on 5/6, on 5/7 with mid-retrosternal chest pain with radiation to left lower rib cage and left neck - still with pains on 5/13. 5/30/08 ER record from 5/07/2008 received with DX: Chest pain, possibly musculoskeletal in origin. Pt reported sudden onset of stabbing constant chest pain, unrelieved. 7/10 intensity. Also c/o L sided neck pain. PE WNL. Cause of chest pain unclear. D/C to f/u with cardiologist. 6/20/2008 Received cardio F/U report dated 5/29/08 with DX: Chesp pain noncardiac in origin. PE (+) for tenderness on palpation of the L axilla area to LUQ. Feet puplish and cold with reduced perfusion and face flushed. Suspected muskuloskeletal pain/costochondritis tx with NSAIDs. Pulmonary consult for chest nodule negative with resolution of the nodule.

Other Meds: Lyrica, Lunesta, Florinet Midodrine, Qvar

Lab Data: EKG, CXR, Chemistries. Labs and Diagnostics: CBC WNL except Hgb 15.4. Troponin 0.02. Chem WNL except Albumin 4.4. CXR-no acute abnormalities with LUL ovoid nodular density. EKG with sinus rhythm and sinus arrhythmia. Holter monitoring ben

History: Chronic fatigue syndrome/postural orthostatic tachycardia syndrome, Asthma PMH: Asthma, pneumonia, POTS (postural orthostatic tacycardia syndrome), appy 2004, Ex lap 2007.

Prex Illness: None

Prex Vax Illns:

Vaers Id: 312318-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Apr-2008	29-Apr-2008	7	14-May-2008	22-May-2008	NJ		22-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1425A	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Chills, Pain

Symptom Text: One week following vaccine, noted sudden onset of severe joint pain, chills, aches. No fever no rash or other clinical signs

Other Meds: none

Lab Data: Had a normal lyme, EBV, CBC and parvovirus testing. Other Autoimmune labs pending

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 312345-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Apr-2007	30-Apr-2007	0	15-May-2008	16-May-2008	IL	WAES0707USA01072	16-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Nausea, Pityriasis, Threatened labour

Symptom Text: Initial and follow up information has been received from a Registered Nurse (R.N.) concerning a 17 year old female who on 30-APR-2007 was vaccinated IM with a first dose of Gardasil lot # 657621/0387U. Concomitant therapy included prenatal vitamins (unspecified). The nurse reported that the patient became pregnant sometime after her first injection. Patient was positive over the counter pregnancy test. In follow up it was reported that on 16-AUG-2007 ultrasound showed 7 weeks pregnancy and the expected date 04-MAR-2008. The patient's outcome was unknown. In follow up information from doctor's office it was reported that patient was treated with prenatal vitamins starting from 15-AUG-2007 for pregnancy. On 16-AUG-2007 she was diagnosed pityriasis. On 05-SEP-2007 patient was treated with 10 mg REGLAN for nausea every 6 hour as needed. Fetal arrhythmia was detected at 20 weeks of her pregnancy. She saw maternal Fetal Medicine (MFM) doctor and her fetal cardiac ultrasound was normal. It was reported that she had threatened preterm labor and on 08-NOV-2008, she was treated with magnesium sulfate intravenous (IV) in the hospital for it. After she was off magnesium sulfate she was treated with PROCARDIA 20 mg every 6 hour for preterm labor. On 08-NOV-2008 she was noted to be positive ureaplasma of the vagina/cervix. Other laboratory tests included biophysical profile, Amniotic fluid index (AFI), Non stress test (NST) was done weekly starting 27-DEC-2007 and then twice weekly till 28-JAN-2008. It was reported that patient had a normal female baby on 12-MAR-2008, 41 weeks from her last menstrual period. The baby weighed 8lb 1oz and her Apgar score was 8/9. There were no abnormalities reported. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound 08/16/07 - 7 weeks pregnancy, EDC 3/4/08; diagnostic laboratory - biophysical profile; diagnostic test - Amniotic fluid index (AFI); fetal nonstress test 12/27/07 - Weekly starting 27-DEC-2007 then twice weekly till 28-JAN-2008;

History:

Prex Illness: Pregnancy NOS (LMP = 6/1/2007)

Prex Vax Illns:

Vaers Id: **312353-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	04-Apr-2008	04-Apr-2008	0	15-May-2008	22-May-2008	TX		22-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Pt. received 1st Gardasil injection IM left deltoid on 04/04/08-pt. calling today with continued pain since injection near site in the muscle, esp. with certain arm movements and more so at nite time. No redness, no lumps

Other Meds: None

Lab Data: recommended evaluation by family physician

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312355-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-May-2008	07-May-2008	2	15-May-2008	23-May-2008	PA		23-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2888AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1967U	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1777U	1	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema

Symptom Text: Local erythema 5 x 6cm at injection site of VARIVAX.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 312380-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	13-May-2008	14-May-2008	1	15-May-2008	23-May-2008	MI		23-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2604AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0245U	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Pain in extremity

Symptom Text: Complains of soreness with direct pressure or palpation to left arm. Pain shoots into left lateral neck only with palpation/pressure to injection site. Pain in arm started during night of injections.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **312394-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-May-2008	14-May-2008	0	15-May-2008	23-May-2008	CO		23-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aphthous stomatitis, Headache, Swollen tongue

Symptom Text: 4 hours after administration of HPV vaccine dose #2 patient had swelling of tongue to one and one half normal size. 2-3 cankor sores on tongue and Headache rated 5-6 on a scale of 10. Client took antihistomine and swelling went down but 24 hours later tongue remains swollen. No shortness of breath, difficulty breathing or eating, rash, or other complaints.

Other Meds: None

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312396-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-May-2008	09-May-2008	0	15-May-2008	26-May-2008	SD		27-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MMR	MERCK & CO. INC.	0749U	2	Left arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U2543AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1740U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Confusional state, Dizziness, Dysarthria, Fatigue, Feeling abnormal, Hypoaesthesia, Limb discomfort, Malaise, Nausea, Pain, Tremor, Vision blurred

Symptom Text: Patient presented to office at 0830 for vaccines. MMR, Menactra, and HPV administered by nurse at approximately 0845. Patient went to waiting room after vaccinations for approximately 10-15 minutes. At about 0900, Patient presents back to nurse's office and reports that she felt "funny" after first vaccine, but did not think much of it. Dizziness and shaking worsened while waiting in waiting room and difficult to focus while trying to read her book. Blood pressure at that time noted to be 110/78 and pulse 84. Client states she ate breakfast, does not feel faint, just dizzy. Sprite provided for client and offered to let her lie down. Client states she feels fine in chair. 0915: Client states dizziness and shaking remian the same. Client is conversing with nurse. Conversation appropriate and alert and oriented X 3. 0930: patient's mother was present to sign for vaccines and ask questions, but left before vaccine was given. Mother of child called at 0930 to inform her of situation. Blood pressure 108/74. Mother of child came to the office to get child. 0945: Client states dizziness/shaking the same. Conversing with nurse appropriately. 1005: Dr's office notified regarding patient's condition. Physician not in office at this time, but clerical staff planned to relay message and return call to client for further recommendations or advice. Client discharged to home with mom and sister. States still has shaking feeling, but no worse than it was at 0900. Patient has a history of hypothyroidism and is considered prediabetic. She is on Synthroid and Metformin. Was also diagnosed with pancreatitis in 11-07 with unknown cause. Patient's approximate weight is 225 pounds. 1615: Telephone call to patient to follow up on condition. Child not home, mother reports that she slept for about 4 hours after leaving office and now feeling a little better. Still a little dizzy and nauseated, but did go to work at Firesteel. Dr. returned call to family and was not concerned at this time. Stated that client could take

Other Meds: Synthroid and Metformin

Lab Data:

History: Prediabetic and hypothyroidism

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312399-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-May-2008	01-May-2008	0	15-May-2008	23-May-2008	CA		23-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2826AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2235AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Expired drug administered

Symptom Text: vACCINE EXPIRED 4/24/08, GIVEN TO PATIENT 5/1/08

Other Meds: cLINDAMYCIN 1% LOTION; ACYCLOVIR PRN

Lab Data:

History: NKDA; ACNE; HSV

Prex Illness: MILD ACNE; LABIAL HSV

Prex Vax Illns:

Vaers Id: 312409-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-May-2008	09-May-2008	2	15-May-2008	23-May-2008	MN		23-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1518U	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1710U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oedema peripheral, Skin warm, Swelling, Tenderness

Symptom Text: Severe swelling and tenderness (R) upper at tender arm and swollen.

Other Meds:

Lab Data: None

History: ADHD; Asthma; Seasonal allergies

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312419-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	03-Jan-2007	14-Feb-2007	42	16-May-2008	19-May-2008	UT	WAES0805USA00797	20-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Intra-uterine death, Premature labour

Symptom Text: Information has been received through the pregnancy registry, for Gardasil concerning a 26 year old female patient who on 03-JAN-2007 was vaccinated with the second dose of Gardasil. Concomitant therapy included prenatal vitamins (unspecified). On approximately 14-FEB-2007, six weeks later she became pregnant. She went into labor on 23-JUL-2007 and the baby passed away (reason unspecified). The patient sought medical attention at the hospital. On 02-NOV-2006 the patient received the first dose of Gardasil and it was required that she will not be getting the third dose. The patient's outcome was unknown. No product quality complaint was involved. Upon internal medical review baby passed away and premature labor were considered to be other important medical events. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **312420-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-May-2008	19-May-2008	SC	WAES0805USA01325	03-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Blindness transient, No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with her third dose of GARDASIL (lot# not reported). Subsequently, "right after the vaccine was given", the patient "fainted, her vision went black and she had memory loss" for a few seconds after her third shot of GARDASIL. The physician reported that the patient had no symptoms after the first and second dose of GARDASIL (dates of vaccination not reported). Subsequently, on an unknown date the patient was considered to have recovered from fainting, vision going black and memory loss. Upon internal review, "vision going black" was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312421-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	19-Mar-2007	19-Mar-2007	0	16-May-2008	19-May-2008	MN	WAES0703USA03642	19-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received through the Merck pregnancy registry, for GARDASIL, from a physician concerning a 21 year old female with codeine allergy who on 19-MAR-2007 was vaccinated intramuscularly in the deltoid with the first 0.5 mL dose of GARDASIL. There was no concomitant medication. Later that same day a urine pregnancy test was positive and the patient found out she was pregnant. (LMP: 14-FEB-2007; EDD: 21-NOV-2007). Unspecified medical attention was sought. On 09-May-2009, telephone follow up information was received from a nurse who reported that the patient miscarried at eleven weeks and three days. Upon internal review, miscarriage was considered to be an other important medical event. No further information is available.

Other Meds: None

Lab Data: urine beta-human 03/19/07 posit

History:

Prex Illness: Pregnancy NOS (LMP = 2/14/2007); Specific allergy (drug)

Prex Vax Illns:

Vaers Id: 312422-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Aug-2007	08-May-2008	255	16-May-2008	19-May-2008	TN	WAES0709USA00819	19-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0012U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Breech presentation, Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed practical nurse concerning a 20 year old female with depression, anxiety disorder and migraine and no drug reactions/allergies who on 22-JUN-2007 was vaccinated with a first dose of GARDASIL (lot# 653735/0688F) 0.5mL IM. Concomitant therapy included LYRICA, PROCAC, DEPAKOTE, BUSPAR, trazodone HCl and nabumetone. On 27-AUG-2007 the patient was vaccinated with a second dose of GARDASIL (lot# 655503/0012U) 0.5mL IM and is "2 months pregnant". Medical attention was sought. A urine beta-human chorionic gonadotropin test was positive for pregnancy. The date of the last menstrual period was approximately 06-JUL-2007 and the estimated date of delivery is approximately 11-APR-2007. No other information was available at this time. Follow-up information was received from the L.P.N. The L.P.N. reported that the patient delivered a baby girl "just yesterday, last night" (08-MAY-2008). A C-section was performed since the baby was breech. The baby was 7 pounds 4 ounces and 19 inches long. The baby was healthy with no congenital anomalies. The patient's due date was 06-MAY-2008 so the baby was born at 40 weeks and two days gestation. Upon internal review breech presentation was considered to be an other medical event. Additional information is not expected.

Other Meds: BUSPAR; DEPAKOTE; PROZAC; nabumetone; LYRICA; trazodone hydrochloride

Lab Data: urine beta-human - positive

History:

Prex Illness: Pregnancy NOS (LMP = 7/6/2007); Depression; Anxiety disorder; Migraine

Prex Vax Illns:

Vaers Id: **312423-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		16-May-2008	19-May-2008	IL	WAES0805USA01057	22-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Encephalitis, Headache, Pyrexia, Vision blurred

Symptom Text: Information has been received from a physician concerning a 20 year old female with no allergies, who, on an unspecified date, was vaccinated with a dose of Gardasil. There was no concomitant medication. There were no illnesses at the time of vaccination. It was noted that the reporting physician recommended the HPV vaccination to the patient but she was vaccinated at her college campus. Three to four days post vaccination the patient experienced a high fever, headache, and blurred vision. The patient went to the emergency room but was not admitted. The patient then returned to the emergency room a second time and was admitted to the hospital for two days. The patient was diagnosed with encephalitis. At the time of the report, the outcome of the patient was unknown. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **312424-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		16-May-2008	19-May-2008	--	WAES0805USA01971	19-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cerebrovascular accident, Thrombosis

Symptom Text: Information has been received from a physician concerning an approximately 23 year old female patient who was vaccinated with Gardasil. The physician stated that a patient of hers came into the office telling her that her neighbor's daughter received Gardasil and suffered from a stroke or a clot. No further Information was provided. The physician that the representative calls on, did not have any details about the patient. Upon internal review, stroke was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312425-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	30-Apr-2008	30-Apr-2008	0	16-May-2008	19-May-2008	FL	WAES0805USA02326	19-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a 20 year old female with a "fear of needles" who on 30-APR-2008 was vaccinated with Gardasil (lot# 0152X) 0.5mL IM in the left deltoid. On 30-APR-2008 the patient experienced a seizure "about 45 seconds" after administration of Gardasil. The seizure lasted less than one minute. The patient rested on the exam table until stable but, when the patient stood up she experienced another seizure. Unspecified medical attention was sought. The physician stated that the patient recovered quickly and after resting in the office again she was able to leave the office fully recovered on the same day. No medical treatment was required. No further information was available. Upon internal review convulsion was considered to be an Other Medical Event. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Fear of needles

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312444-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-May-2008	09-May-2008	2	16-May-2008	26-May-2008	WA		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2560AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0086X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0928U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Swelling, Throat tightness, Urticaria

Symptom Text: Pt. started having redness of the left deltoid this morning. She had swelling of the legs deltoid for several hours. She complained of tightness in her throat and hives on her face and neck. She has 5x6 cm tenderness on her left deltoid.

Other Meds:

Lab Data:

History: Asthma

Prex Illness: None

Prex Vax Illns:

Vaers Id: **312448-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-May-2008	08-May-2008	1	16-May-2008	23-May-2008	CA		26-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X		Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1807U		Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site warmth

Symptom Text: May 9, 2008, pt came to clinic with complaint of increased redness and warmth on left arm (injection site of Varicella vaccine received 5/7/2008). MD notes described left arm with 4x4cm redness with central induration on left area inferior to injection site of varicella.

Other Meds: None

Lab Data: No labs ordered.

History:

Prex Illness: No

Prex Vax Illns:

Vaers Id: **312449-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	08-May-2008	08-May-2008	0	16-May-2008	23-May-2008	TN		23-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
VARCEL	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Gaze palsy, Muscle twitching

Symptom Text: Patient received 1st GARDASIL, felt faint, eyes rolled back in her head & twitched. Nurse helped her lay on exam table. After 1-2 minutes she was alert asking what had happened. Remained laying & conscious for 20 minutes - attempted to have her sit up & continued to feel dizzy - laid her back down x another 20-30 min. Felt better, but not well enough to walk to the car with mom. Friday - stayed home because she was still dizzy when she got up. Sat/Sun - felt better. Mon - went to school & came into office because felt dizzy again - in office BP + blood sugar were stable at 120/70 + BS of 88. Exam essentially normal.

Other Meds: None

Lab Data: BP & blood sugar

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312457-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	07-May-2008	08-May-2008	1	16-May-2008	23-May-2008	DE		23-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1800U	2	Left arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB264BA	1	Left arm	Unknown	
HPV4	MERCK & CO. INC.	0523U	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Induration, Oedema peripheral, Skin warm

Symptom Text: L arm was swollen, red, hard, warm.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **312477-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		16-May-2008	26-May-2008	CO		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B019AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0388U	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2604AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Patient received vaccines and later in visit admitted she was sexually acive and had a positive pregnancy test. No treatment given

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **312479-1 (S)** **Related reports:** 312479-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	04-Apr-2008	01-May-2008	27	16-May-2008	20-May-2008	TX		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal discomfort, Acute myeloid leukaemia, Back pain, Bilirubinuria, Colitis, Haematochezia, Hypotension, Malaise, Nausea, Pharyngolaryngeal pain, Pyrexia, Thrombosis in device, Vomiting, Weight decreased

Symptom Text: weight loss, nausea & vomiting, malaise. 5/20/08 Office records received including vax record. Seen for sick visit 5/01/08 with c/o nausea, vomiting, and stomach feeling whoozy x 1 month. Impression Nausea & Vomiting. Tx with metoclopramide. Seen again 5/5/08 with c/o sore throat, nausea, back pain. Impression: N&V, Bilirubinuria, pancytopenia. Referral made to Oncologist. 07/01/2008 MR received for DOS 05/7-31/2008 with D/C DX: Acute Myeloid Leukemia. Pt presented with pancytopenia for eval to r/o acute leukemia. Bone marrow bx confirmed AML. Started on chemo which initially was well tolerated but later developed severe abdominal c/o with hematochezia. DX with pancolitis, likely infectious. Pt had intermittent high fevers and hypotension. Pt developed a clot in her PICC line and it was removed. Blood counts somewhat recovered and pt d/c 5/31/08.

Other Meds: none

Lab Data: pancytopenia, increased liver enzymes; bone marrow biopsy on 5-5-08 showed acute myelogenous leukemia;Gardasil series: 9-26-07, 11-21-07 & 4-4-08 (#13does not allow Gardasil to be entered). Labs and Diagnostics: Urine dipstick orange with

History: none. PMH: none

Prex Illness: none

Prex Vax Illns: none~ ()~~0~In Patient|none~ ()~~0~In Sibling

Vaers Id: **312479-2 (S)** **Related reports:** 312479-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	31-Mar-2008	05-May-2008	35	27-May-2008	28-May-2008	--	WAES0805USA03671	28-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Acute myeloid leukaemia

Symptom Text: Information has been received from a consumer's mother concerning her 19 year old daughter with no pertinent medical history or drug reactions/allergies who at the end of March 2008, was vaccinated with a third dose of GARDASIL 0.5 mL injection. There was no concomitant medication. On 05-MAY-2008 the patient was diagnosed with acute myelogenous leukemia and was hospitalized on 07-MAY-2008, and remained in the hospital at the time of the report. On an unspecified date the patient had a diagnostic laboratory test and a bone marrow biopsy performed. Results of the tests were unknown. The patient's acute myelogenous leukemia persisted. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory; bone marrow biopsy

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312482-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-May-2008	15-May-2008	2	16-May-2008	26-May-2008	NV		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2614AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2936BA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain

Symptom Text: redness, soreness at injestion site Left arm

Other Meds:

Lab Data:

History:

Prex Illness: none

Prex Vax Illns:

Vaers Id: **312483-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Mar-2008	22-Mar-2008	0	16-May-2008	26-May-2008	OH		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Feeling abnormal, Malaise, Postictal state, Syncope

Symptom Text: Felt bad after shot, fainted and then had 2-3 minute generalized seizure, then postictal for 45 minutes to 1 hour, then ok except felt washed out

Other Meds:

Lab Data: Follow up MRI and EEG normal

History: asthma, dizziness

Prex Illness: had been experiencing intermittent dizziness and lightheadedness since 12/2007. Had been evaluated several times for this.

Prex Vax Illns:

Vaers Id: **312484-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-May-2008	13-May-2008	0	16-May-2008	26-May-2008	CA		28-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1758U	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B020AA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2569AA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1252U	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Hypoaesthesia, Myalgia, Nausea, Ovarian cyst, Paraesthesia, Vaccination complication

Symptom Text: AFTER ~1 HOUR AFTER CHILD WAS IMMUNIZED, MOM CALLED STATING THAT CHILD WAS C/O A SEVERE HA, NAUSEA, AND NUMBNESS AND TINGLING IN HER LOWER EXTREMITIES. I ADVISED HER TO SEEK IMMEDIATE MEDICAL ATTENTION.

Other Meds: NONE NOTED ON SCREENING QUESTIONNAIRE

Lab Data: ER PHYSICIAN DIAGNOSED AS "MUSCLE ACHES, PROBABLY RELATED TO IMMUNIZATIONS GIVEN TODAY." ULTRASOUND DONE IN ER SHOWED S/S OF AN OVARIAN CYST,UNLIKELY RELATED TO VACCINES GIVEN.

History: NONE NOTED ON SCREENING QUESTIONNAIRE

Prex Illness: NO, NOT NOTED ON SCREENING QUESTIONNAIRE

Prex Vax Illns:

Vaers Id: **312485-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-May-2008	14-May-2008	0	16-May-2008	26-May-2008	CA		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Pruritus

Symptom Text: Pt. states that her arm became quite swollen, red and itchy after receiving HPV dose #3.She noted the symptoms on 5/14/08 and are persisting until today (5/16/08). Pt has applied ice packs to swelling over bicep area. Advised to cont. w/ ice packs, Benadryl and pain reliever. To return to clinic if S/Sx persist.

Other Meds: unknown

Lab Data:

History:

Prex Illness: None known.

Prex Vax Illns:

Vaers Id: 312525-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-May-2008	06-May-2008	0	19-May-2008	20-May-2008	OH	WAES0805USA01675	20-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Dyspnoea

Symptom Text: Information has been received from a physician concerning a 20 year old female patient who on 06-MAY-2008 "two days ago" was vaccinated a dose of Gardasil (lot # not available). Concomitant therapy included MENACTRA. The physician in the hospital reported that one half hour after the patient received a dose of Gardasil, she started to have trouble breathing and was admitted to the hospital. At the time of this report the patient was in the hospital and had been there for "two day so far." No further information was available. The patient had not recovered. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312526-1** **Related reports:** 312526-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	29-May-2007	13-Jul-2007	45	19-May-2008	20-May-2008	PA	WAES0708USA01062	20-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0388U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Menstruation delayed

Symptom Text: Information has been received from a Nurse for the pregnancy registry, concerning a 26 year old female with asthma and an allergy to Vicodin who on 29-MAY-2007 was vaccinated IM in the left deltoid with a first dose of Gardasil. Concomitant therapy included ALLEGRA, albuterol and vitamins (unspecified). On 13-JUL-2007 the patient was seen in the doctor's office for suppressed menses and later determined to be pregnant. Follow-up information was received from the physician's office. Concomitant therapy also included "DUET DHA" (therapy unspecified) and ZYRTEC. On 29-AUG-2007 the patient had a spontaneous abortion 12 3/7 weeks from LMP. The products of conception were examined and were normal. Upon internal review spontaneous abortion was considered to be an other medical event. Additional information is not expected.

Other Meds: (therapy unspecified); albuterol; ZYRTEC, mg; ALLEGRA; vitamins (unspecified)

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 6/4/2007); Asthma; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **312526-2** **Related reports:** 312526-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	29-May-2007	15-Feb-2008	262	20-Jan-2009	13-Feb-2009	PA	WAES0805USA03565	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0388U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Ankle fracture, Drug exposure during pregnancy

Symptom Text: Information has been received for the Pregnancy Registry from a nurse concerning a 27 year old female with asthma and allergy to VICODIN with a history of 1 pregnancy a history of a spontaneous abortion who on 29-MAY-2007 was vaccinated IM in the left deltoid with a first dose of with GARDASIL 657622/0388U. Concomitant therapy included ALLEGRA, ALBUTEROL, vitamins (unspecified), ZYRTEC and "DUET DHA" [therapy unspecified]. On an unspecified date the patient was vaccinated with a second dose of GARDASIL. On 14-APR-2008 contained the following adverse experience: Broken ankle (31-OCT-2008). Patient Concomitant medication included BRETHINE INJECTION. Maternal Serum Alpha Fetoprotein test was performed on 23-JUN-2008, the results were within normal limits. The licensed practical nurse reported that on 24-NOV-2008 the patient delivered a normal, healthy male baby, APGAR score 8/9. This report contained the following adverse event: Broken ankle (31-OCT-2008). Patient Concomitant medication included BRETHINE INJECTION. Maternal Serum Alpha Fetoprotein test was performed on 23-JUN-2008, the results were within normal limits. The licensed practical nurse reported that on 24-NOV-2008 the patient delivered a normal, healthy male baby, APGAR score 8/9. This report contained the following adverse event: broken ankle (31-OCT-2008) and the patient was treated with HERAPIN from 31-OCT-2008 until 24-NOV-2008. This report is related to 0708USA01062. Additional information is not expected.

Other Meds: ALBUTEROL; ZYRTEC mg; ALLEGRA; BRETHINE INJECTION 5mg; Vitamins (unspecified)

Lab Data: Ultrasound, 04/14/08, WNL; Serum alpha-fetoprotein, 06/23/08, WNL

History: Abortion spontaneous

Prex Illness: Pregnancy NOS (LMP = 2/15/2008); Asthma; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: 312527-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Jan-2008	Unknown		19-May-2008	20-May-2008	--	WAES0801USA05893	20-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from an 18 year old female with no pertinent medical history and no known drug reactions/allergies who on 22-JAN-2008 was vaccinated with a first dose 0.5 mL of GARDASIL. There was no concomitant medication. The patient reported that on 28-JAN-2008 she went to her gynecologist, "had a pap smear done and found out she was pregnant". Her gestation was two weeks and five days. Her last menstrual period was on 10-DEC-2007 and estimated delivery date was 15-SEP-2008. No other information was provided. Follow up information was obtained via telephone call with the patient on 12-MAY-2008 to obtain the patient's obstetrician (OB)/gynecologist (GYN). The patient reported that she was not pregnant any more. When she was asked if she miscarried or decided to terminate, she reported that she "lost it" (date not reported). Upon internal review "lost it" (miscarriage) was determined to be an other important medical event. No additional information is expected.

Other Meds: None

Lab Data: beta-human chorionic 01/28/08 - pt pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 12/10/2007)

Prex Vax Illns:

Vaers Id: **312528-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		19-May-2008	20-May-2008	FR	WAES0803USA04028	20-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Contraception, Eye haemorrhage, Thrombosis

Symptom Text: Information has been received from a physician concerning a 21 year old female with no reported medical history who on an unspecified date was vaccinated with her first dose of Gardasil intramuscularly into the upper arm (lot number not reported). Concomitant therapy included hormonal contraceptives (unspecified) for systemic use. About two to three weeks post vaccination (date not reported) the patient experienced thrombosis in eyeground. Follow up information indicated that the patient was hospitalized from 25-FEB-2008 to 29-FEB-2008. The diagnosis of an unclear hemorrhage in the border area of the papilla of the optic nerve (left eye) was established. A cranial and orbital MRI was without pathologies. The patient was treated with poly (0-2-hydroxyethyl) amylum (HAES, DIAMOX) and cortisone. Hormonal contraceptive use was stopped after diagnosis. The patient recovered in an unspecified time. Additional information is not expected. Other business partner numbers included E2008-02207.

Other Meds: hormonal contraceptives (unspecified), Unk - Unk

Lab Data: magnetic resonance imaging, 25?Feb08, no pathologies, cranial and orbital

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **312529-1 (S)** **Related reports:** 312529-2; 312529-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-May-2008	03-May-2008	2	19-May-2008	20-May-2008	NJ	WAES0805USA01353	10-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Bruxism, Convulsion, Disorientation, Encephalitis, Encephalopathy, Faecal incontinence, Gaze palsy, Headache, Hyperreflexia, Hyporeflexia, Malaise, Mental status changes, Muscle rigidity, Pain in extremity, Pleocytosis, Tremor, Unresponsive to stimuli

Symptom Text: Information has been received from a physician concerning a 11 year old female patient with hypothyroidism who on 01-MAY-2008 was vaccinated with a first dose of Gardasil. Concomitant therapy included SYNTHROID. On 03-MAY-2008 the patient experienced encephalopathy after receiving the first injection, was seen at the emergency room (ER). Subsequently she was hospitalized. Laboratory diagnostic test spinal tap was done. No further information was provided. The patient had not recovered. Additional information has been requested. 06/16/2008 MR received from CDC for DOS 5/6-27/2008 with D/C DX: Meningoencephalitis. Hypothyroidism. Hypocalcemia. Pt presented to local ER with c/o pain in the arms and legs, headache and then episodes of shaking of the arms and legs, stool incontinence and unresponsiveness and progressive changes in mental status. In local ER had witnessed episode of eye rolling and shaking of the arms and legs. Transfered to current facility for further w/u. CSF showed WBC pleocytosis. PE (+) for brisk DTRs on the L and difficult to elicit on the R. 10/6/2008 Additional records received from initial ER 5/3/08. Pt presented with disorientation and not feeling well since 5/2/08. Had Gardasil 5/1/08. In ER had several episodes of tremors, clenched teeth, rigid, downward going toes and clenched hands drawn to the chest. Transfered to above facility to r/o meningitis.

Other Meds: SYNTHROID

Lab Data: spinal tap 05/03/08 - Partially abnormal. Labs and Diagnostics: CSF cell count 322 with 232 RBCs. CSF Glucose 79. CSF protien 113.7. Repeat 5/13/08 with CSF cell count down to 13, glucose 62, protein 22.4. CSF cx (-). Brain MRI c/w meni

History: PMH: Hypocalcemia. Hypothyroidism

Prex Illness: Hypothyroidism

Prex Vax Illns:

Vaers Id: **312529-2 (S)** **Related reports:** 312529-1; 312529-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-May-2008	03-May-2008	2	25-Jun-2008	26-Jun-2008	NJ		26-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Activities of daily living impaired, Aphasia, Convulsion, Encephalopathy, Pyrexia

Symptom Text: 11 year old girl with no prior problems was given GARDASIL on May 1, 2008. The following day she began having fevers. The next day she had seizures. She has been in the hospital since May 3, 2008. She can not walk or talk and must be spoon fed. The mother has been told there is encephalopathy, but no cause has been determined. No physicians have advised the parents of the medical cause. The mother has questioned the drug "GARDASIL" because the girl was fine until having been given the drug. The treating physicians have not determined the nature and extent of any permanency at this time.

Other Meds:

Lab Data: The patient has been in the hospital since May 3, 2008. The mother says CT and MRI scans and spinal taps have been given as well as brain function tests.

History: No pre-existing conditions.

Prex Illness:

Prex Vax Illns:

Vaers Id: **312529-3 (S)** **Related reports:** 312529-1; 312529-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-May-2008	04-May-2008	3	14-Aug-2008	19-Aug-2008	NJ		06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487	0	Left arm	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Encephalitis

Symptom Text: HPV administered on 5/1/08; patient stated above presented to hospital on 5/4/08. Dx - Aseptic meningoencephalitis.

Other Meds: SYNTHROID

Lab Data: CSF - increased WBC; Bacterial and Viral cultures negative.

History: Allergic rhinitis; known hypothyroidism; No allergies

Prex Illness: Allergic rhinitis; Known hypothyroidism

Prex Vax Illns:

Vaers Id: **312530-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Mar-2008	09-May-2008	42	19-May-2008	20-May-2008	FR	WAES0805USA02846	20-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1539F	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Brain stem syndrome, Dizziness, Headache, Infection, Somnolence

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who on 28-MAR-2008 was vaccinated intramuscularly into the deltoid with the third dose of GARDASIL. Six weeks post vaccination, on approximately 09-MAY-2008, the patient experienced brain stem infection with headache, somnolence, and dizziness. She was admitted to the hospital on an unspecified date. At the time of this report, the patient's outcome was unknown. It was reported that the first (14-SEP-2007, Lot # 1539F, batch # NF42170) and second (30-OCT-2007, Lot # 0354U, batch NF58150) vaccinations with GARDASIL were well tolerated. Other business partner numbers include: E200804162. Further information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: **312531-1** **Related reports:** 312531-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-Nov-2007	Unknown		19-May-2008	20-May-2008	FR	WAES0805USA02848	20-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0253U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myoclonic epilepsy

Symptom Text: Information has been received from a physician concerning a 13 year old female patient who on 27-NOV-2007 was vaccinated intramuscularly into the upper arm with the second dose of GARDASIL (Lot # 0253U, batch # NF58540). On 01-JAN-2008 the patient experienced a first episode of juvenile myoclonic epilepsy. The reporter pointed out that the exact onset date cannot be determined as the symptoms only occur for "solit seconds," and the patient might not have perceived them before. Since mid April 2008, the patient was treated with antiepileptics levetiracetam (KEPPRA). At the time of this report, the patient's outcome was unknown. It was reported that on 25-SEP-2007 she was vaccinated intramuscularly into the upper arm with the first dose of GARDASIL (Lot # 0253U, batch # NF58540), and it was well tolerated. Juvenile myoclonic epilepsy was considered to be an other important medical event. Other business partner numbers include: E200804196. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: **312531-2** **Related reports:** 312531-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	25-Sep-2007	01-Jan-2008	98	20-May-2008	21-May-2008	FR	WAES0805USA03053	30-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0253U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myoclonic epilepsy

Symptom Text: Information has been received from a general practitioner concerning a 13 year old female who on 25-SEP-2007 was vaccinated with the first dose of GARDASIL (Lot #0253U, Batch #NF58540), IM into the upper arm which was well tolerated. On 27-NOV-2007, the patient was vaccinated with the second dose of GARDASIL (Lot #0253U, Batch #NF58540), IM into the arm. Concomitant medication was not reported. On 01-JAN-2008, the patient experienced a first episode of juvenile myoclonic epilepsy. The reporter pointed out that the exact onset cannot be determined as symptoms only occur for "split seconds" and the patient might not have perceived them before. Since mid April 2008 the patient was treated with antiepileptics KEPPRA. The outcome and causality of the event was not reported. Other business partner numbers include E2008-04196. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312555-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	08-May-2008	08-May-2008	0	19-May-2008	27-May-2008	IN		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia oral, Lip swelling

Symptom Text: C/O upper lip feeling numb & swollen x 4 days (since vaccine). Denies any other factors, possible allergy triggers or other symptoms. Recommended antihistamine - ZYRTEC as directed & call if not resolved. Clinically - no rash, swelling no alteration of facial movements or symmetry. No sensation loss.

Other Meds: NUVA RING

Lab Data: None

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 312560-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-May-2008	15-May-2008	1	19-May-2008	27-May-2008	NY		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0092X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral

Symptom Text: Swelling size of golf ball to RA - getting larger -> advised ice and MOTRIN. Pt seen by doc on 5/16 good ROM, no fever, recheck if worsens.

Other Meds:

Lab Data: None

History: growth hormone deficiency

Prex Illness:

Prex Vax Illns:

Vaers Id: **312600-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	19-May-2008	19-May-2008	0	19-May-2008	26-May-2008	MO		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Nausea, Tremor, Vertigo

Symptom Text: Vaccine Admin. at 10:30 AM. Pt called the office at 1:00PM with complaints of nausea, shakiness, vertigo and SOB. Pt told to go to ER & call PMD. Pt went to Medical Center and was treated with Prednisone, Benadryl and Xanax(all of this per pt). At approx. 2pm pt called back and talked to RN..pt feeling much better after ER visit and treatment given.

Other Meds:

Lab Data:

History: None Noted

Prex Illness: None Noted

Prex Vax Illns:

Vaers Id: **312601-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	12-May-2008	12-May-2008	0	19-May-2008	26-May-2008	MN		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	C2775AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Lip swelling, Throat tightness

Symptom Text: lightheaded, puffy lips, throat tightness

Other Meds: none

Lab Data: pt did not come to us for care after reaction, she telephoned us the next day and reported that she had gone to urgent care

History: Penicillin

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312645-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	12-Mar-2008	02-Apr-2008	21	20-May-2008	21-May-2008	FR	WAES0805USA02847	21-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1068U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diplopia, Headache, Nausea, Spinal cord oedema, Vomiting

Symptom Text: Information has been received from a physician concerning a 20 year old female with concomitant medications and pertinent medical history unspecified, who on 14-JAN-2008 was vaccinated with the first dose of GARDASIL IM, (dose not reported), (Lot# 0277U, Batch#NG00020), this was tolerated well. On 12-MAR-2008 the patient was vaccinated with the second dose of GARDASIL IM to the Deltoid, (dose not reported) (Lot#10684, Batch#42070). After the vaccination, (approximately 02-APR-2008, 3 weeks post vaccination) the patient complained about headaches, nausea, vomiting and double vision. On 29-APR-2008 she was admitted to the hospital, cranial MRI on an unspecified date showed spinal cord oedema. The patient was treated with cortisone, IV, and GLYCEROL over a period of 4 -5 days. Symptoms of headache, double vision, vomiting and nausea were resolved on approximately 03-MAY-2008. Other business partner numbers include E2008-04237. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging Comment: spinal cord oedema

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312646-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Mar-2008	06-Mar-2008	0	20-May-2008	21-May-2008	FR	WAES0805USA02845	21-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hypoaesthesia, Injection site anaesthesia, Injection site pain, Muscular weakness

Symptom Text: Information has been received from a neurologist concerning a 16 year old female with a history of gastroenteritis (2 weeks prior to 06-MAR-2008), and no reported concomitant medications, who on 06-MAR-2008 was vaccinated with the third dose of GARDASIL IM into the deltoid muscle, (Lot # not reported). On unspecified dates the patient had previously received the first and second doses of GARDASIL injection, (Lot #'s not reported), it was noted that these were well tolerated. On 06-MAR-2008 about 10 minutes post vaccination with GARDASIL, the patient complained about injection site pain and experienced numbness, starting from "below injection site" and spreading down to the hand. In the course she additionally developed weakness of the hand. Injection site pain resolved after 1 day (07-MAR-2008), other symptoms were ongoing. On 22-APR-2008 she was admitted to the hospital for diagnostics. The physician reported that ENG, EMG, SEP, CSF, and cranial MRI showed normal results, (test dates not specified). The symptoms could not be allocated to a concrete nerve. Tentative diagnosis was "plexopathy." Under physiotherapy symptoms improved remarkably. At discharge (date unspecified) only discreet complaints were seen. Other business partner numbers include E2008-03768. Additional information is not available.

Other Meds: Unknown

Lab Data: Electronystagmography, 22?Apr08, normal; Electromyography, 22?Apr08, normal; Somatosensory evoked potential, 22?Apr08, normal; Diagnostic laboratory test, 22?Apr08, csf normal; Magnetic resonance imaging, 22?Apr08, cranial normal.

History: Gastroenteritis

Prex Illness:

Prex Vax Illns:

Vaers Id: 312647-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Dec-2007	21-Dec-2007	1	20-May-2008	21-May-2008	FR	WAES0805USA02844	21-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0277U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blindness, Inflammation, No reaction on previous exposure to drug, Retinal artery spasm, Syncope

Symptom Text: Information has been received from a physician concerning an 18 year old female with Hashimoto's thyroiditis and hay fever and no reported concomitant medications, who on 18-JUN-2007 was vaccinated with the first dose of GARDASIL (dose, and lot# not specified). The second dose of GARDASIL (dose, and Lot# not specified) was administered on 20-AUG-2007. It was reported that the first and second doses were well tolerated. On 20-DEC-2007 the patient received the third dose of GARDASIL, IM to the upper arm, (lot#0277U, Batch#NG00020). On 21-Dec-2007 she experienced a syncope, followed by a loss of vision for about ten minutes. On 31-Dec-2007 another episode of vision loss occurred for about ten minutes. The patient was hospitalised from 04-JAN-2008 till 08-JAN-2008. On admission date she was free of any complaints. physical neurological examinations were normal. Cranial MRI, CT, MR angiography of the cervical arteries and duplex sonography of the brain supplying vessels, EEG, echo cardiography, longterm ECG and ophthalmologic examination were all normal. Vasculitis was ruled out. Laboratory findings were all normal except for slightly increased ANA (>1:120), "BSR" (35/75), and CRP (0.8mg/dl). A lumbar puncture was carried out and revealed "inflammatory liquor cerebrospinalis syndrome." No final diagnosis was established. A cause for the symptoms could not be found. No follow-up lumbar puncture was carried out. The ophthalmologist evoked "relapsing spasms of the retinal vessels" and therapy was started with acetyl salicylic acid (ASS 100). No further episodes occurred. The reporter mentioned "ongoing mild vision discomfort" on 28-FEB-2008. The final outcome was not reported. A causal relation to the vaccine was not discussed. The file was closed. Other business partner numbers include E2008-03019. Additional information is not expected.

Other Meds: Unknown

Lab Data: head computed axial tomography, 04?Jan08, Comment: normal; angiography, 04?Jan08, Comment: cranial-normal; ultrasound, 04Jan08, Comment: cervical arteries normal; spinal tap, 04?Jan08, Comment: inflammatory liquor cerebrospinalis syndrome;

History: Hay fever

Prex Illness: Hashimoto's thyroiditis

Prex Vax Illns:

Vaers Id: 312648-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jan-2008	18-Jan-2008	2	20-May-2008	21-May-2008	FR	WAES0805USA02809	21-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575F	0	Unknown	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Amnesia, Cyanosis, Disorientation, Fall, Loss of consciousness, Mydriasis, Tetany

Symptom Text: Information has been received from a health authority concerning a 14 year old female with a history of rhinitis and conjunctivitis (with no evidence of true allergy: negative cutaneous test to pneumallergens) and family atopic diathesis, who on 16-JAN-2008 was vaccinated intramuscularly with the first dose of GARDASIL (Batch # NE47400/Lot #655127/0575F). The patient was with her mother and was very anxious because of vaccination. Within a few seconds following vaccination, the patient lost consciousness and fell onto the ground. Examination found mydriasis, incipient cyanosis, and tetany of the upper limbs. Pulse was not measurable. No work-up results were provided and no additional examination was performed concerning ruled out etiologies not related to drugs. The patient's legs were raised and she regained consciousness in a few seconds. The patient had total amnesia of her loss of consciousness and was disoriented. Subsequently, the patient recovered. The physician did not wish to continue vaccination. The events were considered to be immediately life-threatening. Additional information is not expected. The case is closed. Other business partner numbers include E2008-04343.

Other Meds: Unknown

Lab Data: Unknown

History: Rhinitis; Conjunctivitis

Prex Illness:

Prex Vax Illns:

Vaers Id: 312649-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jul-2007	01-Dec-2007	153	20-May-2008	21-May-2008	FR	WAES0805USA02804	21-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anaplastic large cell lymphoma T- and null-cell types, Radiotherapy, Skin lesion

Symptom Text: Information has been received from a health authority (reference number EX20080262) concerning a 17 year old female who in July 2007, was vaccinated with the first dose of GARDASIL. In September 2007, the patient received the second dose of GARDASIL (route of administration and site of injection were not reported). In December 2007, the patient had a dermatological lesion. A biopsy revealed a CD30 cutaneous lymphoma. It was also reported ALK-positive lymphoma with 2.5 translocation which was unusual for a primitive cutaneous lymphoma. The patient was hospitalised, however no further details were provided. The patient was prescribed radiotherapy and was under intensive supervision because of an eventual risk of secondary ganglionic impairment. At the time of this report, the outcome was not specified. Additional information has been requested. Other business partner numbers include E2008-04329.

Other Meds: Unknown

Lab Data: biopsy, ??Dec07, CD30 cutaneous lymphoma ALK-positive lymphoma with 2.5 translocation

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312650-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Nov-2007	Unknown		20-May-2008	21-May-2008	FR	WAES0805USA02769	21-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Asthenia, Chest pain, Headache, Hepatic function abnormal, Menstruation irregular, Urinary tract infection, Vertigo

Symptom Text: Information has been received from a health authority (reference number DJ20080289) concerning a 16 year old female with no relevant medical history who on 22-NOV-2007 was vaccinated intramuscularly with GARDASIL. Subsequently, in the following days, the patient experienced cephalgia, vertigo, menstrual disturbance, abdominal pain, and very significant asthenia. On 15-JAN-2008, the patient developed urinary tract infection for which she received corrective treatment with MONURIL. On 21-JAN-2008, the patient experienced thoracic pain which induced hospitalization. On 22-JAN-2008, anomalies were found in the patient's hepatic work-up with ASAT at 1.3N, ALAT at 1.4N, alkaline phosphatase at 1.3N, creatine kinase at 168 and D-Dimers at 520. The patient's condition rapidly improved allowing her discharge. Since then, auto-immunity work-up was performed and was negative. Serologies for viral hepatitis A, B, and C, CMV and mononucleosis were negative and noncontributory. Creatine kinase were found back to normal, and hepatic work-up was relatively stable. Gamma GT were normal. The reporter specified that alkaline phosphatases are virtually always above normal until the age of 20 and thought that consequently it was not necessary to take them into account. The reporter added that the moderate increase in transaminases should be put under surveillance with no particular worry. The reporter also specified that as far as GARDASIL vaccine was concerned, only symptoms that appeared 48 hours after vaccination should be taken into account. According to the reporter, the patient could have possibly experienced unidentified virosis in January 2008, which could have induced both painful syndrome and hepatic impairment. D-Dimers were at 713 and seemed to regress. However there was an increase in type A immunoglobulins. As of 31-MAR-2008, asthenia had virtually resolved. Additional information has been requested. Other business partner numbers include E2008-04333.

Other Meds: Unknown

Lab Data: cytomegalovirus antigen, ??08, negative; serum creatine kinase,??08, normal; serum hepatitis B Ab, ??08, negative; serum hepatitis C antibody test, ??08, negative; serum Epstein-Barr virus antibody test, ??08, negative; serum hepatitis A an

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 312652-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Sep-2007	04-Sep-2007	1	20-May-2008	21-May-2008	FR	WAES0709USA02308	21-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1518F	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Autoimmune thyroiditis, Hypersensitivity, Oedema peripheral, Systemic lupus erythematosus

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who on 03-SEP-2007 was vaccinated into the upper arm with the first dose of GARDASIL (Lot #1518F, batch #NF23330). There was no concomitant medication. One day post vaccination, the patient experienced generalised joint pains, followed by swelling of soft tissue of extremities. As the symptoms were lasting despite analgesics (ibuprofen), she was admitted to the hospital on 09-SEP-2007 for further check-up. A reaction due to the vaccination was supposed. A diagnosis of systemic lupus erythematosus with joint involvement and moderate activity as suspicion of lapsed Hashimoto thyroiditis and allergic reaction after GARDASIL were established on an unknown date. Anti-nuclear antibodies were negative, also BSR. Diagnostic laboratory tests performed in September 2007 included: leukocytes were 4.900/mcl, haemoglobin was 13.1 g/cl, erythrocytes were 4.42 Mio/mcl, BSR 2mm/1hour, thrombocytes were 211,000/mcl, creatinine was 0.9 mg/dl, serum thyroid-stimulating hormone test (TSH) was 1.56, free serum triiodothyronine test (FT3) was 3.06 mg/l, total serum thyroxine test (FT4) was 1.10 mg/dl, IgG was 1600 mg/dl, IgA was 108 mg/dl, IgM was 66 mg/dl, IgE 101 IU/ml, serum C-reactive protein (CRP) was 4 mg/l, serum rheumatoid factor test (RF) <3IE/ml, antistreptolysin 143 IE/ml. The patient was discharged on 12-SEP-2007. On 17-SEP-2007 the patient was instructed to present to the hospital since at that time the results for Diagnostic laboratory testing antinuclear antibodies (ANA), ANCA, urine status, and proteins were pending. It is to be noted that the information was not received regarding this check up. On 07-FEB-2008 the patient presented to an outpatient department. Examination showed no swelling of the hands, feet, or joints (recovered). The patient was medicated with DECORTIN, L-THYROXIN, JODID and QUENSYL. Diagnostic laboratory testing performed in February 2008 included: leukocytes were 9.500/mcl, haemoglobin was 14.5 g

Other Meds: None

Lab Data: diagnostic laboratory test, ??Sep07, BSR 2 mm/1hour; diagnostic laboratory test, 07Feb08, AAK double-strand molecule DNS with borderline values; WBC count, ??Sep07, 4.900 mcl; hemoglobin, ??Sep07, 13.0 g/dl; platelet count, ??Sep07, 211,000

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **312667-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		20-May-2008	28-May-2008	TX		28-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0742U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pruritus generalised, Rash generalised

Symptom Text: Patient complained of rash/itching all over. Patient also complained of nausea and dizziness. Patient denies any fever or vomiting. Patient reports symptoms started the evening after getting the injection. Per patient symptoms lasted one week. Patient did not notify us right away.

Other Meds: Ortho Tri Cyclen Lo

Lab Data:

History: Sulfa allergic

Prex Illness:

Prex Vax Illns:

Vaers Id: **312671-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	13-May-2008	Unknown		20-May-2008	28-May-2008	IN		28-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB253AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0384U	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1351U	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain of skin, Pyrexia, Skin warm

Symptom Text: Left upper arm 3in x 3in warm, tender area fever 101 deg; BENADRYL/Ice

Other Meds: Unknown

Lab Data:

History: Allergy: CEFZIL, Encopresis, Recent MACE procedure

Prex Illness: Unknown

Prex Vax Illns: Local reaction~Varicella (no brand name)~2~8~In Sibling

Vaers Id: 312673-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	16-May-2008	17-May-2008	1	20-May-2008	27-May-2008	NH		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Face oedema, Urticaria

Symptom Text: Hives developed ~24 hrs after GARDASIL #2 (5-16-08). On call MD called 5-18-08 when facial edema began. BENADRYL recommended & taken. 5-19-08 - hives cont'd - seen in office - rec 24 hr antihistamine QD-BID x7d.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 312675-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	16-May-2008	17-May-2008	1	20-May-2008	28-May-2008	NH		28-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Face oedema, Urticaria

Symptom Text: Hives developed about 24 hrs with GARDASIL #2 (5-16-08). On call MD called 5-18-08 when facial edema began. BENADRYL recommended and taken. 5-19-08 - hives continued - seen in office - received 24hrs antihistamine QD-BID x7d.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312715-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-May-2008	19-May-2008	18	20-May-2008	26-May-2008	LA		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0004X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1968U	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2551AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Patient was ~34-35 weeks pregnant at time of the immunization administration. No UPT was done prior to administration. Patient delivered an infant girl on 5/19/2008 at ~37 weeks EGA. No prenatal care received. Infant appears well at this time, but will report this immunization administration if adverse events were to occur at a later date.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 312722-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	19-May-2008	19-May-2008	0	20-May-2008	26-May-2008	PA		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Heart rate increased, Hypersensitivity, Immediate post-injection reaction, Pallor, Pharyngeal oedema, Urticaria, Wheezing

Symptom Text: Severe allergic reaction to HPV vaccine immediately after injection including hives, swelling of throat, wheezing, paleness and increased heart rate. Given Epi injection with improvement. Taken to ER via ambulance and was observed for several hours. Started on Prednisone for the next 4 days and given an Epipen.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 312723-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	16-May-2008	20-May-2008	4	20-May-2008	26-May-2008	MN		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Malaise

Symptom Text: Patient had felt sick all weekend (received vaccine on friday); joint pain significantly increased 4 days following injection; patient given opoid medication for pain

Other Meds: NKDA; Ethinyl estradiol, cetirizine, celecoxib, calcium

Lab Data:

History: lymphoblastic lymphoma, avascular necrosis

Prex Illness: avascular necrosis

Prex Vax Illns:

Vaers Id: **312735-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		20-May-2008	27-May-2008	--		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: Pt developed groin nodal enlargements. Obtained ID consult. Negative w/u. Hematology/oncology consult suggest possible vaccine related. Now, it is resolved.

Other Meds: YAZ

Lab Data: CT-negative

History: Irregular menstruat, aller to amoxi, erythro

Prex Illness: None

Prex Vax Illns:

Vaers Id: 312785-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	22-Mar-2007	15-Dec-2007	268	19-May-2008	11-Jun-2008	--	WAES0704USA05046	11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Complication of delivery, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received from a physician concerning a female with a history of obesity and no concurrent medical conditions, who on 22-MAR-2007 was vaccinated IM with a first dose of GARDASIL (Lot# 657006/0188U). Subsequently, the patient was pregnant. The physician reported that the patient was in her first trimester. The patient's last menstrual period was 16-FEB-2007 and her estimated delivery date was 23-NOV-20067 (also reported as 18-DEC-2007). On 10-JUL-2007 a Maternal Serum Alpha-Fetoprotein Screening (MSAFP) was performed and was low risk. On 17-JUL-2007 an ultrasound was performed and showed normal anatomy. The patient took prenatal vitamins throughout the duration of her pregnancy, calcium during the 2nd and 3rd trimester, and iron during the last month of her pregnancy. It was reported that the patient had one previous pregnancy and one spontaneous abortion at 5 weeks. No further information was available. Follow-up information indicated that 43 weeks from her last menstrual period (also reported as 38 weeks) on 15-DEC-2007 the patient delivered a female infant that weighed 7 pounds 4 ounces, and had an Apgar score of 8/9. It was reported there was a complication of fetal intolerance to labor during the delivery. The patient received routine prenatal testing during her pregnancy. It was reported that the infant was normal with no congenital anomalies, complications, or abnormalities. Additional information has been requested.

Other Meds: calcium (unspecified), iron (unspecified), vitamins (unspecified)

Lab Data: ultrasound, 07/17/07, normal anatomy screening; serum alpha-fetoprotein, 07/10/07, screening-low risk

History: Miscarriage

Prex Illness: Pregnancy NOS (LMP = 2/16/2007); Obesity

Prex Vax Illns:

Vaers Id: 312786-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	15-May-2007	15-May-2007	0	19-May-2008	12-Jun-2008	--	WAES0705USA05476	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1426F		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Haemorrhage, Herpes simplex, Urinary tract infection

Symptom Text: Initial and follow up information has been received for the pregnancy registry for GARDASIL from a registered nurse concerning a 26 year old female with allergies, bipolar, depression, Von Willebrand disease type 1 due to aspirin intake, genital herpes, irritable bowel syndrome, migraine headaches, panic attacks and allergies to Pseudophedrine, Ibuprofen and Aspirin who on 15-MAY-2007 was vaccinated IM with 0.5 mL GARDASIL (lot # 655205/1426F). Concomitant therapy included ZYRTEC and EFFEXOR. On 29-MAY-2007 the patient had a positive pregnancy test (LMP 21-APR-2007, EDD 26-Jan-2008) and therapy with venlafaxine HCL was discontinued. On 02-AUG-2007 an ultrasound revealed a subchorionic hemorrhage which resolved without intervention on unspecified date. A maternal serum alpha fetoprotein test on 15-AUG-2007 was normal. On 11-OCT-2007 the patient was diagnosed with a urinary tract infection and treated with Ceftin, 250 mg, PO, BID. On 03-JAN-2008 the patient began treatment with Acyclovir, 400 mg, BID for herpes simplex virus. On 05-JAN-2008 at 37 weeks the patient had a spontaneous rupture of membranes and gave birth to a normal male infant who weighed 7 lbs. 5 oz. His apgar scores were 9/9. The patient completed therapy with Acyclovir on 15-JAN-2008. Additional information has been requested.

Other Meds: ZYRTEC; EFFEXOR

Lab Data: Ultrasound, 08/02/07, subchorionic hemorrhage; Beta-human chorionic, 05/29/07, positive; Serum alpha-fetoprotein, 08/15/07, normal.

History:

Prex Illness: Pregnancy NOS (LMP = 4/21/2007); Hypersensitivity; Bipolar disorder; Depression; Von Willebrand's disease; Genital herpes; Irrit

Prex Vax Illns:

Vaers Id: 312787-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	01-May-2007		19-May-2008	11-Jun-2008	--	WAES0706USA05349	11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received from a healthcare professional and a physician, via the Merck pregnancy registry, concerning a 20 year old female patient with no previous pregnancies, with gastrooesophageal reflux disease and papilloma viral infection and a history of anaemia, pneumonia, infectious mononucleosis, ulcer, Papanicolaou smear abnormal and colposcopy, who in May 2007, was vaccinated with the first dose of GARDASIL. The date of the LMP was approximately 01-May-2007, date of conception estimated as 15-MAY-2007. On 25-JUN-2007, an ultrasound confirmed the patient to be 8 weeks and 1 day into the pregnancy; the estimated date of delivery was 05-FEB-2008. Follow-up information was received from the physician's office. On 06-FEB-2008 the patient delivered a healthy 7 pound 2 ounces baby boy with an Apgar score of 8/9. The patient was 40 weeks from LMP. The patient was Group B streptococcus positive (GBS+). From 19-DEC-2007 to 22-JAN-2008 fetal activity both reactive was monitored for decreased fetal motion. Additional information is not expected.

Other Meds:

Lab Data: ultrasound, 06/25/07, 8 weeks 1 day; diagnostic laboratory, group B streptococcus positive; fetal activity test, 12/19/07, both reactive

History: Anaemia; Colposcopy; Infectious mononucleosis; Papanicolaou smear abnormal; Ulcer; Pneumonia

Prex Illness: Pregnancy NOS (LMP = 5/1/2007); Gastrooesophageal reflux disease; Papilloma viral infection

Prex Vax Illns:

Vaers Id: **312788-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	23-May-2007	23-May-2007	0	19-May-2008	11-Jun-2008	KS	WAES0708USA02585	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1208F	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Drug exposure during pregnancy, Postpartum haemorrhage, Upper respiratory tract infection, Urinary tract infection

Symptom Text: Information has been received from a Merck pregnancy registry for GARDASIL from a 25 year old female with a history of previous pregnancy/full term delivery and no drug allergies who on 24-JAN-2007 was vaccinated with her first dose of GARDASIL (lot# 654741/1208F). On 23-MAY-2007 the patient was vaccinated with her second dose of GARDASIL (lot# 654741/1208F). There was no concomitant medication. The patient is 19 weeks pregnant. Unspecified medical attention was sought. Follow up information received, indicated that the patient was on prenatal vitamins for all through the pregnancy, ferrous sulfate 28 to 40 weeks, 325 mg daily for anemia, BACTRIM as prescribed for urinary tract infection and Z-PACK for upper respiratory infection. On 18-Feb-2008, the patient delivered a normal female baby week from LMP 38. The baby weighed 7 pounds and 9.8 ounces with an Apgar score 7/8. The patient experienced postpartum haemorrhage during labour and delivery. The patient's outcome was not reported. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 10/02/07, normal mid pregnancy

History:

Prex Illness: Pregnancy NOS (LMP = 5/28/2007)

Prex Vax Illns:

Vaers Id: 312789-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Apr-2007	13-Jun-2007	51	19-May-2008	11-Jun-2008	--	WAES0708USA04753	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1426F	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour, Umbilical cord abnormality

Symptom Text: Information has been received from a licensed practical nurse through the Pregnancy Registry for GARDASIL concerning a 16 year old, female smoker, with no previous pregnancies, who on 20-FEB-2007 was vaccinated intramuscularly with the first dose of GARDASIL (Lot # 654389/0961F). On 23-APR-2007, the patient was vaccinated intramuscularly with her second dose of GARDASIL (Lot # 655205/1426F). On 22-AUG-2007, the patient was vaccinated intramuscularly with her third dose of GARDASIL (Lot # 655620/0171U) and in addition was vaccinated with a VAQTA vaccine (MSD; not lot # reported). On 24-AUG-2007 the patient was seen at the doctor's office for a urine pregnancy test which was positive (LMP 13-JUN-2007). On 12-SEP-2007, the patient had an ultrasound for the purpose of dating which was normal and indicated that the fetus was 12 weeks and 4 days gestation. From November 2007 to January 2008, the patient was taking vitamins with iron daily. On 07-NOV-2007, the patient had an ultrasound for Level II screening which had the fetus at 20 weeks and 1 day gestation and showed an eccentric cord insertion (not further specified). The patient also has an MSAFP for screening purposes and the results were within normal limits. On 31-Jan-2008, the patient gave birth to a live 3 lb, 12 oz female infant (32 weeks and 6 days from LMP). It was also reported that the patient had preterm delivery at 32 weeks and 4 days. The baby had Apgar scores of 7 and 8, and there were no congenital anomalies. No additional information is expected.

Other Meds: Unknown

Lab Data: ultrasound, 09/12/07, normal (12 week 4 day); ultrasound, 11/07/07, Eccentric cord insertion; urine beta-human, 08/24/07, positive; serum alpha-fetoprotein, 11/07/07, within normal limits

History:

Prex Illness: Pregnancy NOS (LMP = 6/13/2007); Smoker

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312790-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Apr-2007	19-Jun-2007	78	19-May-2008	16-Jun-2008	NJ	WAES0709USA02732	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Delivery, Drug exposure during pregnancy, No adverse event

Symptom Text: Information has been received from a nurse through the Merck pregnancy registry concerning an 18 year old female with attention deficit/hyperactivity disorder and allergies to codeine and ULTRAM who 26-JAN-2007 was vaccinated intramuscularly with her first dose of GARDASIL (Lot 3 654741/0013U). On 02-APR-2007, the patient was vaccinated intramuscularly with her second dose of GARDASIL vaccines (Lot # 657617/0384U). On 03-JUL-2007, the patient was vaccinated intramuscularly with her third dose of GARDASIL (Lot # 658100/0525U). On 18-SEP-2007, it was reported that the patient was at 13 weeks gestation (LMP=19-JUN-2007). There was no adverse experienced related to this event. The nurse reported information based on information provided by the patient's grandmother during a telephone conversation. "The baby was born in March 2008 and is doing fine. Only has a little bit of gas/GI Issues but is fine. As far as they know the baby is healthy and normal with no congenital anomalies." No additional information is expected.

Other Meds:

Lab Data:

History:

Prex Illness: Pregnancy NOS (LMP = 6/19/2007); Attention deficit/hyperactivity disorder; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: 312791-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	31-May-2007	28-Jun-2007	28	19-May-2008	16-Jun-2008	RI	WAES0710USA03482	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0011U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cholestasis of pregnancy, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse through the Pregnancy Registry for GARDASIL concerning a 16 year old female, with a history of obesity (BMI 35), and no previous pregnancies, who on 29-MAR-2007 received her first vaccination with GARDASIL (Lot # 654702/0011U). On 31-MAY-2007, the patient received her second vaccination with GARDASIL (Lot # 654702/0011U). Subsequently, the patient became pregnant (LMP = 28-JUN-2007). On 18-SEP-2007, the patient had an ultrasound for dating purposes which was normal indicated a single IUP at 10 weeks. On 02-OCT-2007 and 01-NOV-2007, the patient had integrated screening for maternal serum alpha-fetoprotein which were negative. On an unspecified date, the patient developed cholestasis of pregnancy and was treated with URSO FORTE, outcome was not reported. It was reported that at 16 weeks (approximately 30-OCT-2007) through approximately 19 weeks (approximately 20-Nov-2007), the patient was treated with REGLAN. Other medications used during pregnancy included prenatal vitamins (not specified) and permethrin cream (not further specified). Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, 09/18/07, single IUP 10 weeks; normal; fetal monitoring tests, 10/02/07, MSAFP screening-negative; fetal monitoring tests, 11/01/07, MSAFP screening-negative

History: Obesity

Prex Illness:

Prex Vax Illns:

Vaers Id: 312792-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	21-Sep-2007	27-Sep-2007	6	19-May-2008	16-Jun-2008	--	WAES0710USA05808	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Appendicectomy, Appendicitis, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received through the Merck pregnancy registry through a 25 year old female who on 21-SEP-2007 was vaccinated with intramuscularly with her first dose of GARDASIL. On 25-OCT-2007, the patient was vaccinated intramuscularly with her second dose of GARDASIL. There was no concomitant medication. The patient reported that after receiving her second vaccination on 25-OCT-2007 she discovered she was "4 weeks pregnant" (LMP approximately 27-SEP-2007). It was reported by the patient that "everything was fine" and she was probably going to have a cesarean section in June. On 21-APR-2008 the patient had an appointment and "everything looked great." The baby's weight was "fine" and her fungal height was normal. "A few weeks ago" the patient experienced appendicitis and was hospitalized in order to have her appendix removed. The patient did not think the appendicitis was related to the vaccine. The patient recovered and it was reported that the patient and the baby were doing fine. No further information was provided. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory, fundal height-normal

History: Pregnancy NOS (LMP = 9/27/2007)

Prex Illness:

Prex Vax Illns:

Vaers Id: 312793-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Aug-2007	02-Aug-2007	0	19-May-2008	13-Jun-2008	NE	WAES0711USA02488	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	188U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received through the Pregnancy Registry for GARDASIL through a nurse practitioner concerning a 15 year old white, non-smoker female, with acne and no previous pregnancies, who on 02-AUG-2007 was vaccinated intramuscularly with her first dose of GARDASIL (Lot #657006/0188U). Concomitant therapy included ORTHO EVRA and "minocycline". Subsequently, the patient found out she was pregnant (LMP = 22-JUN-2007). The patient had an ultrasound (not further specified). The patient sought unspecified medical attention. Follow-up information received 10-APR-2008 from the physician reported that on 01-NOV-2007, the patient had an ultrasound which was normal except "small venous lakes in the placenta". The reporter also indicated that the patient had stopped therapy with ORTHO EVRA (date not specified). From November 2007 until present, the patient has been on prenatal vitamins (not further specified). The patient discontinued treatment with minocycline for acne in November 2007. On 04-Jan-2008, the patient was given a flu shot (not further specified). There were no complications during pregnancy. On 02-Mar-2008, the patient delivered a female infant, 5 pounds, 7 ounces, 18 1/4 inches long, and an apgar score of 8/9. Delivery was 36 weeks and 2 days from LMP. The infant had no congenital anomalies, no complications or abnormalities, and there were no complications during labor and delivery. No additional information is expected.

Other Meds: ORTHO EVRA; Minocycline 50mg

Lab Data: Ultrasound, 11/01/07, small venous lake in placenta.

History:

Prex Illness: Pregnancy NOS (LMP = 6/22/2007); Acne; Non-smoker

Prex Vax Illns:

Vaers Id: 312794-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Oct-2007	30-Oct-2007	0	19-May-2008	12-Jun-2008	AZ	WAES0711USA02620	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1425F	0	Unknown	Intramuscular	
	HEPA	MERCK & CO. INC.	0304U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a certified medical assistant, for the Pregnancy Registry for GARDASIL, concerning a 17 year old female who on 30-OCT-2007 (also reported as 18-JUL-2007) was vaccinated intramuscularly with the first dose of GARDASIL (655165/1425F). Per the reporter, the patient was pregnant at the time of vaccination (Gestation = 36 weeks; LMP approximately 04-Mar-2007). The pregnancy was confirmed by a pregnancy test. Concomitant therapy included vaccination with the first dose of VAQTA (653616/0511F) on 18-SEP-2006 and the second dose of VAQTA (654514/0304U) on 30-OCT-2007 (dose, duration not reported). The patient is not experiencing any known symptoms. No further information is available. It was reported that on 02-DEC-2007 the patient delivered a baby girl via vaginal delivery that is normal, no congenital anomalies. "but has had some illnesses". Birth weight was 6lbs 10oz, Apgar scores were 9 and 9. The baby did have a right parietal cephalohematoma at birth due to probable vacuum use during delivery. The baby also experienced some illnesses, most respiratory issues including RSV pneumonitis which has resolved. The reporter indicated that the patient has a high level of exposure to school aged children family members. There was also some jaundice at birth which has also resolved. The baby has also had some thrush. On 04-APR-2008 it was indicated by the physician that the baby was a "healthy baby girl with some eczema. No additional information is expected.

Other Meds: Unknown

Lab Data: beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 3/4/2007)

Prex Vax Illns:

Vaers Id: **312795-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	07-Dec-2007	01-Jan-2008	25	19-May-2008	12-Jun-2008	SC	WAES0803USA01559	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1211U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Nausea, Vomiting

Symptom Text: Information and follow up has been received from a physician for the Pregnancy Registry for GARDASIL concerning a 25 year old female with a history of 1 pregnancy and 1 live birth who was vaccinated on 12-OCT-2007 with her first dose of GARDASIL (lot# 0530U). On 07-DEC-2007 the patient was vaccinated with her second dose of GARDASIL (lot# 655322/1211U) and became pregnant. Concomitant therapy included prenatal vitamins (unspecified). The patient's LMP was reported as 01-JAN-2008 with an estimated due date of 10-OCT-2008. The patient had an ultrasound on 01-JAN-2008 and the results of the test were IUG-6W4D. On 17-MAR-2008 the patient developed nausea and vomiting which were treated with PHENERGAN. At the time of this report it was unknown if the patient had recovered from nausea and vomiting. No further information was available.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 01/01/08, IUG-6W4D, vitamins (unspecified)

History:

Prex Illness: Pregnancy NOS (LMP = 1/1/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312796-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	11-Mar-2008	11-Mar-2008	0	19-May-2008	12-Jun-2008	NC	WAES0804USA00305	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect route of drug administration, Injection site pain

Symptom Text: Information has been received from a health professional concerning a 24 year old female who on 11-MAR-2008 was vaccinated SQ with the third dose of GARDASIL (659182/1757U). On 11-MAR-2008 the patient experienced injection site soreness and incorrect route of administration. Subsequently, the patient recovered from the injection site soreness and incorrect route of administration. Per the reporter, there were no reactions with the first two doses. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312797-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	14-Nov-2007	15-Nov-2007	1	19-May-2008	12-Jun-2008	--	WAES0804USA00354	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Headache, Nausea, Pyrexia, Vomiting

Symptom Text: Information has been received concerning a 19 year old female with a history of allergic reaction to antibiotics who on 14-NOV-2007 was vaccinated IM in the deltoid with the first dose of GARDASIL (658560/1062U). Concomitant therapy included LOESTRIN. On 15-NOV-2007 the patient experienced nausea, vomiting, fever, chills and headache. Additional information received from NSC call (14-APR-2008): The caller states that she continues to receive letters from WPS about WAES 0804USA00354. The patient's name is Crystal and the caller does not know who the WPS letter was addressed to. The caller was unable to locate the SR associated with this WAES #. The caller states that she has returned a previous letter from WPS and does not want to receive any more letters. Additional information is not expected.

Other Meds: LOESTRIN

Lab Data:

History: Allergic reaction to antibiotics

Prex Illness:

Prex Vax Illns:

Vaers Id: **312798-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	18-Oct-2007	18-Oct-2007	0	19-May-2008	16-Jun-2008	NY	WAES0804USA00384	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1264U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised, Urticaria

Symptom Text: Information has been received from a physician concerning a 19 year old female with penicillin allergy who on 18-OCT-2007 was vaccinated intramuscularly in the left deltoid with a first dose of GARDASIL (Lot # 658488/1264U). There was no concomitant medication. On 18-OCT-2007, within hours of vaccination, the patient developed hives all over her body. Subsequently, several days later, the patient recovered from hives all over her body without any treatment. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: 312799-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Mar-2008	31-Mar-2008	14	19-May-2008	18-Jun-2008	--	WAES0804USA00433	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash erythematous, Skin lesion

Symptom Text: Information has been received from a health professional concerning an 18 year old female with a history of recurrent rash after the second dose of GARDASIL who on approximately 17-MAR-2008 was vaccinated intramuscularly with her third dose of GARDASIL (lot# not reported). There was no concomitant medication. On 31-MAR-2008 the patient experienced a red rash on her feet, right thigh and elbows. The rash was made up of clusters of reddish circular lesions, about 1cm in diameter. The centers of the lesions were more purple in color than the borders. The patient was treated with Prednisone and ALLEGRA and was recovering. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Rash recurrent

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312800-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	FL	WAES0805USA01479	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning a female patient who reported her friend who on an unspecified date was vaccinated at another physicians office with a dose of GARDASIL (lot #unknown, site and route not reported). There was no concomitant medication. The patient had reported that her friend had "experienced lightheadedness while" driving 2.5 hours after receiving the vaccination. No additional information was reported. The patient's outcome was not reported. No further information is expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 312801-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Mar-2008	Unknown		19-May-2008	18-Jun-2008	FL	WAES0805USA01521	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site pain, Pain in extremity

Symptom Text: Information has been received from a nurse concerning a 12 year old female who on 24-JAN-2008 was vaccinated IM with the first dose of GARDASIL. On 28-MAR-2008, the patient was vaccinated IM with the second dose of GARDASIL. The patient reported pain in the arm at the injection site for 3 days after the vaccination was given. The pain in the arm included not being able to lift the arm. The nurse also reported that since multiple patients (3 patients) reported pain in their arms, they started giving the vaccination in the buttocks to an unspecified number of patients. Unknown medical attention was sought through contact with the nurse. Patient outcome was unknown. No product quality complaint was involved. This is one of the multiple cases from the same source (WAES # 0804USA05546 and 0805USA01522). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312802-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Oct-2007	Unknown		19-May-2008	12-Jun-2008	FL	WAES0805USA01522	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site pain

Symptom Text: Information has been received from a nurse concerning a 14 year old female who on 18-OCT-2007 was vaccinated IM with the first dose of GARDASIL. On 30-OCT-2007, the patient was vaccinated IM with the second dose of GARDASIL and on 14-MAR-2008, the patient was vaccinated IM with the third dose of GARDASIL. The patient reported pain in the arm at the injection site for 3 days after the vaccination was given. The pain in the arm included not being able to lift the arm. The nurse also reported that since multiple patients (3 patients) reported pain in their arms, they started giving the vaccination in the buttocks to an unspecified number of patients. Unknown medical attention was sought through contact with the nurse. Patient outcome was unknown. No product quality complaint was involved. This is one of the multiple cases from the same source (WAES # 0804USA05546 and 0805USA01521). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312803-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Mar-2008	15-Mar-2008	0	19-May-2008	18-Jun-2008	--	WAES0804USA00449	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Sneezing

Symptom Text: Information has been received from a company representative, as told by the patient's mother, concerning an 11 year old female who on 15-MAR-2008 was vaccinated with her third dose of GARDASIL (lot# not reported). There was no concomitant medication. On 15-MAR-2008 the patient started sneezing which lasted for 4 days. Subsequently, the patient recovered from sneezing. The mother gave the patient BENADRYL, but it did not help. The patient sought unspecified medical attention. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **312804-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Mar-2008	18-Mar-2008	0	19-May-2008	18-Jun-2008	--	WAES0804USA00450	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a health professional concerning a 16 year old female who on approximately 18-MAR-2008 was vaccinated with GARDASIL (lot# not reported). Concomitant therapy included VARIVAX, for the treatment of prophylaxis (duration and dose not reported) and VAQTA, for the treatment of prophylaxis (duration and dose not reported). Other concomitant therapy included MENACTRA. On approximately 18-MAR-2008 the patient fainted shortly after the vaccinations. Subsequently, the patient completely recovered from fainting before leaving the office. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312805-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	13-Jun-2008	PA	WAES0804USA00454	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a physician concerning a female who in January 2008, was vaccinated with her second dose of GARDASIL. In January 2008, the patient experienced swelling, pain and redness at the injection site. The patient's swelling, pain and redness at injection site persisted. The patient sought unspecified medical attention in the office and had an MRI. Additional information has been requested.

Other Meds: Unknown

Lab Data: Magnetic resonance

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312806-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	04-Apr-2007	04-Apr-2007	0	19-May-2008	18-Jun-2008	VA	WAES0804USA00470	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1426F	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Dizziness

Symptom Text: Information has been received from a physician concerning a 12 year old female who was recently IM vaccinated with GARDASIL (lot number 655208/1426F). Subsequently the patient felt woosie. While the patient was in office, she started to have some mild dizziness which she recovered from. However, at home, she complained of increasing dizziness and was unable to get out of bed all evening. The patient recovered on 05-Apr-2007. No other information was available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312807-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	12-Jun-2008	--	WAES0804USA00472	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Vaccine positive rechallenge

Symptom Text: Information has been received from a health professional concerning a female who was IM vaccinated with all three doses of GARDASIL (lot numbers unspecified). Subsequently after each dose, the patient experienced a headache that lasted all day then resolved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312808-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	21-Nov-2007	04-Feb-2008	75	19-May-2008	12-Jun-2008	CA	WAES0804USA00592	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	HEP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal distension, Back pain, Cystitis, Kidney infection, Stomach discomfort, Vomiting, Wrong drug administered

Symptom Text: Information has been received from a consumer concerning her daughter, a 20 year old female with a kidney infection and bladder infection and a history of occasional bladder infections and yeast infections who on 21-NOV-2007 was IM vaccinated with her first dose of GARDASIL (lot number unspecified). On 04-Feb-2008 she went to the physician's office to receive the second dose of GARDASIL and was inadvertently given hepatitis B vaccine (lot number and manufacturer unspecified). On 04-Feb-2008 the patient experienced wrong drug administered. On 16-Mar-2008 the patient was taken to the emergency room with low back pain, vomiting and swelling in abdomen. The patient was diagnosed with a bad kidney infection and bladder infection. Patient was given IV antibiotics and IV for hydration and sent home with oral antibiotics. Patient tried taking the oral antibiotics and would vomit after taking them from upset stomach. On 19-Mar-2008 the patient went back to the Emergency room and was treated with IV antibiotics and saline IV. On 01-Apr-2008 the patient completed the oral antibiotics and is feeling better. Subsequently, the patient recovered from the wrong drug being administered, kidney infection, bladder infection, and vomiting. Unspecified blood work was done at the hospital however the reporter did not know the results. Additional information has been requested.

Other Meds:

Lab Data: (procedure unspecified)

History: Bladder infection; Yeast infection

Prex Illness:

Prex Vax Illns:

Vaers Id: **312809-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	12-Jun-2008	--	WAES0804USA00699	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a female who was vaccinated on an unspecified date with a dose of GARDASIL (lot# not reported) and fainted. Subsequently, the patient recovered from fainting. The nurse was told about this AE from another source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312810-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	14-Mar-2008	14-Mar-2008	0	19-May-2008	12-Jun-2008	MS	WAES0804USA00906	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site swelling

Symptom Text: Information has been received from a physician concerning a 22 year old female who on 31-JUL-2007 was vaccinated with her second dose of GARDASIL (lot# not reported). On 14-MAR-2008 the patient was vaccinated with her third dose of GARDASIL (lot# not reported). On approximately 14-MAR-2008 the patient experienced a raised area at the injection site. The area was the size of an egg. The patient's raised area at the injection site persisted and was coming to the office on 02-APR-2008 for an examination. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312811-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA00912	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a registered nurse concerning a college-age female who on unspecified dates, was vaccinated with the first, second and third doses of GARDASIL. Subsequently the patient experienced five abnormal pap smears since receiving GARDASIL. Prior to receiving GARDASIL, the patient had normal pap smears. The patient sought unspecified medical attention. At the time of the report, the patient's outcome was unknown. No product quality complaint was involved. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test - abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312812-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA00933	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Information has been received from a Licensed Practical Nurse concerning a patient's friend who was vaccinated with GARDASIL and developed Bell's Palsy. No specified symptoms, duration, or treatment reported. No other information was available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312813-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Mar-2008	Unknown		19-May-2008	18-Jun-2008	TN	WAES0804USA00975	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea

Symptom Text: Information has been received from a medical assistant concerning a female in her teens with no pertinent medical history who in March 2008, was vaccinated with a first dose of GARDASIL from her OB/GYN. There was no concomitant medication. Subsequently, "soon after administration" the patient developed persistent nausea for the last 2 weeks. The patient has an appointment to see the office (her primary physician). At the time of reporting the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 312814-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	11-Jan-2008	12-Jan-2008	1	19-May-2008	18-Jun-2008	--	WAES0804USA01002	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0954F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Local swelling, Rash

Symptom Text: Information has been received from a physician's assistant concerning a 20 year old female with no drug reactions/allergies and no pertinent medical history who on 11-JAN-2008 was vaccinated with GARDASIL (lot#653938/0954F) 0.5 mL IM. Concomitant therapy included hormonal contraceptives (unspecified). On approximately 12-JAN-2008 or 13-JAN-2008 the patient experienced swelling of neck with a rash and bumps on the neck, no difficulty breathing. Unspecified medical attention was sought in the office. On an unspecified date the symptoms resolved in a few days. No additional information at this time. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **312815-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	27-Mar-2008	27-Mar-2008	0	19-May-2008	18-Jun-2008	MI	WAES0804USA01009	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB256AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1967U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea

Symptom Text: Information has been received from a health professional concerning an 11 year old white female who on 27-MAR-2008 at 14:00 was vaccinated intramuscularly into the left deltoid with the third dose of GARDASIL (Lot # 660387/1967U). Concomitant therapy included a second dose given intramuscularly into the left deltoid of HAVRIX (Lot # AHAVB256AA). On 27-MAR-2008 at 14:00 the patient experienced nausea. On 27-MAR-2008 the patient recovered. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312816-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	31-Jan-2008	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA01015	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Migraine

Symptom Text: Information has been received from a nurse practitioner concerning a 14 year old female who on 31-JAN-2008 was vaccinated with the first dose of GRADSIL, 0.5 mL, IM. Concomitant medication was not reported. On an unspecified date in 2008, the patient had "periods of blacking out" after she received the vaccination. It was also reported that the patient was having migraine headaches. The reporting nurse practitioner stated that the neurologist felt that the symptoms were not related to GARDASIL. The patient will not complete the series of vaccinations. Additional information is not expected.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312817-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Feb-2008	15-Feb-2008	1	19-May-2008	18-Jun-2008	--	WAES0804USA01021	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site papule, Injection site swelling, Pyrexia, Urticaria

Symptom Text: Information has been received from a health professional concerning a 14 year old female with depression who on 14-FEB-2008 was vaccinated with a second GARDASIL (lot# 659657/1487U) injection. Concomitant therapy included CELEXA and LOESTRIN. On 15-FEB-2008 the patient developed fever. On 16-FEB-2008 the patient developed hives. On 19-FEB-2008 the patient had swelling at the injection site about the "size of a fist". On 20-FEB-2008 the patient came into the office and only had a "pin head size papular at the injection site". All other symptoms were gone. At the time of reporting the patient had recovered. It was reported that the patient had no reaction to the first dose and the patient will not be receiving the third dose. No further information was provided. Additional information has been requested.

Other Meds: CELEXA; LOESTRIN

Lab Data: Unknown

History:

Prex Illness: Depression

Prex Vax Illns:

Vaers Id: **312818-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Mar-2008	27-Mar-2008	0	19-May-2008	18-Jun-2008	MI	WAES0804USA01032	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB256AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1967U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea

Symptom Text: Information has been received from a health professional concerning a 15 year old white female who on 27-MAR-2008 at 14:00 was vaccinated intramuscularly into the left deltoid with the third dose of GARDASIL (Lot # 660387/1967U). Concomitant therapy included a first dose intramuscularly given into the left deltoid on the same day at 14:00 of HAVRIX (Lot # AHAVB256AA). On 27-MAR-2008 at 14:10 the patient experienced nausea. On 27-MAR-2008 the patient recovered. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312819-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	03-Dec-2007	Unknown		19-May-2008	12-Jun-2008	--	WAES0804USA01048	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash erythematous, Urticaria

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female who on 03-DEC-2007 was vaccinated intramuscularly with a 0.5 ml first dose of GARDASIL. Subsequently the patient developed a hive like, red rash over her entire body. The patient sought unspecified medical attention. The rash lasted approximately two weeks and then resolved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312820-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	12-Jun-2008	LA	WAES0804USA01093	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a health professional (reported as a nurse or a medical assistant) concerning a female (age unknown), who, on an unspecified date, was vaccinated with a dose of GARDASIL. Subsequently, the patient passed out in the office post vaccination. The patient recovered on an unspecified date. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312821-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
32.0	F	01-Oct-2007	01-Oct-2007	0	19-May-2008	18-Jun-2008	CA	WAES0804USA01100	09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0929U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Burning sensation, Inappropriate schedule of drug administration, Rash pruritic, Urticaria

Symptom Text: Information has been received from a certified medical assistant concerning a 33 year old female with a history of an abnormal papanicolaou smear, on 01-OCT-2007 was vaccinated with a prefilled syringe IM in the arm with a first dose of GARDASIL (Lot# 658282/0929U). On 03-DEC-2007 the patient was vaccinated with a second dose of GARDASIL (Lot# 659437/1266U). Concomitant therapies included hormonal contraceptives (unspecified) and "hormones." About a month post vaccination, on 07-JAN-2008 the patient developed a "hive type rash." The rash was reported to be itchy and burning. The patient called the office. On 08-JAN-2008 the patient saw an allergist. The patient recovered on an unspecified date. No product quality complaint was involved. Additional information has been requested.

Other Meds: [therapy unspecified]; hormonal contraceptives

Lab Data: Unknown

History: Papanicolau smear abnormal

Prex Illness:

Prex Vax Illns:

Vaers Id: **312822-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		19-May-2008	12-Jun-2008	--	WAES0804USA01118	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a physician concerning a 13 year old female who on an unspecified date was vaccinated with the first dose of GARDASIL, 0.5 mL. Concomitant medication was not reported. Subsequently on an unspecified date, the patient experienced a missed menstrual period after she received GARDASIL. Unspecified medical attention was sought. It was reported that the patient missed her menstrual period for a period of 3 months after vaccination with GARDASIL. The outcome and causality of the event was not reported. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312823-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	CA	WAES0804USA01128	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin discolouration

Symptom Text: Information has been received from a physician concerning a female (age not reported) who, on an unspecified date, was vaccinated with a dose of GARDASIL. Subsequently the patient developed skin discoloration (area of skin discoloration was not reported). The outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312824-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA01132	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Myalgia

Symptom Text: Information has been received from a physician concerning a female (age not reported) who, on an unspecified date, was vaccinated with a dose of GARDASIL. Subsequently, on an unspecified date, the patient developed muscle soreness after vaccination. It was unknown which muscles were involved. The patient was seen in the office. A creatine phosphokinase test was done, results not reported. The outcome was unspecified. Additional information has been requested.

Other Meds: Unknown

Lab Data: plasma creatine kinase not

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312825-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	29-Nov-2007	Unknown		19-May-2008	12-Jun-2008	--	WAES0804USA01166	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Musculoskeletal pain, Neck pain, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered nurse concerning a 13 year old female who on 19-SEP-2007 was vaccinated with the first dose of GARDASIL (Lot #658556/1060U). On 29-NOV-2007, the patient was vaccinated with the second dose of GARDASIL (Lot #659435/1265U). On 02-APR-2008, the patient was vaccinated with the third dose of GARDASIL (Lot #659653/1448U). Concomitant medication was reported as none. On an unspecified date in December 2007 a few days after the second vaccination, the patient experienced severe neck and shoulder pain. The pain was severe enough that the patient was examined at the emergency room, but not admitted. On 02-APR-2008 the evening of the third vaccination, the patient developed neck and shoulder pain which was not as severe as the pain following the second vaccination. There was no local reaction at the injection site. Unspecified medical attention was sought as the patient contacted the physician's office. The patient's neck pain and shoulder pain persisted. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312826-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	13-Jun-2008	--	WAES0804USA01175	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a female certified medical assistant who was vaccinated IM with the second 0.5 mL dose of GARDASIL (lot # not reported). It was reported that she had pain at the injection site of her second dose of GARDASIL (lot # not reported) series. The pain lasted a few hours and then resolved. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312827-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	11-Dec-2007	02-Feb-2008	53	19-May-2008	13-Jun-2008	--	WAES0804USA01179	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Drug exposure during pregnancy, Headache, Injection site discomfort

Symptom Text: Information has been received through the pregnancy registry concerning a 22 year old female patient with no known drug allergies and no medical history reported, who on 11-DEC-2007 and 01-APR-2008 was vaccinated with the first and second doses of GARDASIL respectively. There was no concomitant medication. The patient reported that after receiving the second dose of GARDASIL she found out she was pregnant. She reported that her last menstrual period was from 02-FEB-2008 till around 14-FEB-2008 and that she was eight weeks and three days pregnant. She also reported that after receiving the second dose, on approximately 01-APR-2008, of GARDASIL her head, stomach and her arm hurt at the injection site. Unspecified medical attention was sought. Diagnostic laboratory studies included a pregnancy test. At the time of this report the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: Beta-human chorionic

History:

Prex Illness: Pregnancy NOS (LMP = 2/2/2008)

Prex Vax Illns:

Vaers Id: **312828-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	18-Jan-2008	02-Feb-2008	15	19-May-2008	18-Jun-2008	--	WAES0804USA01199	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Flank pain, Herpes zoster, Pain in extremity

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female with a history of "absent periods" who on 18-JAN-2008 was vaccinated with the first dose of GARDASIL (lot # not reported). Concomitant therapy included YASMIN. On 02-FEB-2008 the patient thought she had a bug bite. On 04-FEB-2008 the patient went to the doctor's office and was diagnosed with herpes zoster. The patient was prescribed ZOVIRAX and recovered a few days later. Follow up information was received. A nurse called to report patient received the second dose of GARDASIL (lot # not reported) 0.5 mL IM in the left deltoid on 04-APR-2008 and experienced left arm pain for 2 days. On days 3 through 5 the patient was pain free. On day 5 the patient had increased pain down her left arm. The patient was concerned the herpes zoster had come back because she was experiencing the same type of pain. The patient also noticed one mark on her back but a physician later determined this was an old lesion from the initial herpes zoster occurrence. The patient was given NAPROSYN for the pain. The patient was seen in the physician's office on 14-APR-2008 and informed the nurse the NAPROSYN was not helping with the pain. The patient had a "CBC, chem scan and herpes zoster panel done on 14-APR-2008 - results unknown. The nurse mentioned after the first dose of GARDASIL (lot # not reported), the location of what the patient thought was bug bites was on the middle of her back and on the side. There was also pain on the side. Unspecified which side it was. Additional information has been requested.

Other Meds: YASMIN

Lab Data: diagnostic laboratory, 04/14/08 - "chem scan" - results unknown; complete blood cell, 04/14/08 - results unknown; Herpes simplex virus, 04/14/08 - results unknown

History: Absence of menstruation

Prex Illness:

Prex Vax Illns:

Vaers Id: **312830-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Feb-2008	19-Mar-2008	30	19-May-2008	12-Jun-2008	MD	WAES0804USA01222	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a consumer concerning her 14 year old daughter with an allergy to AUGMENTIN who on 18-FEB-2008 was vaccinated with the first 0.5 ml dose of GARDASIL. There was no concomitant medication. On 19-MAR-2008 the patient had a positive PAP smear. Unknown medical attention was sought with the physician. Patient outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory; Pap test, 03/20/08, posit

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **312831-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Apr-2008	03-Apr-2008	0	19-May-2008	18-Jun-2008	AZ	WAES0804USA01282	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 17 year old female who on an unknown date was vaccinated with the first dose of GARDASIL and 03-APR-2008 was vaccinated with the second dose of GARDASIL. The patient experienced dizziness after receiving a first dose of GARDASIL. She also experienced dizziness on 03-APR-2008 after receiving the second dose of GARDASIL as well another vaccine MENACTRA. Unknown medical attention was sought. Patient outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312836-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		19-May-2008	12-Jun-2008	TX	WAES0804USA01311	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back crushing, Back pain, Dyspnoea

Symptom Text: Information has been received from a medical assistant concerning a 26 year old female who last week (approximately 27-March 2008), was vaccinated with the first dose of GARDASIL. The patient developed back pains post vaccination. The patient awoke at 2 am in the morning and felt like something was crushing her back like a "bear hug" and she could not breathe. Medical attention was sought through a call to the medical assistant. Patient outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312837-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	29-Feb-2008	29-Feb-2008	0	19-May-2008	12-Jun-2008	OH	WAES0804USA01329	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Crying, Hypoaesthesia, Musculoskeletal stiffness, Respiratory rate increased

Symptom Text: Information has been received from a nurse concerning a 24 year old female who on an unspecified date was vaccinated with the first dose of GARDASIL and at the end of February 2008 was vaccinated IM in the arm with the second 0.5 ml dose of GARDASIL. The patient passed out after receiving the first dose of GARDASIL. The patient had what was described as a "high anxiety" response after receiving the second dose of GARDASIL. The patient reported both hands and legs went numb. The patient "stiffened up" and began breathing rapidly and crying hysterically. No treatment besides observation and supportive methods for either episode. Unknown medical attention was sought in the physician's office. Patient outcome was recovered on an unspecified date. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: vital sign

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312838-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Nov-2007	01-Nov-2007	0	19-May-2008	18-Jun-2008	--	WAES0804USA01339	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site, Erythema, Skin warm, Swelling

Symptom Text: Information has been received from a nurse, who was the patient's grandmother, concerning her 14 year old granddaughter who in November 2007, was vaccinated in the outer thigh with a first dose of GARDASIL. Sometime in November 2007, the patient developed swelling, redness and warmth that lasted for about a week. She was reported to have improved (date not specified). No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312839-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	31-Mar-2008	31-Mar-2008	0	19-May-2008	18-Jun-2008	NJ	WAES0804USA01352	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Vomiting

Symptom Text: Information has been received from an office manager concerning a 15 year old female who on 31-MAR-2008 was vaccinated with the first dose of GARDASIL. The patient fainted and threw up after getting the first dose of GARDASIL. Unknown medical attention was sought. On an unspecified date patient was recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312840-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Mar-2008	31-Mar-2008	20	19-May-2008	18-Jun-2008	--	WAES0804USA01367	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site bruising, Pain

Symptom Text: Information has been received from a 16 year old female consumer regarding herself with a history of kidney problems when younger and no known allergies who 6 months ago was vaccinated with the first dose of GARDASIL and on 11-MAR-2008 was vaccinated with the third 0.5 ml dose of GARDASIL (no lot number provided). On 31-MAR-2008 the patient noticed a bruise at the injection site. Everytime the patient puts ice on the bruise it feels like her arm is "throbbing". There was no concomitant medication. Unknown medical attention was sought. Patient outcome was not recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory - blood work

History: Renal disorder

Prex Illness:

Prex Vax Illns:

Vaers Id: 312841-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		19-May-2008	12-Jun-2008	NY	WAES0804USA01372	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a nurse concerning a 20 year old female who was vaccinated with the third dose of GARDASIL (Lot # 658556/1060U). The patient experienced pain at the injection site and in the arm after the third dose. Patient outcome was unknown. Unknown medical attention was sought in the office. No product quality complaint was involved. This is one of two cases from the same source (WAES # 0804USA03130). Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312842-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA01378	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Ovarian cyst

Symptom Text: Information has been received from a health professional concerning a 16 year old female with ovarian cysts who was vaccinated with her third dose of GARDASIL (lot number unspecified). Subsequently the patient's ovarian cysts worsened and became larger. The patient sought unspecified medical treatment. The patient's ovarian cyst persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Ovarian cyst

Prex Vax Illns:

Vaers Id: 312843-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Jan-2008	22-Jan-2008	14	19-May-2008	18-Jun-2008	--	WAES0804USA01397	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Gait disturbance, Menorrhagia, Muscle spasms

Symptom Text: Information has been received from a health professional concerning a female who on 08-JAN-2008 was vaccinated with her first dose of GARDASIL (lot number unspecified). About two weeks after being vaccinated, on approximately 22-JAN-2008 the patient experienced heavy menstrual periods, and severe cramping which was causing her to have difficulty in walking. Patient is now visiting a specialist, but specifics unknown. The patient's heavy menstrual periods and severe cramping and difficulty walking persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312844-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	PA	WAES0804USA01410	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a female who in February 2008, was vaccinated with the first dose of GARDASIL (lot# not reported). Per the reporter, the patient developed hives within an hour and a half of vaccination. No other symptoms were involved. The patient sought unspecified medical attention in the physician's office. Topical BENADRYL was used and the symptoms resolved the same day. No further information is available. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312845-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	09-Jan-2007	01-Mar-2007	51	19-May-2008	12-Jun-2008	NV	WAES0804USA01411	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information has been received from a physician concerning a 20 year old female who on 09-JAN-2007 was vaccinated in the right arm with the first dose of GARDASIL (lot# not reported). On 09-MAR-2007 the patient was vaccinated in the left arm with the second dose of GARDASIL (lot# not reported). On 11-JUL-2007 the patient was vaccinated in the right arm with the third dose of GARDASIL (lot# not reported). Per the reporter, the patient experienced one large plantar wart on her right heel immediately following the second dose of GARDASIL. The patient was treated by a podiatrist and had the wart burned off, but 7 more warts branched out on the heel. These were treated with a combination of burning or surgical removal. The patient is still being treated by the podiatrist who feels this is related to GARDASIL. The primary care physician does not feel this is related to GARDASIL. The patient's warts have persisted. No additional information is available at this time. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312846-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Apr-2008	02-Apr-2008	0	19-May-2008	18-Jun-2008	MO	WAES0804USA01417	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature fluctuation, Feeling hot, Headache, Injection site pain, Nausea, Pyrexia

Symptom Text: Information has been received from a consumer, who is the mother of the patient, concerning a 14 year old female who on 02-APR-2008 was vaccinated with the first dose of GARDASIL (lot# not reported). On 02-APR-2008 the patient experienced pain at the injection site. The mother reported that the next day the patient came home and had a bad headache, so she was given TYLENOL and was lying around the house. The consumer reported that later on that night, the patient was still complaining of the headache and that she felt nauseous, so the mother had taken the patient's temperature and it was 98.7 degrees. The mother stated that the patient was lying around the house and around 10:30 PM the patient had felt unusually warm and she had a fever of 101.3. The consumer reported that throughout the night, the patient's temperature went up and down, but she was warm all night. Per the consumer, on 04-APR-2008, the patient stayed home from school and she still feels a little warm. The consumer has not yet spoken with the physician. No further information is available and the patient has not yet recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312847-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		19-May-2008	13-Jun-2008	NC	WAES0804USA01452	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper

Symptom Text: Information has been received from a physician concerning a "16-17 year old" female who was vaccinated on an unspecified date with a first dose of GARDASIL (lot # not reported). Subsequently, on an unspecified date, the patient experienced upper right quadrant pain. The patient sought unspecified medical attention. "She was referred to see a gastroenterologist and found out she had raised liver enzymes." Therapy with GARDASIL was discontinued. Subsequently, the patient recovered from upper right quadrant pain and raised liver enzymes, "after stopping therapy with GARDASIL." No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory, raised liver enzymes.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312848-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
32.0	F	Unknown	Unknown		19-May-2008	12-Jun-2008	--	WAES0804USA01454	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a 32 year old female physician assistant who in February 2008, reported as "a little less than 2 months ago," was vaccinated intramuscularly into the left arm with the first dose of GARDASIL. Subsequently, she experienced pain at the injection site since being vaccinated around 2 months ago. She also reported that she has slight swelling at the injection site or a ball that was visible at the injection site on her left arm. At the time of this report, the patient had not recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312849-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	MA	WAES0804USA01470	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a female who on unspecified date was vaccinated IM with all three dose of GARDASIL (lot# not provided). The patient received all three doses and later she had abnormal pap smear. Unknown medical attention was sought. The patient was not recovered. Attempts were unsuccessful to gain more information. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312850-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		19-May-2008	12-Jun-2008	--	WAES0804USA01484	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a registered nurse concerning a 11 year old female who on an unspecified date was vaccinated IM with the first dose of GARDASIL. It was reported that the patient developed a headache after being vaccinated. Unknown medical attention was sought. The patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312851-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		19-May-2008	13-Jun-2008	--	WAES0804USA01528	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Malaise, Syncope

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter, who on an unspecified date, was vaccinated with a second dose of GARDASIL. Subsequently, the patient didn't feel too well and fainted. The patient was seen at the office. At the time of the report, the outcome of the patient was unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312852-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Jul-2007	Unknown		19-May-2008	12-Jun-2008	PA	WAES0804USA01532	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site nodule

Symptom Text: Information has been received from a physician concerning a 13 year old female who on 06-JUL-2007 was vaccinated with the first dose of GARDASIL (lot# not provided). Subsequently the patient developed a firm nodule on her arm close to the injection site about half centimeter in size. Physician saw the nodule yesterday (03-Apr-2008) when patient visited the clinic. It was unknown when the patient developed the firm nodule. Medical attention was sought by visiting the physician. The patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312853-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA01550	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a health professional concerning a 22 year old female who was vaccinated on an unspecified date with her first dose of GARDASIL (lot# not reported). Subsequently the patient experienced a rash on her neck and chest the same day as the vaccination. Subsequently, the patient recovered from rash on neck and rash on chest. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312854-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	12-Jun-2008	PA	WAES0804USA01701	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Papilloma viral infection, Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with all three doses of GARDASIL (lot numbers unspecified). The patient had all negative Pap tests prior to vaccination. After vaccination, the patient's Pap test came back as positive for high risk papillomavirus. No other information is provided. The patient sought unspecified medical treatment in the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312855-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	02-Aug-2007	Unknown		19-May-2008	12-Jun-2008	NM	WAES0804USA01706	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a physician concerning a 12 year old female with concomitant medications and pertinent medical history reported as unspecified, who on approximately 02-AUG-2007 was vaccinated with the first dose of GARDASIL (Lot# not reported). The second dose of GARDASIL was given on 02-APR-2008 (Lot # not reported). Following the first dose she did not get a period for 5 months (she has had her period since age 11). She sought the medical attention of a physician and her mother refused to allow her to take a pregnancy test. The outcome was unspecified. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312856-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Aug-2007	23-Aug-2007	0	19-May-2008	18-Jun-2008	--	WAES0804USA01733	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts, Vaccine positive rechallenge, Vulvovaginal human papilloma virus infection

Symptom Text: Information has been received from a physician concerning a 17 year old white female (weight 125#, height 62") who on 23-AUG-2007 was vaccinated with the first dose of GARDASIL (Lot #658558/1061U), IM. On 18-OCT-2007, the patient was vaccinated with the second dose of GARDASIL (Lot #658488/1264U), IM in the left arm. On 26-FEB-2008, the patient was vaccinated with the third dose of GARDASIL (Lot #659182/1757U), IM in the left arm. Concomitant medication was not reported. The physician reported that the patient experienced an increased outbreak of vulvar venereal warts after each injection. It was noted that at the time of vaccinations the patient had no warts and had no prior treatment for warts. The outcome and causality of the events were not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312857-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	14-Jun-2007	17-Jun-2007	3	19-May-2008	12-Jun-2008	--	WAES0804USA01748	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Oral contraception, Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a 22 year old female with no pertinent medical history, who on 14-JUN-2007 was vaccinated with a first dose of GARDASIL. Concomitant therapy included ORTHO TRI-CYCLEN. On 17-JUN-2007 the patient fainted. The patient went to the emergency room and was later released. Subsequently, the patient recovered. In August 2007, the patient was vaccinated with a second dose of GARDASIL. In August 2007 2 weeks after vaccination, the patient experienced fainted. Subsequently, the patient recovered. In March 2008, the patient was vaccinated with a second dose of GARDASIL. In approximately March 2008, 3 weeks after vaccination, the patient experienced fainted. The patient was seen by a physician. Unspecified blood tests and computed axial tomography were performed (results not reported). At the time of the report, the patient was recovering. She reported that she "still feels like fainting and dizzy." Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN

Lab Data: diagnostic laboratory, results not reported; computed axial, results not reported

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **312858-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	13-Jun-2008	--	WAES0804USA01752	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Fatigue, Syncope

Symptom Text: Information has been received from a health professional concerning a female who was vaccinated on an unspecified date with her first dose of GARDASIL (lot# not provided). She received this dose at an office and the morning after receiving the vaccine she fainted. At the end of October 2007, the patient was vaccinated with her second dose of GARDASIL (lot# 658558/1061U). She experienced fatigue and felt generally weak. She also received the third dose of GARDASIL (lot#658563/1063U) at the end of February or beginning of March 2008. The patient had no adverse symptoms after this dose. Her outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312859-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	04-Apr-2008	04-Apr-2008	0	19-May-2008	12-Jun-2008	CT	WAES0804USA01759	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0742U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Urticaria, Vomiting

Symptom Text: Information has been received from a registered nurse concerning her 25 year old daughter who on 04-APR-2008 was vaccinated with a third dose of GARDASIL (lot# 654539/0742U) prefilled syringe and had a severe reaction. Concomitant therapy included YASMIN. The patient had no problem with the initial 2 doses. On 04-APR-2008 about 25 minutes after receiving the third dose the patient developed hives that completely covered her body and began vomiting. The patient vomited 5 times that day and only had water before the appointment. The patient was seen at the Emergency Room and was given epinephrine, cortisone, and BENADRYL. The patient was sent home with CLARITIN and has been taking since 04-APR-2008. The vomiting had stopped and the hives were almost completely gone. There are a few on her face but they are fading. At the time of reporting the patient was recovering. No further information was available. The reporter felt that vomiting and urticaria were an other important medical events. Additional information has been requested

Other Meds: YASMIN

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312860-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	12-Jun-2008	LA	WAES0804USA01779	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Syncope

Symptom Text: Information has been received from a nurse concerning a "high school age" female who was vaccinated on an unspecified date with her first dose of GARDASIL (lot# not reported). Subsequently the patient experienced numbness in her hands and arms and fainted in school. The patient was brought to the ER but was not admitted. Per the nurse, the healthcare provider in the ER did not think there was anything wrong with the patient. The patient was then taken to her family practice physician and she had an MRI which came back normal. The numbness lasted 2 - 3 weeks and the patient is now fine. The nurse stated that the patient will not be continuing with the GARDASIL series. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312861-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	11-Sep-2007	11-Sep-2007	0	19-May-2008	13-Jun-2008	MA	WAES0804USA01782	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness

Symptom Text: Information has been received from a physician concerning a 19 year old female who on 11-SEP-2007 was vaccinated intramuscularly with her second dose of GARDASIL (lot# reported "0232U"). Within 2 minutes of getting GARDASIL, the patient experienced lightheaded and passed out. The patient has a history of getting lightheaded with vaccines. The patient was monitored until feeling better then left the office. Subsequently, the patient recovered from lightheaded and passing out. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312862-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Jan-2007	30-Jan-2007	0	19-May-2008	12-Jun-2008	MA	WAES0804USA01787	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1447F	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Inappropriate schedule of drug administration, Loss of consciousness

Symptom Text: Information has been received from a nurse concerning a 13 year old female student who on 30-JAN-2007 was vaccinated IM in the left arm with the first dose of GARDASIL (Lot # 655617/1447F). On 06-Apr-2007, the patient was vaccinated IM in the left arm with the second dose of GARDASIL (Lot # 656051/0244U) and on 18-MAR-2008, the patient was vaccinated IM in the left arm with the third dose of GARDASIL (Lot # 659964/1978U). On 30-JAN-2007 the patient passed out in the hallway after the first dose of the vaccine and was monitored until feeling better then allowed to leave. After the second dose the patient felt a little dizzy and sat in the office for 20 minutes. The patient was fine after the third dose and sat in the office for 20 minutes. Patient outcome was recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312863-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Apr-2008	Unknown		19-May-2008	12-Jun-2008	NJ	WAES0804USA01789	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Information has been received from a nurse concerning a 17 year old female with seasonal allergies and an allergy to CECLOR who on 01-APR-2008 was vaccinated IM in the left arm with 0.5 cc dose of GARDASIL (Lot # 0151X). No concomitant medication. Medical attention was sought through a call to the office. Patient outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds:

Lab Data: None

History:

Prex Illness: Seasonal allergy; Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **312864-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	NM	WAES0804USA01805	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a physician concerning a 14 year old female who was vaccinated with a dose of GARDASIL. The patient missed her period for two months after receiving both her second and third dose of GARDASIL. Unknown medical attention was sought at the office. Patient outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312865-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-Apr-2008	07-Apr-2008	0	19-May-2008	18-Jun-2008	CA	WAES0804USA01838	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0133X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope, Urticaria, Vaccine positive rechallenge

Symptom Text: Information has been received from a health professional concerning a 13 year old female with an upper respiratory tract infection and a history of seasonal allergies who on 07-APR-2008 was IM vaccinated with her second dose of GARDASIL (lot number reported as 654490/0133X). Concomitant therapy included TYLENOL, VICKS DAYQUIL (OLD FORMULA) and VICKS NYQUIL (OLD FORMULA). On 07-APR-2008 the patient fainted. Initially she was dizzy, then collapsed. Additionally she had a urticaria rash on her left amber blood pressure at that time was 142/80 and pulse rate was 47. Fifteen minutes later her blood pressure was 122/68 and pulse rate was 85. There was no sign of anaphylactic shock. The patient had and upper respiratory infection for the past 3 days with some symptoms that include coughing and mucous. The MA also reported that then patient fainted with Dose #1 but did not have any other details. The patient has recovered from the fainting but it is unspecified if her rash has also resolved. The patient sought unspecified medical treatment while at the office. Additional information has been requested.

Other Meds: TYLENOL, VICKS NYQUIL (OLD FORMULA); VICKS DAYQUIL (OLD FORMULA)

Lab Data: blood pressure, 04/07/08, 142/8; blood pressure, 04/07/08, 122/6 - 15 minutes later; total heartbeat count, 04/07/08, 47; total heartbeat count, 04/07/08, 85 - 15 minutes

History: Seasonal allergy

Prex Illness: Upper respiratory tract infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312866-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	03-Apr-2008	03-Apr-2008	0	19-May-2008	12-Jun-2008	--	WAES0804USA01851	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Oral contraception

Symptom Text: Information has been received from a health professional concerning a 22 year old female who on 30-JAN-2008 was IM vaccinated with her first dose of GARDASIL (lot number 655327/1287U). Concomitant therapy included ORTHO TRI-CYCLEN LO. On 03-APR-2008 the patient was IM vaccinated with her second dose of GARDASIL (lot number 655327/1287U) and experienced injection site pain. The patient's injection site pain persisted. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312867-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA01912	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a female patient who, on an unspecified date, was vaccinated with a 0.5 mL dose of GARDASIL and fainted. No further information was provided. Outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312868-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA01913	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a female patient who, on an unspecified date, was vaccinated with a 0.5 mL dose of GARDASIL and fainted. No further information was provided. Outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312869-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	02-Apr-2008	03-Apr-2008	1	19-May-2008	18-Jun-2008	CT	WAES0804USA01961	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Information has been received from a office manager concerning a 22 year old female who on 02-APR-2008 was vaccinated IM with the first dose of GARDASIL (Lot #0151X). Concomitant therapy included hormonal contraceptives (unspecified). On 03-APR-2008, the patient experienced numbness in both of her hands and went away over the weekend (approximately 05-APR-2008). The numbness recurred on 07-APR-2008. Medical attention was sought through a call to the office. Patient outcome was unknown. No product quality complaint was involved. Additional information was received from a health care professional indicating that on 03-APR-2008 the patient experienced numbness in both hands that lasted 2 days. The numbness went away over the weekend but has since returned as of 07-APR-2008. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **312870-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Apr-2008	01-Apr-2008	0	19-May-2008	13-Jun-2008	--	WAES0804USA01963	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness

Symptom Text: Information has been received from a physician assistance concerning a 15 year old female who on 01-APR-2008 was vaccinated with a dose of GARDASIL. Concomitant therapy included DTAP. The patient passed out in the office after the vaccination and recovered after a short interval. No treatment was required. Medical attention was sought in the office. The patient was seen in the office because she had been experiencing some dizziness. The PA thought it might be low blood sugar. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Dizziness

Prex Vax Illns:

Vaers Id: 312871-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Oct-2007	Unknown		19-May-2008	18-Jun-2008	GA	WAES0804USA01971	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Infectious mononucleosis, Pyrexia

Symptom Text: Information has been received from a consumer concerning her 18 year old daughter who on 22-OCT-2007 was vaccinated with the first 0.5 ml dose of GARDASIL. The was no concomitant medication. In early February 2008, the patient developed mono. The patient had a high fever of 101 deg F and missed 2 weeks of school. The patient has not yet received the second dose. Unknown medical attention was sought. Patient outcome was recovered on an unspecified date. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory - blood work

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **312872-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Apr-2008	03-Apr-2008	0	19-May-2008	18-Jun-2008	--	WAES0804USA01978	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a health professional concerning a 17 year old female who on 16-FEB-2008 was vaccinated by injection with her first dose of GARDASIL (lot number unspecified). On 16-Apr-2007 the patient was vaccinated by injection with her second dose of GARDASIL (lot number unspecified). On 05-Mar-2008, the patient was vaccinated by injection with her third dose of GARDASIL (lot number unspecified). On 03-Apr-2008 the patient was vaccinated by injection with her fourth dose of GARDASIL (lot number unspecified). The patient experienced headaches after receiving four doses. Lot numbers were not provided. No additional information was provided. The patient sought unspecified medical attention . Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312873-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Mar-2008	24-Mar-2008	0	19-May-2008	13-Jun-2008	NY	WAES0804USA01989	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 24-MAR-2008 was vaccinated with her first dose of GARDASIL (lot number 658556/1060U). Concomitant therapy included HAVRIX. The patient was fine in the office then went immediately to dance practice. During dance practice, she noticed the arm she received the GARDASIL and one side of her body turned red (unspecified which arm and which side). This red color lasted 30 minutes then she completely recovered. No further information available. The patient sought unspecified medical treatment with a call to the office. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312874-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Sep-2007	11-Sep-2007	0	19-May-2008	18-Jun-2008	MA	WAES0804USA02077	23-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0960F	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Dizziness, Headache, Nausea, Pain in extremity, Palpitations, Pharyngitis streptococcal, Vaccine positive rechallenge, Vertigo

Symptom Text: Information has been received from a consumer, who is the patient's mother, concerning a 15 year old female who in September 2007, was vaccinated with the first dose of GARDASIL (lot# not reported). Concomitant therapy included meningococcal vaccine (unspecified). Per the mother, the patient experienced a headache after receiving the first dose. The patient recovered from her headache. In November 2007, the patient was vaccinated with he second dose of GARDASIL (lot# not reported). Again, the patient experienced headache after receiving the second dose. In March 2008, the patient was vaccinated with a third dose of GARDASIL (lot# not reported) and the patient started to experience a headache that lasted for 3 weeks. The patient also developed chest pain that she is still experiencing until today. The patient was brought to the ER on 08-APR-2008, but was not admitted to the hospital. The mother mentioned that the patient was absent from school 10 days last month because of the symptoms. No further information was provided. Additional information has been requested. 5/29/08 Reviewed ER medical records of 4/2008. FINAL ER Dx: atypical chest pain Records of 4/8/08 visit for chest pain, HA & left arm pain intermittently x 1 mo. Had vertigo since last HPV vax on 3/17/08. 6/3/08 Reviewed PCP medical records & vaccine records. Patient received HPV #1 0960F on 9/11/2007 unknown site; HPV #2 1266U on 11/16/2007 LUE; HPV #3 1486U on 3/17/2008 LUE. Nausea, dizziness, HA day after 1st HPV. On 3/11/08 woke w/heart racing, sharp chest pain & dizziness. On antibiotic at that time for strep throat dx 3/6/08. Referred to peds cardio. On 3/18, parent reported dizziness & nausea day after each HPV vaccine. Cardio consult 3/15/08 WNL.

Other Meds:

Lab Data: diagnostic laboratory; computed axial; X-ray; cardiac monitoring 4/3/08 LABS: CT of head WNL. CBC WNL except for mono 14.10% (H). Monospot neg. 4/8/08 D-dimer 93 (N). CXR revealed mild mid thoracic dextroscoliosis. C-spine WNL. L

History: Unknown PMH: both parents w/cardiac hx. Mother w/pancreatitis, IBS, tinnitus. Family history of heart disease

Prex Illness:

Prex Vax Illns:

Vaers Id: **312875-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		19-May-2008	12-Jun-2008	TX	WAES0804USA02103	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site oedema, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a physician concerning a 12 year old female who was vaccinated IM with the first 0.5 ml dose of GARDASIL. The patient developed pain, swelling, and edema at the injection site. Unknown medical attention was sought in the office. Patient outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312876-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA02114	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Clonus, Dizziness, Dyskinesia, Nausea, Pallor, Syncope, Tremor

Symptom Text: Initial and follow up information has been received from a physician, concerning a 15 year old female patient with a history of "fainted once with a blood draw," who on an unspecified date, was vaccinated IM with the second dose, 0.5 ml, of GARDASIL (lot # 659655/1486U). After vaccination, the patient became pale, and felt shaky; the physician indicated that "it could have been a complicated fainting spell." The patient "had 10 seconds of jerking- some clonus." She recovered, but "Thurs. still dizzy & nauseated." The outcome of dizzy and nauseated was not specified. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Syncope

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312877-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Apr-2008	05-Apr-2008	1	19-May-2008	12-Jun-2008	--	WAES0804USA02130	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female with no previous medical history and no known drug allergies, who on 04-APR-2008 was vaccinated with the first dose of GARDASIL (lot# 6596551486U). There was no concomitant medication. The patient had three syncopal episodes beginning 24 hours after receiving the vaccination. The patient sought treatment for the syncopal episode in the emergency room. The episodes were described as lasting 10 seconds in duration with full loss of consciousness. The patient was evaluated in the physician's office on 07-Apr-2008 and had fully recovered with no need for treatment. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312878-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	12-Jun-2008	--	WAES0804USA02171	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Vomiting

Symptom Text: Information has been received from a physician concerning a adolescent female who was vaccinated with a third dose of GARDASIL (date, route and Lot# not provided). Two months post vaccination the patient experienced vomiting and stomach cramps. Unknown medical attention was sought. The patient's outcome was unknown. The reporting physician was not the primary physician. No product quality complaint was involved. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312879-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	28-Mar-2008	07-Apr-2008	10	19-May-2008	13-Jun-2008	--	WAES0804USA02194	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Urticaria

Symptom Text: Information has been received from a health professional concerning a 25 year old female who on 28-MAR-2008 was vaccinated with her first dose of GARDASIL (lot# not reported). On 07-APR-2008 the patient experienced hives all over her body, mildly itchy. She called the nurse on 08-APR-2008 to report the hives. The patient has no medication or food allergies, but mild lactose intolerance. She has not been exposed to any new things. She was taking antihistamines and the hives were improving; no trouble breathing or swallowing. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312880-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	02-Jan-2008	16-Jan-2008	14	19-May-2008	18-Jun-2008	--	WAES0804USA02220	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lip swelling, Oedema peripheral, Swelling face, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse practitioner through the patient's mother concerning her 19 year old daughter with an allergy to penicillin and sulfanomide who on 02-JAN-2008 was vaccinated IM in the deltoid with the first 0.5 ml dose of GARDASIL (Lot # 659055/1522U) and on 05-MAR-2008 was vaccinated IM in the deltoid with the second 0.5 ml dose of GARDASIL (Lot # 659657/1487U). Concomitant therapy included LEVORA. Approximately two weeks after receiving the first dose of GARDASIL the patient experienced swelling of lips. Approximately two weeks after receiving the second dose of GARDASIL the patient experienced more severe swelling of lips, swelling of the face and swelling of the hands. The patient was treated by an unspecified primary care physician after the second occurrence of swelling with unspecified steroids. The symptoms resolved by an unspecified date. No other symptoms or treatment reported. No product quality complaint was involved. Additional information has been requested.

Other Meds: LEVORA

Lab Data: None

History:

Prex Illness: Penicillin allergy; Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **312882-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		21-May-2008	22-May-2008	--	WAES0805USA02019	22-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Premature labour

Symptom Text: Information has been received from a consumer concerning her 18 year old granddaughter, who, on an unspecified date, was vaccinated with a dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). Subsequently, the patient was pregnant when vaccinated. The patient did not seek medical attention and did not received prenatal care. It was reported that bloodwork was performed. On 06-APR-2008 the baby was born prematurely at approximately 36 weeks and was diagnosed with a terminal illness Trisomy 18. At the time of the report the outcome of the patient was unknown. No product quality complaint was involved. Additional information is not available.

Other Meds: hormonal contraceptives

Lab Data: diagnostic laboratory, blood work; hormonal contraceptives

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **312883-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	09-Apr-2008	09-Apr-2008	0	19-May-2008	12-Jun-2008	--	WAES0804USA02224	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Erythema, Immediate post-injection reaction, Local reaction, Sensation of heaviness, Skin warm

Symptom Text: Information has been received from a nurse concerning a 24 year old female who on 09-APR-2008 was vaccinated IM in the right arm with the first 0.5 ml dose of GARDASIL (Lot # 660387/1967U). Concomitant therapy included vitamins (unspecified). On 09-APR-2008 the patient experienced immediate local reaction to the right arm (injection site arm), developed redness up to inches in diameter, increased warmth, heaviness in the right arm and heaviness in chest. The office has been observing the patient and the redness has begun to lessen. Patient outcome is unknown. Medical attention was sought in the office. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **312884-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	31-Mar-2008	31-Mar-2008	0	19-May-2008	13-Jun-2008	AZ	WAES0804USA02257	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: Information has been received from a health professional concerning a female who during the week of 31-MAR-2008 was vaccinated with the first dose of GARDASIL (lot# not reported). Concomitant therapy included vaccination with the first dose of MENACTRA. After receiving both vaccinations the patient immediately fainted and hit her head as she fell. Per the reporter, she came to right away. The patient was observed in the office and later sent home. There is no additional information at this time. Additional information has been requested.

Other Meds:

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312885-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	12-Jun-2007	13-Jun-2007	1	19-May-2008	12-Jun-2008	--	WAES0804USA02275	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U		Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a physician concerning a 11 year old female with no reported medical history and no drug reactions/allergies who on 12-JUN-2007 was vaccinated with a dose of GARDASIL (lot # 657868/0523U). Concomitant therapy included a dose of Tdap. On 13-JUN-2007 the patient developed a moderately severe injection site reaction. The patient was seen by a physician on 14-JUN-2007. The patient was prescribed an unspecified antibiotic for the treatment of pain, swelling and redness in the left arm. The patient fully recovered on an unspecified date. No other symptoms or treatment reported. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **312886-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		19-May-2008	13-Jun-2008	--	WAES0804USA02296	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Syncope

Symptom Text: Information has been received from a registered nurse concerning 3 patients who were vaccinated with a dose of GARDASIL. It was reported that the patients were between the ages of 14-19 years old and in the last 3 weeks have experienced fainting and/or site pain that lasts up to 5 to 7 days after vaccination with GARDASIL. The nurse did not specify if the 3 patients experienced both the fainting and pain or one or the other. The patient's status was not reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312887-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Apr-2008	08-Apr-2008	0	19-May-2008	12-Jun-2008	CO	WAES0804USA02341	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	
	UNK	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female patient who on 08-APR-2008 was vaccinated intramuscularly with the second 0.5 mL dose of GARDASIL. Concomitant therapy included an unspecified immunization. It was reported that she then had blood work drawn and fainted after the blood draw. The nurse mentioned that the parents believe that the patient had a seizure and that it was caused from the GARDASIL. The nurse mentioned that the patient did not have a seizure. The patient recovered in the office and was discharged home. No diagnostic laboratory testing was performed. The patient is going to be having an electrocardiogram performed for follow up. The parents have requested that the patient not receive any additional doses of GARDASIL. No product quality complaint was involved. Additional information has been requested.

Other Meds:

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312888-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	31-Mar-2008	31-Mar-2008	0	19-May-2008	12-Jun-2008	--	WAES0804USA02343	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1967U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Urticaria

Symptom Text: Information has been received from a physician concerning a 16 year old female with no medical history who on 10-APR-2007 was vaccinated with the first dose of GARDASIL (lot not reported). On 29-JUN-2007 the patient was vaccinated with the second dose of GARDASIL (lot not reported). On 10-APR-2008 the patient was vaccinated with the third dose of GARDASIL (lot 660387/1967U). Concomitant therapy included a dose of MENACTRA. On 31-MAR-2008 after receiving the third dose of GARDASIL the patient developed hives later in the day. The hives resolved within 24 to 48 hours. The patient was instructed to take BENADRYL for the hives. It was also reported that the patient had no adverse reactions of any kind with the two previous doses of GARDASIL (lot not reported). Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **312889-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Feb-2007	15-Dec-2006	-49	21-May-2008	22-May-2008	LA	WAES0703USA02093	03-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0960F		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received from a licensed practical nurse concerning an 18 year old female patient with a history of human papilloma viral infection, who on 02-FEB-2007 was vaccinated with an 0.5ml, IM dose of GARDASIL (Lot # 654535/0960F). There was no concomitant medication. The nurse reported that the patient "subsequently determined she is pregnant." The date of the LMP was 15-DEC-2006, with an estimated due date of 22-OCT-2007. The nurse added that there were "no problems reported." Follow-up information indicated that the nurse thought the abortion was an elective termination. Although it was also reported that "the patient wasn't truthful about many things with them." The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Human papilloma virus infection

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312890-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-Mar-2008	21-Mar-2008	0	19-May-2008	18-Jun-2008	--	WAES0804USA02362	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye disorder, Injection site swelling, Injection site warmth, Pruritus, Urticaria

Symptom Text: Information has been received from a physician concerning a 16 year old female with no reported medical history who on 21-MAR-2008 was vaccinated with the second dose of GARDASIL (lot number not reported). There was no concomitant medication. On 21-MAR-2008 the patient experienced itchiness, bumps on her eyes, swelling and warmth at injection site. The patient was rushed to the ER on 23-MAR-2008 but not hospitalized. The patient was rushed to the ER again on 25-MAR-2008 after breaking out in hives all over her body and also not hospitalized. Subsequently, on an unspecified date the patient recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **312891-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		19-May-2008	13-Jun-2008	NJ	WAES0804USA02391	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old patient who on an unspecified date, was vaccinated with a dose of GARDASIL (lot number unspecified) and fainted post vaccination. The physician was not certain if the event occurred after the patient's first or second vaccination with GARDASIL but knew it was definitely not with administration of the third dose. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312893-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA02465	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema

Symptom Text: Information has been received from a health professional concerning a female who was IM vaccinated with her first dose of GARDASIL (lot number unspecified). Subsequently the patient experienced a red mark where the band aid came into contact with skin at injection site, which was not from the stickiness of the band aid. The patient sought unspecified medical treatment. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312894-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	28-Feb-2008	28-Feb-2008	0	19-May-2008	12-Jun-2008	PA	WAES0804USA02468	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contraception, Erythema, Induration, Injection site pain, Injection site swelling, Muscle necrosis, Scar, Skin atrophy

Symptom Text: Initial and follow-up information has been received from a physician and a clinical manager concerning a 24 year old female with a history of pharyngitis streptococcal ("1 to 2 weeks prior to vaccination"), who on approximately 28-FEB-2008 was vaccinated intramuscularly with a 0.5 mL first dose of GARDASIL (lot # 655327/1287U). Concomitant therapy included hormonal contraceptives (unspecified). The physician and case manager reported that "on the same day", approximately 28-FEB-2008, the patient "experienced pain and swelling at the injection site that lasted for 6 weeks." The patient sought medical attention and was seen by the physician. The physician and clinical manager reported that "the patient was followed-up today", 10-APR-2008, and the physician found signs of scarring and muscle necrosis. The area was red, hard, and concave." The patient had not improved. The patient reported that she had an appointment with a plastic surgeon scheduled for 11-MAY-2008. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: Pharyngitis streptococcal

Prex Illness:

Prex Vax Illns:

Vaers Id: **312895-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Apr-2008	03-Apr-2008	0	19-May-2008	12-Jun-2008	NV	WAES0804USA02473	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Information has been received from a physician concerning a 12 year old female who on 03-APR-2008 was vaccinated intramuscularly with a 0.5 mL dose of GARDASIL (lot # not reported). Concomitant therapy included Tdap and MENACTRA administered "at the same visit" on 03-APR-2008. It was reported that as the patient started to leave the office she felt lightheaded. She sat down and fainted and shortly "came around". The physician reported that this occurred around 3:00 in the afternoon and the only thing the patient had consumed that day was a soda and a glass of milk. The patient recovered and left the office. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 312897-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Apr-2008	04-Apr-2008	3	19-May-2008	12-Jun-2008	ME	WAES0804USA02475	23-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Coeliac disease, Contraception, Muscle spasms, Musculoskeletal stiffness, No reaction on previous exposure to drug, Oedema peripheral, Pain, Rash, Rash pruritic, Vasculitis

Symptom Text: Information has been received from a nurse concerning a 17 year old female with codeine intolerance who on 31-JAN-2008 was vaccinated intramuscularly with a 0.5 mL first dose of GARDASIL (lot # 659657/1487U). On 01-APR-2008 the patient was vaccinated intramuscularly with a 0.5 mL second dose of GARDASIL (lot # 659180/1758U). Concomitant therapy included hormonal contraceptives (unspecified). On 04-APR-2008, "three days later", the patient developed a rash on her legs. It was reported that she went to the emergency room. On 07-APR-2008 the patient was followed up at her doctor's office and was diagnosed with vasculitis. On 09-APR-2008 the patient "had a flare up again". The nurse reported that she had "many tests done". At the time of this report the vasculitis persisted. The patient is being treated with prednisone. Laboratory tests performed on an unspecified date showed an "elevated sed rate" and an "elevated white count". Additional information has been requested. 6/3/08 Reviewed PCP medical records for 4/7-5/1/2008. FINAL DX: vasculitis Records reveal on 4/7 visit, patient experienced itchy rash over bilateral LEs, aching in bilateral LEs & muscle spasms. Had been seen in ER on 4/4, 2 days s/p 2nd HPV vax, & diagnosed w/vasculitis, unclear etiology. Had undergone tanning session on day of ER visit. Intolerant of steroids. Tx w/antihistamine. Had no reaction s/p 1st HPV vax. Exam revealed bilateral LE multiple erythematous round macules & plaques generalized over lower pretibial area. Returned to office 4/9 w/worsening symptoms of rash & calf pain. Exam at that time revealed tenderness of bilateral calves w/trace edema, diffuse nodular urticarial erythematous lesions, coalescent purpura mostly over distal tibial area w/sparse involvement over thighs. Attempted tx w/steroids & additional labs. Testing for celiac disease (+) on 5/1/08. 6/3/08 Reviewed ER medical records of 4/4/2008. FINAL DX: vasculitis Records reveal patient experienced rash which started at ankles & progressed

Other Meds: hormonal contraceptives

Lab Data: erythrocyte, elevated; WBC count, elevated LABS: WBC 26.4 (H), plts 515,000 (H). WBC 11.8 (H), segs 79% (H), lymphs 15% (L). Sed rate 51 (H). ANA (+). CRP 1.9 (H). ASO 333 (H). Throat c/s w/rare B-hemolytic strep goup A. Rheumatoid

History: PMH: mild allergic rhinitis, GERD, mono 2006, recurrent strep throat & tonsillectomy 2007.

Prex Illness: Drug intolerance

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312902-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	05-May-2008	06-May-2008	1	21-May-2008	28-May-2008	TX		28-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Malaise, Nausea, Vomiting

Symptom Text: Patient received the vaccine on May 5th at 3:45 pm. She felt okay that afternoon. When she woke up the next day, she felt nauseated and started throwing up with some diarrhea. Patient went to school but called to have help picked up at 11:00 am - still not feeling well. She slept that whole afternoon. Patient started vomiting again on Sunday 5-11-08.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 312911-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		19-May-2008	13-Jun-2008	--	WAES0804USA02484	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a healthcare worker concerning her 15 year old daughter who on an unspecified date was vaccinated intramuscularly with a 0.5 mL second dose of GARDASIL (lot # not reported). Concomitant therapy included an injection of tetracycline. Subsequently the patient developed hives. At the time of this report the patient had not recovered from the hives. Additional information has been requested.

Other Meds: Tetracycline

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312912-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	21-Jun-2007	21-Jun-2007	0	19-May-2008	18-Jun-2008	--	WAES0804USA02490	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: Information has been received from a consumer concerning her daughter who on 12-FEB-2007 was vaccinated with a first dose of GARDASIL. On 21-APR-2007 the patient was vaccinated with a second dose of GARDASIL. On 21-JUN-2007 the patient received a third dose 2 months after the second dose. The reporter did not provided any other information. Per reporter, the patient did not report any adverse event. No further information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312913-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	19-Jan-2007	19-Jan-2007	0	19-May-2008	18-Jun-2008	NE	WAES0804USA02492	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427F	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache

Symptom Text: Information has been received from a medical assistant concerning a female with a codeine allergy who on 19-JAN-2007 was vaccinated intramuscularly with her first dose of GARDASIL (lot# 655619/1427F). Concomitant therapy included MICROGESTIN. On approximately 19-JAN-2007 the patient experienced dizziness and headaches for one week. Subsequently, the patient recovered from dizziness and headaches. On 23-MAR-2007 the patient was vaccinated intramuscularly with her second dose of GARDASIL (lot# 657006/0188U) and did not experienced any symptoms. The patient sought medical attention by telling the physician about her symptoms. Additional information has been requested.

Other Meds: MICROGESTIN

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312916-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	16-May-2008	16-May-2008	0	21-May-2008	26-May-2008	NJ		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope following HPV vaccine

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 312917-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-May-2008	05-May-2008	0	21-May-2008	26-May-2008	NY		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2620AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1968U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Autonomic nervous system imbalance, Dysaesthesia, Pain in extremity, Peripheral coldness, Vaccination complication

Symptom Text: Patient presented the next day with painful and cold left hand and forearm. It began the night of the vaccine and continued ot worsen until she presented to the office on the afternoon of May 6, 2008. She was referred to the emergency room for further evaluation of the vascular system.

Other Meds: none

Lab Data: cbc/electrolyes/calcium all normal. ekg normal. evaluation by pediatric surgery showed normal pulses and vascular flow. evaluation by pediatric neurology- Brain CT scan was normal. diagnosis felt to be autonomic dysfunction and dysesthesi

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312927-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Jan-2008	01-Feb-2008	15	21-May-2008	26-May-2008	NJ		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amenorrhoea, Lactose intolerance, Nasopharyngitis, Oral herpes, Vaccine positive rechallenge

Symptom Text: 1st shot 7/07- cold symptoms. 2nd shot 1/08 -she missed her period, then severe cold symptoms with what seemed to be a massive herpes-type infection, sores on her gums, face and throat. 3rd shot 4/08- the herpes-like reaction recurred, but milder - then she stopped menstruating for 3 months!

Other Meds:

Lab Data:

History: lactose intolerant

Prex Illness: none

Prex Vax Illns:

Vaers Id: **312936-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-May-1991	02-May-1991	0	21-May-2008	26-May-2008	CA		27-May-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	C2904AA	2	Left arm	Intramuscular	
IPV	SANOFI PASTEUR	A0125	2	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0171U	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB215AA	1	Left arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB340AA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Blood pressure, Cold sweat, Dizziness, Heart rate, Nausea, Pallor, Respiratory rate

Symptom Text: Pt developed dizziness, nausea and weakness 10min following immunizations.Public Health staff assisted her in lyingdown HR=60RR=20 no difficulty breathing, no skin rash. Color was pale and skin clammy.She reported that this may be her "period" coming. She was assisted to an exam room and observed for and additional 30 min BP 98/60 HR 64. She was alert and oriented Gave pt 4 oz of juice. She ambulated from clinic with her mother and brother.

Other Meds: none

Lab Data: none

History: none reported

Prex Illness: no

Prex Vax Illns:

Vaers Id: 312938-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Nov-2007	05-Jan-2008	54	21-May-2008	26-May-2008	TX		03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Left arm	Intramuscular	FLU
	TDAP	SANOFI PASTEUR	C2825AA		Right arm	Intramuscular	HEPA
							HPV4
							VARCEL

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Back pain, Convulsion, Diarrhoea, Fatigue, Headache, Loss of consciousness, Muscle spasms, Musculoskeletal stiffness, Myalgia, Nausea, Neck pain, Pain, Pallor, Pyrexia

Symptom Text: 7 weeks after HPV #2 patient blacked out and c/o severe headache, stiff neck. Admitted to hospital (after ER visit) all tests were negative. She has since had several seizures and c/o muscle and joint pain so severe she has missed 3 weeks of school. 6/2/08-records received for DOS 1/30/08-C/O morning stiffness, fatigue neck and back hurt. Back pain began in January. Knees, ankles hurt since January, tender to touch. Last week with fever 102 and diarrhea. PE WNL. Assessment: Pain 7/2/08-records received for DOS 1/6-1/9/08-DC DX: neck stiffness, headache, joint pain, cervical muscle spasm. C/O blacking out and nausea next day followed by headache and paleness. Next day increased neck stiffness and shooting pains down shoulder.

Other Meds: Clarinex and Singulair

Lab Data: Lumbar Puncture-negative. MRI head-negative. C-spine (MRI)-negative. chest x-ray-negative. extensive blood work-negative. 6/2/08-records received-MRI spinal tap negative. 7/2/08-records received-MRI head and brain no acute intracranial pro

History: Allergies 6/2/08-records received-December with strep. 7/2/08-2 episodes of pneumonia, underlying reactive airway disease, allergies and an episode of strep.

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: 312946-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	21-Jan-2008	Unknown		21-May-2008	23-May-2008	GA		23-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	1	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Balance disorder, Benign intracranial hypertension, Blindness, Headache, Lumboperitoneal shunt, Neck pain, Vomiting

Symptom Text: One month after vaccine, diagnosed with Pseudo Tumor Cerebri. Major symptoms: headache, loss of vision, vomiting, neck pain, balance off. Lumbar shunt was put from spine to abdomen to drain spinal fluid.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 312947-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-May-2008	20-May-2008	0	21-May-2008	27-May-2008	PA		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1447F	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Paraesthesia, Tenderness

Symptom Text: R arm and neck tingling, weakness, tenderness, sensation, strength reflexes intact

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **312950-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	09-May-2008	10-May-2008	1	21-May-2008	27-May-2008	CT	CT200804	27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2616AA	0	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling, Pyrexia

Symptom Text: Significant swelling and pain at injection site with fever over 101.5 degrees F developed within 18 hours of injection and lasted for more than 3 days.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **312962-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		22-May-2008	23-May-2008	FR	WAES0805CZE00002	23-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Joint swelling

Symptom Text: Information has been received from a physician a concerning a 16 year old female with a history of allergy on aluminous carrier in a vaccine who was vaccinated with GARDASIL. Subsequently the patient experienced joint swelling (similar to rheumatic symptoms) and was admitted to a hospital on May 9, 2008. The reporter felt that joint swelling was related to therapy with GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Allergy to vaccine

Prex Illness:

Prex Vax Illns:

Vaers Id: 312964-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	02-Apr-2008	Unknown		22-May-2008	23-May-2008	NC	WAES0805USA03398	23-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U		Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Hepatic enzyme increased, Joint swelling, Myalgia, Nausea, Pain, Pyrexia, Rash, Vomiting, Weight increased

Symptom Text: Information has been received from a certified medical assistant concerning a 22 year old female with a history of removal of condylomas/genital warts, and a family history of breast cancer, who on 02-APR-2008 was vaccinated IM in the left upper quadrant of the thigh with a dose of GARDASIL (Lot# 659437/1266U). Concomitant therapy included PROVERA. On 04-APR-2008 the patient felt ill, feverish and achy. On 05-APR-2008 the patient developed a rash and swollen joints which were painful. The patient went to the emergency room and it was suspected that the patient had chicken pox, which was later ruled out. At this time the patient was not admitted to the hospital. On 09-APR-2008 the patient was admitted to the hospital for possible inflammatory arthritis, possible lupus, or possible rheumatoid arthritis. The patient experienced nausea, vomiting, and a rash with myalgia and arthralgias. Other symptoms included swelling and aches in her joints, elevated liver enzymes, fever, malaise, body aches, a rash over her trunk, arms, and legs, and an immediate weight gain of 20 pounds. It was unknown when the weight gain actually started. Rheumatoid studies were conducted. The patient's phosphatase level was 283 and her Creatinine reactive protein test was high. The patient's electrolytes, glucose, and abdominal ultrasound were normal and the blood culture was negative for infection. The patient was treated with intravenous fluid, intravenous pain medications, SOLU-MEDROL and MOTRIN. The patient was admitted to the hospital for three days and discharged with a diagnosis of a possible reaction to the vaccination. It was reported that there was a 75% resolution of acute symptoms with the use of SOLU-MEDROL and MOTRIN. The patient recovered on an unspecified date. No product quality complaint was involved. Additional information has been requested.

Other Meds: PROVERA

Lab Data: abdominal ultrasound, 04/??/08, normal; serum alkaline, 04/??/08, 283; serum C-reactive, 04/??/08, high; blood culture, 04/??/08, negative for infection; serum electrolytes test, 04/??/08, normal; serum glucose, 04/??/08, normal

History: Genital wart; Wart excision; Condyloma

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312965-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Apr-2008	01-Apr-2008	0	22-May-2008	23-May-2008	FR	WAES0805USA03563	23-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Purpura, Vasculitis

Symptom Text: Information has been received from a dermatologist concerning an 18 year old female, who in April 2008, was vaccinated with a second dose of GARDASIL. The route and site of administration were not reported. Ten days post vaccination the patient developed significant arthralgia in the knees and the hip, and a purpuric rash on the lower limbs. A biopsy revealed vasculitis and tests also showed speckled-type antinuclear antibodies at a rate of 1/320. At the time of the report, the patient had not recovered. The reporter considered the arthralgia, vasculitis, and purpuric rash to be other important medical events. Other business partner numbers included: E2008-04408. Additional information is not available.

Other Meds: Unknown

Lab Data: biopsy, 08, vasculitis; serum ANA, ??Apr08 1/320, speckled-type antinuclear antibodies

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312966-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		22-May-2008	23-May-2008	--	WAES0805USA03518	23-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Gait disturbance, Neurological symptom

Symptom Text: Information has been received from a health care professional concerning a female (age unknown), who was vaccinated with a dose of GARDASIL. Subsequently, the patient experienced neurological changes and had difficulty walking. It was reported that she would not receive her third dose. At the time of the report, the outcome of the patient was unknown. No product quality complaint was involved. The reporter considered the neurological changes and difficulty walking to be disabling. Additional information is not available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 312967-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Jan-2008	12-Feb-2008	32	22-May-2008	23-May-2008	FR	WAES0805USA02815	23-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Joint swelling, Leukocytosis, Myalgia, Oedema peripheral

Symptom Text: Information has been received from an agency concerning a 16 year old female occasional tobacco user with a history of acne and hypersensitivity who on 11-JAN-2008 was vaccinated with GARDASIL. Concomitant suspect therapies included minocycline and JASMINE. On 12-FEB-2008 the patient developed muscle soreness with myalgia, oedema of the fingers, swelling knees and joint pain and was hospitalized. Laboratory results revealed a transient hyper leucocytosis (11000 leucocyte and then 7500 leukocyte) and an increase of the inhibitor of component C1-INH test at 0.43 and of component C4 test at 0.4. Laboratory results for cryoglobulinemia, antinuclear factors and hematology laboratory test were all negative. No etiology was found. On an unspecified date the patient was considered to have recovered from the events. Additional information has been requested. Other business partner numbers included: E2008-04334.

Other Meds: minocycline; JASMINE, 05?Feb08 - Unk

Lab Data: WBC count, 12?Feb08, 11000; WBC count, ??Feb08, 7500; hematology, ??Feb08, Comment: negative; serum ANA, ??Feb08, Comment: negative; component C1-INH test, ??Feb08, 0.43; component C4 test, ??Feb08, 0.4; serum cryoglobulins test, ??Feb08, C

History: Acne; Hypersensitivity

Prex Illness: Tobacco user; Contraception

Prex Vax Illns:

Vaers Id: 312968-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Feb-2008	13-Feb-2008	8	22-May-2008	23-May-2008	FR	WAES0805USA02813	23-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Thrombocytopenia

Symptom Text: Information has been received from a health care authority (reference number PO20080132) concerning a 17 year old female with a history of appendicitis, adenoidal disorder and myringotomy and a history of a 29-SEP-1999 laboratory results with a blood platelet count at 261000/mm3 who on 05-FEB-2008 was vaccinated IM with GARDASIL (Lot # not reported). There were no concomitant medications reported. Eight days post vaccination on 13-FEB-2008 the patient's laboratory results included a blood platelet count at 46000/mm3, the patient was diagnosed with thrombocytopenia and was hospitalized. On 20-FEB-2008 laboratory results revealed a blood platelet count at 40000/mm3, the patient was treated with CORTANCYL, 50mg. On 03-MAR-2008 her blood platelet count was 222000/mm3 and she was treated with prednisone, 40 mg. On 10-MAR-2008 her blood platelet count was 215000/mm3 and she was treated with prednisone, 20mg. On 17-MAR-2008 her blood platelet count was 235000/mm3 and she was treated with prednisone, 10mg. On an unspecified date a myelogram showed normal marrow and antibodies anti platelets were negative. It was reported that on an unspecified date the patient was considered to have recovered from thrombocytopenia. Additional information has been requested. Other business partner numbers included: E200804338.

Other Meds: None

Lab Data: bone marrow myelogram, normal; platelet count, 29Sep99, 261000 mm3; platelet count, 13Feb08, 46000 mm3; platelet count, 20Feb08, 40000 mm3; platelet count, 03Mar08, 222000 mm3; platelet count, 10Mar08, 215000 mm3; platelet count, 17Mar08, 2

History: Appendicitis; Adenoidal disorder; Myringotomy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312969-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	09-May-2008	09-May-2008	0	22-May-2008	23-May-2008	FR	WAES0805KOR00005	23-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cerebral haemorrhage, Dizziness, Fall, Head injury, Loss of consciousness, Vomiting

Symptom Text: Information has been received from a physician concerning a 25 year old Asian female who on 09-MAY-2008 was vaccinated with GARDASIL. Right after vaccination with GARDASIL at approximately 14:30 on 09-MAY-2008, the patient experienced loss of consciousness and fell down. When falling down, the patient hit the back of her head on the floor. The patient was treated with 5% glucose 500 ml and SOLU-CORTEF injection. After 1 minute after loss of consciousness, the patient regained consciousness. However she complained dizziness and vomiting. The patient went home at 18:00 after 3 hour and 30 minute-bed rest. The physician made a call to the patient's parent at night on the same day and found dizziness and vomiting persisted. The physician recommended the patient to visit the hospital. The patient visited to a general hospital for the further evaluation on 10-MAY-2008 and received the CT. The CT result showed the brain hemorrhage due to hitting her head on the floor and the patient was hospitalized on 10-MAY-2008. The dizziness and vomiting still persisted on 13-MAY-2008. The patient was treated for the brain hemorrhage and follow up CT will be performed soon. The causality with GARDASIL was not reported so far. Additional information has been requested.

Other Meds: Unknown

Lab Data: Computed axial tomography, 10May08, brain hemorrhage.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **312977-1** **Related reports:** 312977-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Sep-2007	Unknown		22-May-2008	28-May-2008	RI		08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2358AA	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0389U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia areata, Arthralgia, Bronchospasm, Condition aggravated, Eczema, Fatigue, Gait disturbance, Hypoaesthesia, Joint stiffness, Lethargy, Lyme disease, Muscular weakness, Pain in extremity, Paraesthesia, Pyuria, Rhinitis allergic

Symptom Text: Lower extremity pain and numbness and pins and needles, fatigue. Also with hand and lower arm weakness, multiple consults. Rheumatology, Psych, Emg - normal, MRI of head and spine - normal. 6/3/08 Reviewed PCP medical records. FINAL DX: (+)ANA syndrome w/arthralgia/alopecia; allergic rhinitis; exercise induced bronchospasm. Records reveal patient experienced alopecia areata (from age 2), arthralgia, lethargy, tiredness, eczema & joint stiffness in 2002. Episode of Lyme disease 9/2007 & developed tingling in hands & feet. Seen in ER 1/2008 w/increased weakness & tingling in hands & legs & difficulty walking. Had been on antibiotics for pyuria. Neuro & rheum consults done.

Other Meds:

Lab Data: LABS: ANA (+) (also from age 2). Allergy tests (+). Lyme test (+). MRI head & spine WNL.

History: Patient with prior history of alopecia prior to age 7 plus ANA 1:1280 PMH: allergy to pollens, dust mite, cats & mold.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **312977-2** **Related reports:** 312977-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Aug-2007	01-Oct-2007	57	16-Jun-2008	10-Jul-2008	--	WAES0805USA00638	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Pain in extremity, Paraesthesia

Symptom Text: Information has been received from a consumer concerning her daughter with autoimmune problems and a history of a reaction to the DPT shot who on 05-AUG-2007 was vaccinated with her first dose of GARDASIL (lot# not provided). There was no concomitant medication. On 01-OCT-2007 the patient experienced tingling in hands, numbness in hands and pain in hands. In January 2008, the patient experienced pain in legs, numbness in legs and tingling in legs. The patient had "labs and an MRI". The patient's tingling, numbness and pain in her hands and legs persisted. The patient will not be receiving the other 2 doses of GARDASIL. No further information is available.

Other Meds: None

Lab Data: diagnostic laboratory; magnetic resonance

History: Nonspecific reaction

Prex Illness: Autoimmune disorder

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **312980-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	19-May-2008	19-May-2008	0	22-May-2008	29-May-2008	PA		05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Flushing, Throat tightness, Urticaria, Wheezing

Symptom Text: Shortly after shot approximately 5-10 minutes, patient complained of throat feeling tight, flushed, hivey face - chest sounded like a few faint wheeze by stethoscope. I gave epi s/c and symptoms resolved.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **312989-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-May-2008	15-May-2008	1	22-May-2008	29-May-2008	CA		29-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAB222AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1758U	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2540AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site rash

Symptom Text: Erythematous rashes over upper extremities - sites of injections. BENADRYL 25 mg every 6 hrs.

Other Meds:

Lab Data: Not Done

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313004-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	23-Jan-2008	24-Jan-2008	1	22-May-2008	29-May-2008	VT		29-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Myalgia, Nausea, Pyrexia, Vaccine positive rechallenge, Vomiting

Symptom Text: Chills, fever, myalgias nausea vomiting 24 hours after GARDASIL vaccine after each dose #1 11-20-07 #2 1-23-08

Other Meds: ORTHO-CYCLIN B, C, P

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313018-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Mar-2008	Unknown		22-May-2008	26-May-2008	WI		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2541AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0188U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: None

Other Meds: none

Lab Data: Client pregnant with EDC 8/3/2008. Pregnancy verified 4/4/2008. Client unaware of pregnancy at time of vaccines-client was asked this question.

History: none

Prex Illness: none-pregnancy

Prex Vax Illns:

Vaers Id: **313025-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	22-Jan-2007	22-Feb-2007	31	22-May-2008	26-May-2008	CA		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia areata, Inappropriate schedule of drug administration

Symptom Text: ALOPECIA AREATA:I received my first shot of Gardasil in January 2007. About a month later we noticed a bald spot in the back of my head. I went back to my ObGyn and asked her if the Gardasil could be the cause as nothing else had recenlty changed and I was not taking any ther medications. She said that she had not heard of this, but she referred me to a dermatologist. I asked him if my hair loss had anything to do with the Gardasil. He replied that I had Alopecia areata and one thing had nothing to do with the other. He advised that I continue with the Gardasil and that he would start treating me for the alopecia. I believe that the Gardasil is the cause of my Alopecia, now over half of my head is bald. I don't know what to do. I keep going back to the dermatologist for treatments for the alopecia, but it just keeps getting worse.

Other Meds: None

Lab Data: Lupus=negative; Thyroid=normal; testosterone=normal; heavy metal=normal

History: Seasonal allergies

Prex Illness: None

Prex Vax Illns:

Vaers Id: 313037-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	22-May-2008	22-May-2008	0	22-May-2008	26-May-2008	IL		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Fall, Immediate post-injection reaction, Loss of consciousness, Malaise

Symptom Text: Immediately after administering vaccination, the patient reported feeling "not good". Pt laid head down on coutner for a moment, then slumped over, unconscious. After helping pt sit up, she immediately awoke and denied further medical intervention. Pt was observed for 15 minutes and showed no further signs of fainting, but reported no memory of event.

Other Meds: fluoxetine 20mg daily; methylphenidate 20mg three times daily as needed (not filled since 12/07)

Lab Data: N/A

History: n/a

Prex Illness: Pt reported a cough (not observed)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313038-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-May-2008	21-May-2008	1	22-May-2008	26-May-2008	PA		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	VARCEL	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Erythema, Headache, Oedema peripheral, Pain in extremity, Pyrexia, Skin warm

Symptom Text: She received four vaccines on Tuesday, May 20. She received the Chickenpox vaccine booster,meningococcal vaccine, HPV first vaccine, and tDAP. On Wednesday morning she had fever, headache, and two hot, three-inch diameter red swellings- one on each arm. We gave her Motrin and kept her home from school. By Thursday morning, the fever was gone. Her arms were still very sore and one site on each arm was red, swollen and hot to the touch.

Other Meds:

Lab Data:

History: Asthma, Celiac disease

Prex Illness: None

Prex Vax Illns:

Vaers Id: **313042-1 (S)** **Related reports:** 313042-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Apr-2008	21-Apr-2008	0	22-May-2008	23-May-2008	FR	D0057331A	23-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NG34780		Unknown	Unknown	
	TD	GLAXOSMITHKLINE BIOLOGICALS	AC12B016GA		Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Burning sensation, Paraesthesia, Pruritus

Symptom Text: This case was reported by a regulatory authority (vaccines, biologicals) # DE-PEI-PEI2008006370) and described the occurrence of burning sensation in a 17-year-old female subject who was vaccinated with TD-RIX (GlaxoSmithKline). Co-suspect vaccination included GARDASIL (Sanofi Pasteur MSD). Previous vaccination included a booster dose of TD-RIX (GlaxoSmithKline) given in 1996 and GARDASIL (Sanofi Pasteur MSD) given on 25 February 2008. On 21 April 2008 the subject received a dose TD-RIX (unknown route, right upper arm) and a dose of GARDASIL (unknown route, left upper arm). Few hours after co-administered vaccination with GARDASIL and TD-RIX, the subject experienced burning sensation, tingling and itching of both feet, lower legs, both hands and arms over a period of 10 days. The subject was hospitalised. No further information will be available.

Other Meds:

Lab Data: UNK

History:

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **313042-2 (S)** **Related reports:** 313042-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Feb-2008	21-Apr-2008	56	11-Jul-2008	14-Jul-2008	FR	WAES0805USA06093	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0513I	1	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Burning sensation, Paraesthesia, Pruritus

Symptom Text: Information has been received via a health authority concerning a 17 year old female patient booster vaccination with TD-RIX in 1996 was well tolerated who on 25-FEB-2008 was vaccinated with a first dose of GARDASIL (lot # not reported) which was well tolerated. On 21-APR-2008, the patient was vaccinated with a second dose of GARDASIL (Batch # NG34780) (lot # 0513U) into the left upper arm (route not reported). Simultaneously the patient was vaccinated with a booster dose of TD-RIX (lot # AC12B016GA) into the right upper arm (route not reported). A few hours p.v. the patient experienced a burning sensation, tingling and pruritus of feet, hands, arms and lower legs. Without medical advice the patient treated the reactions with cetirizine which led to intermittent improvement. The patient recovered completely after 10 days. Other business partners numbers included: E2008-04451. This report was also received from FDA through the freedom of information act. It is also reported "the patient was hospitalised". No further information is available. File closed. The VAERS ID # is 313042.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313047-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-May-2008	16-May-2008	0	22-May-2008	29-May-2008	CT		30-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1259U	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1799U	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2172AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1757U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breath holding, Depressed level of consciousness, Mydriasis, Syncope

Symptom Text: Syncopal episode 6 minutes after receiving 4 vaccines. Possible tonic due to breath holding-difficult to arouse verbally but responded to sternal rub. Pupils dilated 453; P.O. 99; HR 60; B/P 152/78; 5pm Pulse Ox 99, HR 78, 142/72

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313048-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-May-2008	21-May-2008	1	22-May-2008	29-May-2008	ND		03-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Balance disorder, Dizziness, Fatigue, Gait disturbance, Headache, Positive Rombergism, Pyrexia, Syncope

Symptom Text: Fainting, dizziness, H/A, balance changes, positive Rhomberg. 5/27/08 MR received for OV 5/21/08 with Assessment: headache, low grade fever, unsteady gait. Pt returned to office with fever, h/a, tiredness and balance problems. Pt fainted in shower that am. PE significant for (+) Romberg. Sx almost resolved by 5/23/08 per reporter.

Other Meds: None

Lab Data: Labs and Diagnostics: Head CT (-). CBC unremarkable. UA WNL.

History: None. PMH: Febrile seizure as infant. NKDA

Prex Illness: No

Prex Vax Illns:

Vaers Id: 313049-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-May-2008	17-May-2008	5	22-May-2008	29-May-2008	DC		11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688F		Left arm	Intramuscular	ANTH
	SMALL	ACAMBIS, INC.	VV04003A		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Dyspnoea, Insomnia

Symptom Text: Patient in usual state of great health on leave from work for 2 wks decided to have her small pox vaccination and GARDASIL vaccine May 12, 2008 with a good take of small pox after 15 jabs and had no fever no chills no sweats no red or swelling around the site no sore lymphnodes but felt perhaps tight. She did not chest pain on May 16 (4 days post) sharp pain upper mid sternum lasting all night after beginning 2000 and going to the next day approx 12 hours nonradiating approx 9/10 causing some shortness of breath and difficulty sleeping worse with rolling over and deep breath but not worse with palpation or meals and made better by nothing except time neither sitting up nor eating anything made it better. She did not take anything for it no ASA no TYLENOL she did note some associated symptoms of breath with this hurting and is able to distinguish that this shortness of breath was more due to not wanting to cause pain rather than a suffocating sensation. She had no palpitations no dizziness no syncope no tachy or brady sensations. She has had CHF symptoms no PND no orthopnea no edema no nocuturia change from usual nightly no cough on wgt gain. Symptoms: Chest pain, sub-sternal.

Other Meds: None

Lab Data: 5/19/08, Cardiac enzymes negative; 5/19/08, ECG within normal limits; 5/20/08, ECHO within normal limits

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 313056-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA02812	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Information has been received from a health professional concerning a 16 year old female who was vaccinated with her second dose of GARDASIL (lot# not reported) and developed a case of genital warts. Concomitant therapy included rizatriptan benzoate, (dose, duration and indication not reported). Other concomitant therapy included hormonal contraceptives (unspecified). The patient's genital warts persisted and she sought unspecified medical attention. Additional information has been requested.

Other Meds: hormonal contraceptives; MAXALT

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313057-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA02837	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Nausea, Pyrexia

Symptom Text: Information has been received from a certified medical assistant concerning her daughter with no known drug allergies and no previous medical history who was vaccinated with her first dose of GARDASIL (lot# unspecified). There was no concomitant medication. Subsequently the patient experienced headache dizziness, fever and nausea. She took OTC Tylenol and the symptoms resolved within 24 hours. No other information was available. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **313058-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	MI	WAES0804USA02848	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning her 19 year old daughter who in 2007 was vaccinated with three dose series (0.5 ml) of GARDASIL (No lot numbers were provided). The patient experienced dizziness after each dose of the three doses series of GARDASIL. The dizziness only lasted approximately 24 hours after each injection. Medical attention was not sought. Patient outcome was recovered on an unspecified date. No product quality complaint was involved. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313059-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	11-Apr-2008	12-Apr-2008	1	19-May-2008	12-Jun-2008	NJ	WAES0804USA02889	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site swelling

Symptom Text: Information has been received from a nurse concerning a 22 year old female with no previous medical history and no known drug allergies, who on 11-APR-2008 was vaccinated IM in the left deltoid with the third 0.5 ml dose of GARDASIL (Lot # 659182/1757U). There was no concomitant medication. On 12-APR-2008 the patient experienced redness, swelling, and hardness at the injection site. The patient was not treated. The redness and swelling had improved. Unspecified medical attention was sought. Patient outcome was recovering. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **313060-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	Unknown	Unknown		19-May-2008	12-Jun-2008	--	WAES0804USA02928	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection, Smear cervix abnormal

Symptom Text: Information has been received from a consumer concerning her 24 year old daughter who was vaccinated with the third 0.5 ml dose of GARDASIL. The patient had a PAP smear that showed positive for HPV after she received three doses of GARDASIL. Unknown medical attention was sought with the physician. At the time of reporting, patient had not recovered. No product quality complaint was involved. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313061-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	08-Apr-2008	08-Apr-2008	0	19-May-2008	12-Jun-2008	IN	WAES0804USA02937	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pyrexia, Rash

Symptom Text: Information has been received from a nurse concerning a 24 year old female with no medical history and no known drug allergies who on 08-APR-2008 was vaccinated IM in the left deltoid with the first dose of GARDASIL. There was no concomitant medication. On 08-APR-2008 the patient developed a fever in the evening that lasted through the next day. When the fever broke on 09-APR-2008 or 10-APR-2008 the patient developed a rash. The rash was not at the injection site, but on the right forearm, left side of the face and left forehead. The patient sought medical attention on 11-APR-2008 in the office and was told to take BENADRYL. On 14-APR-2008 the office contacted the patient by phone and the patient indicated that the rash was getting better. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **313062-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA02962	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a medical technologist, concerning a female patient (age not specified), who on an unknown dates was vaccinated with the first, second and third doses of GARDASIL. Subsequently, during a routine cervical cancer screen, the patient was found to be positive for both low risk and high risk human papilloma virus (HPV). At the time of this report, the patient had not recovered. No further information was available. Additional information has been requested. This is one of 2 reports from the same source.

Other Meds: Unknown

Lab Data: cervical smear - positive HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313063-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	NY	WAES0804USA03130	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Herpes zoster, Pain in extremity, Rash, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning a 19 year old female who was vaccinated with a dose of GARDASIL (Lot # 658556/1060U). The patient experienced shingles and rash after her first dose. The patient called the office indicating a rash on her abdomen and was seen in the office with a rash on her back after the second dose. During her office visit she also complained of pain in her arm. The nurse practitioner advised the patient to take Naprosyn. She also advised the patient not to receive the third dose of GARDASIL. Patient outcome was unknown. No product quality complaint was involved. This is one of the multiple cases from the same source (WAES #0804USA01372). Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313064-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Feb-2008	01-Feb-2008	0	19-May-2008	12-Jun-2008	--	WAES0804USA03141	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass

Symptom Text: Information has been received from a medical assistant concerning a female in her early 20's who in February 2008, was vaccinated with her first dose of GARDASIL (lot# unknown, injection site and route not reported). There was no concomitant medication. In February 2008, the patient developed a lump after her first vaccination. The patient came in today on 14-Apr-2008 (two months after the first vaccination) for her second dose and still had a "small lump" above the injection site. The second of the vaccine was not administered due to the lump. The physician of the patient could not be identified (group practice) at the time of the report. The patient was reported as not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **313065-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	10-Apr-2008	14-Apr-2008	4	19-May-2008	12-Jun-2008	RI	WAES0804USA03152	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a registered nurse concerning a 26 year old female with no known drug allergies and no previous medical history who on 10-APR-2008 was vaccinated with GARDASIL (lot#659964/1978U) route and site not reported. There was no concomitant medication. The nurse indicated that the patient developed a rash on 14-Apr-2008 after she was given the vaccination. The rash is on the patient's trunk and spread to her arms and feet. No further information is available from the nurse. The patient's outcome was reported as not recovered. Additional information has been requested.

Other Meds: None

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 313066-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	10-Apr-2008	Unknown		19-May-2008	12-Jun-2008	--	WAES0804USA03192	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Syncope

Symptom Text: Information has been received from a company representative concerning a 13 year old female who on 10-APR-2008 was vaccinated IM with her first dose of GARDASIL (lot# unknown, site not reported). Concomitant therapy included VARIVAX. The patient was given the vaccination standing up and subsequently fainted. She was sent to the hospital emergency room because she fell but was not hospitalized. The patient recovered. No further information was available. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313067-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Jan-2008	01-Jan-2008	0	19-May-2008	12-Jun-2008	OH	WAES0804USA03234	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a physician concerning a 11 year old female who in approximately January or February 2008, was vaccinated with the first dose of GARDASIL. The patient recently (approximately April 2008) came in for her second dose of GARDASIL. The patient experienced excruciating pain at the injection site after the first dose of the vaccine. The patient outcome was recovered. The duration of the pain was not provided. It is unknown whether medical attention was sought. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313068-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	12-Jun-2008	PA	WAES0804USA03237	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a first dose of GARDASIL (route and lot# not provided) was one day late on getting her menstrual cycle. She might be pregnant (to be determined by office). Physician did not want to provide more information yet. He might call back. The patient had an appointment with the physician (date unknown). The patient's outcome unknown. No product quality complaint was involved. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313069-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	25-Mar-2008	27-Mar-2008	2	19-May-2008	12-Jun-2008	--	WAES0804USA03248	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Joint range of motion decreased, Musculoskeletal pain

Symptom Text: Information has been received from a health professional concerning a 22 year old female who on approximately 25-MAR-2008 was vaccinated intramuscularly with her first dose of GARDASIL vaccine (lot# not reported). On approximately 27-MAR-2008 the patient experienced pain in her shoulder and disabled range of motion in her arm. She was seen in the doctors office, but her outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313070-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	16-Jun-2008	KS	WAES0804USA03251	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female who was vaccinated intramuscularly on an unspecified date with her third dose of GARDASIL (lot# not reported). Concomitant therapy included hepatitis A vaccine (unspecified) on the same day. Subsequently the patient fainted at her home that day. Her father is also a physician sent her for bloodwork. The results showed her liver enzymes were elevated. Subsequently the patient recovered from fainting. Additional information has been requested.

Other Meds:

Lab Data: diagnostic laboratory, liver enzymes were elevated

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313071-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Mar-2008	18-Mar-2008	0	19-May-2008	18-Jun-2008	OK	WAES0804USA03252	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Injection site pain

Symptom Text: Information has been received from a physician for the merck pregnancy registry concerning a 16 year old female with no previous medical history or no drug allergies, who on 18-MAR-2008 was vaccinated with a first 0.5 ml dose of GARDASIL. There was no concomitant medication. On 14-Apr-2008 the patient found out that she was 7 weeks pregnant. The patient also experienced soreness at the injection site. Unknown medical attention was sought. The patient's outcome was not reported. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory

History:

Prex Illness: Pregnancy NOS (LMP = 2/22/2008)

Prex Vax Illns:

Vaers Id: **313072-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	15-Feb-2008	16-Mar-2008	30	19-May-2008	29-May-2008	CO	WAES0804USA03269	29-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	655327-1287U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Acne, Anxiety, Cough, Decreased appetite, Depression, Diarrhoea, Dizziness, Fatigue, Formication, Inappropriate schedule of drug administration, Menstruation irregular, Metrorrhagia, Nasopharyngitis, Nausea, Palpitations, Paraesthesia, Peripheral coldness, Presyncope, Upper respiratory tract congestion, Weight decreased

Symptom Text: Information has been received from a physician concerning a 27 year old female with no previous medical history or no known drug allergies, who on 15-FEB-2008 was vaccinated IM with a 0.5 ml first dose of HPV rL1 6 11 18 VLP vaccine (yeast) (lot# 655327-1287U). There was no concomitant medication. On 16-MAR-2008 the patient experienced tingling and formication of both hands, feet, and bilateral anterior thighs. The patient was examined in the office on 21-MAR-2008. Neurological exam was normal. Complete blood count, metabolic panel, and thyroid stimulating hormone levels were normal. The patient was examined by an unspecified neurologist in early April 2008. Nerve conduction testing on the right leg and neurological exam were normal. The physician added that the patient received an unspecified steroid injection in the sacr-iliac joint 2 weeks prior to the onset of symptoms. Medical attention was sought in the office. At the time of reporting the patient was recovering. No product quality was involved. 5/27/08-records received-office visit 2/15/08-Current problems: acne vulgaris, depression with anxiety, dizziness. 3/21/08-C/O tingling sensation began 5 days ago, mild intensity, constant. Paresthesia in both hands (stocking glove distribution) both feet and both anterior thighs. Not associated with numbness or weakness just odd sensation. Two weeks prior had steroid injections in back followed by week of nocturia now resolved. Currently fighting a cold. May likely be a side effect from steroid injections. Two weeks later seen for C/O nausea and wave of dizziness, intermittent, decrease in appetite and weight loss, diarrhea. Currently on Flexeril. Heart races when dizzy. Mild cough and chest congestion. Felt like passing out. Feet seem more cold, although hands and feet are always cold. Irregular period, 2 weeks early. spotting for 7-8 days. Skin crawling sensation intermittent 1 month after first HPV vaccine.Symptoms worsen with fatigue and when anxious. Feels worse after eating cake. Neuro consult 4/4/08-Sensor

Other Meds: None

Lab Data: Nerve conduction study normal. Neurological exam normal. Complete blood cell count normal. Full chemistry normal. Serum TSH normal. 5/27/08-records received-Labs WNL. EMG normal, Brain MRI normal. Neurological exam normal.

History: None 5/27/08-records received-PMH: abnormal pap smear. TMJ-wears splint at night. Chronic low back pain/SI since 2003. Facet joint dysfunction. Pulsing sensation in ear. frequent otitis media as child.

Prex Illness:

Prex Vax Illns:

Vaers Id: 313073-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Mar-2008	01-Apr-2008	4	19-May-2008	16-Jun-2008	CA	WAES0804USA03277	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Human papilloma virus test positive

Symptom Text: Information has been received from a mother concerning her 17 year old daughter with depression and no known drug allergies, who on 28-MAR-2008 was vaccinated with the first dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified), LEXAPRO and ABILIFY. The patient also received MENACTRA on the same day she received GARDASIL. Four days after receiving her first dose of GARDASIL the patient tested HPV positive. Medical attention was sought via telephone. The patient had not recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: ABILIFY; LEXAPRO; Hormonal contraceptives

Lab Data: None

History:

Prex Illness: Depression

Prex Vax Illns:

Vaers Id: 313074-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
8.0	F	Unknown	30-Jan-2008		19-May-2008	18-Jun-2008	FL	WAES0804USA03280	07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Menstruation delayed

Symptom Text: Information has been received from a health professional concerning an 8 year old female who on 30-JAN-2008 was vaccinated IM with a first dose of GARDASIL (lot#656050/0245U). There was no concomitant medication. The patient had her period in January but did not get it in February and March. The office did a pregnancy test before administering the second dose and it was negative. The office went ahead and administered the second dose of GARDASIL (lot# 659655/1486U) on 31-Mar-2008. No medical attention was sought. The office did not follow up on the patient yet to see if her menstrual cycle was back to normal. The patient's outcome is unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic, 03/??/08 - negative

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **313075-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		19-May-2008	16-Jun-2008	--	WAES0804USA03281	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0171U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a health professional concerning an 18 year old female with no previous medical history or no known drug allergies, who was vaccinated with 3 dose series of GARDASIL. The patient received the first two doses in an other location (lot# not provided). She also received MMR and DTAP (manufacturer unknown) with the first dose. The patient was vaccinated IM with a 0.5 ml third dose of GARDASIL at this location (lot# 655620/0171U). No concomitant medication. After this she experienced amenorrhea. The same happened after the second dose and she was given a PROVERA challenge to restart the menstrual cycle, which it did. The patient's mother called the office to report the patient had amenorrhea again after receiving the third dose. Unknown medical attention was sought via phone. The patient's outcome reported as not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313076-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	31-Oct-2007	01-Jan-2008	62	19-May-2008	18-Jun-2008	FL	WAES0804USA03287	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from an office manager at the physician's office concerning a female consumer who on 31-OCT-2007 was vaccinated with a first dose of GARDASIL (lot # 657736/0389U). It was reported that "after the 1st dose", the patient has her period in November and December; however she did not have it in January, February and March. On 06-MAR-2008 the patient received her second dose of GARDASIL (lot # 659655/1486U). It was reported that the patient was not pregnant. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313077-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	04-Apr-2008	04-Apr-2008	0	19-May-2008	13-Jun-2008	OH	WAES0804USA03294	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a nurse concerning a 20 year old female who on 04-APR-2008 was vaccinated intramuscularly in the left arm with a 0.5 mL first dose of GARDASIL (lot # 659182/1757U). The nurse reported that by 11-APR-2008 the patient had a rash on both wrists. The nurse also reported that the rash was more prominent on the left wrist. On 14-APR-2008 the patient called the doctor's office and reported that she will follow up with her primary care provider. It was reported that therapy with GARDASIL will be discontinued "pending outcome". Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313078-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		19-May-2008	16-Jun-2008	--	WAES0804USA03295	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning an "18 to 19 year old" female consumer who on an unspecified date in April 2008, was vaccinated intramuscularly with a "second dose" of GARDASIL (lot # not reported). There was no concomitant medication. The nurse reported that the patient "fainted ten minutes after vaccination". The nurse noted that "the patients who read the GARDASIL fact sheet prior to vaccination seemed more prone to fainting". It was also reported that "most of the patients did not have breakfast and this may play a role because the vaccinations were given early in the day". The patient sought unspecified medical attention during an office visit. The patient recovered from fainting "on the same day". This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313079-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA03445	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information has been received from a physician concerning a female (age not reported) who was vaccinated with a dose of GARDASIL (lot not reported). Subsequently the patient developed warts on her back after vaccination. It reported that the patient implied the patient was not sexually active. The warts were treated topically. The patient's warts persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313080-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	16-Jun-2008	--	WAES0804USA03457	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a health professional concerning females who were vaccinated with GARDASIL (lot# not provided). Subsequently 2 out of 3 patients experienced pain at the injection site that lasted for several days post-vaccination. There was no prevalence in the series of the doses in terms of pain intensity. Subsequently, the patients recovered from pain at the injection site. The patients sought unspecified medical attention at the doctor's office. A phone call was placed on 22-APR-2008 to obtain more information. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313081-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		19-May-2008	16-Jun-2008	MO	WAES0804USA03495	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a 15 year old female with no known drug allergies, who was vaccinated with the first dose of GARDASIL (lot# 0152X) (date and route of vaccination was not reported). There was no concomitant medication. About ten minutes after the vaccination the patient fainted. It was unknown whether medical attention was sought. The patient's outcome is unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313082-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	OK	WAES0804USA03529	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with GARDASIL (lot # not reported). The physician reported that " the patient experienced dizziness while still in the office and this subsided". The patient sought unspecified medical attention. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313083-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Apr-2008	15-Apr-2008	0	19-May-2008	18-Jun-2008	CA	WAES0804USA03577	07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Syncope

Symptom Text: Information has been received from a physician concerning an 11 year old female who on 15-APR-2008 was vaccinated with her first dose of GARDASIL (lot# not provided). Concomitant therapy included VARIVAX, (duration and dose not reported). Other concomitant therapy included MENACTRA and diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid. On 15-APR-2008 the patient fainted after receiving the first dose of GARDASIL. The patient was recovering from fainting. She sought medical attention in the clinic. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313084-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Apr-2008	15-Apr-2008	1	19-May-2008	18-Jun-2008	NJ	WAES0804USA03581	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site rash

Symptom Text: Information has been received from a physician concerning a 12 year old female who on 14-APR-2008 was vaccinated with a third dose of GARDSIL (lot 3 not reported). Dates and lots of the previous two vaccinations were not reported. The physician reported that the patient's "parent phoned the office on 15 or 16-APR-2008 to state the patient had experienced a rash at injection site." The patient sought unspecified medical attention during the phone call. A the of this report the patient had not recovered from the rash. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313085-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	09-Apr-2008		19-May-2008	16-Jun-2008	TX	WAES0804USA03593	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Information has been received from a 17 year old female consumer who on an unspecified day was vaccinated IM with a first dose of GARDASIL and received her second injection approximately on 09-APR-2008. She reported that she experienced nausea and vomiting after receiving the first dose of vaccine. She reported these side effects on 09-APR-2008 after she received the second dose of GARDASIL. No side effects had been reported from the patient after receiving her second dose as of this date. The outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313086-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA02493	07-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
IPV	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Syncope

Symptom Text: Information has been received from a health professional concerning an 11 year old female who was vaccinated intramuscularly on an unspecified date with her first dose of GARDASIL (lot# not reported). Concomitant therapy included DTAP-IPV and MENACTRA. Subsequently the patient experienced syncope after receiving GARDASIL. She sought unspecified medical attention and her outcome was not reported. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313087-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-Apr-2008	08-Apr-2008	1	23-May-2008	01-Jul-2008	MO	WAES0804USA02499	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypokinesia, Muscle spasms, Musculoskeletal pain, Neck injury, Neck pain, Rhinorrhoea, Torticollis

Symptom Text: Initial and follow up information has been received from a physician and emergency room records concerning a 17 year old female student who at 3:45PM on 07-APR-2008, was vaccinated into the right arm with her second dose of GARDASIL (lot# 659964/1978U). The patient had an upper respiratory infection at the time of vaccination. On 08-APR-2008 (reported as 2:00PM and also as "in the AM") the patient experienced severe pain in the left shoulder and had a hard time moving her neck. She was sent to the ER where she received IV fluids. Follow up information from the physician indicated that the patient woke up in the AM on 08-APR-2008 with a severe spasm of her left neck and left shoulder. The emergency room records indicated that the patient presented at 14:45 with right side neck spasm which had progressively worsened through out the day. Torticollis along with palpable muscle spasms were noted in the emergency room evaluation. There was no known trauma or abnormal activities. The patient had pain with movement and no systemic symptoms, no fever, no nausea, vomiting or diarrhea. She denied paresthesia/weakness. She was reported to have tried heat and BENGAY with relief. Emergency room diagnosis was neck strain. The patient was treated with one shot of TORADOL, 30 mg IV and VALIUM, 20 mg IV. She was discharged to home with instructions to take either ibuprofen or TORADOL, apply heat and follow up with primary physician. The reporting physician also indicated that patient stayed on TORADOL for a few days and did well. Further information is not expected. 5/29/08-records received for DOS 4/8/08-DX: Neck strain. ER visit with C/O right side neck pain began morning of ER visit and worsened throughout day. Now with Torticollis. Pain with movement. Denies paresthesia and weakness. URI symptoms recently. PE: yellow discharge from nose. Palpable muscle spasm neck left neck.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness: Upper respiratory tract infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313088-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Apr-2008	14-Apr-2008	0	19-May-2008	18-Jun-2008	TX	WAES0804USA03615	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Nausea, Vomiting

Symptom Text: Information has been received from a physician, via a company representative, concerning a 13 year old female patient, who on 14-APR-2008 was vaccinated IM with a dose of GARDASIL. Concomitant suspect therapy included a dose of VARIVAX, and a dose of MENACTRA. On 14-APR-2008 the patient experienced headaches, vomiting, nausea and dizziness. At the time of this report, the outcome of the events was not specified. The patient sought unspecified medical attention. Additional information has bee requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313089-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	16-Jun-2008	CA	WAES0804USA03629	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from an office manager concerning a female who was vaccinated IM with a 0.5 ml dose of GARDASIL (dose # unknown). Within minutes the patient fainted. The patient was transported to Emergency room where she was treated and released. She had recovered. This is one of two cases from the same source (WAES# 0804USA02539). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313090-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Mar-2008	25-Mar-2008	0	23-May-2008	01-Jul-2008	--	WAES0804USA02510	01-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Emotional distress, Syncope, Syncope vasovagal

Symptom Text: Information has been received from a health professional concerning a 16 year old female who on approximately 25-MAR-2008 was vaccinated with her first dose of Gardasil vaccine (lot# not reported). The patient fainted twice after receiving the vaccine. She was at the clinic when this occurred. She was taken to the ER where she was treated and released for vasovagal response to the immunization. The patient's mother reported that her daughter ate very little that day and was also emotionally upset that day. Her outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313091-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Apr-2008	04-Apr-2008	0	19-May-2008	16-Jun-2008	OH	WAES0804USA03661	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a health professional concerning a 14 year old female with no pertinent medical history or drug reactions/allergies who in June 2007 was vaccinated with a first dose of GARDASIL 0.5 mL IM. There was no concomitant medication. On 04-APR-2008 the patient was vaccinated with a second dose of GARDASIL 0.5 mL IM. The patient was at the physician's office when she experienced syncope and she remained there until she recovered and was able to leave. Unspecified medical attention was sought at the physician's office. On 04-APR-2008 the patient recovered. No further information was available. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313092-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Apr-2008	15-Apr-2008	0	19-May-2008	18-Jun-2008	--	WAES0804USA03869	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling, Pruritus generalised, Urticaria

Symptom Text: Information has been received from a physician concerning a 22 year old female with history of pollen allergy who on 15-APR-2008 was vaccinated IM in the right upper arm with a 0.5 mL dose of GARDASIL (lot # 655327/1287U). Concomitant therapy included ALLEGRA and ORTHO EVRA. On 15-APR-2008 the patient experienced generalized hives and itching, as well as redness, tenderness and swelling at the injection site of the right arm, several hours after receiving the vaccine on 15-APR-2008. The patient called the office on 16-APR-2008 and reported that the hives had resolved but she still had generalized itchiness. No treatment was recommended. There was no laboratory test performed. The patient was reported to be recovering. Additional information has been requested.

Other Meds: ORTHO EVRA; ALLEGRA

Lab Data: None

History: Pollen allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **313093-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA03721	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a nurse concerning an "18 to 19 year old" female consumer who on unspecified date in April 2008, was vaccinated with a "second dose" of GARDASIL (lot # not reported). There was no concomitant medication. The nurse reported that the patient "fainted ten minutes after vaccination." The nurse noted that "the patients who read the GARDASIL fact sheet prior to vaccination seemed more prone to fainting". It was reported that "most of the patients did not have breakfast and this may play a role because the vaccinations were given early in the day". The patient sought unspecified medical attention during an office visit. The patient recovered from fainting "on the same day". This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **313094-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Apr-2008	01-Apr-2008	0	19-May-2008	13-Jun-2008	--	WAES0804USA03722	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning an "18 to 19 year old" female consumer who on an unspecified date in April 2008, was vaccinated with a "second dose of GARDASIL (lot # not reported). There was no concomitant medication. The nurse reported that the patient "fainted ten minutes after vaccination". The nurse noted that "the patients who read the GARDASIL fact sheet prior to vaccination seemed more prone to fainting". It was also reported that "most of the patients did not have breakfast and this may play a role because the vaccinations were given early in the day". The patient sought unspecified medical attention during an office visit. The patient recovered from fainting "on the same day". This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **313095-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA03723	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning an "18 to 19 year old" female consumer who on an unspecified date in April 2008, was vaccinated with a "second dose" of GARDASIL (lot # not reported). There was no concomitant medication. The nurse reported that the patient "fainted ten minutes after vaccination". The nurse note that "the patients who read the GARDASIL fact sheet prior to vaccination seemed more prone to fainting". It was reported that "most of the patients did not have breakfast and this may play a role because the vaccinations were given early in the day". The patient sought unspecified medical attention during an office visit. The patient recovered from fainting "on the same day". This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313096-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	07-Apr-2008	07-Apr-2008	0	19-May-2008	13-Jun-2008	--	WAES0804USA03738	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a company representative reporting that a physician reported that a female (age not reported) who during the week of 07-APR-2008 was vaccinated with the first dose of GARDASIL (lot not reported) and experienced hives all over her body. By the next morning the hives were gone. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313097-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	13-Jun-2008	PA	WAES0804USA03742	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain, Pallor

Symptom Text: Information has been received from a physician concerning a female who was vaccinated on an unspecified date with her third dose of GARDASIL (lot# 654272/0073X). Subsequently the patient experienced excruciating pain in the right arm and turned all white. Patient had no problems after the first and second dose of GARDASIL. The patient's outcome was not reported and she sought unspecified medical attention. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313098-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	NC	WAES0804USA03794	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with three doses of GARDASIL. It was reported that patient was positive for GARDASIL getting all three doses of vaccination. The patient did not get the vaccination at the reporting physician's office. The physician reported that the patient was High Risk for HPV. No other information to report. The outcome was reported as patient positive for HPV at the time of this report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Papilloma viral infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313099-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	17-Apr-2008	17-Apr-2008	0	19-May-2008	18-Jun-2008	FL	WAES0804USA03796	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site, Injection site pain

Symptom Text: Information has been received from a medical assistant concerning a female in her early 20s, who on 17-APR-208 was vaccinated with the first dose of GARDASIL in the gluteal region. This was administered in another office so details about administration such as dose or route were unspecified. On 17-APR-2008 the patient experienced pain at the injection site. Unknown medical attention was sought in the office. The patient's outcome is unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313100-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	13-Jun-2008	NJ	WAES0804USA03803	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nasal congestion, Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning a female who on 15-JAN-2008 was vaccinated with her first dose of GARDASIL (lot# 660387/1967U). On an unspecified date the patient was vaccinated with her second dose of GARDASIL (lot# not provided). Subsequently the patient experienced nausea, vomiting, headache and stuffy nose since she was given the second dose. The patient was recovering from nausea, vomiting, headache and stuff nose. She sought medical attention by calling the nurse. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313101-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	13-Jun-2008	--	WAES0804USA03830	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Skull fracture, Syncope

Symptom Text: Information has been received from a physician concerning a male patient who was vaccinated with a dose of GARDASIL. The physician reported that after receiving the vaccination, the patient fainted, hit her head and ended up getting a skull fracture. The patient sought unspecified medical attention. The reporting physician is not the physician of the patient. At the time of this report, the outcome was unknown. No product quality complaint was involved. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313102-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA03856	07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Guillain-Barre syndrome

Symptom Text: Information has been received from a physician's assistant as told her by the patient's primary care physician concerning a 14 year old female who was vaccinated with a dose (dose number unknown) of GARDASIL on an unspecified date (lot number, route and site not reported). Subsequently the patient was diagnosed with Guillain-Barre Syndrome after receiving GARDASIL. The patient sought unspecified medical attention (date not reported). The patient's outcome was not reported. No further information was provided. The reporter considered Gullain-Barre Syndrome to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313103-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	13-Jun-2008	MO	WAES0804USA03869	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Somnolence

Symptom Text: Information has been received from a physician concerning a female who was vaccinated on an unspecified date with GARDASIL (lot# not provided). Concomitant therapy included DEPO-PROVERA. Subsequently the patient experienced extreme drowsiness within an hour after receiving the GARDASIL. Subsequently, the patient recovered from extreme drowsiness the next day. The patient sought medical attention by speaking with the physician. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313104-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	15-Apr-2008	15-Apr-2008	0	19-May-2008	18-Jun-2008	OH	WAES0804USA03937	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pyrexia, Vomiting

Symptom Text: Information has been received from a medical assistant concerning a 23 year old female who on 15-APR-2008 was vaccinated with a first dose of GARDASIL (lot # not reported). The medical assistant reported "that same evening the client called the doctor office mail stating she had a fever of 100F, nausea and vomiting." Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313105-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	24-Mar-2008	24-Mar-2008	0	19-May-2008	18-Jun-2008	TX	WAES0804USA03948	07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Inappropriate schedule of drug administration, Injection site bruising, Pain in extremity

Symptom Text: Information has been received from a 21 year old female consumer with hydrocodone allergy who on 24-MAR-2008 was vaccinated with a first dose of GARDASIL (lot # not reported). Concomitant therapy included diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid. It was reported that the patient was approximately six weeks pregnant (estimated LMP 20-OCT-2007) when she received dose of GARDASIL. It was also reported that the patient developed a bruise at the injection and her arm was sore for several days. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 10/20/2007; Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 313106-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	12-Dec-2007	Unknown		19-May-2008	18-Jun-2008	MD	WAES0804USA03949	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain

Symptom Text: Information has been received from a physician concerning a female who on 12-OCT-2007 was vaccinated with a first dose of GARDASIL (lot # not reported). On 12-DEC-2007 the patient was vaccinated with a second dose of GARDASIL (lot # not reported). Subsequently the patient developed soreness and redness at the injection site which lasted for one week. It was reported that the patient "did not have this reaction after the first dose of GARDASIL." The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313107-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	08-Apr-2008	08-Apr-2008	0	23-May-2008	01-Jul-2008	TX	WAES0804USA02598	01-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 10 year old female with a history of fainting when receiving shots, who on 08-APR-2008 was vaccinated with the first dose of Gardasil vaccine. After receiving the vaccination the patient fainted. Also, the patient had a history of disliking shots and she had fainted before and after receiving vaccinations, unknown medical attention was sought. The patient was recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Concurrent Conditions: Syncope

Prex Vax Illns:

Vaers Id: 313108-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Apr-2008	16-Apr-2008	1	19-May-2008	18-Jun-2008	--	WAES0804USA03969	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Vomiting

Symptom Text: Information has been received from a Nurse Practitioner concerning a 13 year old female who on 15-APR-2008 was vaccinated intramuscularly with a 0.5 mL dose of GARDASIL (lot # not reported). Subsequently, on 16-APR-2008 the patient experienced severe headaches and vomiting. It was reported that the patient sought medical attention in a phone call to the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313109-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	08-Apr-2008	10-Apr-2008	2	19-May-2008	16-Jun-2008	NM	WAES0804USA03971	09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Exfoliative rash, Injection site rash, Rash, Rash erythematous, Rash vesicular

Symptom Text: Information has been received from a physician concerning a 19 year old female who on 08-APR-2008 was vaccinated with her second dose of GARDASIL (lot# not provided). On 10-APR-2008 the patient experienced a rash at the injection site, rash on her chest and rash on her abdomen. The rash was a scaly red rash with vesicles. The patient feels well and was afebrile. The patient was being seen at the urgent care center. The patient's rash at the injection site and rash on her chest and rash on her abdomen persisted. No further information is available.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **313110-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	NJ	WAES0804USA02613	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a medical assistant concerning a female (age unknown) who on unknown dates was vaccinated (route unknown) with a first and second dose of GARDASIL (Lot # 's unknown). Subsequently, unspecified dates, the patient experienced mild pain at injection site after 1st dose and severe pain at injection site after 2nd dose. Subsequently, on an unknown date, the patient recovered. Unspecified medical attention was sought at the time of the vaccination. The physician gave the patient TYLENOL in the office after the second dose. No product quality control was involved. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313111-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		19-May-2008	16-Jun-2008	NJ	WAES0804USA02616	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 16 year old patient who on an unspecified date, was vaccinated with a dose of GARDASIL (lot number unspecified) and fainted post vaccination. The physician was not certain if the event occurred after the patient's first or second dose of GARDASIL but knew it was definitely not with administration of the third dose. Additional information has been requested. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313112-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	16-Jun-2008	MD	WAES0804USA03979	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated intramuscularly with GARDASIL (lot # not reported). Subsequently, the patient fainted. The patient sought unspecified medical attention. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313113-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	MD	WAES0804USA03980	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated intramuscularly with GARDASIL (lot # not reported). Subsequently, the patient fainted. The patient sought unspecified medical attention. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313114-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	17-Jun-2008	MD	WAES0804USA03981	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated intramuscularly with GARDASIL (lot # not reported). Subsequently, the patient fainted. The patient sought unspecified medical attention. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313115-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	04-Apr-2008	04-Apr-2008	0	19-May-2008	16-Jun-2008	FL	WAES0804USA02627	09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Medical device complication, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 19 year old female with unknown medical history, who on 04-APR-2008 was vaccinated (route unknown) with a second dose of GARDASIL (Lot # 655604/0052X). The date and the lot number of the first vaccination were not reported. The physician reported that the patient was "stuck" twice with two different prefilled syringes, because the first syringe did not function properly and did not release the vaccine. The patient reported arm pain to the physician. No laboratory diagnostic studies were performed. The patient sought unspecified medical attention at the physician's office. Subsequently, on an unspecified date the patient recovered. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313116-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	NY	WAES0804USA04003	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	IPV	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Conversion disorder, Psychomotor hyperactivity, Syncope, Tremor

Symptom Text: Information has been received from a physician concerning a 17 year old female who was vaccinated on an unspecified date with GARDASIL (lot# not provided). Concomitant therapy included MENACTRA and poliovirus vaccine. Subsequently the patient fainted after receiving the vaccines. When she came to she had a "conversion reaction" where she was anxious, shaky and hyperactive. The patient was taken to the ER, but was not admitted. Subsequently, the patient recovered from fainting, being anxious, shaky and hyperactive. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313117-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	NJ	WAES0804USA04010	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female who was vaccinated intramuscularly on an unspecified date with GARDASIL (lot# not reported). Subsequently the patient experienced a syncope episode. The patient had also experienced syncope at another patient visit when she received a different vaccine. Her outcome was not reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313118-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	16-Jun-2008	SC	WAES0804USA04028	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated IM with a third 0.5 ml dose of GARDASIL. Subsequently the patient experienced abnormal Pap test. At the time of this report, the patient was recovering. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313119-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		19-May-2008	17-Jun-2008	MN	WAES0804USA04031	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain lower

Symptom Text: Information has been received from a physician concerning a 13 or 14 year old female who in January 2008, was vaccinated with the first dose of GARDASIL (Lot number not provided). In January 2008, the patient developed pain in right lower quadrant. The patient went to the ER but was not admitted. The series of doses was discontinued. Patient outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313120-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	08-Feb-2008	08-Feb-2008	0	19-May-2008	16-Jun-2008	PA	WAES0804USA04052	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort

Symptom Text: Information has been received from medical assistant concerning a 19 year old female with no previous medical history and no known drug allergies, who on 08-FEB-2008 was vaccinated IM with the first dose of GARDASIL (Lot # 660387/1967U). There was no concomitant medication. The patient developed chest tightening that started after she left the office the same day she received the dose of vaccination. Unknown medical attention was sought in the office. The patient did not report the event until she arrive for her second dose of GARDASIL, which she did not receive. Patient outcome was recovered on an unknown date. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Acne

Prex Vax Illns:

Vaers Id: 313121-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	16-Apr-2008	17-Apr-2008	1	19-May-2008	16-Jun-2008	NY	WAES0804USA04157	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Dyspnoea, No reaction on previous exposure to drug, Pruritus, Rash

Symptom Text: Information has been received from a office manager concerning a 17 or 18 year old female with breathing issues and unspecified allergies and no known drug allergies who on 19-FEB-2008 was vaccinated with the first dose of GARDASIL (Lot# 658488/1264U). On 16-APR-2008, the patient was vaccinated with the second dose of GARDASIL (Lot # 660387/1967U). There was no concomitant medication. Twenty four hours after the second dose of the vaccine, the patient was itchy, had a rash on the body and breathing difficulty. Patient did not experience any problems after the first dose of the vaccine. Patient outcome was recovered on an unknown date. Unknown medical attention was sought in the office. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Breathing difficult; Hypersensitivity

Prex Vax Illns:

Vaers Id: 313130-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	15-Apr-2008	Unknown		23-May-2008	29-May-2008	NM		30-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass, Injection site pain

Symptom Text: 1 month after vaccine, patient still has soreness and knot at site of administration.

Other Meds:

Lab Data:

History: Penicillin; Amoxicillin; CECLOR

Prex Illness: None

Prex Vax Illns:

Vaers Id: 313138-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Feb-2008	26-Feb-2008	1	23-May-2008	27-May-2008	FR	WAES0804USA00567	27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Eye rolling, Influenza like illness, Lip discolouration, Loss of consciousness, Muscle contracture, Nausea, Pallor, Syncope vasovagal

Symptom Text: Information has been received from a pharmacist concerning an eighteen year old female patient who received a first dose of GARDASIL (batch number not reported) on 25-FEB-2008, administered intramuscularly in the left arm. The morning after on 26-FEB-2008, during her breakfast, the patient looked white, had nausea and had a loss of consciousness. The patient's mother reported an impressive reaction. The patient went to the emergency at the hospital and the diagnosis was a vagal malaise. Follow up information indicated that the patient had loss of consciousness, eye rolling and black lips 23 hours after injection. She also experienced contractures in the arms and the body and abdominal pain, "like in flu-like syndrome", 28 hours after injection. Contractures were reported as moderate and abdominal pain was reported as severe. The three events were reported as serious and severe. The events of nausea and pallor were no longer mentioned. One hour after her syncope, the patient was transferred to the emergency unit where vasovagal syncope was diagnosed. The patient recovered (date not reported). The reporter considered the patient's vagal reaction, contracture and abdominal pain as other important medical events. Other business partner numbers included E2008-02391.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 313142-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Oct-2007	02-Oct-2007	0	23-May-2008	27-May-2008	FR	WAES0805CAN00084	27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Breast abscess, Breast swelling, Cellulitis, Erythema, Fatigue, Injection site pain, Malaise, Nausea, Pyrexia, Scar

Symptom Text: Information has been received from a mother concerning her 13 year old daughter who on 02-OCT-2007 was vaccinated with her first dose of GARDASIL, (lot # not available). Subsequently, on approximately 02-OCT-2007 the patient experienced soreness at the injection site for 3 - 5 days. On 11-DEC-2007 the patient was vaccinated with her second dose of GARDASIL, (lot # not available). Subsequently, on approximately 11-DEC-2007 the patient experienced soreness at the injection site for 3 - 5 days. On 21-APR-2008 the patient was vaccinated with her third dose of GARDASIL, (lot # not available). The mother reported that on 22-APR-2008 the patient did not feel well - her stomach hurt and she felt queasy and tired, plus she had a slight fever and a small red spot on her breast. On 23-APR-2008 the patient's temperature was higher and her whole breast was very swollen and red. It was reported that the patient was taken to her physician who recommended that she go to the hospital. The patient was hospitalized from 23-APR-2008 to 27-APR-2008, given IV antibiotics and diagnosed with an abscess in he breast and got cellulitis. The mother reported that the patient now has scar tissue in her breast. It was reported that the physicians at the hospital believed that abscess in her breast and got cellulitis and now has scar tissues in her breast were not related to therapy with GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313143-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		23-May-2008	27-May-2008	FR	WAES0805KOR00004	27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Heart rate irregular, Loss of consciousness, Pain, Pallor, Shock

Symptom Text: Information has been received from a nurse concerning a 13 year old female who in early April 2008, was vaccinated with GARDASIL during the physical check-up in a general hospital. On a same day right after the vaccination with GARDASIL, the patient fell down and her face became pale. The patient experienced pain shock and loss of consciousness. The nurse checked her consciousness, but the patient did not respond and her pulse was unstable. The nurse was about to bring the patient to the emergency room, but the patient became conscious within 30 to 60 seconds after the patient fell down. Subsequently, the patient recovered from pain shock and loss of consciousness for about 30 - 60 seconds and unstable pulse. Her pulse became stable. The patient just remembered that she felt severe pain after vaccination. Thereafter the patient had no significant finding and went home. No follow up information has been reported from the patient so far. The causality with GARDASIL was not reported. The patient's pain shock and loss of consciousness for about 30 - 60 seconds and unstable pulse were considered as other important medical events. Additional information is not expected.

Other Meds: Unknown

Lab Data: total heartbeat count, ??Apr08, unstable during loss of consciousness; total heartbeat count, ??Apr08, stable after recovery

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313144-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	03-Apr-2008	04-Apr-2008	1	23-May-2008	27-May-2008	NC	WAES0805USA02288	06-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal tenderness, Arthralgia, Arthritis reactive, Asthenia, Fatigue, Gait disturbance, Immunisation reaction, Joint swelling, Joint warmth, Mouth ulceration, Presyncope, Pyrexia, Rash erythematous, Rash generalised, Rash macular, Serum sickness, Urticaria

Symptom Text: Initial and follow up information has been received from a physician and by telephone call from the healthcare professional concerning a 22 year old female patient with family history of rheumatoid arthritis and autoimmune disease who on 03-APR-2008 was vaccinated IM with a dose of GARDASIL (lot # not available). The physician reported that the patient experienced serum sickness, full body rash, and severe arthritis and joint pain. She was taken to the emergency room and was admitted to the hospital. In follow up telephone call the health care professional reported that on 04-APR-2008 patient developed fatigue, temperature of 102, weakness, near syncope episode at work, blanchable rash all over body, very achy joints hands, knees and ankles, and had trouble walking. She went to the emergency room (E.R.) on 04-APR-2008 and was sent home. On 05-APR-2008, she went to the ER and was told she had chicken pox and was sent home. On 08-APR-2008 the patient went to the ER and was sent home. On 09-APR-2008 the patient was admitted to the hospital. The patient's final diagnosis was reactive arthritis, possible reaction to GARDASIL, urticaria associated with reactive arthritis, abnormal liver function test (LFT's) possibly related to fatty liver or polycystic ovary syndrome or possibly related to reactive arthritis. Her hepatitis A, hepatitis B and hepatitis C, Lyme, Rocky Mountain fever, serum antinuclear antibodies (ANA), serum antineutrophil cytoplasmic antibody (ANCA) test was normal. Her Rheumatoid factor tests were all normal and her sed rate was slightly elevated. Serum C Reactive protein test was 29.9. The patient was treated with intravenous (IV) steroids and improved. She was in the hospital for four days. On 21-APR-2008, the patient was seen in the office and it was noted that she was "remarkably better". Skin rash was resolved, ache in joints/stiffness still there especially after sleeping. Fever was gone. The patient was recovering. Additional information has been requested. 06/04/2008 MR re

Other Meds: Unknown

Lab Data: diagnostic laboratory, 04/09?/08, Rocky Mountain Fever titer (normal); erythrocyte, 04/09?/08, slightly elevated; serum C-reactive, 04/09?/08, 29.9; serum ANCA, 04/09?/08, Normal; serum hepatitis A, 04/09?/08, normal; serum rheumatoid facto

History: Unknown. PMH: Polycystic Ovary Syndrome

Prex Illness:

Prex Vax Illns:

Vaers Id: 313145-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	23-Jul-2007	29-Jul-2007	6	23-May-2008	27-May-2008	--	WAES0805USA03350	27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion

Symptom Text: Information has been received from a Registered Nurse (R.N.) and by telephone concerning a 22 year old female patient with a history of seizure for which she was on therapy. On 23-MAY-2007 patient was vaccinated with a first dose of GARDASIL and on 23-JUL-2007 she was vaccinated with a second dose of GARDASIL in another doctor's office. No lot number was provided. Concomitant therapy included TEGRETOL, DIAMOX and YAZ. The nurse reported that on 29-JUL-2007, patient had a seizure type episode six days after she received her second dose of GARDASIL. The patient sought unspecified medical attention. She reported that patient had no seizures since this incident. No further information was provided. Upon internal review seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: DIAMOX, mg; TEGRETOL, mg; YAZ

Lab Data: Unknown

History:

Prex Illness: Convulsion disorder

Prex Vax Illns:

Vaers Id: 313162-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	17-Apr-2008	18-Apr-2008	1	19-May-2008	18-Jun-2008	--	WAES0804USA04182	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a nurse practitioner concerning a female who on 17-APR-2008 was vaccinated with a dose of GARDASIL. Concomitant therapy included MOBIC and antifugal (unspecified). On 18-APR-2008 the patient experienced rash on face. Unknown medical attention was sought with the nurse practitioner. Patient outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: antimicrobial (unspecified); MOBIC

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313163-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Oct-2007	06-Oct-2007	0	19-May-2008	16-Jun-2008	TX	WAES0804USA04389	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site reaction, Pallor, Rash papular

Symptom Text: Information has been received from a nurse concerning a 15 year old female with a history of scarring from a motor vehicle accident and no known drug allergies who on 06-OCT-2007 was vaccinated IM in the left arm with the first dose of GARDASIL. There was no concomitant medication. On 06-OCT-2007 the patient experienced injection site reaction described as covering a 2 to 3 inch area around the injection site that was blanched with small pea sized elevations. The reaction occurred several hours after the injection and lasted for about 2 months. The rash subsided without any treatment. The patient reported the reaction about six months after receiving the vaccination. No other symptoms reported. Unknown medical attention was sought in the office. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Motor vehicle accident

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313165-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	04-Apr-2008	04-Apr-2008	0	19-May-2008	18-Jun-2008	FL	WAES0804USA04504	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Medical device complication, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 21 or 22 years old female with unknown medical history, who on 04-APR-2008 was vaccinated (route unknown) with a second dose of GARDASIL (Lot # 655604/0052X). The date and lot number of the first vaccination were not reported. The physician reported that the patient was "stuck" twice with two different prefilled syringes, because the first syringe did not function properly and did not release the vaccine. The patient reported arm pain to the physician. No laboratory diagnostic studies were performed. The patient sought unspecified medical attention at the physician's office. Subsequently, on an unspecified date the patient recovered. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313166-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Dec-2007	17-Dec-2007	0	19-May-2008	17-Jun-2008	TX	WAES0804USA04529	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Injection site pain, Syncope

Symptom Text: Information has been received from a mother concerning her 16 year old daughter with a sulfonamide allergy who on approximately 17-DEC-2007 was vaccinated with her first dose of GARDASIL (lot# not reported) and fainted. She also experienced headaches and injection site pain. Subsequently, the patient recovered from fainting, headaches and injection site pain after a couple days. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: 313167-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		19-May-2008	17-Jun-2008	--	WAES0804USA04531	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site pain, Injection site pruritus, Nausea

Symptom Text: Information has been received from a 25 year old female who was vaccinated on unspecified dates with the first and second doses of GARDASIL (lot #'s not reported) and experienced nausea, pain and itching at the injection. About one month later she developed a "knot" at the injection site that lasted for about 2-3 months. After getting the third dose of GARDASIL (lot # not reported) she did not have any adverse reactions. The first two doses were given by the same nurse and the third dose was given by another nurse at the same office. Subsequently, the patient recovered from nausea, pain, itching at the injection site and knot at the injection site. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313168-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	02-Apr-2008	07-Apr-2008	5	19-May-2008	18-Jun-2008	PA	WAES0804USA04539	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a health professional from an OB/GYN office concerning a female who on 28-JAN-2008 was vaccinated IM with a 0.5 ml first dose of GARDASIL. On 02-Apr-2008 the patient was vaccinated IM with a 0.5 ml second dose of GARDASIL. On 07-APR-2008 the patient developed rash on her arms and legs. At the time of reporting the patient's rash was spreading. The patient went to primary care physician. At the time of reporting the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313169-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Nov-2007	30-Jan-2008	61	19-May-2008	18-Jun-2008	CA	WAES0804USA04603	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0802U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 30-Nov-2007 was vaccinated IM in the right arm with the first dose (lot# 658490/0802U) and on 30-Jan- 2008, vaccinated IM in the left arm with the second dose of GARDASIL (lot# 658490/0802U). Concomitant therapy included MENACTRA (lot# 42375BA) and diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (lot# AC52B019AA). After the first dose the patient did not get her period for four months. She was on no medication at that time. Negative labs and negative pregnancy test. On 14-Apr-2008 she had her period. The patient recovered. Additional information has been requested.

Other Meds:

Lab Data: diagnostic laboratory - negative; beta-human chorionic - negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313170-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	FL	WAES0804USA04622	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with GARDASIL (lot # not reported). Subsequently the patient experienced severe headaches. The physician reported that he did not believe that this experience was related to therapy with GARDASIL. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313171-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	09-Apr-2008	11-Apr-2008	2	19-May-2008	17-Jun-2008	OH	WAES0804USA04633	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus generalised

Symptom Text: Information has been received from a nurse concerning a 15 year old white female student who on 09-APR-2008 at 10 am was vaccinated in the right deltoid with the second dose of GARDASIL (Lot # 659964/1978U). Concomitant therapy included TRINESSA. The patient's mother called office indicating that on 11-APR-2008 the patient experienced generalized itching, site not reddened and no rash. The patient recovered on 14-APR-2008. No product quality complaint was involved. Additional information has been requested.

Other Meds: TRINESSA

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313175-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	18-Apr-2008		19-May-2008	18-Jun-2008	--	WAES0804USA04717	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Incorrect route of drug administration, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 19 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL IM. On approximately 18-APR-2008 was vaccinated with a second dose of GARDASIL IM. The patient received the first dose of vaccine in her arm and experienced so much pain that for her second dose the physician injected it in her back. The patient experienced the same pain in her back as she did in her arm. The outcome of the event was not reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313176-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	PA	WAES0804USA04745	07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0702F		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alanine aminotransferase, Aspartate aminotransferase, Blood alkaline phosphatase, Blood creatine phosphokinase increased, Inappropriate schedule of drug administration, Oedema peripheral

Symptom Text: Information has been received from a registered nurse concerning a 28 year old female who in October 2006, was vaccinated intramuscularly with the third 0.5 mL dose of GARDASIL (Lot # 653650/0702F). The nurse reported that the patient received the three dose series of GARDASIL. Concomitant therapy included influenza virus vaccine (unspecified). In December 2006, the patient experienced swelling around her knuckles. It was reported that she also saw a rheumatologist sometime in 2007. Diagnostic laboratory testing performed included creatine phosphokinase was 2096, glutamic-oxaloacetic transamine, was 59; gultamic-pyruvic transaminase was 55, alkaline phosphatase was 37. At the time of this report the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds:

Lab Data: serum aspartate, ?/?/07, 59; serum alanine, ?/?/07, 55; serum alkaline, ?/?/07, 37; serum creatine kinase, ?/?/07,2096

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313177-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Aug-2007	29-Sep-2007	59	19-May-2008	18-Jun-2008	CA	WAES0804USA04760	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0530U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection, Smear cervix abnormal

Symptom Text: Information has been received from a certified medical assistant concerning a 15 year old female patient with a sulfonamide allergy, who in June 2007, August 2007 and December 2007 was vaccinated intramuscularly with the first, second and third dose 0.5 ml doses of GARDASIL (Lot # first dose 0469U, second dose 0530U and third dose 0530U), respectively. On 29-SEP-2007, after her second dose of GARDASIL, she had an abnormal pap of atypical squamous cells. The patient went to the physicians office for a pap and follow up. She also had a colposcopy that identified HPV types: 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68. At the time of this report the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear 09/??/07 - atypical squamous cells; colposcopy 09/??/07 - HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68 were identified.

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **313182-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	29-Feb-2008	29-Feb-2008	0	19-May-2008	16-Jun-2008	--	WAES0804USA04771	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Somnolence

Symptom Text: Information has been received from a consumer concerning her 21 year old daughter with no medical history or allergies reported, who on 29-FEB-2008 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. On 29-FEB-2008, after receiving her first dose, the patient became very sleepy and developed a rash across her breast line and under her neck. The patient sought unspecified medical attention with a gynecologist. At the time of this report the patient's outcome was not recovered. No product quality complaint was involved. No further information is available.

Other Meds: None

Lab Data: Non

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **313185-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
64.0	F	01-Nov-2007	01-Nov-2007	0	19-May-2008	18-Jun-2008	FL	WAES0804USA04787	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Deafness unilateral, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a physician's wife concerning a 64 year old female who in November 2007 and February 2008 was vaccinated with the first and second doses of GARDASIL, respectively. There was no concomitant medication. Subsequently, after receiving the second dose, the patient experienced hearing loss in the right ear. The patient sought unspecified medical attention. The patient did not experience any problems after the first dose. The patient's date of birth and vaccine were verified. At the time of this report the patient had not recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 313186-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
30.0	F	Unknown	08-Apr-2008		19-May-2008	16-Jun-2008	--	WAES0804USA04791	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injection site mass

Symptom Text: Information has been received from a pharmacist concerning a 30 year old female physician who in April 2008, was vaccinated intramuscularly with the second dose of GARDASIL. On approximately 08-APR-2008, "about two weeks ago," the patient developed a cyst like lump at the injection site. The patient sought unspecified medical attention. At the time of this report the patient not recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313205-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Mar-2008	11-Mar-2008	0	23-May-2008	26-May-2008	NY		27-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Body temperature, Heart rate, Hyperhidrosis, Immediate post-injection reaction, Pallor, Syncope

Symptom Text: Approximately 10 minutes after giving shot patient fainted in waiting area at front desk. NP was first to aid student. No apparent injury noted. LOC 3-5 seconds. Responsive. Pale and diaphorectic but alert. P:96 4:30 taken via wheelchair to infirmary. B/P: 100/76 P: 96. Dr. aware. Given water and gatorade and crackers. Lying in bed elevated legs. Cool compress to forehead. 4:45pm B/P96/78P:96 Dangled legs at bedside before ambulating. Color back to faceand no reports of dizziness. Stable and A&Ox3 before discharge.

Other Meds: Welbutrin, Yaz, Paxil

Lab Data: na

History: Depression, Anxiety

Prex Illness: no

Prex Vax Illns: nausea, blurry vision, no dizzines~HPV (Gardasil)~1~18~In Patient

Vaers Id: 313208-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Jan-2008	10-Jan-2008	0	23-May-2008	26-May-2008	MA		04-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Cough, Injected limb mobility decreased, Injection site pain, Limb discomfort, Malaise, Muscular weakness, Nasal congestion, Neuritis, Oedema peripheral, Pain, Pain in extremity, Pyrexia

Symptom Text: Patient has had chronic deltoid pain since 1/10/08. There is pain to palpation, and weakness in the arm. MRI normal. 6/3/08- records received-C/O arm pain 4/14/08-arm swollen, arm weakness, discomfort with moving. Injection site tender, pain is aching. C/O getting sick constantly since 3/08, aches and chills, fevers up to 101, nasal congestion, cough. PE: pain on palpation of arm. Assessment:neuritis.

Other Meds:

Lab Data: MRI 5/13/08 normal 6/3/08-records received-C-reactive protein 1.0, ESR 30.MRI normal left arm.

History: 6/3/08-records received-exercise induced asthma

Prex Illness:

Prex Vax Illns:

Vaers Id: 313210-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-May-2008	22-May-2008	1	23-May-2008	26-May-2008	WA		26-Jun-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B016BA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2563AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1967U	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB222AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Areflexia, Asthenia, Erythema, Fatigue, Hypoaesthesia, Injected limb mobility decreased, Musculoskeletal pain, Neuropathy peripheral, Paraesthesia, Radial nerve palsy, Sensory loss

Symptom Text: Left arm had a radial nerve palsy after receiving 2 vaccines in it. HPV and MCV4 given in the left arm. 6/24/08 Reviewed PCP medical records & vax records of 5/21-6/10/08. FINAL DX: left arm neuropathy Records reveal patient w/concerns about weight, thyroid check up, acid reflux & occasional nosebleeds on day of vax. Day after vax, had left finger tingling, numbness, unable to move left arm well & had fatigue. RTC on 5/30 w/left arm redness, forearm & finger numbness, no pain in deltoid but had pain w/movement of arm from shoulder. Decreased left biceps & triceps strength, absent left arm reflexes, decreased sensation. Referred to peds neuro. RTC 6/10 with same symptoms. Had been seen by consultant & was to start accupuncture.

Other Meds: none

Lab Data:

History: hx of asthma, acid reflux PMH: Seizure in 2006. Allergic rhinitis. family hx of DM, asthma, allergy & obesity.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313224-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	21-May-2008	Unknown		23-May-2008	30-May-2008	OH		18-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt walked to front making next appointment. The next thing the pt fainted. Pt got up rested a few minutes and was fine. Pt walked to front of the office and fell down. We helped her up a made her rest we gave her water/pop and crakers.

Other Meds: None

Lab Data:

History: Hypoglycemia

Prex Illness:

Prex Vax Illns:

Vaers Id: 313225-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-May-2008	Unknown		23-May-2008	30-May-2008	AR		30-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2567AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0086X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: As I was injecting the 3rd vaccine ordered for this patient-the patient's mother asked me if we did a pregnancy test on patient. I told her no and asked if a pregnancy test was needed. Mother stated yes. I then asked pt if she was sexually active and she said no. I notified doctor immediately and she ordered a urine pregnancy test. The result of the pregnancy test was positive. I notified doctor immediately. The vaccines that the patient received were Varivax, Gardasil and Menactra. Doctor ordered a referral to OB/GYN. I called doctor's office to get patient an appointment as soon as possible. The receptionist informed the doctor of the situation and he stated patient needed checked in mid-June 08 due to the fact patient states is about 10 days late for menstrual cycle. The receptionist informed med that this patient also had a history of miscarriage in 2007. I informed doctor of this. Patient has an appointment with doctor June 18, 2008. Referral for the appointment was given to Mother and I stressed importance of keeping the appointment as scheduled. Mother verbalized understanding.

Other Meds: None known

Lab Data: CBC; Urine HCG done 3:15 pm + result

History: Anemia, Scoliosis

Prex Illness: None known

Prex Vax Illns:

Vaers Id: **313239-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	FL	WAES0804USA04810	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a dose of GARDASIL. Subsequently the patient fainted after receiving GARDASIL. On an unspecified date the patient recovered. No product quality complaint was involved. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313240-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	22-Feb-2008	22-Feb-2008	0	19-May-2008	16-Jun-2008	IL	WAES00804USA04849	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a consumer concerning her 12 year old daughter with a penicillin allergy, who on 22-FEB-2008 was vaccinated with the first dose of GARDASIL (Lot # 654272/0073x). There was no concomitant medication. On 22-FEB-2008, approximately one hour post vaccination, the patient developed hives or her legs. The patient sought unspecified medical attention. Diagnostic testing included testing for yeast allergy with no results reported. On 22-FEB-2008 the patient recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: allergy test, for yeast-results not reported

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: 313241-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-Apr-2008	22-Apr-2008	1	19-May-2008	16-Jun-2008	FL	WAES0804USA04876	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	PPV	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Allodynia, Hyperaesthesia

Symptom Text: Information has been received from a pharmacist concerning her 11 year old daughter with allergic reaction to AUGMENTIN who on 21-APR-2008 was vaccinated into the arm (which arm not specified) with a dose of GARDASIL. Concomitant suspect therapy included PNEUMOVAX 23 (manufacturer unknown) into the other arm. The reporter reported that on 22-APR-2008, her daughter experienced allodynia or hyperestesia on the left thigh. She sought medical attention from her physician father. The patient had not recovered. No other details available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **313242-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	TX	WAES0804USA04877	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning an approximately 19 year old female patient who was vaccinated with a dose of GARDASIL. The physician reported that the patient out in hives after she got the dose GARDASIL. It was reported that patient received her injection at another location and a family member who was a nurse administered the vaccination. The outcome of the patient was unknown. No further information was available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313243-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	NH	WAES0804USA04878	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vaginal discharge

Symptom Text: Information has been received for Merck Pregnancy Registry for GARDASIL from a Registered Nurse (R.N.) concerning an 18 year old female patient who had received first and second dose of GARDASIL. It was reported that the second vaccination was given in January or February, 2008. The patient was tested positive on a home pregnancy urine test and sought treatment with the obstetrical provider on 22-APR-2008 who reported this report. It was reported that patient's last menstrual period was on "22-DEC-2008". She was due to be examined on 25-APR-2008 for vaginal discharge that the patient described as "leaking". No adverse symptoms were reported. No other information was available. Patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: beta-human chorionic, 04/22?/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = 12/22/2007)

Prex Vax Illns:

Vaers Id: 313244-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	PA	WAES0804USA04890	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy, Tenderness

Symptom Text: Information has been received from a physician concerning his 16 year old granddaughter with no medical history and no drug allergies, who, on an unspecified date, was vaccinated with a third dose of GARDASIL. There was no concomitant medication. Subsequently, the patient experienced cervical lymphadenopathy of the left side and the area was tender. The patient was seen by the physician. A complete blood count was performed. At the time of the report, the patient had not recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: complete blood cell

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 313245-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		19-May-2008	16-Jun-2008	--	WAES0804USA04949	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Dyspnoea, Eye swelling, Fatigue, Muscular weakness, Nausea, Ocular hyperaemia, Pain, Pharyngolaryngeal pain, Respiratory tract congestion, Swelling, Throat tightness

Symptom Text: Information has been received from a consumer concerning her 18 year old daughter who, on an unspecified date was vaccinated with her second dose of GARDASIL (Lot # and site not reported). Subsequently the patient experienced swelling, pain when being touched or taking a shower, joint pain, muscle weakness, nausea, difficulty breathing, general tiredness, congestion, eye redness, eyes swelling shut. It was reported "the swelling seems to come and go in different places". She has also experienced throat pain, and throat tightness. The mother also reported that her daughter is still experiencing "hurtful swelling and pain to her arms. She can not stay in school she hurts so bad." No further information was provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313246-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	22-Apr-2008	22-Apr-2008	0	19-May-2008	18-Jun-2008	NY	WAES0804USA04951	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Concussion, Head injury, Suture insertion, Syncope

Symptom Text: Information has been received from a physician concerning a female (age not reported) with a history of syncope who on 22-APR-2008 was vaccinated with a second dose of GARDASIL 0.5 IM. On 22-APR-2008 the patient fainted, hit her head in the office after the second dose of GARDASIL. The patient received stitches to the head at this office and was diagnosed with a concussion. At the time of reporting it was unknown if the patient had recovered. No other information was available at this time. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Syncope

Prex Vax Illns:

Vaers Id: 313247-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	23-Apr-2008	23-Apr-2008	0	19-May-2008	18-Jun-2008	NY	WAES0804USA04959	07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Muscle contractions involuntary, Pallor, Tremor

Symptom Text: Information has been received from a physician concerning a 23 year old female who on 23-APR-2008 was vaccinated with the first dose of GARDASIL, (Lot# 0151X), 0.5ml IM to the left deltoid. There was no concomitant medication or other pertinent medical history reported. The physician reported that "3 to 5 seconds post vaccination the client developed trembling of her face muscles which lasted for 6 seconds, and she was pale. This incident occurred just now and the physician observed it happening." The client reported to the physician" she could feel her face muscles shaking." At the tine of the report, the client was resting and being monitored. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 313248-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	21-Apr-2008	21-Apr-2008	0	19-May-2008	16-Jun-2008	--	WAES0804USA04961	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Myalgia, Oral contraception

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female who on 21-APR-2008 was vaccinated with her first dose of GARDASIL (Lot # 660387/1967U). Concomitant therapy included ORTHO-CYCLEN. On 21-APR-2008 the patient experienced generalized muscle aches and dizziness. The patient sought unspecified medical attention by contacting the nurse practitioner. No further information was provided. Additional information has been requested.

Other Meds: ORTHO-CYCLEN

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313249-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA05002	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a physician concerning "a number of patients" (ages not reported), who were vaccinated with GARDASIL (date, dose and route not reported). No concomitant medications or pertinent medical history were specified. "Physician reported that a number of patients stated that it hurt when receiving GARDASIL. The patients reported this after administration while still in the office. The outcome of the event was not reported. No product quality complaint was involved. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313250-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Apr-2007	05-Apr-2007	2	19-May-2008	18-Jun-2008	PA	WAES0804USA05005	07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1757U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Hypoaesthesia, Neck pain, Pain, Paraesthesia, Pharyngolaryngeal pain, Sensory disturbance, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female who on 03-APR-2007 was vaccinated intramuscularly with her first dose of GARDASIL (Lot # 659182/1757U). Concomitant therapy included MENOMUNE-A/C/Y/W-135). On 05-APR-2007, ("two days after vaccination") the patient experienced sensory changes, headaches, numbness and tingling in her arms and legs. By 19-APR-2008, the patients symptoms related to sensory changes, headaches, numbness and tingling in her arms and legs and numbness and tingling in her arms and legs were resolved. On 15-APR-2008 the patient was vaccinated intramuscularly with her second dose of GARDASIL (Lot # 659182/1757U). On 18-APR-2008 was she experienced generalized body aches and a sore throat. By 23-APR-2008 the patient experienced headaches, neck aches, numbness of head, dizziness and body aches. The patient's generalized body aches and sore throat and headaches and neck aches and numbness of head and dizziness and body aches persisted. The patient sought unspecified medical attention with an office visit. No further visit. No further was provided. Additional information has been requested.

Other Meds:

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 313251-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	16-Jun-2008	--	WAES0804USA05028	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inflammation

Symptom Text: Information has been received from an office manager concerning a female (age not reported), who was vaccinated with the 2nd dose of GARDASIL (Lot# not reported, dose, dates, and routes not reported). Concomitant medication and pertinent medical history were unspecified. On an unspecified date the patient developed "inflammation during a pap smear" right around the time she got her second dose of GARDASIL. Unspecified medical attention was sought. The outcome of the event was unspecified. No product quality complaint was involved. Additional information has been requested

Other Meds: Unknown

Lab Data: Pap test, no report

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313252-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	17-Jun-2008	--	WAES0804USA05083	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a health professional concerning a female who was recently vaccinated intramuscularly with her first dose of GARDASIL (lot# 659655/1486U). Subsequently after the vaccination the patient felt woozy. The patient sat down for a while in the office and recovered from being woozy. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313253-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA05089	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain lower, Adverse event

Symptom Text: Information has been received from a nurse practitioner concerning a 14 or 15 year old female who on an unspecified date was vaccinated with her second dose of GARDASIL (lot #, route and site not reported). "A couple of days later" the patient developed "symptoms of appendicitis; right lower quadrant pain". The patient went to the emergency room and "was told her symptom was a known adverse event related to GARDASIL". The patient was not hospitalized and on an unspecified date recovered. The patient has been vaccinated with her third dose of GARDASIL and had no other symptoms. No other information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313254-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	16-Jun-2008	ID	WAES0804USA05100	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraception, Pain, Pyrexia

Symptom Text: Information has been received from a medical assistant concerning a female who in December 2007, was vaccinated with her first dose of GARDASIL (lot# not reported). Concomitant therapy included hormonal contraceptives (unspecified). In February 2008, the patient was vaccinated with her second dose of GARDASIL (lot# not reported). Subsequently, the patient experienced a fever of 101F and body aches. The patient recovered from a fever of 101F and body aches after 2-3 days. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 313255-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	03-Apr-2008	03-Apr-2008	0	19-May-2008	17-Jun-2008	NJ	WAES0804USA05120	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash erythematous, Rash pruritic

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female who on 03-APR-2008 was vaccinated intramuscularly with her first dose of GARDASIL (lot# 0151X). Concomitant therapy included PROZAC, SEROQUEL and YAZ. On 03-APR-2008 the patient experienced a generalized pruritic erythematous rash. She called the physician's office and was instructed to take BENADRYL 50 mg and ice the site of injection. Subsequently, the patient recovered from generalized pruritic erythematous rash after a few hours. Additional information has been requested.

Other Meds: YAZ, PROZAC, SEROQUEL

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 313256-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		19-May-2008	16-Jun-2008	--	WAES0804USA05121	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Dizziness

Symptom Text: Information has been received from a Nurse concerning a 11 year old female who was vaccinated IM with a 0.5 ml first dose of GARDASIL (lot# 659655/1486U). After the vaccination the patient said she felt anxious and light headed. Unspecified medical attention was sought in the office. The patient sat down for a while and recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313257-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-Aug-2007	27-Oct-2007	60	19-May-2008	17-Jun-2008	NY	WAES0804USA05168	16-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0243U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site necrosis

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with a dose of GARDASIL. Subsequently the patient developed a tissue necrosis. The outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown 7/14/08-records received-10/27/07-site of Gardasil vaccination scar tissue.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313258-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		19-May-2008	16-Jun-2008	MT	WAES0804USA05205	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Injection site pain

Symptom Text: Information has been received from a consumer, for the Pregnancy Registry for GARDASIL, concerning herself, a 23 year old female with a history of drug hypersensitivity to PAXIL who in December 2007 was vaccinated with a first dose of GARDASIL (lot# not reported). On an unspecified date the patient was vaccinated 0.5mL, IM with a second dose of GARDASIL (lot# not reported). Subsequently the patient became pregnant after her second dose (LMP approximately 12-MAR-2008, "1.5 to 2 months gestation"). On an unspecified date the patient had a pregnancy test and a sonogram. Also, it was reported that the patient experienced soreness at the injection site after the second vaccination with GARDASIL. The patient sought unspecified medical attention. The patient outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound; beta-human chorionic, posit

History: Drug hypersensitivity

Prex Illness:

Prex Vax Illns:

Vaers Id: **313259-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	17-Jun-2008	--	WAES0804USA05213	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who was vaccinated with the first dose of GARDASIL (Lot number not reported). Subsequently the patient developed redness on the injection site. The patient sought medical attention by speaking with the nurse practitioner. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313260-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA05217	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Injection site erythema, Injection site pain, Injection site swelling, Myalgia, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning her 17 year old old daughter who in January 2007, was vaccinated IM with a 0.5 ml first dose of GARDASIL. In March, 2007 the patient received IM a 0.5 ml second dose of GARDASIL. There was no concomitant medication. The mother reported that the patient had swelling on her arm at the injection site, redness, pain, muscle pain over body, and chills lasting for 3 days a few hours after her second dose in March 2007. Patient was not able to attend school. The first dose, which had same symptoms but to a lesser degree, was in January 2007 and was not sure how long the lasted. Medical attention was not sought. On an unspecified date the patient recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313261-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	04-Jan-2008		19-May-2008	16-Jun-2008	IL	WAES0804USA05235	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Crying, Musculoskeletal pain

Symptom Text: Information has been received from a nurse concerning a 15 year old female with no medical history and no known allergies who on 23-OCT-2007 was vaccinated IM with the first 0.5 ml dose of GARDASIL. On 04-JAN-2008 the patient was vaccinated with IM with the second 0.5 ml dose of GARDASIL (Lot # 658563/1063U) and on an unspecified date was vaccinated IM with the third 0.5 ml dose of GARDASIL (Lot # 65863/1063U). Concomitant therapy included birth control shot. The patient cried with the second dose but did not have severe pain. After the third dose, the patient experienced severe pain radiating to her shoulder and elbow. She was doubled over in pain. She was treated at home with an ice pack and TYLENOL. At the time of reporting, patient was recovering. Unknown medical attention was sought in the office. No product quality complaint was involved. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313262-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	17-Jun-2008	--	WAES0804USA05236	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema

Symptom Text: Information has been received from a nurse practitioner concerning a female (age unknown), who, on an unspecified date, was vaccinated with a first dose of GARDASIL. Subsequently, the patient developed redness at the injection site in the "shape of a band aid." It was reported that the patient would put a band aid on the area and the mark was still there. On an unspecified date the patient returned to the office for her second dose of GARDASIL and the redness at the injection site had not resolved. The patient sought unspecified medical attention. At the time of the report, the outcome of the patient was unknown. No product quality complaint was involved. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313263-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Apr-2008	14-Apr-2008	0	19-May-2008	17-Jun-2008	VA	WAES0804USA05250	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Syncope

Symptom Text: Information has been received from a billing manager concerning a 14 year old female who on 25-SEP-2007 was vaccinated with a 1st dose of GARDASIL (lot# 658282/0929U). On 10-DEC-2007 the patient was vaccinated with a 2nd dose of GARDASIL (lot# 656372/0243U). On 14-APR-2008 the patient was vaccinated with a 3rd dose of GARDASIL (lot# 659441/1446U). Concomitant therapy included HAVRIX, lot# AVB223AA). Subsequently, on 14-APR-2008 the patient fainted 5 minutes after receiving her 3rd dose. The nurse held the patient. The patient felt weak so she laid down for 10-15 minutes. The patient was given water and after 15 minutes, she was fine. The patient had no symptoms following the previous 2 doses. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313264-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	17-Jun-2008	--	WAES0804USA05273	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a medical technologist, concerning a female patient (age not specified), who on unknown dates was vaccinated with the first and second doses of GARDASIL. Subsequently, during a routine cervical cancer screen, the patient was found to be positive for both low risk and high risk human papilloma virus. At the time of this report, the patient had not recovered. No further information was available. Additional information has been requested. This is one of 2 reports from the same source.

Other Meds: Unknown

Lab Data: Cervical smear, positive HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313265-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	AL	WAES0804USA05281	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a 0.5 ml third dose of GARDASIL (lot# not provided). The physician reported patient about 6 months after receiving her third dose of GARDASIL experienced genital warts. Unspecified medical attention was sought. The patient's outcome is unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313266-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-May-2007	Unknown		19-May-2008	18-Jun-2008	PA	WAES0804USA05285	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Inappropriate schedule of drug administration, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 14 year old female who between October 2006 and May 2007 the patient was vaccinated with her 3 doses of GARDASIL (lot# not reported). It was reported that after May 2007 the patient inadvertently received 2 additional doses of GARDASIL (lot# not provided) from a different physician's office. In April 2008 ("last week"), the patient developed headaches and leg pain. Patient outcome was not reported. The patient sought medical attention at the physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313276-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Oct-2007	22-Oct-2007	0	19-May-2008	16-Jun-2008	--	WAES0804USA05303	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Injection site rash, Nausea, Pyrexia

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female who on 22-OCT-2007 was vaccinated with a 2nd dose of GARDASIL (lot#658563/1063U). On 22-OCT-2007 the patient developed a fever, rash at injection site, and also experienced nausea and chills after receiving her vaccination. Subsequently, the patient recovered from fever, rash at injection site, nausea and chills 1 or 2 days later. The patient sought unspecified medical attention by calling the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313277-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	TX	WAES0804USA05328	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the first 0.5 ml dose of GARDASIL (no lot number provided). The patient developed hives a few days after the vaccination. The hives did clear up but broke out again after a few weeks. The patient had not received the second dose of GARDASIL yet which was why the physician believed her experienced was not related to the GARDASIL. Unknown medical attention was sought. At time of reporting, patient outcome was not reported. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313278-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	22-Feb-2008	Unknown		19-May-2008	18-Jun-2008	GA	WAES0804USA05338	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site anaesthesia

Symptom Text: Information has been received from a nurse concerning a 22 year old female who on 22-FEB-2008 was vaccinated with GARDASIL (Lot # site and route not reported). Subsequently the patient experienced numbness at injection site. No further information was available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313279-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	23-Apr-2008	23-Apr-2008	0	19-May-2008	17-Jun-2008	AL	WAES0804USA05357	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female who on 23-APR-2008 was vaccinated with GARDASIL (Lot #, dose and site not reported). On 23-APR-2008 the patient fainted after receiving GARDASIL. Approximately 10 minutes after fainting, the patient recovered. No further information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313280-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	04-Apr-2008	14-Apr-2008	10	19-May-2008	18-Jun-2008	OH	WAES0804USA05371	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a health professional concerning a white patient (gender not reported) who on 04-APR-2008 was vaccinated IM into the deltoid with a first dose of GARDASIL (lot # 659182/1757U). On 14-APR-2008 the patient complained of rash ("7 days after injection") to both wrists. Subsequently, the patient recovered on it's own on 18-APR-2008. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313281-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	18-Apr-2008	18-Apr-2008	0	19-May-2008	16-Jun-2008	CA	WAES0804USA05434	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a "13-15 year old" female who "last week" (on approximately 18-APR-2008) was vaccinated with a first dose of GARDASIL (Lot # not reported). Concomitant therapy included MENACTRA and Tdap. It was reported that the patient received GARDASIL and fainted. Subsequently, the patient recovered from fainting (date unspecified). The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313282-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	24-Apr-2008	24-Apr-2008	0	19-May-2008	17-Jun-2008	FL	WAES0804USA05435	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cold sweat, Deafness, Dizziness, Flushing, Injection site pain, Visual disturbance

Symptom Text: Information has been received from a physician concerning a 19 year old Caucasian female student with moderate dysplasia, HPV, and abnormal pap smear (CIN 2 with high risk HPV types) who on 24-APR-2008 was vaccinated IM in the left deltoid with the first 0.5 ml dose of GARDASIL (Lot# 659437/1266U). Concomitant therapy included DEPO-PROVERA. On 24-APR-2008 the patient became dizzy, clammy, flushed and reported that the injection was painful. Subsequently, the patient recovered on 24-APR-2008 from dizzy, clammy, flushed and injection pain. Unknown medical attention was sought in the office. No product quality complaint was involved. Follow up information was received that indicated that immediately following the injection, the patient became very dizzy, clammy, and her cheeks were flushed. The patient felt as though she was going to lose consciousness. She also reported visual and audible "waves". The symptoms lasted approximately 8 - 10 minutes. On 24-APR-2008, the patient was recovered. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: Colposcopy, 04/23/08, colposcopy with biopsy; Pap test, CIN 2 with high risk HPV types identified.

History:

Prex Illness: Papilloma viral infection; Papanicolaou smear abnormal.

Prex Vax Illns:

Vaers Id: **313283-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA05481	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contusion, Oral mucosal petechiae, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse practitioner concerning a female with a history of rhabdomyosarcoma who was vaccinated IM with the second 0.5 ml dose of GARDASIL. After the vaccination, the patient developed bruising on the arm opposite the injection site and on both thighs. She also had petechiae on her pallet. The patient noted that the same symptoms also developed after dose one of the series. Unknown medical attention was sought in the office. At the time of reporting, the patient was recovering. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Rhabdomyosarcoma

Prex Illness:

Prex Vax Illns:

Vaers Id: **313284-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA05505	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with her first dose of GARDASIL (Lot #, site and route not reported). Subsequently, the patient developed a lump at the injection site. The lump lasted 3 to 4 days. No further information was provided. Additional has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313285-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	24-Apr-2008	24-Apr-2008	0	19-May-2008	18-Jun-2008	NY	WAES0804USA05540	18-Jun-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HIBV	MERCK & CO. INC.	NULL		Unknown	Unknown	
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a female who on 24-APR-2008 was vaccinated with a dose of GARDASIL (number of dose and lot number not reported). Concomitant therapy included PEDVAXHIB and MENACTRA (lot numbers not reported). On 24-APR-2008 the patient fainted after receiving GARDASIL. Subsequently, the patient recovered from fainting on an unspecified date. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313286-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	27-Apr-2007	Unknown		19-May-2008	16-Jun-2008	FL	WAES0804USA05546	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site pain

Symptom Text: Information has been received from a nurse concerning her 12 year old daughter who on 02-MAR-2007 was vaccinated IM with the first dose of GARDASIL. On 27-APR-2007, the patient was vaccinated IM with the second dose of GARDASIL and on 17-AUG-2007, the patient was vaccinated IM with the third dose of GARDASIL. The patient reported pain in the arm at the injection site for 3 days after the vaccination was given. The pain in the arm included not being able to lift the arm. The nurse also reported that since multiple patients (3 patients) reported pain in their arms, they started giving the vaccination in the buttocks to an unspecified number of patients. Unknown medical attention was sought through contact with the nurse. Patient outcome was unknown. No product quality complaint was involved. This is one of the multiple cases from the same source (WAES # 0805USA01521 and 0805USA01522). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313287-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Oct-2007	01-Oct-2007	0	19-May-2008	18-Jun-2008	--	WAES0804USA05937	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Amenorrhoea, Diarrhoea, Nausea, Rash, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning her sister who on an unspecified date in October 2007, was vaccinated "by injection" with a 0.5 mL first dose of GARDASIL (lot # not reported). On an unspecified date in November 2007 the patient was vaccinated with a second dose of GARDASIL (lot # not reported). On an unspecified date in April 2008, the patient was vaccinated with a third dose of GARDASIL (lot # not reported). There was no concomitant medication. The consumer reported that "the patient experienced nausea, stomach ache, diarrhea, abdominal pain and rash after getting all three doses". It was also reported that the "patient's LMP was in November 2007 and did a pregnancy test but she is not pregnant". The patient sought unspecified medical attention. The nausea, stomach ache, diarrhea, abdominal pain, rash and amenorrhea persisted. Laboratory tests included a CT scan, blood test and urine test. The results of the CT scan, blood test and urine test were not reported. No further information is available.

Other Meds: None

Lab Data: computed axial; diagnostic laboratory - blood test; beta-human chorionic - not pregnant; urinalysis

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 313288-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	25-Mar-2008	25-Mar-2008	0	19-May-2008	18-Jun-2008	--	WAES0804USA06011	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pain in extremity

Symptom Text: Information has been received from a consumer concerning a female (age unknown), who on approximately 25-MAR-2008 was vaccinated with a second dose of GARDASIL. Subsequently, the patient was pregnant and experienced a sore arm. The patient sought unspecified medical attention. At the time of the report the patient was approximately 8 weeks gestation. The patient's last menstrual period was approximately 02-MAR-2008 and her estimated delivery date was 07-DEC-2008. No laboratory diagnostics were performed. At the time of the report, the outcome of the patient was unknown. No product quality complaint was involved. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 3/2/2008)

Prex Vax Illns:

Vaers Id: **313289-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	26-Apr-2008	26-Apr-2008	0	19-May-2008	16-Jun-2008	RI	WAES0804USA06016	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a nurse concerning a female who on 26-APR-2008 was vaccinated intramuscularly with a third dose of GARDASIL (lot # not reported). The nurse reported that the patient received the dose in the morning and in the afternoon, she complained of hives that appeared from her neck up. The patient sought medical attention during a phone call to the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313290-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	26-Apr-2008	26-Apr-2008	0	19-May-2008	17-Jun-2008	RI	WAES0804USA06054	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash papular

Symptom Text: Information has been received from a health professional concerning a 25 year old female with no medical history and no drug allergies, who on 22-OCT-2007 was vaccinated IM in the right deltoid with a first dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). On 20-DEC-2007 the patient was vaccinated with a second dose of GARDASIL. The patient received dose one and two without any complaints. On 26-APR-2008 the patient was vaccinated with a third dose of GARDASIL (Lot# 654272/0073X). On 26-APR-2008 the patient developed bumps all over her face and on the arms. The bumps were not itchy or red. The patient called the office. No laboratory diagnostics were performed. At the time of the report, the patient had not recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 313291-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		19-May-2008	16-Jun-2008	--	WAES0804USA06060	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Migraine

Symptom Text: Information has been received from a registered nurse concerning a 12 year old female with no medical history and no drug allergies, who "one month ago" was vaccinated with a first dose of GARDASIL. There was no concomitant medication. Subsequently, the patient experienced prolonged migraine headaches. The patient was seen by her physician. At the time of the report, the patient had not recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 313292-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		19-May-2008	16-Jun-2008	ME	WAES0804USA06067	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site mass

Symptom Text: Information has been received from a physician concerning a 19 female, who, on an unspecified date, was vaccinated with a second dose of GARDASIL. Subsequently, the patient developed a delayed injection site reaction. It was reported that the vaccine was administered on a Friday and Saturday the patient developed redness at the injection site. On Sunday the patient developed a hard lump on the arm. It was noted that the patient had tested positive for human papilloma virus at a prior Pap smear. The patient sought unspecified medical attention. The patient recovered on an unspecified date. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear, positive for HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313293-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	CA	WAES0804USA02539	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from an office manager concerning a female who was vaccinated IM with a 0.5 ml dose of GARDASIL (dose# unknown). Within minutes the patient fainted. Unknown medical attention was sought in the physician's office. The patient was quickly recovered. This is one of two cases from the same source (WAES# 0804USA03629). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313294-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	NY	WAES0804USA06162	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician, via a company representative, concerning a female patient (age not reported) with an allergy to aluminum, who on an unknown date was vaccinated with the first dose of GARDASIL (lot # not reported). Within 24 hours, she developed hives. The patient called the physician, and was instructed to take BENADRYL. Subsequently, the patient recovered (duration not specified). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Allergy to metals

Prex Vax Illns:

Vaers Id: **313296-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Feb-2008	Unknown		19-May-2008	16-Jun-2008	CA	WAES0804USA06272	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Menstrual disorder

Symptom Text: Information has been received through the Merck pregnancy registry, for GARDASIL concerning a female patient who in February 2008, was vaccinated with a dose of GARDASIL. Subsequently, the patient had abnormal periods and became pregnant. The patient sought unspecified medical attention. At the time of this report the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 313297-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	16-Jun-2008	OK	WAES0804USA02633	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Human papilloma virus test positive

Symptom Text: Information has been received from a nurse concerning her daughter (age unknown) with unknown medical history, who was vaccinated (route unknown) with all three doses of GARDASIL (Lot #'s unknown). Subsequently, on an unknown date, the patient tested positive for "high grade" HPV infection even after receiving all three doses. Lab diagnostic studies performed was a "HPV test" (results: + for "high grade" HPV). Outcome unknown. The patient was seen by a physician for unspecified medical attention. No product quality complaint was involved. Additional information is not expected.

Other Meds: Unknown

Lab Data: cervix HPV DNA assay, + "high grade" HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313298-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Apr-2008	08-Apr-2008	7	19-May-2008	17-Jun-2008	KY	WAES0804USA06303	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site mass

Symptom Text: Information has been received from a licensed practical nurse concerning a 25 year old female patient with no medical history and a penicillin allergy who on 01-APR-2008 was vaccinated intramuscularly into the left arm with the first 0.5 ml dose of GARDASIL (Lot # 659962/1740U). Concomitant therapy included hormonal contraceptives (unspecified), ACIPHEX and minocycline. On approximately 08-APR-2008, about one week after receiving the vaccination, the patient developed a hardened knot at the injection site. On 27-APR-2008 the patient reported that the hardened knot had increased by five times. The patient was examined by the physician on 28-APR-2008 and the adverse injection site reaction was palpable and the size of a marble. The area was not reddened, painful or swollen. The nurse reported that she did not know if the patient had a hematoma. The nurse called the patient on 06-MAY-2008 to inquire if the patient recovered. The patient did not return the nurse's phone call. It was reported that there are no other symptoms. No treatment was provided. No diagnostic laboratory studies were performed. At the time of this report the patient's outcome had not recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: Hormonal contraceptives; minocycline; ACIPHEX

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **313299-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	VA	WAES0804USA06305	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has bee received from a physician concerning a female patient who was vaccinated intramuscularly with a 0.5 ml dose of GARDASIL. "Within five minutes" of vaccination, the patient fainted. The patient sought unspecified medical attention. Subsequently, the patient recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313300-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	OR	WAES0804USA02710	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with all three doses of GARDASIL (lot#'s not reported) at a different office. The physician is treating the patient because she is experiencing headaches that she did not have before the vaccination series. The patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313301-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	CO	WAES0804USA06335	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site vesicles, Skin reaction

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated intramuscularly with the first dose of GARDASIL. Subsequently, the patient experienced a skin reaction or what was described as half a boiled egg and her skin was bubbling a little at the injection site. No medical attention was sought. Subsequently, the patient recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313302-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Apr-2008	28-Apr-2008	2	19-May-2008	18-Jun-2008	PA	WAES0804USA06343	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Rash pruritic

Symptom Text: Information has been received from a staff member of a physician's office, via a company representative, concerning a 15 year old female patient, who on 26-APR-2008 was vaccinated IM, with the second dose, 0.5 ml, of GARDASIL (lot # 659182/1757U). On 28-APR-2008 the patient developed an itchy rash on her arms and legs. The patient called the physician on the phone, but an office visit was not reported (treatment not specified). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313303-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	16-Jun-2008	MD	WAES0804USA02759	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated intramuscularly with GARDASIL (lot # not reported). Subsequently, the patient fainted. The patient sought unspecified medical attention. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313304-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	MO	WAES0804USA06344	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Somnolence

Symptom Text: Information has been received from a physician concerning a female who was vaccinated on an unspecified date with GARDASIL (lot # not provided). Concomitant therapy included DEPO-PROVERA. Subsequently the patient experienced extreme drowsiness within an hour after receiving GARDASIL. The patient's outcome was not reported. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313305-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	17-Jun-2008	NY	WAES0804USA06353	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a nurse and a physician concerning a female (age not reported) who, on an unspecified date, was vaccinated with a 0.5 mL dose of GARDASIL into the gluteal. There was no concomitant medication. Subsequently, the patient developed notable pain at the injection site. Outcome was not reported. The patient sought medical attention in the office. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313306-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Apr-2008	22-Apr-2008	0	19-May-2008	16-Jun-2008	CA	WAES0804USA06365	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Ear pain, Mastication disorder, Syncope

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 22-APR-2008 was vaccinated with a first dose of GARDASIL (lot# 659964/1979U). Concomitant therapy included a dose of MENACTRA. It was reported that the patient fainted after her vaccination. On approximately 22-APR-2008 "one to one and a half weeks ago" the patient experienced an earache and had problems

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313307-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	16-Jan-2007	01-Apr-2007	75	19-May-2008	18-Jun-2008	--	WAES0804USA06373	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0961F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Gastrointestinal disorder, Inappropriate schedule of drug administration, Lymphadenopathy, Pain

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female who on 16-JAN-2007, 11-JUL-2008, and on 18-JAN-2008 was vaccinated IM with a 0.5 ml first, second and third dose of GARDASIL, respectively (first dose lot# 654389/0961F, second dose lot # 658100/05250, and third dose lot# 659653/1448U . There was no concomitant medication. Within the past year, the patient experienced swollen glands, fatigue and digestive problems. The patient had an office visit with the family physician. An HIV test was negative and the patient underwent other unspecified lab diagnostic studies. The patient's swollen glands and fatigue and digestive problems persisted. No product quality complaint was involved. Additional quality has been requested. 06/03/2008 Brief office note dated 4/30/08 received. Pt called to say she had a 1 yr long hx of swollen glands, aches, and fatigue. Testing has been (-) for Lymes, mono, and HIV. Was not treated or seen in that office since vaccines

Other Meds: None

Lab Data: diagnostic laboratory - unspecified lab and diagnostic studies; HIV genotypic drug - negative . Testing has been (-) for Lymes, mono, and HIV.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **313308-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	17-Jun-2008	PA	WAES0804USA06388	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise, Vomiting

Symptom Text: Information has been received from a physician concerning a female who was vaccinated on an unspecified date with her first dose of GARDASIL (lot# 654272/0073X). Subsequently the patient became violently ill and was throwing up. The patient was brought back into the office the next day. Her outcome was not reported and it was unclear whether the patient would continue the GARDASIL series. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313309-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		19-May-2008	17-Jun-2008	UT	WAES0804USA06393	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Injection site erythema, Smear cervix abnormal

Symptom Text: Information has been received from a registered nurse concerning a 26 year old female with a penicillin allergy and no medical history, who in January 2007, was vaccinated with a first dose of GARDASIL. There was no concomitant medication. In approximately January 2008, the patient developed a reddened injection site and then a delayed onset of fatigue three weeks later. It was also reported that the patient had an abnormal papanicolaou test (it was negative for human papillomavirus). It was also reported that the patient was under the care of another provider. The patient did not seek medical treatment for the symptoms. Subsequently, the patient recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: Pap test, abnormal - negative for human papillomavirus.

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **313310-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	08-Apr-2008	09-Apr-2008	1	19-May-2008	18-Jun-2008	VA	WAES0804USA02773	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hepatic enzyme abnormal, Infectious mononucleosis

Symptom Text: Information has been received from a physician concerning an 18 year old female, with a history of cardiac irregularity detected during an athletic physical, who on 08-APR-2008 was vaccinated with second dose of GARDASIL (lot # not reported). Concomitant therapy included HAVRIX, administered on 08-APR-2008. Blood work taken on 09-APR-2008 showed elevated liver enzymes were positive for mononucleosis. AST (SGOT) level was 129 and her ALT (SGPT) level was 223. Her only symptom was fatigue. The patient sought unspecified medical attention during an office visit. The patient's elevated liver enzymes and mononucleosis persisted. Additional information has been requested.

Other Meds:

Lab Data: diagnostic laboratory, 04/09/08, posit, mononucleosis; serum aspartate, 04/09/08, 129; serum alanine, 04/09/08, 223

History: Cardiac disorder

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313311-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		27-May-2008	30-May-2008	OK	WAES0804USA02795	02-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with GARDASIL (lot # not reported). Subsequently on an unspecified date, the patient "experienced a rash." The patient sought unspecified medical attention. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313312-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	17-Jun-2008	TX	WAES0804USA02801	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain, Syncope

Symptom Text: Information has been received from a physician concerning a female (age unknown) with no pertinent medical history, who was vaccinated (route unknown) with a first and second dose of GARDASIL (Lot #'s unknown). The physician indicated that the patient reported after the first dose it was painful. When the patient received the second dose, "just last week", she reported no pain; however, she fainted. The patient's outcome is reported as recovered. Unspecified medical attention was sought. No product quality complaint was involved. No additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313313-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	29-May-2007	29-May-2007	0	19-May-2008	16-Jun-2008	--	WAES0804USA06400	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Malaise, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a 25 year old female with no allergies or medical history, who on 29-MAY-2007 was vaccinated with a first dose of GARDASIL. There was no concomitant medication. On 29-MAY-2007 a couple hours post vaccination, the patient felt sick, tired and experienced a fever. On 08-FEB-2008, the patient was vaccinated with a second dose of GARDASIL. On 08-FEB-2008 the patient felt tired, sick and developed a fever. Unspecified medical attention was sought. No diagnostic studies were performed. The next day after experiencing the events, the patient recovered. No product quality complaint was involved. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **313314-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	28-Apr-2008	28-Apr-2008	0	19-May-2008	17-Jun-2008	AZ	WAES0804USA06414	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Nausea, Syncope

Symptom Text: Information has been received from a physician concerning an 11 year old female who on 28-APR-2008 was vaccinated with a first dose of GARDASIL 0.5 ml IM in the arm. Concomitant therapy also given at the same office visit on 28-APR-2008 included MENACTRA, and "PTD" (unspecified). GARDASIL and "PTD" was given in the same arm. On 28-APR-2008, immediately after being vaccinated, the patient experienced syncope, nausea, and passed out. The patient was kept in the office for 30 minutes until her "high pressure went down". On an unspecified date, the patient recovered. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313315-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Aug-2007	28-Aug-2007	0	19-May-2008	16-Jun-2008	NY	WAES0804USA06445	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a physician's office concerning a 15 year old female patient who on 28-AUG-2007 at 10:30 AM was vaccinated IM into right upper arm with a first dose of GARDASIL lot # 658556/1060U) and on 14-NOV-2007 she was vaccinated IM into left upper arm with a second dose of GARDASIL (lot #658488/1264U). It was reported that patient got nausea and vomiting for two days after each vaccination of GARDASIL. She was reported to be recovered on an unspecified day. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313316-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0804USA02810	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaginal haemorrhage

Symptom Text: Information has been received from a company representative who overheard a physician in a hospital talking to another physician and he said that a female who was vaccinated with a single dose of GARDASIL (lot# not provided) experienced heavy vaginal bleeding. The patient's outcome was not reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313317-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	17-Jun-2008	--	WAES0804USA06461	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Syncope

Symptom Text: Information has been received from a consumer concerning her daughter who in April 2008, was vaccinated with a dose of GARDASIL. The reporter reported that her daughter fainted after receiving the GARDASIL. Shortly after the vaccination, the patient experienced a debilitating anxiety attack and she was in a fragile state of anxiety. The outcome was unknown. Additional information is not available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313318-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Feb-2008	29-Feb-2008	0	19-May-2008	17-Jun-2008	PA	WAES0804USA06474	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site swelling

Symptom Text: Information has been received from a health care worker concerning a 17 year old female with pertinent medical history and concomitant medications reported as unspecified, who on approximately 29-FEB-2008 (2 months ago), was vaccinated with her first dose of GARDASIL, IM, (Lot# not reported). A few hours after her vaccination, she developed injection site swelling and sought unspecified medical attention. It was reported that the swelling measured 6 inches by 3 inches, and resolved about 5 days later (approximately 05-Mar-2008). No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313319-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	22-Apr-2008	22-Apr-2008	0	19-May-2008	18-Jun-2008	--	WAES0805USA00022	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 10 year old female who on approximately 22-APR-2008 (a week ago) was vaccinated with a dose of GARDASIL, 0.5 mL. Concomitant medication was not reported. While in the physician's office, the patient experienced syncopal episode after receiving the GARDASIL. The outcome and causality of the event were not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313320-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	07-Feb-2008	07-Feb-2008	0	19-May-2008	18-Jun-2008	--	WAES0805USA00025	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from the agency (#2008023-2478662) from a nurse concerning an 11 year old female, who had reached menarche 8 months prior (approximately Nov-2006), who on 31-JUL-2007 was vaccinated with the first dose of GARDASIL, IM, (Lot # and dose not specified). On 04-OCT-2007 the second dose of GARDASIL, IM, (Lot # and dose not specified) was administered. On 07-FEB-2008 the third dose of GARDASIL (Lot #, dose and route not specified) was administered. The patient's mother reports that the GARDASIL vaccinations caused her daughter to stop menstruating. It was unknown if the daughters periods were regular. The outcome of the event was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313321-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		19-May-2008	17-Jun-2008	NY	WAES0805USA00044	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Appendicitis

Symptom Text: Information has been received from a medical assistant concerning a 14 year old female with pertinent medical history reported as unspecified, who was vaccinated with a second dose of GARDASIL (Lot#, date, dose, and route unspecified). Concomitant therapy included other unspecified vaccines normal to that age frame during the same visit. It was reported that the patient developed appendicitis 2 - 3 months later, sought unspecified medical attention and recovered on an unspecified date. No other details were provided. No product quality complaint was involved. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313322-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Apr-2008	16-Apr-2008	1	19-May-2008	18-Jun-2008	NJ	WAES0805USA00051	07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Gaze palsy, Headache, Muscle rigidity, Opisthotonus, Posturing, Syncope

Symptom Text: Information has been received from a nurse concerning a 12 year old female with a history of "fainting incidence with medical procedures" (the patient's mother stated that the patient has had "3 previous fainting incidence with medical procedures throughout her life; the patient had fainted once when she was 3 years old when she skinned her knee and it was being cleaned by her mother), who on 10-SEP-2007 was vaccinated with the first dose of GARDASIL, (Lot# dose, and route not reported) and VARIVAX, (Lot #, dose and route not reported). On 16-APR-2008, the patient was vaccinated with her first dose of VAQTA, second dose of GARDASIL (Lot# dose, and route not reported) and VARIVAX, (Lot #, dose and route not reported), the patient fainted after the injections as per the physician report. The nurse reported that when she was called into the room by the physician the patient was sitting in the chair. Her back arched, eyes were opened and rolled back. She had posturing of the left hand and her body was rigid. The patient was lowered to the floor and came to. The incident lasted a total of one minute. The patient had not eaten breakfast, she was given something to eat, observed in the office, and was released home with her mother. The next day the patient suffered from a headache that she was kept home from school for. It was reported that the patient recovered on 18-APR-2008. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Syncope

Prex Illness:

Prex Vax Illns:

Vaers Id: **313323-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	17-Jun-2008	MI	WAES0805USA00057	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Heart rate increased

Symptom Text: Information has been received from a physician concerning a female (age unreported) with a history of being overly anxious who was vaccinated with her first dose of GARDASIL (Lot# date, dose and route unspecified). Concomitant therapy included ADACEL. A little while after receiving her vaccination with GARDASIL she returned to the physicians office with an increased heart rate that subsided that afternoon. No product quality complaint was involved. Additional information has been requested.

Other Meds:

Lab Data:

History: Anxiety

Prex Illness:

Prex Vax Illns:

Vaers Id: **313324-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Apr-2008	29-Apr-2008	0	19-May-2008	16-Jun-2008	NY	WAES0805USA00096	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Eye rolling, Fall, Hyperhidrosis, Influenza, Muscle spasms, Pain, Pallor

Symptom Text: Information has been received from a nurse concerning a 14 year old female with no medical history or known drug allergies who on 20-FEB-2008 was vaccinated IM in the left deltoid with a first dose of GARDASIL (lot # 659437/1266U). On 29-APR-2008 the patient was vaccinated at 4 PM with a second dose of GARDASIL (lot # 660391/0063X). Later that day she started her period. She took naproxen. On 30-APR-2008, at 4 AM the patient was diaphoretic, pale, and experienced cramps. The patient took 3 tablets of ADVIL. The mother of the patient, who called the office on 30-APR-2008 at 9:10 AM, also reported that the patient fell on the floor, her eyes rolled back and "came to", the patient continues to be extremely diaphoretic, dizzy, weak, pale with body aches and pains, and her symptoms are similar to the flu. At the time of reporting, the patient had not recovered. The mother was advised to take the patient to her primary physician if symptoms did not improve. No product quality complaint was involved.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **313325-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	GA	WAES0805USA00105	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Information has been received from a physician concerning a female (age not reported) who on an unspecified date was vaccinated with second dose of GARDASIL. Subsequently on an unspecified date the patient experienced joint pain after receiving the second dose of GARDASIL. Unspecified medical attention was sought. No additional information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313326-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	24-Apr-2008	24-Apr-2008	0	19-May-2008	16-Jun-2008	OH	WAES0805USA00108	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Rash erythematous

Symptom Text: Information has been received from a nurse concerning a 13 year old female with no medical history or known drug allergies who on 24-APR-2008 was vaccinated IM with a 0.5 mL first dose of GARDASIL (lot # 659653/1448U). There was no concomitant medication. On 24-APR-2008, 20 minutes after receiving the dose, the patient developed a red rash on her left face, chin, and neck. The rash consisted of an area of redness, without lesions. There was no itching or respiratory problems. The nurse practitioner treated the patient with an unspecified steroid injection and prescribed a MEDROL dose pack. The patient was seen in the office on 28-APR-2008, for an unrelated illness, and the rash had resolved. No product quality complaint was involved.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **313327-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0805USA00113	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a health care worker concerning a female (age not reported) who on an unspecified date was vaccinated with a second dose of GARDASIL. Subsequently the patient fainted after receiving the second dose of GARDASIL. Unspecified medical attention was sought. At the time of reporting it was unknown if the patient had recovered. No further information is available. This report is one of two reports from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313328-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Feb-2008	01-Mar-2008	11	19-May-2008	18-Jun-2008	MA	WAES0805USA00178	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a physician concerning a female with a history of obesity who on 19-FEB-2008 was vaccinated with a first dose of GARDASIL (lot # not reported) and has not menstruated. Concomitant therapy included MENACTRA (lot # not reported). The parent placed a call to the physician's office on 28-APR-2008 the notify and inquire about the situation. Pregnancy has not been determined. Patient outcome was not reported. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Obesity

Prex Illness:

Prex Vax Illns:

Vaers Id: 313329-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Jun-2007	01-Jun-2007	0	19-May-2008	18-Jun-2008	TX	WAES0805USA00197	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pharyngolaryngeal pain

Symptom Text: Information has been received from a physician concerning a 21 year old female who in approximately June 2007, "9 or 10 months ago", was vaccinated "by injection" with a first dose of GARDASIL (lot # not reported). The physician reported that the patient developed a sore throat after receiving the first dose of GARDASIL. The patient sought unspecified medical attention. The patient outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313330-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Oct-2007	Unknown		19-May-2008	16-Jun-2008	MA	WAES0805USA00208	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Polymenorrhoea

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 23-OCT-2007 was vaccinated with GARDASIL (lot number not specified). In October 2007, the patient experienced an increase in the number of menstrual cycles. The doctor is trying an unspecified birth control to help regulate her cycles. On approximately 14-Feb-2008 the patient received her second dose of GARDASIL (lot number not specified). The patient sought unspecified medical attention in the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313331-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	14-Apr-2008	21-Apr-2008	7	19-May-2008	18-Jun-2008	--	WAES0805USA00211	07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Ear pain, Hypoaesthesia, Inappropriate schedule of drug administration, Paraesthesia

Symptom Text: Information has been received from a health professional concerning a 29 year old female who on 14-APR-2008 was IM vaccinated in her left arm with her first dose of GARDASIL (lot number 659964/1978U). Concomitant therapy included hormonal contraceptives (unspecified). On 21-APR-2008 the patient experienced a very painful ear ache. On 22-APR-2008 the patient experienced numbness in the lower left arm and tingling in the lower left arm. This numbness and tingling was not at time of injection site. Subsequently, the patient recovered from the very painful ear ache. The patient's numbness and tingling in the lower left arm persisted. The patient sought unspecified medical care with an office visit. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313332-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	13-Nov-2007	13-Nov-2007	0	19-May-2008	18-Jun-2008	NY	WAES0805USA00214	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Influenza like illness, Injection site pain, Pain, Sleep disorder

Symptom Text: Information has been received from a physician concerning a 24 year old female with a history of sulfonamide allergy who on 13-NOV-2007 was IM vaccinated with her first dose of GARDASIL (lot number 659435/1265U). On 14-JAN-2008 the patient was IM vaccinated with her second dose of GARDASIL (lot number 659435/1265U). On 29-APR-2008 the patient received her third dose of GARDASIL (lot number 660389/1968U) intramuscularly. Concomitant therapy included APRI. On 13-NOV-2007 the patient experienced injection site pain. On 14-JAN-2008 the patient experienced injection site pain. On 29-APR-2008 the patient experienced body aches, felt like she had the flu and barely slept overnight. The patient's body aches, flu-like symptoms and difficulty sleeping persisted. The patient sought medical attention by calling the office. The patient was told to drink fluids and take TYLENOL. The patient missed work due to her symptoms. Additional information has been requested.

Other Meds: APRI

Lab Data: None

History: Sulfonamide allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **313333-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	02-Apr-2008	02-Apr-2008	0	19-May-2008	16-Jun-2008	--	WAES0805USA00218	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a health professional concerning a female who on approximately 02-APR-2008 was vaccinated with GARDASIL (lot number unspecified). "Approximately four weeks ago", on 02-APR-2008, the patient experienced persistent pain in her arm localized to the injection site. There was no nerve pain or pain any where else in her arm. The patient's persistent pain in her arm localized to the injection site persisted. The patient sought unspecified medical treatment. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313334-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	01-Apr-2008		19-May-2008	18-Jun-2008	--	WAES0805USA00255	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hirsutism

Symptom Text: Information has been received from a physician concerning a 12 year old female who was vaccinated with all three 0.5 mL doses of GARDASIL (lot # not reported). After the third dose was administered a small growth of facial hair was noted under her chin within a month. The patient's status was not reported. No laboratory diagnostic test was performed. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313335-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0805USA00257	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Malaise, Syncope

Symptom Text: Information has been received from a physician concerning a female)age not reported) who was vaccinated with the first and second dose of GARDASIL (lot # not reported). The physician reported that the patient fainted after her first dose of GARDASIL (lot # not reported). After the second dose of GARDASIL (lot # not reported), she was lightheaded and complained of being unwell. The patients complaints of not feeling well since the first vaccination. The patient's status was reported as not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 313336-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	23-Apr-2008		19-May-2008	18-Jun-2008	--	WAES0805USA00263	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female (age not reported) who was vaccinated with the first 0.5 mL dose of GARDASIL (lot # not reported). On approximately 23-APR-2008 "last week" the patient fainted after getting the first dose of GARDASIL (lot # not reported). The patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313337-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Jan-2008	01-Jan-2008	0	19-May-2008	18-Jun-2008	--	WAES0805USA00272	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depression, Feeling abnormal, Mood swings, Panic attack

Symptom Text: Information has been received from the mother of a 19 year old female consumer who in early January 2008, was vaccinated with the first dose of GARDASIL (lot not reported), In later February 2008 the patient was vaccinated with the second dose of GARDASIL (lot not reported). There was no concomitant medication. In January 2008, the patient began to experience depression and a feeling of "just not being herself with no known reason". Two weeks after her second dose of GARDASIL (lot not reported), she experienced a panic attack. Her current condition was described as resembling a "hormonal mood swing reaction." There does not seem to be an explanation for these feelings. She experienced these feeling away at college as well as at home. She is being seen by a physician and has an upcoming appointment in early May 2008 for these symptoms. The patient's status was reported as not recovered. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **313338-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-Mar-2008	11-Mar-2008	0	19-May-2008	18-Jun-2008	--	WAES0805USA00348	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hyperhidrosis, Pallor

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 11-Mar-2008 was vaccinated with the first dose of GARDASIL (lot # 659182/1757U). There was no concomitant medication. On 11-MAR-2008 within 15 minutes of sitting after the vaccination, she became pale and started to sweat for 2 to 3 minutes. It was reported that the patient is an athlete and had practice prior to vaccination. The patient's blood pressure and heart rate were taken yielding normal results. The patient recovered on 11-MAR-2008. Additional information has been requested.

Other Meds: None

Lab Data: Blood pressure - normal; diagnostic laboratory - heart rate (normal).

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **313339-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	18-Jun-2008	--	WAES0805USA00354	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a health care worker concerning a female (age not reported) who on an unspecified date was vaccinated with a third dose of GARDASIL. Subsequently the patient developed a rash on her chest after receiving the third dose of GARDASIL. Unspecified medical attention was sought. At the time of reporting it was unknown if the patient had recovered. No further information is available. This is one of two reports from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313340-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	14-Apr-2008	14-Apr-2008	0	19-May-2008	12-Jun-2008	--	WAES0805USA00389	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Ear pain, Hypoaesthesia, Inappropriate schedule of drug administration, Pain of skin, Paraesthesia

Symptom Text: Information has been received from a physician's assistant concerning a 29 year old female who on 14-APR-2008 was vaccinated in the left arm with her first dose of GARDASIL (Lot # not provided). Concomitant therapy included ORTHO TRI-CYCLEN LO. The patient experienced a left ear ache and pain at the left scalp. On or around 20-APR-2008, the patient developed numbness and/or tingling of the left arm. The pain on the ear and scalp did resolve, but the arm sensation still persisted. The patient was treated with VALTREX (time unspecified by reporter) by the primary physician because he suspected that it was shingles, but later ruled that out. The patient sought unspecified medical attention by seeing her primary physician. No other details were provided. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313341-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	12-Jun-2008	KY	WAES0805USA00480	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a female who, on an unspecified date was vaccinated intramuscularly with her first GARDASIL (Lot # and site not reported). "About 2 weeks post vaccination", the patient developed a rash on her torso and the backs of her legs. The patient sought unspecified medical attention. No additional information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313342-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	12-Jun-2008	NC	WAES0805USA00562	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with three doses of GARDASIL. It was reported that patient was positive for HPV r11 6 11 16 18 vlp after getting all three doses of vaccination. The patient did not get the vaccination in the reporting physician's office. No other information to report. The patient was positive for hpv r11 6 11 16 18 vlp at the time of this report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313343-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	23-Apr-2008		19-May-2008	12-Jun-2008	--	WAES0805USA00756	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a female (age not reported) who was vaccinated with the first 0.5 mL dose of GARDASIL (lot # not reported). On approximately 23-APR-2008 "last week" the patient fainted after getting the first dose of GARDASIL (lot # not reported). It was also reported that the patient received on an unspecified date the second dose of GARDASIL (lot # not reported). The patient fainted after the second dose of GARDASIL (lot # not reported) also. The patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313344-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	05-Jun-2007	Unknown		19-May-2008	12-Jun-2008	CA	WAES0805USA00887	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0014U	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Information has been received from a health care professional concerning a 26 year old female who on 03-JUN-2007 was vaccinated with a first dose of GARDASIL (lot# 653736/0014U) in the left deltoid. The consumer reported that she went to the emergency room after her whole left side of her body was numb 2 days after receiving her vaccine. At the time of reporting it was unknown if the patient had recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313345-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-May-2008	12-Jun-2008	KY	WAES0805USA01038	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a female who, on an unspecified date was vaccinated intramuscularly with her first dose of GARDASIL (Lot # and site not reported). "About 72 hours post vaccination", the patient developed a rash on her arms and chest. The patient sought unspecified medical attention. No additional information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313346-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		19-May-2008	12-Jun-2008	--	WAES0805USA01477	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema

Symptom Text: Information has been received from a nurse practitioner concerning a "few" patients (ages and genders unknown), who, on an unspecified dates, were vaccinated with doses of GARDASIL. Subsequently, when the patients were returning to receive another dose of GARDASIL the patients had redness in the :shape of a band aid" at the injection site. At the time of the report, the outcomes of the patients were unknown. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313380-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		27-May-2008	28-May-2008	--	WAES0805USA04719	28-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from the Merck Pregnancy registry for GARDASIL from a female who was vaccinated with a first dose of GARDASIL. Subsequently the patient became pregnant and had a miscarriage. The patient required an doctor office visit. The patient reported that she felt her "doctor was inept and responsible for this." Upon internal review, miscarriage was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313381-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	05-Nov-2007	05-Feb-2008	92	27-May-2008	28-May-2008	FR	WAES0805USA04647	28-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Paralysis, Vocal cord paralysis

Symptom Text: Information has been received from a gynaecologist concerning a 21 year old female who on 05-NOV-2007 was vaccinated with a second dose of GARDASIL. Concomitant medication was not reported. The first dose of GARDASIL was received on 05-NOV-2007 and was well tolerated. On 06-FEB-2008, the patient was diagnosed with paralysis of the recurrent nerve and was admitted to the hospital. The reporting gynaecologist felt that paralysis of the recurrent nerve was not related to therapy with GARDASIL. The symptoms, further course and outcome have not been reported. Other business partner numbers included E2008-04503. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313382-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		27-May-2008	28-May-2008	IL	WAES0805USA04084	28-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for the pregnancy registry for GARDASIL, concerning a female (age not reported) who on an unspecified date was vaccinated with a dose of GARDASIL. The physician reported that the patient did not know she was pregnant, she had a miscarriage. Follow up phone call information provided by a physician's assistant reported that the patient experienced a spontaneous abortion sometime after the first dose of GARDASIL, and prior to the second dose of GARDASIL. The physician's assistant was unable to provide the administration date, dose, or lot numbers. It was reported that the patient's outcome was unknown. Upon internal review, spontaneous abortion was determined to be an other important medical event. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 313383-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-Jul-2007	01-Aug-2007	5	27-May-2008	28-May-2008	MA	WAES0805USA03813	25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain lower, Anaemia, Colitis ulcerative, Fatigue, Haematochezia, Vomiting

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with no medical history or drug allergies reported, who on 27-JUL-2007, 02-SEP-2007 and 06-FEB-2008 (3rd dose also reported as 27-JUL-2008 administered intramuscularly) was vaccinated with the first, second and third doses of GARDASIL, respectively. There was no concomitant medication. In August 2007, after the physician reviewed the patient's past medical history, he noticed that the patient experienced bloody stools in the beginning of August 2007 after her first dose of GARDASIL. On 04-JAN-2008 the patient saw her physician and stated that she was experiencing constant fatigue and tiredness. A blood test was taken and showed that the patient was anemic. The patient was diagnosed with ulcerative colitis and was hospitalized on 08-MAY-2008 (the number of days spent in the hospital were unspecified). At the time of this report the patient has not recovered. No product quality complaint was involved. Ulcerative colitis was considered to be disabling. Additional information has been requested. 6/20/08-records received for DOS 5/7-5/12/08-DC DX:Ulcerative colitis. Blood in stools. Admitted for a flare with worsening bloody stools and crampy lower abdominal pain over past 2-3 weeks.Emesis, diminished urine output. Diagnosed with ulcerative colitis 2/08. Began having blood in stool in 7/07, hid her symptoms, determine to be anemic.

Other Meds: None

Lab Data: diagnostic laboratory, 01/04?/08, anemia 6/20/08-records received-KUB WNL. CBC and chemistry WNL. Endoscopy:Moderate pancolitis.

History: None 6/20/08-records received-Thyroglossal dut cyst status post repair. Minimal GER. Postive ANCA 34.1.

Prex Illness:

Prex Vax Illns:

Vaers Id: **313384-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	12-May-2008	12-May-2008	0	27-May-2008	28-May-2008	--	WAES0805USA03613	06-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cyanosis, Fall, Jaw fracture, Syncope

Symptom Text: Information has been received from a physician concerning a 11 year old female with a history of fainting, who on 12-MAY-2008 was vaccinated with a first dose of GARDASIL. Concomitant vaccination included diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid. On 12-MAY-2008 the nurse had the patient wait for around five minutes post vaccination. The nurse left the room for a second. The patient fainted and fell off of the exam table. The patient was found lying face down and started to turn blue, but had a pulse. The patient was rushed to the hospital and ended up having a maxillary fracture. At the time of the report, the outcome of the patient was unknown. No product quality complaint was involved. The physician considered the fainting, fall off the exam table, turning blue, and maxillary fracture to be other important medical events. Additional information has been requested.

Other Meds:

Lab Data: Pulse oximetry, 05/12/08

History: Syncope

Prex Illness:

Prex Vax Illns:

Vaers Id: **313385-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-May-2008	12-May-2008	0	27-May-2008	28-May-2008	KS	WAES0805USA02363	28-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Cold sweat, Dizziness, Nausea, Pallor

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female patient with no medical history or allergies reported, who on 12-MAY-2008 was vaccinated intramuscularly with the first dose 0.5 ml dose of GARDASIL (Lot #655604/0052X). Concomitant therapy included oral contraceptives (unspecified). On 12-MAY-2008, "within a few minutes of receiving her first dose," the patient became lightheaded, pale, developed a cold sweat and nausea. No diagnostic laboratory testing was performed. On 12-MAY-2008 the patient recovered while in the office. No product quality complaint was involved. The reporter considered lightheadedness, pale, cold sweat and nausea to be disabling for a short time while the patient was in the office. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 313386-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-May-2007	31-May-2007	10	27-May-2008	28-May-2008	--	WAES0707USA04689	09-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Breech delivery, Caesarean section, Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received for the Pregnancy Registry for GARDASIL from a registered nurse concerning a 17 year old female who on 21-MAY-2007 was vaccinated with a first dose of GARDASIL (lot # unknown). On 21-MAY-2007, a cervical smear was performed and the results were within normal limit. A gonorrhea test, HIV test and a rapid plasma reagin card (RPR) test was performed and the results were negative. A Chlamydia test was performed and the results were positive. The date of the patient's last menstrual period was 31-MAY-2007. Medical attention was sought. On 24-JUL-2007, the patient had a beta-human chorionic gonadotropin test (unspecified) that showed positive results for pregnancy. On 24-Jul-2007, the patient was vaccinated with a second dose of GARDASIL (lot# unknown). On 24-JUL-2007, the patient was treated with one gram of ZITHROMAX and 125 mg of ceftriaxone sodium for Chlamydial infection. An HIV and rapid plasma reagin card (RPR) test were also performed and results are pending. The estimated date of delivery is 6-MAR-2008. Follow-up information was received from the physician's office from a health professional. It was reported that the patient delivered a normal, healthy baby girl on 18-FEB-2008 via C-section (baby was breech). The baby weighed 6 pounds 7 ounces. The patient did not breastfeed the infant. The infant developed reflux shortly after birth. No additional information was available. Upon internal review breech presentation was considered to be an other medical event. Additional information is not expected.

Other Meds: ZITHROMAX; ceftriaxone sodium

Lab Data: cervical smear, 05/21/07, within normal limits; Neisseria gonorrhoeae, 05/21/07, negative; cervix Chlamydia, 05/21/07, positive; serum HIV-1 pol, 05/21/07, negative; Rapid plasma reagin, 05/21/07, negative; beta-human chorionic, 07/24/07, p

History:

Prex Illness: Pregnancy NOS (LMP = 5/31/2007); Chlamydial infection

Prex Vax Illns:

Vaers Id: 313387-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-May-2007	20-May-2007	0	27-May-2008	28-May-2008	MA	WAES0707USA04008	28-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Breech presentation, Caesarean section, Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received through the pregnancy registry from a certified nurse midwife concerning an 18 year old female, with no pertinent medical history, who in November 2006, was vaccinated with a dose of GARDASIL. In January 2006, the patient was vaccinated with a second dose of GARDASIL. On 20-MAY-2007, the patient was vaccinated with a third dose of GARDASIL. There was no concomitant medication. Subsequently, the patient became pregnant. In follow up it was reported that on 28-JUN-2007 patient had an ultrasound which was within normal limits. Prenatal lab testing was done, results not reported. The last menstrual period was 20-MAR-2007, with an estimated date of delivery was 25-DEC-2007. Ultrasound done on 28-JUN-2007 for date was reported to be within normal limits. Follow up information was received from a health care professional at the nurse midwife's office on 04-APR-2008. She reported that the baby was normal and healthy. The birthdate was 05-DEC-2007. She didn't have any more information. Follow up information was received from the doctor's office that on 07-DEC-2007, patient had a cesarean section for breech presentation and delivered 39 weeks from her last menstrual period. This information was conflicting with the previously reported information that patient had a normal delivery on 05-DEC-2007. Upon internal review patient's breech baby delivery which required a cesarean section delivery was determined to be an other important medical event. Additional information is not expected.

Other Meds: None

Lab Data: Diagnostic laboratory, prenatal lab testing; Ultrasound, 06/28/07, within normal limits.

History:

Prex Illness: Pregnancy NOS (LMP = 3/20/2007)

Prex Vax Illns:

Vaers Id: **313388-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Jun-2007	12-Jul-2007	16	27-May-2008	28-May-2008	ME	WAES0707USA02304	09-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion, Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed practical nurse concerning a 14 year old female with no pertinent medical history or drug reactions/allergies on 27-FEB-2007 was vaccinated with a first dose of GARDASIL (lot# 654335/0960F) 0.5mL. The date of the last menstrual period was 03-JUN-2007. On 26-JUN-2007 the patient was vaccinated with a second dose of GARDASIL (lot# 658094/0524U). On the same day a urine pregnancy test was performed prior to vaccination and the results was negative for pregnancy. On 12-JUL-2007 a urine test was performed and the results was positive for pregnancy. Medical attention was sought. The estimated date of delivery is 09-MAR-2008. No symptoms have been reported. Follow-up information was received from a health care professional. The HCP indicated that the patient either had a miscarriage or an elective abortion on 02-AUG-2007. No additional information was available. Upon internal review unspecified abortion is considered to be an other medical event. Additional information is not expected.

Other Meds: None

Lab Data: urine beta-human, 06/26/07, negative; urine beta-human, 07/12/07, positive

History:

Prex Illness: Pregnancy NOS (LMP = 6/3/2007)

Prex Vax Illns:

Vaers Id: 313389-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-May-2007	20-Apr-2007	-21	27-May-2008	28-May-2008	--	WAES0706USA02793	03-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0014U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abnormal labour, Anaemia, Caesarean section, Drug exposure during pregnancy, Vomiting

Symptom Text: Information has been received from a nurse practitioner for the Pregnancy Registry for GARDASIL, concerning a 15 year old female with asthma, infection, nausea and oppositional defiant disorder (ODD). On an unspecified date the patient was vaccinated with the first dose of GARDASIL (lot number unknown). Follow up information was received. The nurse practitioner reported that on 11-MAY-2007 the patient received her second dose of GARDASIL (lot# 653736/0014U) and then became pregnant. The date of the last menstrual period was approximately 20-APR-2007. Concomitant therapy included XOPENEX, ZITHROMAX and PENERGAN TABLETS/SUPPOSITORIES. There was no adverse event reported. Medical attention was sought. On 15-JUN-2007 the patient had an ultrasound that revealed 8 weeks on date. Additional information was not provided. The estimated date of delivery is 25-JAN-2008. Follow-up information was received from a nurse practitioner. The NP reported that on 22-JAN-2008 the patient had a healthy baby boy weighing 7 pounds 13 ounces and 39 3/7 weeks from LMP. The patient had a primary c-section for failure to descend. The patient also had anaemia during pregnancy. Other medications used during the pregnancy included CLARITIN for allergies, ZOFRAN for hyperemesis and ferrous sulfate for anaemia. Upon internal review primary c-section for (failure to descend) was considered to be an other medical event. Additional information is not expected.

Other Meds: ZITHROMAX; XOPENEX; CLARITIN; PHENERGAN

Lab Data: ultrasound, 06/15/07, 8 weeks on date

History:

Prex Illness: Pregnancy NOS (LMP = 4/20/2007); Asthma; Oppositional defiant disorder; Infection; Nausea; Hypersensitivity; Anaemia

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313439-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Mar-2008	18-Mar-2008	0	27-May-2008	30-May-2008	SC		30-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Metrorrhagia

Symptom Text: Transient numbness in hands, metrorrhagia

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313449-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-May-2008	01-May-2008	0	27-May-2008	30-May-2008	NC		02-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Patient passed out, approx, 5 mins. after injection.

Other Meds:

Lab Data:

History:

Prex Illness: Contact Dermatitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313451-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-May-2008	19-May-2008	0	27-May-2008	30-May-2008	NC		02-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2622AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Loss of consciousness

Symptom Text: Pt passed out and hit her head after receiving injection.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313452-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	12-May-2008	13-May-2008	1	27-May-2008	30-May-2008	MA		02-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **313475-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-May-2008	23-May-2008	0	27-May-2008	28-May-2008	MI		28-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB222AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1968U	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2428AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B015AA	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Inappropriate schedule of drug administration, Unresponsive to stimuli

Symptom Text: Immediately after injecting HPV, which was the fourth injection, client began having jerking movement of upper extremities and was non-responsive for approximately 30 seconds.

Other Meds: none

Lab Data:

History: none

Prex Illness: No

Prex Vax Illns:

Vaers Id: 313476-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-May-2008	13-May-2008	1	27-May-2008	28-May-2008	PR		28-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	3	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2564AA	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inflammation, Pain, Pruritus, Skin warm

Symptom Text: Heat, pain, imflamation and itching in the right superior limb,where one of the vaccines was administered.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **313649-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Sep-2007	17-Sep-2007	0	23-May-2008	07-Jul-2008	MA	WAES0709USA03842	07-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLU	SANOFI PASTEUR	U2436AA	4	Unknown	Intramuscular	
VARCEL	MERCK & CO. INC.	658406/1175U	1	Left arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B015AA	0	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	658560/1062U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site pain, Injection site pruritus, Injection site swelling

Symptom Text: Information has been received from a registered nurse concerning a 17-year-old female with no pertinent medical history or allergies who on 27-APR-1998 was vaccinated subcutaneous with her first 0.5 ml dose of varicella virus vaccine live (Oka/Merck) (lot # 658406/1175U) and her second dose on 17-SEP-2007. Concomitant therapies included amitriptyline hydrochloride (MSD), ethinyl estradiol/norgestimate (TRI-SPRINTEC) and another vaccine administered on 17-SEP-2007. On 20-SEP-2007 the patient experienced redness, pain, swelling and itching at the injection site of the left upper arm. The patient was examined in the office later the same day and the exam revealed 8x7 cm area of redness with a central 1.5x1.5 cm induration. The physician recommended cool compress and BENADRYL. No diagnostic labs were performed. At the time of the report the patient's status was unknown. A product quality complaint was not involved. Follow-up information received on 07-DEC-2007 indicated the patient was vaccinated at 15:00 subcutaneous in the left arm on 17-SEP-2007 with a second dose of varicella virus vaccine live (Oka/Merck) (lot # 658406/1175U) (lot # 658406/1175U was previously reported as the first dose). There were no illnesses at the time of vaccination. Concomitant vaccines administered on 17-SEP-2007 at 15:00 included a first intramuscular dose of BOOSTRIX (lot # AC528015AA), a first intramuscular dose of MSD vaccine (yeast) (lot # 658560/1062U) and a fifth intramuscular dose of FLUZONE vaccine inactivated (lot # U2436AA). On 19-SEP-2007 (previously reported as 20-SEP-2007) the patient experienced 8x7 cm area of redness with a 1.5x1.5 cm induration on the left post arm at the site of the varicella virus vaccine live (Oka/Merck) injection. The patient was seen in the office of the 20-SEP-2007 for red, swollen itch. On 01-OCT-2007 the patient was seen at a "visit" and was "okay". Additional information is not expected.

Other Meds: ELAVIL, TRI-SPRINTEC

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 313735-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	08-Mar-2007	08-Mar-2007	0	28-May-2008	29-May-2008	LA	WAES0705USA04399	29-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0186U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Cervix disorder, Drug exposure during pregnancy, Foetal disorder, Thrombosis

Symptom Text: Initial and follow-up information have been received from a registered nurse and a licensed practical nurse through a Merck pregnancy registry concerning a 19 year old female with papanicolaou smear abnormal and a history of hypothyroidism who on 22-DEC-2009 was vaccinated with the first dose of GARDASIL (Lot #653938/0954F). On 08-MAR-2007, the patient received the second dose of GARDASIL (Lot #655618/0186U). Concomitant medication was not reported. In approximately April 2007, it was determined that the patient was pregnant. On an unspecified date, the patient had a positive urine pregnancy test. The date of the patient's last menstrual period was 19-APR-2007 and estimated delivery date is 24-JAN-2008. On 01-JUN-2007 and 17-JUL-2007, ultrasounds performed were normal. On 31-AUG-2007, was third ultrasound performed showed funneling of the cervix. On 13-SEP-2007, a fourth ultrasound showed a blood clot only. On 03-OCT-2007 at 26 weeks and 2 days of pregnancy, the patient had an emergency caesarean section performed due to the funneling of the cervix. At this time, the patient delivered two normal male infants one weighed 1 lb 12 oz and the second weighed 1 lb 13 oz with no congenital anomalies. Apgar scores were 6/7 for both infants. The infants experienced the following complications or abnormalities prematurity, bronchopulmonary dysplasia and ductus arteriosus. It was reported that there were no infections or illnesses during pregnancy and no complications during labor/delivery. The outcome and causality of these events were not reported. Upon internal review the following were considered to other important medical events: premature baby, bronchopulmonary dysplasia, caesarean section, ductus arteriosus and small for dates baby. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, 06/01/07, norma; ultrasound, 07/17/07, norma - Twins/cervix length; ultrasound, 08/31/07, abnor - showed funneling; ultrasound, 09/13/07, abnor - showed blood clot only; urine beta-human - positive

History: Hypothyroidism

Prex Illness: Pregnancy NOS (LMP = 4/19/2007); Papanicolaou smear abnormal

Prex Vax Illns:

Vaers Id: **313736-1 (S)** **Related reports:** 313736-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Apr-2008	01-May-2008	3	28-May-2008	29-May-2008	WA	WAES0805USA02970	18-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2604AA		Unknown	Unknown	
IPV	UNKNOWN MANUFACTURER	AC52B06BAA		Unknown	Unknown	
HPV4	MERCK & CO. INC.	1758U	0	Unknown	Unknown	
DTAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B06BAA		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Dehydration, Headache, Inappropriate schedule of drug administration, Lip dry, Nausea, Pain, Pain in extremity, Pyrexia, Urine output decreased, Vomiting

Symptom Text: Initial and follow up information has been received from a physician and by telephone from a registered nurse (R.N.) concerning a 17 year old female patient who on 28-APR-2008 was vaccinated with a first dose of GARDASIL lot # 659180/1758U. Concomitant therapy included DTAP-IPV, MENACTRA and ACCUTANE. On 01-MAY-2008 the patient experienced severe headache and nausea and after getting the first injection and went to the emergency room (ER). The next day, on 02-MAY-2008 she went to her physician's office and her physician sent her to the hospital. While at the hospital she was given Intravenous (IV) Fluids and narcotics for the pain. Unspecified laboratory blood work was done. In follow up telephone call to the office the nurse reported that there was no documentation regarding patient's hospitalization. No additional information was provided. The patient was reported as recovered at the time of this report. Additional information has been requested. 8/15/08 Reviewed hospital medical records of 5/2/2008. FINAL DX: acute HA; fever; vomiting; & dehydration Records reveal patient experienced severe vomiting, HA, low grade fever & dehydration. Patient admitted to HA prior to vaccination & was on Accutane. Also had leg pain. Seen in PCP office where she could not stand w/o vomiting. Had been seen in ER on 5/1 as well w/decreased urine output & dry lips. Tx w/IVF & improved. D/C to home on same day.

Other Meds: ACCUTANE

Lab Data: diagnostic laboratory, 05/01?/08 LABS: 5/1/08 LABS: Hgb 12.7 (L). AST 3(L). CT scan WNL.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **313736-2 (S)** **Related reports:** 313736-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Apr-2008	01-May-2008	3	10-Jun-2008	11-Jun-2008	WA	200801392	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	M1758U	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2604A	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B06BAA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Blood pressure, Dehydration, Headache, Pyrexia, Vomiting

Symptom Text: Initial report was received on 02 May 2008 from a physician. A 17-year-old female patient, who had no known allergies, or concurrent illnesses, but who had a history of chronic constipation, had received on 28 April 2008 a first intramuscular dose of MENACTRA (Lot # U2604AA); a dose of "Tdap" (trade name and manufacturer name not provided, Lot # AC52B016BA [not a valid Sanofi Pasteur lot number]); and a first dose of GARDASIL (manufacturer Merck, Lot # M1758A). The routes and sites of administration were not provided for the "Tdap" or GARDASIL; and the site of administration was not provided for the MENACTRA. Three days post-vaccination, the patient complained of severe headache and fever of 102.2 degrees Fahrenheit. The patient was taken to the emergency room that day. A CAT scan of the head was performed that was negative; and the patient was treated with DARVON for her severe headache. The following day, the patient was seen in the physician's office with continued severe headache and fever of 101.6 degree Fahrenheit. Diagnostic tests and treatments received were not provided. At the time of this report, the patient had not recovered. Follow-up information was received on 27 May 2008 from the original reporting physician. On 28 April 2008 the patient had received a first intramuscular right deltoid injection of MENACTRA, lot # U2604AA; a first intramuscular left deltoid injection of BOOSTRIX (previously reported as "Tdap"), manufacturer GlaxoSmithKline, Lot # AC52B06BAA also reported as AC52B020AA (previously reported as AC52B016BA); and a first intramuscular right deltoid injection of GARDASIL, manufacturer Merck, Lot # M1758U (Lot # previously reported as M1758A). On 01 May 2008, i.e. three days post-vaccination, the patient went to the emergency room as reported in the above narrative. During that emergency room visit, the patient had blood work completed that included a Complete Blood Count and a Complete Metabolic Panel, in addition to the CAT scan of the head which was negative. The results

Other Meds: "ACCUTANE"

Lab Data: 01 May 2008: CT scan of head was negative, Complete Blood Count and a Complete Metabolic Panel-results not provided. 02 May 2008: A Complete Metabolic Panel revealed blood urea nitrogen 5 mg/dL, and creatinine 0.8mg/dL. A Complete Blood Cou

History: The patient has a history of chronic constipation and no known allergies (NKA). She denied having any illnesses at vaccination time or adverse events following prior vaccination. The patient had not received any other vaccinations within four weeks of 28 April 2008.

Prex Illness:

Prex Vax Illns:

Vaers Id: 313739-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		28-May-2008	29-May-2008	OH	WAES0805USA03807	29-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female, who, on an unspecified date, was vaccinated with a 0.5mL first dose of GARDASIL. Subsequently, the patient experienced a syncope episode and a seizure. The patient sought unspecified medical attention. The patient recovered on the same day as the episode. No product quality complaint was involved. Upon internal review seizure was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **313741-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Apr-2008	02-Apr-2008	1	28-May-2008	29-May-2008	FR	WAES0805USA03985	29-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Chest pain, Fear of death, Neurological examination normal, Pain, Paraesthesia, Psychosomatic disease

Symptom Text: Information has been received from a physician concerning a 25 year old female who in the beginning of April 2008 was vaccinated with a dose of GARDASIL. One day post-vaccination, the patient experienced paraethesia and stinging chest pain, the symptoms continued in the course and she developed severe anxiety with fear of death. Exhaustive examinations were carried out including a neurological check-up. All findings were normal. The neurological evoked psychosomatic causes. This was contraindicated by the patient. She presented to the reporter who is specialized in homeopathic medicine. He started a therapy to divert the vaccine which temporarily led to improvement. The patient's paraesthesia and severe anxiety with fear of death and stinging chest pain persisted. Severe anxiety with fear of death, paraesthesia, and tingling chest pain were considered to be other important medical events. Other company numbers include: E200804494. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313817-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-Jan-2008	06-Jan-2008	1	28-May-2008	06-Jun-2008	OH		11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Hypersensitivity, Musculoskeletal chest pain, Vaccination complication

Symptom Text: Joint pain - chest wall pain. Joint pain is constant, not relieved by IBUPROFEN. 6/3/08 Reviewed OB/GYN medical records & vax records. FINAL DX: probable hypersensitivity to Gardisil. Vax records reveal 2nd HPV 0052Y given RUE 3/1/08. Patient had been on Yasmin & then was switched to some other BCP. Well for both doses. 5/27/08 reports that patient experienced constant joint pain after 1st HPV along w/chest pain. Seen by pediatrician & dx w/chest wall pain.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 313823-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-May-2008	27-May-2008	4	28-May-2008	06-Jun-2008	NH		23-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2613AA	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Contraception, Dizziness, Drug hypersensitivity, Pallor, Syncope

Symptom Text: Syncopal episodes 4 days after vaccines administered occurred x3. First time in shower. 6/6/08 Reviewed PCP medical records & vax records. Good health on day of vax, only hx of dysmennorhea. Started bcp 2 days s/p vax & then 2 days later stared syncope. 6/13/08 Reviewed ER medical records of 5/27/08. FINAL DX: syncope, orthostatic Records reveal patient experienced dizziness & weakness while in the shower, felt things going black. Had syncopal episodes x 3. In ER, pale & weak. Had started birth control 2 days prior. Orthostatic in ER. D/C to home to be f/u by PCP next day.

Other Meds: Began Sprintec 5/25

Lab Data: CBC, EKG, CXR in ER, IV fluids LABS: pregnancy test neg. CBC & chemistry WNL. Lyme test neg. CXR neg.

History: Penicillin, Sulfa, Acetaminophen PMH: parent had syncope w/BCP.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **313825-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	12-May-2008	20-May-2008	8	28-May-2008	02-Jun-2008	VA		03-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	0	Gluteous maxima	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site, Injection site erythema, Injection site pain, Paraesthesia

Symptom Text: C/o soreness, redness at inj. site. C/o tingling both R & L buttock 1 wk after Inj.

Other Meds: LO ESTRIN 24 FE

Lab Data:

History: NKDA

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313837-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-May-2008	21-May-2008	0	28-May-2008	09-Jun-2008	NC		09-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024CA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1968U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Gaze palsy, Hallucination, visual, Pain in extremity, Syncope

Symptom Text: Within 3 minutes of administering HPV & Tdap (BOOSTRIX), patient's eyes rolled back and patient fainted. Came to within 1-2 minutes. Doesn't remember episode. States she saw lights and was dizzy. Episode happened after 2nd shot (HPV) given. Pt. stated it hurt and arm felt achy just before fainting

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **313840-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	07-Jun-2007	01-Aug-2007	55	28-May-2008	09-Jun-2008	MD		12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Herpes zoster

Symptom Text: Developed shingles after third injection 6/3/08 Reviewed PCP medical records & vax records. Patient received HPV #1 0688F on 12/15/2006 LUE; HPV #2 0811U RUE 2/16/2007; & HPV #3 as reported. Office note of 1/10/08 states had shingles 6/2007 as did her twin sister who had also received all 3 HPV vaccines on different dates.

Other Meds: Orthotricyclen

Lab Data:

History: PMH: allergy: amoxicillin. 1/2005 LGSIL; subsequent pap smears WNL. Family history of breast cancer.

Prex Illness:

Prex Vax Illns: Shingles~HPV (Gardasil)~3~26~In Sibling

Vaers Id: **313842-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	04-Apr-2008	25-Apr-2008	21	28-May-2008	02-Jun-2008	MD		16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Herpes zoster, Sick relative

Symptom Text: Developed shingles after 3rd shot. 6/3/08 Reviewed PCP medical records & vax records. Patient received HPV #1 0928U 10/15/2007 LUE; HPV #2 1266U 12/14/2007 LUE; & HPV #3 as reported. No mention of shingles in notes provided. Patient's twin sister had shingles after HPV #3 on different dates.

Other Meds: ORTHOTRICYCLEN

Lab Data:

History: PMH: asthma. Allergy: latex Family Hx: breast cancer.

Prex Illness:

Prex Vax Illns: developed shingles~HPV (Gardasil)~3~26~In Sibling

Vaers Id: **313843-1** **Related reports:** 313843-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-May-2008	20-May-2008	0	28-May-2008	09-Jun-2008	TX		09-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dry skin, Unresponsive to stimuli

Symptom Text: About 45 or 60 seconds after HPV vaccination became non-responsive for 15-20 seconds - mom reports has happened on other occasions such as after blood work. Did not quit breathing, chewed gum, skin w/dry - walked to exam table 4 ft away rested few minutes; B/P 108/64 HR 74 - left unassisted.

Other Meds:

Lab Data: None

History: Client reported penicillin allergy

Prex Illness: None

Prex Vax Illns: Ststed had to lay down at home after last HPV shot - only reported this today~ ()~~0~In Patient

Vaers Id: **313843-2** **Related reports:** 313843-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-May-2008	20-May-2008	0	23-Jun-2008	30-Jun-2008	TX		09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Unresponsive to stimuli

Symptom Text: WITHIN 45 OR 60 SECONDS AFTER HPV VACCINATION BECAME NON-RESPONSIVE FOR 15 - 20 SECONDS - MOM REPORTS HAS HAPPENED ON OTHER OCCASIONS SHOH AS AFTER BLOOD WORK, DID NOT QUIT BREATHING; CHEWED GUM, SKIN W/DRY - WALKED TO EXAM TABLE 4 FT AWAY RESTED FEW MINUTES B/P 108/64 HR 74 - LEFT UNASSISTED.

Other Meds:

Lab Data:

History: CLIENT REPORTED PENICILLIN ALLERGY

Prex Illness:

Prex Vax Illns: STATED HAD TO LAY DOWN AT HOME AFTER LAST HPV SHOT - ONLY REPORTED THIS TODAY~HPV (no brand name)~NULL~~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313855-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	25-Mar-2008	Unknown		28-May-2008	30-May-2008	RI		02-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthma, Condition aggravated, Rash pruritic

Symptom Text: reported rash on arm-- across entire back, itchy lasting 1-2 wks (not seen by provider) and worsening of asthma symptoms

Other Meds: Allegra

Lab Data: none

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **313864-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-May-2008	28-May-2008	0	28-May-2008	29-May-2008	GA		30-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	2	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB234BA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Medication error

Symptom Text: Patient was given third HepA vaccine.

Other Meds: N/A

Lab Data: N/A

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313869-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-May-2008	21-May-2008	0	28-May-2008	29-May-2008	CT		30-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling hot, Heart rate, Hyperhidrosis, Nausea, Pain in extremity, Pallor, Paraesthesia

Symptom Text: About 5 minutes after receiving vaccine, pt felt "hot" then became dizzy, nauseous and pale. She complained of pain in her right arm and a "tingly" feeling in her fingers and arms. + diaphoresis. Pulse 60 BP 92/58 Recovered after about 20 minutes of laying down with her feet elevated, few sips of juice and a hard candy.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 313876-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	21-Dec-2006	05-Nov-2007	319	28-May-2008	29-May-2008	NM	WAES0704USA04385	29-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Breech delivery, Drug exposure during pregnancy, Foetal disorder, Pain, Premature baby, Sinusitis

Symptom Text: Information has been received through the Merck pregnancy registry from a health professional and medical records concerning a 26 year old female with sulfonamide allergy who on 06-OCT-2006 was vaccinated with a first dose of GARDASIL. On 21-DEC-2006, the patient was vaccinated with a second dose of GARDASIL. Subsequently the patient became pregnant. Last menstrual period was on 21-FEB-2007 and the estimated date of delivery was 28-NOV-2007. Unspecified medical attention was sought. The patient underwent "prenatal labs" (results not reported). On 05-NOV-2007 a male infant was born (5 pounds 7 ounces, 17 1/2 inches long) (reported as pre-mature birth at 36 weeks). The only complication was the infant was in the breech position. The pregnancy included ZITHROMAX Z-PACK on 08-MAY-2007 for a sinus infection (4 days), KEFLEX on 21-AUG-2007 for a sinus infection (TID x 5 days) and TYLENOL #3 on 04-OCT-2007 for pain. On 05-NOV-2007, the infant's total serum bilirubin test at 12 hours of life was 7.2. At 24 hours of life it was reported as 7.3. The infant was jaundice but was reported to be recovering. It was reported in the physician's notes that the infant was at a high risk for rebound hyperbilirubinemia. On 09-NOV-2007, the infant's total serum bilirubin was 13.1. Instructions were given to the infant's mom that there would be no more bili checks but to call of the infant's appetite decreased. On 14-NOV-2007 the infant had newborn screening tests done. They were reported as normal. On 19-NOV-2007, the infant's parents noticed a lump on the left side of the infant's neck. The physician noted it was not tender or red. It measured 1 to 2 cm and his range of motion was OK. The physician assessed the lump as torticollis. On 27-NOV-2007, the infant was seen by the physician and it was reported that he had an upper respiratory infection. The mother was instructed to call if the infant had an increase in cough, difficulty breathing, emesis or if he was not eating. On 29-NOV-2007, the infant experienced

Other Meds: TYLENOL WITH CODEINE #3; ZITHROMAX Z-PAK; KEFLEX

Lab Data: diagnostic laboratory - "prenatal labs"

History:

Prex Illness: Pregnancy NOS (LMP = 2/21/2007); Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **313882-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	25-May-2008	26-May-2008	1	28-May-2008	03-Jun-2008	WA		03-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B015AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1978U	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2552AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin warm, Swelling

Symptom Text: Swelling L upper arm 8 cm wide warm to touch.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 313985-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	04-Sep-2007	06-Sep-2007	2	23-May-2008	17-Jul-2008	TN	WAES0710USA02678	17-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	658422/1030U		Left arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024AA	5	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	1061U	0	Right leg	Intramuscular	
HPV4	MERCK & CO. INC.	658558/1061U	0	Left leg	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB186AA	0	Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Induration, Skin warm, Urticaria

Symptom Text: Information has been received from a registered nurse concerning a 11 year old female with no pertinent medical history, with an allergy to amoxicillin (+) clavulanate potassium (AUGMENTIN) who on 04-SEP-2007 was vaccinated subcutaneously into the left arm with a second dose varicella virus vaccine live (Oka/Merck) (Lot # 658422/1030U). Concomitant vaccine therapy that same day included a first dose of human papillomavirus vaccine, for the treatment of prophylaxis, administered intramuscularly into the left thigh (Lot # 658558/1061U), a first dose of hepatitis A vaccine (inactive) (HAVRIX) administered intramuscularly into the left thigh (Lot# AHAVB196AA), a fifth dose of diphtheria toxoid (+) pertussis acellular 3-component vaccine (+) tetanus toxoid (BOOSTRIX) administered intramuscularly into the right arm (Lot# AC52B024AA) and a first dose of meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA) administered intramuscularly into the right thigh (Lot # 1061U). On 06-SEP-2007 the patient developed a red, hard, welt "about the size of a silver dollar", which was warm to touch. There was no illness at the time of vaccination. There were no diagnostic tests performed. The patient had no prior history of adverse events following prior vaccinations. The patient recovered on an unspecified date. No further information is expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **313987-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Sep-2007	Unknown		23-May-2008	17-Jul-2008	NH	WAES0710USA02679	17-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2386BA	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	0853U	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0930U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Skin warm

Symptom Text: Information has been received from a health professional concerning a 16 year old female with an allergy to penicillin who on 19-SEP-2007 @ 15:00 was vaccinated subcutaneously into the right arm with a second dose of varicella virus vaccine live (Oka/Merck) (Lot # 658197/0853U). Concomitant vaccine therapy that same day included a first dose of Gardasil for the treatment of prophylaxis administered into the left arm (Lot # 658488/0930U) and a first dose of Menactra administered into the right arm (Lot # U2386BA). On an unknown date the patient developed a mildly warm, swollen right tricep area. There was no illness at the time of vaccination. There were no diagnostic tests performed. The patient recovered on an unspecified date. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **314020-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Sep-2007	Unknown		29-May-2008	30-May-2008	FR	WAES0805USA04808	30-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1518F	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Renal failure

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who on 04-SEP-2007 was vaccinated intramuscularly into the upper arm with the second dose of GARDASIL (Lot # 0233U, batch # NF46740). Subsequently, onset not reported, the patient experienced renal insufficiency and was admitted to the hospital. She recovered within an unspecified time. It was also reported that on 11-JUL-2007 the first dose of GARDASIL (Lot # 1518F, batch # NF23330) was administered and was well tolerated. Other business partner numbers include: E200804484. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: 314021-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Sep-2007	Unknown		29-May-2008	30-May-2008	FR	WAES0805USA04821	30-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1518F	1	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Diplopia, Dizziness, Headache, Hyperventilation, Hypoaesthesia, Migraine, Syncope, Tension headache

Symptom Text: Information has been received from a health authority concerning an 18 year old female patient with a history of diplopia that occurred first at the age of four and headaches since the age of two and a half years, who on 28-SEP-2007 was vaccinated intramuscularly into the left upper arm with the second dose of GARDASIL (Lot #1518F, batch # NF27880). In the discharge summary it was reported that the patient was hospitalized from 16-DEC-2007 to 21-DEC-2007. She complained about headaches for two years which aggravated in the course of time. She experienced numbness, dizziness and increasing headache one month ago. She experienced the first syncope five days before admission. On 16-Dec-08 she experienced syncope twice. The diagnostic and clinical investigations showed no pathologies and gave no indication for physical cause of the symptoms. The diagnosis of tension headache and migraine were established. It was intended to refer the patient to the adolescent psychologist and to the electrophysiological outpatient department. On 18-Jan-2008 the diagnosis of hyperventilation syndrome was established and the physicians assumed that syncope and dizziness were caused by hyperventilation syndrome. Further information received first, (11-FEB-2008) and a second report on (05-Mar-2008) from the outpatient ophthalmological and neurological department. It was reported that the patient complained of diplopia in January 2008 which persisted. At the age of four years the patient experienced diplopia for the first time. Treatment included specialized glasses containing prisms, which improved the diplopia. Diagnostic studies performed included a second cranial magnetic resonance imaging (MRI) (first MRI not reported) showed little unspecific lesions in the occipital area of the white matter. Electroencephalography (EEG), echocardiography and ear, nose and throat (ENT) examination showed no pathologies. The patient's mother assessed the symptoms as a causal relation to the vaccine. There was no indication for epilep

Other Meds: Unknown

Lab Data: magnetic resonance imaging, cranial-little unspecific lesions in the occipital area of white matter; electroencephalography, no pathologies; ears, nose, and throat examination, no pathologies; echocardiography, no pathologies

History: Diplopia; Headache

Prex Illness:

Prex Vax Illns:

Vaers Id: 314022-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Feb-2008	26-Feb-2008	1	29-May-2008	30-May-2008	FR	WAES0805USA04956	30-May-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Gaze palsy, Influenza like illness, Lip discolouration, Loss of consciousness, Malaise, Nausea, Pallor, Syncope vasovagal

Symptom Text: Information has been received from a pharmacist concerning an 18 year old female who on 25-FEB-2008 was vaccinated with a dose of GARDASIL (batch # was unknown because the package was discarded after the injection) IM in the left arm. On 26-FEB-2008, the morning after vaccination during her breakfast, the patient looked white, had nausea, and had a loss of consciousness. The patient's mother reported an impressive reaction. The patient went to the emergency unit at the hospital and the diagnosis was a vagal malaise. The patient recovered. Follow-up information was received on 13-MAY-2008. The case was upgraded to serious: the reporter considered the loss of consciousness, rolling eyes and black lips as serious events (Other Important Medical Events). The three events were reported as serious and severe. She also experienced contractures in the arms and body 28 hours after injection, and abdominal pain like in flu-like syndrome. Contractures were reported as moderate and abdominal pain was reported as severe. The events of nausea and pallor were no longer mentioned. One hour after her syncope, the patient was transferred to the emergency unit where vasovagal syncope was diagnosed. The patient recovered. The case is closed. Other business partner numbers included: E2008-02391. No further information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 314109-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	29-May-2008	29-May-2008	0	29-May-2008	05-Jun-2008	CO		06-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: 5 minutes after vaccine given, patient fainted while seated. She was aided to the floor where in a supine position she quickly came to. After 15-20 minutes she felt well enough to sit up. She was able to walk out of the clinic after another 10 minutes.

Other Meds: None

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **314138-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Mar-2008	19-Mar-2008	1	29-May-2008	09-Jun-2008	IN		09-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: After receiving second HPV, later patient had a seizure.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **314140-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-Aug-2007	24-Apr-2008	247	29-May-2008	03-Jun-2008	MI		24-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0930U	0	Left arm	Intramuscular	MNQ

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial pain, Facial palsy, Headache, Sleep disorder

Symptom Text: Noticed L facial droop - corner of mouth when eating/smiling x few months, GARDASIL series started 8/07. 7/3/08-office note 5/28/08-presented with left facial droop especially when eating parent noticed it 1-2 months ago. Questionable Bell's palsy vs asymmetry. 7/23/08-records received for DOS 12/21/07-Neurology consult for evaluation of intermittent headache over past 2 years, now increasing in frequency. Headaches throbbing bifrontal involving face bilaterally improve with sleep. Now waking up at night unable to fall back asleep. Impression headaches most likely migrainous in nature with photosensitivity. Facial pain could be related to sinus like pressure. Neurologic exam normal.

Other Meds: None

Lab Data: None

History: + ADD 7/23/08-records received-PMH:exercise induced asthma.

Prex Illness:

Prex Vax Illns: minor facial droop~HPV (Gardasil)~1~16~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **314142-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-May-2008	22-May-2008	0	29-May-2008	09-Jun-2008	IL		09-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted after receiving 1st GARDASIL injection while leaving office. Alert x3 after using smelling salt. Patient given juice and observed 15 minutes longer. Patient did not eat breakfast day of appt. Patient stable and left office on her own.

Other Meds: none

Lab Data: None

History: none

Prex Illness: none

Prex Vax Illns: none~ ()~~0~In Sibling|none~ ()~~0~In Patient

Vaers Id: **314155-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Oct-2007	13-Oct-2007	2	23-May-2008	18-Jul-2008	AZ	WAES0710USA03758	04-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Limb discomfort, Oedema peripheral, Pruritus

Symptom Text: Information has been received from a physician concerning an 11 year old female who on 11-OCT-2007, received a 0.5 ml second dose of varicella virus vaccine live (Oka/Merck). Concomitant vaccinations included human papillomavirus vaccine (MSD), meningococcal ACYW conjugated vaccine (diphtheria toxoid) (MENACTRA) and diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid. On 13-OCT-2007, she developed itchiness, soreness, as well as being red and swollen down back of right arm to the elbow. The patient sought unspecified medical attention. It was reported that the physician recommended hydrocortisone cream and diphenhydramine (BENADRYL). Current patient status was not reported. A product quality complaint was not reported. No further information was available. Additional information has been requested.

Other Meds:

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 314184-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-Oct-2007	19-Oct-2007	0	23-May-2008	18-Jul-2008	AZ	WAES0710USA05576	04-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Subcutaneously	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Swelling

Symptom Text: Information has been received from a registered nurse concerning an 18-year-old 200 lb. 69 in. female with a history of benign neoplasm of the pituitary gland and craniopharyngeal duct with no known drug reactions/allergies who on 19-OCT-2007 was vaccinated SC with a 0.5mL second dose of varicella virus vaccine live (Oka/Merck). Concomitant vaccinations included Gardasil and diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (manufacturer unspecified). Concomitant medications included replacement hormones (therapy unspecified) and numerous medications (therapy unspecified). There was no reported illness at the time of the vaccinations. On 19-OCT-2007 at 20:00 hours, (also reported as "two days later"), the reporter indicated that the patient's worse day was 20-OCT-2007. She presented to the physician on 22-OCT-2007, who indicated the area was the "size of 2 inches all around "(also reported as about 3" in diameter). The patient was treated with cold compresses, OTC Benadryl cream and ice. There were no laboratory or diagnostic studies performed. The patient's vaccination history included: 26-JUN-1989, diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (manufacturer unspecified), and OPV (manufacture unspecified); 25-AUG-1989, a second dose of diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (manufacturer unspecified), and a second dose of OPV (manufacture unspecified); 27-OCT-1989, a third dose of diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (manufacturer unspecified) and a third dose of OPV (manufacture unspecified); 13-JAN-1990, a fourth dose of diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (manufacturer unspecified); 09-FEB-1990, rubella virus vaccine (therapy unspecified); 11-AUG-1990, a first dose of measles virus vaccine live(Enders-Edmonston) (+) mumps virus vaccine live (Jeryl Lynn) (+) rubella virus vaccine live (Wistar RA 27/3), and

Other Meds: (therapy unspecified); estrogens (unspecified)

Lab Data: None

History: Pituitary tumor; Craniopharyngioma benign

Prex Illness:

Prex Vax Illns:

Vaers Id: 314205-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	22-Oct-2007	24-Oct-2007	2	23-May-2008	21-Jul-2008	IA	WAES0710USA06851	21-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLU	SANOFI PASTEUR	NULL		Unknown	Unknown	
HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
VARCEL	MERCK & CO. INC.	1173U		Unknown	Unknown	
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema

Symptom Text: Information has been received from a nurse concerning a 12 year old female who on 22-OCT-2007 was vaccinated with a dose of varicella virus vaccine live (Oka/Merck) (lot number: 658287/1173U). Concomitant therapy that day included Gardasil, Hepatitis A vaccine (inactive) (MSD), Fluzone (manufacturer unknown) Menactra (manufacturer unknown). On 24-OCT-2007, the "patient reported redness surrounding the injection site approximately 48 hours after receiving the vaccination." No further information was given. The outcome was reported as recovered on 26-OCT-2007. There was no product quality complaint. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **314210-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	22-Oct-2007	Unknown		23-May-2008	21-Jul-2008	IA	WAES0710USA06933	21-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
VARCEL	MERCK & CO. INC.	1173U		Unknown	Unknown	
FLU	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema

Symptom Text: Information has been received from a nurse concerning a 9 year old female who on 22-OCT-2007 was vaccinated with a dose of varicella virus vaccine live (Oka/Merck) (lot number: 658287/1173U). Concomitant therapy that day included Fluzone (manufacturer unknown), Gardasil and hepatitis A vaccine (inactive) (MSD). "The patient experienced 2 centimeters of irregular erythema on her left arm after receiving the vaccination." No further information was given. The outcome was reported as recovered on 26-OCT-2007. There was no product quality complaint. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 314316-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Mar-2007	22-Mar-2007	0	30-May-2008	02-Jun-2008	--	WAES0705USA01527	02-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Failed trial of labour

Symptom Text: Information has been received through the Merck pregnancy registry from the mother of a 17 year old female who on 22-MAR-2007 was vaccinated with GARDASIL. The mother reported that her daughter was pregnant at the time of vaccination. She experienced no adverse experiences. at the time of this report, the patient was 18 weeks pregnant. Date of LMP was 30-DEC-2006, estimated delivery date is 06-OCT-2007. Follow-up phone call information from a registered nurse reported that the patient had spontaneous rupture of membranes and arrest of first stage of labor which led to a primary cesarean section at 37 weeks gestation (full term) on 01-OCT-2007. The patient delivered a healthy, normal, baby. Upon internal review arrest of first stage of labour leading to a cesarean section was considered an other important medical event. No additional information is expected.

Other Meds: Unknown

Lab Data:

History:

Prex Illness: Pregnancy NOS (LMP = 12/30/2006)

Prex Vax Illns:

Vaers Id: **314317-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Jan-2007	01-Feb-2007	29	30-May-2008	02-Jun-2008	--	WAES0705USA03062	02-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688F	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a health professional concerning a 17 year old female who on 06-NOV-2006 was vaccinated with the first dose of GARDASIL (lot #653735/0688F). On 03-JAN-2007, the patient was vaccinated with the second dose of GARDASIL (lot #653735/0688F). On 02-MAY-2007, the patient presented for the third dose of GARDASIL. Prior to the vaccination, a pregnancy test was performed, which was positive. The patient last menstrual period was in February 2007, with an expected delivery date of November 2007. In follow up telephone call to the doctor's office the nurse reported that the patient terminated her pregnancy. No further information was provided. Upon internal review "abortion induced" was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 2/1/2007)

Prex Vax Illns:

Vaers Id: **314318-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Jan-2008	03-Jan-2008	0	30-May-2008	02-Jun-2008	FR	WAES0802USA02824	02-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Breech presentation, Caesarean section, Drug exposure during pregnancy, Premature labour, Uterine contractions during pregnancy

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 03-JAN-2008 was vaccinated IM into the upper arm with a third dose of GARDASIL. On 21-JAN-2008, the physician diagnosed the pregnancy at 10 weeks. Last menstrual period was on 17-NOV-2007. It was reported that the pregnancy was timely and normal. On 03-MAY-2008, the patient was admitted to the hospital by ambulance due to regular increased uterine contractions and breech presentation. An emergency cesarean section was performed due to a completely opened cervix and a prolapsed amniotic sac. A premature female was born in week 24 with a weight of 784 grams. The APGAR score was 5/6/7. The child was transferred to a pediatric hospital on 03-MAY-2008. On 07-MAY-2008 the patient was discharged in good condition. It was reported that the first and second vaccination with GARDASIL were well tolerated. Other business partner numbers include: E2008-00657. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: **314319-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Dec-2007	01-Jan-2008	31	30-May-2008	02-Jun-2008	FR	WAES0805USA04649	02-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anorexia, Aspartate aminotransferase increased, Asthenia, Blood cholesterol increased, Constipation, Helicobacter infection, Hepatic haemorrhage, Red blood cell sedimentation rate increased, Splenomegaly

Symptom Text: Information has been received from a physician concerning an 18 year old female with no medical history reported who in December 2007 was vaccinated with the first dose of GARDASIL. Concomitant medication was not reported. In approximately January 2008, 4 week post vaccination, the patient developed weakness, constipation and wasn't able to eat. The patient was hospitalized for 4 days. The findings showed increased liver parameters especially serum aspartate aminotransferase test (SGOT); increased cholesterol; and blood sedimentation (35/70). Further to this an abdominal sonography was performed and it showed a splenomegaly and the liver showed haemorrhagic bleeding. A gastroscopy showed an infection with helicobacter, so treatment with PANTOLOC was started. Subsequently on an unspecified date, the patient recovered from weakness, constipation and wasn't able to eat. Other business partner numbers included E2008-04606. It was also reported that the patient was vaccinated with a second dose of GARDASIL and experienced adverse events (E2008-04621). Additional information has been requested.

Other Meds: Unknown

Lab Data: abdominal ultrasound, ??Jan?08, splenomegaly and liver showed haemorrhagic bleeding; gastroscopy, ??Jan?08, infection with helicobacter

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **314320-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	13-May-2008	13-May-2008	0	30-May-2008	02-Jun-2008	--	WAES0805USA04693	02-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Nervousness, Tongue biting

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female who on 13-MAY-2008 was vaccinated with a first dose of GARDASIL IM. On 13-MAY-2008 the patient experienced a seizure after receiving GARDASIL. The patient was found on the floor, in the fetal position with her hands drawn up to her chest, was shaking and bit her tongue after receiving GARDASIL. The same thing occurred when the patient was at the dentist. The nurse practitioner suggested that the patient go to the emergency room (ER), but declined. The patient was fine before leaving the office and drove home. At the time of reporting the patient had recovered on an unspecified date. Upon internal review seizure is considered to be an other medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Convulsion

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **314321-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-May-2008	17-May-2008	8	30-May-2008	02-Jun-2008	FR	WAES0805USA04983	02-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Aphasia, Dyspnoea, Malaise, Paraesthesia, Sensation of heaviness, Skin warm

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 09-MAY-2008 was vaccinated in the shoulder (route not reported) with the third dose of GARDASIL. On 17-MAY-2008 (eight days after the vaccination), the patient experienced severe malaise with loss of speech and paresthesia in the left lower limb. She was brought to the hospital. A doppler ultrasound was performed for suspected phlebitis. The result was negative and the patient was discharged the same day. on 18-MAY-2008, the patient experienced a second episode of malaise and paresthesia and was brought to the hospital again. The patient also experienced dyspnea. A chest CT scan was performed as pulmonary embolism was suspected. The result was normal. A head CT scan was performed and had normal results. The patient was seen by a cardiologist and a neurologist who both found nothing. All reflexes were present, however the patient had sequelae of paresthesia in the left lower limb: she felt heaviness and warmth in the leg. Complete blood work-up was performed. No diagnosis was reported further to hospitalization. No local reaction was observed. Noted was that the patient was coming back from a trip to a foreign country. The patient also experienced (vasovagal reaction 10 to 15 days after first and second injection of GARDASIL (dates not reported) (cf. linked case E2008-4653). Other business partner numbers include E2008-04583 and E2008-04653.

Other Meds: Unknown

Lab Data: Ultrasound, 17May08, negative; Chest computed axial tomography, 18May08, Normal; Head computed axial tomography, 18May2008, Normal.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **314322-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Sep-2007	12-Dec-2007	97	30-May-2008	02-Jun-2008	FR	WAES0805USA05466	02-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1475F	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epilepsy, Grand mal convulsion

Symptom Text: Information has been received from a physician concerning a 16 year old female, who on 13-JUL-2007 was vaccinated with a first dose of GARDASIL (Lot# 654948/0903F; Batch# NE47410). The first dose was well tolerated. On 06-SEP-2007 the patient was vaccinated in the upper arm with a second dose of GARDASIL (Lot# 1475F; Batch# NF37120). The route was not reported. On 12-DEC-07 the patient experienced her first epileptic fit. A second fit occurred on 15-JAN-2008 and was treated with anticonvulsants, LAMOTRIGIN 250mg daily by mouth. It was reported that under this treatment no further epileptic fits appeared. During a former hospitalization (admission date not reported) an electroencephalography (EEG) showed distinct spike wave complexes and the diagnosis of epilepsy grand mal was established. On 19-FEB-2008 the patient was vaccinated with a third dose of GARDASIL (Lot# 0510U; Batch# NG20180). The patient recovered with sequelae. Upon internal review epilepsy grand mal was considered to be an other important medical event. Epileptic fit was considered as a comanifestation of epilepsy grand mal. Other business partner numbers included: E2008-03454. Additional information is not expected. The case is closed.

Other Meds: Unknown

Lab Data: electroencephalogram, Comment: distinct spike wave complexes

History: No reaction on previous exposure to vaccine.

Prex Illness:

Prex Vax Illns:

Vaers Id: **314359-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	20-May-2008	22-May-2008	2	30-May-2008	04-Jun-2008	PA		04-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Pt woke up 5/22/08 with hives down the arm she received the vaccine on also her L side of her body. No resp difficulty.

Other Meds:

Lab Data:

History: None known

Prex Illness: None

Prex Vax Illns:

Vaers Id: **314396-1** **Related reports:** 314396-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	F	22-Jan-2008	22-Jan-2008	0	30-May-2008	05-Jun-2008	MD		20-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1274U		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	C2775AA		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2418AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1265U		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Asthenia, Dizziness, Dyspnoea, Fatigue, Headache, Immediate post-injection reaction, Influenza like illness, Malaise, Muscle atrophy, Myalgia, Myositis, Pain in extremity, Upper respiratory tract infection, Vaccination complication

Symptom Text: Immediate pain in arms and dizziness. Chronic stomach pain , chronic fatigue, roaming muscle pain and atrophy to muscle sites (upper extremity, lower extremities, headaches. 6/13/2008 MR received for OVs and consultations beginning 1/22/2008 with a healthy WCC. Vax given, TDaP, Varicella, Gardasil and Menactra. Seen again 2/13 and 2/28/08 with c/o Flu-like sx, stomach aches, feeling weak and tired, and abdominal pain. DX: URI. Periumbilical Pain. Fatigue and Malaise. Consult 3/11/08 for above c/o as well as SOB with Impression: Adverse reaction to vaccination-Gardasil. Drug Allergy. Fatigue and Malaise. Seen by PCP again with new c/o pain in the back and calf muscles. Continues to have abdominal pain. Added DX: Unspecified Myalgia and Myositis. W/U (-) thus far.

Other Meds: None

Lab Data: lab, EMG/NCV, abdominal ultrasound, allergy consult, neurology consult, complex disorder consult, Neurontin prescribed by neurologist. Labs and Diagnostics: NCS WNL. EMG WNL. Abd US unremarkable. Abd X-ray (-). CBC WNL. CMP WNL. ANA 132.

History:

Prex Illness: none

Prex Vax Illns:

Vaers Id: **314396-2 (S)** **Related reports:** 314396-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Jan-2008	Unknown		03-Feb-2009	04-Feb-2009	MD	WAES0901USA00845	04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1274U	1	Right arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C2775AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2418AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1265U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Abdominal pain, Asthenia, Cough, Dizziness, Dyspnoea, Fatigue, Feeling abnormal, Gait disturbance, Immediate post-injection reaction, Injection site pain, Myalgia, Pain in extremity, Paraesthesia, Presyncope, Sinus disorder

Symptom Text: Information has been received from a consumer concerning her 11 year old daughter with no medical history or drug allergy who on 22-JAN-2008 was vaccinated with the first dose of GARDASIL, 0.5ml, IM. On the same visit as GARDASIL, the patient administered MENACTRA, ADACEL, and her second dose of VARIVAX (Oka/Merck). Immediately after receiving GARDASIL, the patient experienced upper arm pain, dizziness and "did not feel right". The patient's symptoms progressed into chronic fatigue, chronic abdominal pain, allergy symptoms ("sinus issues") and roaming muscle pain. At one point the patient was unable to walk. The patient was treated with NEURONTIN, and her symptoms have since improved. However if the NEURONTIN dose was decreased or stopped the symptoms return. The patient sought medical attention by office visit. Follow-up information has been received from a registered nurse who confirmed that on 22-JAN-2008, the patient received GARDASIL (lot # 659435/1265U), VARIVAX (Oka/Merck) (lot # 658589/1274U), MENACTRA and ADACEL. Follow-up information was received on 26-JAN-2009 and 29-jan-2009 from a physician via medical records concerning a female student gymnast with "no chronic medical conditions and no known drug allergies". On 22-JAN-2008 the patient was vaccinated intramuscularly in the upper right arm with a first dose of GARDASIL (lot # 659435/1265U). On the same day, she also received a second dose of VARIVAX (Oka/Merck) (lot # 658589/1274U) subcutaneously in the upper right arm, a first dose of MENACTRA (Lot #U2418AA) intramuscularly in the upper left arm and a first dose of ADACEL (Lot #C2775AA) intramuscularly in the upper left arm. There was no illness at time of vaccination. On 13-JAN-2008 (previously reported as 22-JAN-2008) the patient experienced abdominal pain. On 22-JAN-2008 the patient experienced pain at injection site and intermittently pre-syncope. On 22-JAN-2008 the patient experienced weakness, myalgia and fatigue. On 15-MAR-2008 the patient developed intermittent difficulty breathing and troub

Other Meds:

Lab Data: diagnostic radiology, 03/20/08, abdomen non-diagnostic for an acute process; abdominal ultrasound, 03/25/08, unremarkable ultrasound of the upper abdomen; bladder ultrasound, 03/25/08, unremarkable ultrasound of the urinary bladder; nerve c

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **314399-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	17-May-2008	17-May-2008	0	30-May-2008	05-Jun-2008	IL		06-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Groin pain, Lethargy, Mass

Symptom Text: after first dose: painful lump in groin area on right side of body, which is the side of injection site. lethargy and overwhelming fatigue lasting for roughly one week.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **314418-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-May-2008	24-May-2008	3	30-May-2008	06-Jun-2008	PA		09-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Limb discomfort, Local reaction, Paraesthesia

Symptom Text: Shot given R arm 5/21. Had minor local reaction now c/o tingling & strange feeling R arm. Started 3-5 days after shot.

Other Meds:

Lab Data:

History:

Prex Illness: mild otitis externa

Prex Vax Illns:

Vaers Id: **314446-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	14-Nov-2007	28-Nov-2007	14	02-Jun-2008	09-Jun-2008	MI	M12008009	09-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal behaviour, Affect lability, Anxiety, Depression, Feeling abnormal, Irritability

Symptom Text: Given 1st HPV4 on 11-14-07 about 2 weeks after received vaccine began to have symptoms of depression, increased crabby, feeling of doom, emotional. Went to the doctors in March when symptoms didn't go away. Did not notice any change after the 2nd dose. While getting the 3rd dose told this info to nurse and VAERS was completed

Other Meds: Vicodin prn - herniated disc. 500 mg; Zoloft 25mg x 1 day

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **314450-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	27-May-2008	29-May-2008	2	02-Jun-2008	09-Jun-2008	NM		09-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	U2569AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	1061U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration

Symptom Text: 7.5 x 9 cm redness and induration; surrounding injection site at 72 hours

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **314465-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	30-Jul-2007	30-Jul-2007	0	23-May-2008	24-Jul-2008	--	WAES0708USA00744	24-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a 13 year old female who on 30-JUL-2007 was vaccinated with 0.5 mL of varicella virus vaccine live (Oka/Merck). Concomitant therapy that same day included human papillomavirus vaccine. On 30-JUL-2007, one half hour after receiving both varicella virus and human papillomavirus vaccine, the patient broke out in hives. Unspecified medical attention was sought. There was no product quality complaint. No lot numbers provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **314518-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-May-2007	23-May-2007	22	02-Jun-2008	03-Jun-2008	LA	WAES0707USA03459	03-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received from the Merck Pregnancy Registry from an 18 year old female with a penicillin allergy who in May 2007 was vaccinated with a dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). Subsequently the patient became pregnant. A pregnancy test was performed to confirm the patient's pregnancy. The patient's last menstrual period was on 23-MAY-2007. The patient's estimated date of delivery was 27-FEB-2007. The patient did not continue series of GARDASIL during her pregnancy. Unspecified medical attention was sought. At the time of the initial report, the patient was nine weeks gestation. Follow-up reported that on approximately 07-AUG-2007, the patient miscarried at 11 weeks. It was reported that had no procedures done and was doing "fine." At the time of the follow-up report, the patient was pregnant again (WAES #0805USA06056). Upon internal review, miscarried at 11 weeks was considered to be an other important medical event. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: diagnostic laboratory - reports not reported; beta-human chorionic - positive

History:

Prex Illness: Pregnancy NOS (LMP = 5/23/2007); Penicillin allergy

Prex Vax Illns:

Vaers Id: 314520-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	05-Feb-2008	06-Feb-2008	1	02-Jun-2008	03-Jun-2008	--	WAES0803USA04942	03-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Condition aggravated, Drug exposure during pregnancy, Haemorrhage, Herpes virus infection, Ureaplasma infection

Symptom Text: Initial and follow-up information has been received from a certified medical assistant, for the Pregnancy Registry, concerning a 25 year old female with anxiety, herpes, and no drug allergies, and with a history of pyelonephritis (reported as phylonephritis), caesearean section in 2002, chlamydia, 3 previous pregnancies, 1 full term delivery, 2 elective terminations, who on 29-NOV-2007 was vaccinated IM with a first dose of GARDASIL (lot # 659437/1266U) and on 05-FEB-2008 was vaccinated IM with a second dose of GARDASIL (lot # 659653/1448U). Concomitant therapy included EFFEXOR, KLONOPIN, and VALTREX. The patient was pregnant. The patient's last menstrual period was 06-FEB-2008 and her estimated delivery date was 13-NOV-2008. The patient saw her physician for medical attention. On 19-MAR-2008 an ultrasound was performed for viability and the results were viable, the fetal heart tones were positive. On 25-MAR-2008 an ultrasound was performed for a threatened Ab and the results were viable. On 07-APR-2008 an ultrasound was performed due to first trimester bleeding and the results nonviable and a probable spontaneous abortion. On 07-APR-2008 at 8 4/7 weeks from her last menstrual period the patient experienced a spontaneous abortion. The products of conception were not examined. It was unknown if the fetus was normal. The complications during the pregnancy was first trimester bleeding. Illnesses during the pregnancy were Herpes and Ureaplasma urealyticum. The patient's outcome was unknown. A product quality complaint was not involved. Upon internal review the spontaneous abortion was considered to be an other important medical event. Additional information is not expected.

Other Meds: KLONOPIN; VALTREX; EFFEXOR

Lab Data: ultrasound, 03/19/08, reason-viability result-viable; FHT positive; diagnostic laboratory; ultrasound, 03/25/08, reason-viability result-threatened Ab; viable; ultrasound, 04/07/08, spontaneous abortion; nonviable

History: Pyelonephritis; Chlamydial infection; Termination of pregnancy-elective

Prex Illness: Pregnancy NOS (LMP =2/6/2008); Herpes simplex; Anxiety; Herpes virus infection

Prex Vax Illns:

Vaers Id: **314525-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		02-Jun-2008	03-Jun-2008	MA	WAES0805USA05092	03-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Confusional state, Convulsion, Injection site erythema, Injection site pain

Symptom Text: Information has been received from a registered nurse concerning her 22 year old daughter with a history of a seizure disorder who "recently" (date unspecified), was vaccinated intramuscularly with the third 0.5 ml dose of GARDASIL. Two hours post vaccination, the patient developed pain and redness at the injection site. About four hours post vaccination, the patient had a seizure and seemed confused for the next 24 hours. The patient sought unspecified medical attention. The patient has since recovered. No product quality complaint was involved. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Convulsion disorder

Prex Vax Illns:

Vaers Id: **314526-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		02-Jun-2008	03-Jun-2008	FR	WAES0805USA05465	03-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal discomfort, Abdominal pain, Dizziness, Menstruation irregular

Symptom Text: Information has been received from the Health Authority agency (ref. # PEI2008006884) concerning a 14 year old female with no reported history who on an unspecified date was vaccinated with a first dose of GARDASIL. On an unspecified date, the patient was vaccinated with a second dose of GARDASIL. Subsequently, the patient was hospitalized due to severe abdominal pain and a tense abdomen. Appendicitis was ruled out and she was discharged within a few days. Since then, the patient complained about irregular menstruation, recurring mild to intense abdominal pain as well as frequent dizziness. At the time of reporting, she has not yet recovered. Other business partner numbers included: E2008-04679. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **314527-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-May-2008	19-May-2008	0	02-Jun-2008	03-Jun-2008	FR	WAES0805USA05505	03-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chills, General physical condition abnormal, Nausea, Pallor, Vomiting

Symptom Text: Information has been received from a pediatrician concerning a 14 year old female who on 19-MAY-2008 was vaccinated with a third dose of GARDASIL (lot # not reported) IM into the upper arm. On 19-MAY-2008 in the evening post vaccination the patient experienced chills, pallor, nausea and vomiting. The general condition was reduced. The patient was hospitalised for diagnostics. At the time of reporting the symptoms were still ongoing. Previous two vaccinations with GARDASIL were given on unknown dates and were well tolerated. Other business partner numbers included are: E2008-04584. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Previous two vaccinations with GARDASIL were given on unknown dates and were well tolerated.

Prex Illness:

Prex Vax Illns:

Vaers Id: 314528-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	26-Jul-2007	26-Aug-2007	31	02-Jun-2008	03-Jun-2008	FR	WAES0805USA05506	03-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1518F	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Autoimmune disorder, Chorea, Condition aggravated, Dizziness, Dyskinesia, Headache, Hepatomegaly, Muscle disorder, Visual disturbance

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 31-MAY-2007 was vaccinated with a first dose of GARDASIL (lot# 654740/0859F; batch # NE29660) and was well tolerated. On 26-JUL-2007, the patient was vaccinated with a second dose of GARDASIL (lot# 1518F; batch # NF32800). Concomitant therapy included hormonal contraceptives (unspecified) for systemic use. From 26-AUG-2007 onwards the patient experienced episodical headaches. On 29-AUG-2007 the patient developed abnormal vision of left side and further aggravation of headache. On 19-NOV-2007 the patient was vaccinated with a third dose of GARDASIL (Lot# 0354U; batch number NF58150). Since the beginning of December 2007 the patient developed abnormal vision on both eyes. Dizziness since January 2008 and since 29-FEB-2008 the patient experienced abnormal involuntary movements of her extremities and her mimic muscluature. On 03-Mar-2008 a serum Borrelia IgG antibody test and IgM AB test were performed and were negative, serum C-reactive protein test was 54.4 mg/L (normal range <5.0 mg/L), liquor albumine was 90.7 (normal range 139 to 246), liquor proteine was 176 (normal range k.A. <450), urinic acid was 368 mcmo1/1 (normal range 140 to 340 leuckocyte count was 5.45 Gpt/1 (normal range was 4.0 to 9.8 Gpt/1). On 05-Mar-2008 a cranial MRI was without pathological findings. On 10-Mar-2008 a serum copper test was 33.4 (normal range 10.1 to 18.4). On 11-Mar-2008 ds-DNA-autoantibodies was 32.9 (normal range k.A. <30). On 13-Mar-2008 a brain (SPECT) single photon emission computed tomography was with no pathological findings. On 14-Mar-2008 abdominal ultrasound showed a slight enlargement of the liver. The patient was hospitalised from 20-MAR-2008 to 07-APR-2008. At the admission examination showed a hypotonic-hyperkinetic left accentuated syndrome with choreactic hyperkinesias of upper extremities. On 27-Mar-2008 a cranial MRI showed without pathological findings and without evidence for Morbus Wilson of huntington chorea. Morbus Wilson

Other Meds: hormonal contraceptives (unspecified)

Lab Data: diagnostic laboratory test, 03Mar08, 90.7, Normal Range: 139 - 246, Comment: liquor albumine; diagnostic laboratory test, 03Mar08, 176, Normal Range: k.A. < 450, Comment: liquor proteine; diagnostic laboratory test, 03Mar08 368 mcmol/l, Nor

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **314530-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	14-Jan-2008	11-Mar-2008	57	02-Jun-2008	03-Jun-2008	FR	WAES0805USA05582	03-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Abortion induced, Drug exposure during pregnancy, Menstruation delayed

Symptom Text: This is a case of pregnancy follow-up reported on 14-APR-2008 by a consumer through the pregnancy registry. Information has been received from a 19 year old female who on 14-JAN-2008 was vaccinated with a first dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). The patient started a spontaneous pregnancy (estimated date of conception: 23-MAR-2008) 9 days after receiving the second dose of GARDASIL (batch number not reported) on 14-MAR-2008. No adverse reaction was reported. The patient had her last menstrual period on 11-MAR-2008. To be noted that the two doses of vaccine were administered by the patient's mother who was a nurse. It was reported that due to pimple observed by her dermatologist, the dosage of the patient's contraceptive pill was reduced. on 12- or 13-APR-2008, the patient noticed a delay in her menstruation and experienced abdominal pain. In April 2008 an ultrasound was performed and revealed incipient pregnancy. The patient had a voluntary termination of pregnancy on 25-APR-2008. The reason was that vaccination was performed about one week before ovulation. The patient chose abortion because she was not 100% sure that there was no risk. In hospital, she was also advised to abort. At the time of vaccination, the patient was on contraceptives, however she had gastroenteritis shortly before, then reducing the efficiency of the pill according to the mother. The outcome was not reported. The case is closed. The reporter felt that abortion was an other medical event. Other business partners included are: E2008-03459. No further information is available.

Other Meds: Hormonal contraceptives (unspecified) unk - unk

Lab Data: ultrasound, ??Apr08, Comment: due to abdominal pain and revealed incipient pregnancy

History: Gastroenteritis

Prex Illness:

Prex Vax Illns:

Vaers Id: 314546-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-May-2008	28-May-2008	0	02-Jun-2008	05-Jun-2008	GA		06-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2937BA	5	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0524U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure immeasurable, Cold sweat, Heart rate, Heart rate normal, Hypotonia, Oxygen saturation normal, Pain in extremity, Pallor, Wheezing

Symptom Text: Pt. was slumped over to Rt side, skin pale, cool & clammy to touch, c/o severe pain to Rt arm, cool compress applied to forehead & feet elevated, v/s unable to obtain B/P x3, P 68, SPO2 97%. EMS responded, wheezing auscultated x3 lobes, albuterol breathing Tx given, EMS transported pt to ER for evaluation.

Other Meds:

Lab Data:

History: None known

Prex Illness: None known

Prex Vax Illns:

Vaers Id: **314559-1 (S)** **Related reports:** 314559-2; 314559-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-May-2008	31-May-2008	9	02-Jun-2008	05-Jun-2008	NC		11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Chest pain, Dyspnoea, Pericardial effusion, Pericarditis

Symptom Text: 05/31/08- SOB and chest pain 06/01/08- Chest pain, pericardial effusion, Pericarditis 6/3/08-records received for DOS 5/31-6/2/08-DC DX: Pericarditis. Presented with chest pain for about 10 days and 2 days after vaccination for human papilloma virus.

Other Meds: Ventolin, Prednisone, Zithromax, Ibuprofen

Lab Data: 6/3/08-records received-D-dimer mildly elevated, CK increased 198, WBC 15.4, eosinophils % low 0.1, total protein elevated 8.8, anion gap elevated 17, globulin elevated 4.0. CT scan showed evidence of mild pericardial effusion.6/6/08-lab re

History: Asthma 6/3/08-records received- PMH: asthma. PMH: bronchial asthma. Penicillin allergy, peanut allergy, allergy to pertussis vaccine.

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **314559-2 (S)** **Related reports:** 314559-1; 314559-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-May-2008	24-May-2008	2	11-Jun-2008	12-Jun-2008	NC		12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Chest pain, Pericarditis

Symptom Text: Pericarditis Chest Pain

Other Meds:

Lab Data: Chest xray Labs Echo and CT

History: PCN Pertussis Peanuts

Prex Illness: None

Prex Vax Illns: screamed for hours~DTP (no brand name)~1~0~In Patient

Vaers Id: **314559-3 (S)** **Related reports:** 314559-1; 314559-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-May-2008	24-May-2008	2	14-Aug-2008	15-Aug-2008	--	WAES0807USA05030	15-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Chest pain, Dyspnoea, Pericardial effusion, Pericarditis

Symptom Text: This report was identified from a line listing obtained on request by the Company from an agency under the Freedom of Information Act. A 16 year old female with a medical history of asthma, bronchial asthma, penicillin allergy, peanut allergy and allergy to pertussis vaccine ("screamed for hours"), was vaccinated with the first dose of GARDASIL (Lot #660393/0067X) IM in the left arm on 22-MAY-08. Concomitant therapies include Ventolin, Zithromax, ibuprofen and prednisone. On 24-MAY-2008, the patient experienced chest pain and pericarditis. The patient went to the emergency room and was hospitalized. On 31-MAY-2008, the patient experienced chest pain and dyspnoea. On 01-JUN-2008, the patient experienced chest pain, pericardial effusion, and pericarditis on 03-JUN-2008. The patient went to the emergency room and was hospitalized. The diagnosis was pericarditis. The patient presented with chest pain for about 10 days and 2 days after vaccination with GARDASIL. No further information is available. The patient's chest pain and pericarditis were considered immediately life threatening. The originally reported source was not provided. The VAERS ID is 314559. A standard lot check investigation was performed. All in-process quality checks for the lot in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the center and was released. No further information is available.

Other Meds: VENTOLIN; ZITHROMAX; ibuprofen, prednisone

Lab Data: computed axial, 06/03/08 - CT scan showed evidence of mild pericardial effusion.; plasma D-dimer test, 06/03/08 - mildly elevated; serum creatine kinase, 06/03/08 198 - increased; WBC count, 06/03/08, 15.4; absolute eosinophil, 06/03/08 0.1

History: Asthma; Bronchitis asthmatic; Allergy to vaccine.

Prex Illness: Penicillin allergy; Peanut allergy

Prex Vax Illns:

Vaers Id: 314562-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	02-Jun-2008	02-Jun-2008	0	02-Jun-2008	09-Jun-2008	TX		09-Jun-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1758U	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2405AA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB236AA	0	Right arm	Intramuscular	
HEP	MERCK & CO. INC.	0723F	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Loss of consciousness, Muscle rigidity, Oral contraception

Symptom Text: On 06/02/2008 at approximately 11:20 a.m. client, Dora Hugo (20 years of age)lost consciousness after she received four vaccines (HPV #1; Adult dose of Hepatitis A; Adult dose of Hepatitis B; and Meningococcal Conjugate). Client stated that she was feeling light-headed after receiving the vaccines. She was instructed to lower her head beneath the level of the heart when she leaned over. She was escorted to the floor when her feet were elevated above the level of her head. Client did not strike her body or her head to the ground. Client's body was fully extended and rigid like fashion for a couple of seconds. The episode lasted for approximately 8-10 seconds and client regained consciousness. She immediately asked for a cookie. Client was asked if she had lost consciousness and she stated "yes". Client was asked to remain on the floor for a little while. Her feet were cold and her head was clammy. Client was asked if she could sit up. She was assisted to a sitting position and then she was sat in a chair. Client stated that she does not have a history of seizures; however, she stated that it was common for her to pass-out when she is hypoglycemic. Client stated that she had not eaten anything for breakfast. Client recovered and stated that she was well. She did refuse medical attention. Client is currently taking birth control pill (Drospirenone/Ethinyl Estradiol 3mg/.02mg once daily by mouth. Also, she stated that she completed a six day regimen of Azithromycin 250 mg once daily by mouth for a throat infection. Azithromycine was last taken on 06/01/2008. Client stated that she is not currently under a doctor's care and has no medical history. Client was escorted to the lobby where she waited 20 minutes before leaving the clinic.

Other Meds: N/A

Lab Data: N/a

History: N/A

Prex Illness: None

Prex Vax Illns:

Vaers Id: 314564-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	20-May-2008	20-May-2008	0	02-Jun-2008	09-Jun-2008	AL		09-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acne, Chills, Condition aggravated, Fatigue, Folliculitis, Headache, Lymphadenopathy, Migraine, Pain, Petit mal epilepsy, Rash, Scab, Stomatitis, Vaccine positive rechallenge

Symptom Text: Shot 1: Headache lasting several days; Shot 2: Headache lasting several days; Shot 3: Starting with 1 "pimple" on the day of the shot, there is a gradual developing folliculitis or rash on face and upper neck and hairline. This was treated as acne initially, because it took 2 weeks for me to realize my symptoms were from the shot. I suddenly began getting very frequent migraines almost immediately after the shot and they are ongoing. I also had a petit mal seizure after 1 week. I haven't had a seizure in years; the timing is proof that it is related to the shot. I have increasingly swollen glands, after a week and a half I developed sores on my gums, chills, fatigue, and now after 2 weeks I am unable to tame this painful scabbing rash all over my face.

Other Meds: Yaz, Adderall, Ambien, Ranitidine, Diflucan

Lab Data: I was given a strep test a week after the shot, as well as being examined for allergies, and diagnosed with migraines. A return visit to my GP resulted in an antibiotic prescription for Keflex, and a steroid shot.

History: Milk allergy, Dilantin allergy, Benzoyl Peroxide allergy

Prex Illness: None

Prex Vax Illns: Extended Headache~HPV (Gardasil)~2~27~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **314581-1** **Related reports:** 314581-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	02-Jun-2008	02-Jun-2008	0	02-Jun-2008	09-Jun-2008	CA		09-Jun-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2825AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1740U	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2552AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Hypotonia, Musculoskeletal stiffness, Pain, Unresponsive to stimuli

Symptom Text: Vaccines given at 11:20AM which consisted of HPV, MENACTRA and Tdap. MENACTRA given first then GARDASIL and finally Tdap. Child complained of pain even after first vaccine was given. After administering Tdap mother child called out to mother and went limp. Eyes were open the whole time but unresponsive. Arms tightened and clutched together. Patient came to after about 20 seconds.

Other Meds:

Lab Data: None ordered

History: Non Noted

Prex Illness: None

Prex Vax Illns:

Vaers Id: **314581-2** **Related reports:** 314581-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	02-Jun-2008	02-Jun-2008	0	17-Jul-2008	18-Aug-2008	CA	WAES0806USA02196	18-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2552AA	0	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	1740U	0	Unknown	Intramuscular	
TDAP	SANOFI PASTEUR	C285AA	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incontinence, Muscle contractions involuntary, Pain, Syncope, Unresponsive to stimuli

Symptom Text: Information has been received from a medical assistant concerning a 12 year old female with no medical history, who on 02-JUN-2008 at 11:20 was vaccinated IM in the left arm with a first dose of GARDASIL (Lot# 659962/1740U). Concomitant vaccinations included a first dose of MENACTRA (Lot# U2552AA), administered IM in the left arm, and a first dose of ADACEL (Lot# C2825AA) administered IM in the right arm. There were no illnesses at the time of vaccination. It was reported that the MENACTRA had been administered first, then GARDASIL, and then ADACEL. The child complained about pain after administration of GARDASIL. The medical assistant proceeded to administer the ADACEL and at 11:20 the child fainted upon the needle being withdrawn. The child's eyes were open and glossy, but was unresponsive. The child's arms were tightened and clutched together. The child also voided during this time. The child "came to" after about 20 seconds. No laboratory diagnostics were performed. The patient recovered on 02-JUN-2008. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 314649-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Aug-2007	20-Aug-2007	4	23-May-2008	28-Jul-2008	TN	WAES0708USA03632	28-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB186AA	0	Right leg	Intramuscular	
VARCEL	MERCK & CO. INC.	0645U		Unknown	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
MNQ	SANOFI PASTEUR	NULL	0	Right leg	Intramuscular	
HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site induration, Injection site oedema, Injection site reaction, Injection site swelling

Symptom Text: Information has been received from a registered nurse concerning a 13 year old female with a sulfa and erythromycin allergy with no additional pertinent medical history who on 16-AUG-2007 was vaccinated SC with a 0.5 mL dose of varicella virus vaccine live (Oka/Merck). On approximately 16-AUG-2007, (within 24 hours of vaccination), the patient experienced an injection site reaction. The patient had a hard raised swelling area the size of a "half dollar" following the varicella virus vaccine live (Oka/Merck) vaccination. The overall size of the swelling was about 6 to 8 inches in diameter on the arm. It was reported the patient contacted their physician. No diagnostic laboratory tests were performed. At the time of the report the patient was recovering. A product quality complaint was not involved. Follow-up information has been received from a registered nurse concerning a 13-year-old white female with Biaxin, sulfa and erythromycin allergy who on 16-AUG-2007 was vaccinated subcutaneous with a second 0.5 mL dose of varicella virus vaccine live (Oka/Merck) (lot # 657784/0645U). There were no illnesses at the time of vaccination. Concomitant vaccines administered on 16-AUG-2007 included a first intramuscular dose of Menactra administered intramuscular in the right thigh, a first dose of Havrix administered intramuscular in the right thigh, a dose of Boostrix and a dose of Gardasil (MSD). On 20-AUG-2007, the patient experienced an "injection site reaction; hard, raised edematous area the size of a quarter with outside area 6 to 8 inches in diameter". No diagnostic labs were performed. On an unspecified date the patient recovered from all adverse events. This is one of several reports received from the same source. Additional information is not expected.

Other Meds:

Lab Data: None

History:

Prex Illness: Drug hypersensitivity; Sulfonamide allergy; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: 314655-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	24-Aug-2007	24-Aug-2007	0	23-May-2008	28-Jul-2008	TN	WAES0708USA03653	28-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB186AA	0	Unknown	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B02AA	5	Unknown	Unknown	
VARCEL	MERCK & CO. INC.	0362U	1	Unknown	Subcutaneously	
HPV4	MERCK & CO. INC.	0469U	0	Unknown	Unknown	
MNQ	SANOFI PASTEUR	U2391BA	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Fatigue, Groin pain, Injection site induration, Injection site reaction, Injection site swelling, Lymphadenopathy, Oedema

Symptom Text: Information has been received from a registered nurse concerning a patient who was vaccinated SC with a 0.5 mL dose of varicella virus vaccine live (Oka/Merck). Within 24 hours of the vaccination the patient experienced an injection site reaction. The patient had a hard raised swelling area the size of a "half dollar" following the varicella virus vaccine live (Oka/Merck) vaccination. The overall size of the swelling was about 6 to 8 inches in diameter on the arm. It was reported the patient contacted their physician. At the time of the report the patient was recovering. A product quality complaint was not involved. Follow-up information was received on 13-SEP-2007. Follow-up information has been received from a registered nurse concerning a 12-year-old female with no pertinent medical history or allergies who on 24-AUG-2007 was vaccinated subcutaneous with a second 0.5 mL dose of varicella virus vaccine live (Oka/Merck) (Lot # 657192/0362U). Concomitant vaccines administered on 24-AUG-2007 included a first dose of Gardasil (MSD) (Lot # 6469U), sixth dose of diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (GlaxoSmithKline) (Lot # AC52B02AA), first dose of Menactra (Sanofi Pasteur) (Lot # U2391BA), and first dose of hepatitis A virus vaccine (unspecified) GlaxoSmithKline) (lot # AHAVB186AA). On 24-AUG-2007, the patient developed severe increased left thigh left groin pain; 2 inch edematous; reddened area noted on left thigh; lymph node in groin area enlarged and fatigue. The patient returned to the clinic for medical attention on 27-AUG-2007 and had a mean platelet volume of 10.0 fluid (normal range 0.0-9.9 fl). Subsequently, the patient recovered from all adverse experiences on 29-AUG-2007. This one of several reports received from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: mean platelet volume 08/27/07 10.0 fl

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 314661-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Mar-2008	19-Mar-2008	1	03-Jun-2008	04-Jun-2008	FL	WAES0805USA04752	04-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Vaccine positive rechallenge

Symptom Text: Information has been received from a certified medical assistant concerning a 11 year old female with seizure activity, temporal lobe lesion (is taking topiramate), no history of drug reactions/allergies, and a history of headache and migraine who on 18-MAR-2008 was vaccinated with a first dose of GARDASIL (lot # 659962/1740U) 0.5 ml IM In the left deltoid. Concomitant therapy also given on 18-MAR-2008 included MENACTRA, diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid. Other concomitant therapy included TOPAMAX. On 19-MAR-2008, the day after the first dose of GARDASIL, the patient experienced seizure activity at school, but it was not reported to the doctor's office at that time. On 19-MAY-2008, the patient was vaccinated with a second dose of GARDASIL (lot # 659962/1740U) 0.5 ml IM in the left deltoid. That evening, the patient had a seizure. Medical attention was sought in the office. Spectrascopy test result was normal; unknown when the test was performed. There was no fever post vaccination. Subsequently, the patient recovered from the seizure. Upon internal review, the seizures were considered to be Other Important Medical Events. Additional information has been requested.

Other Meds: TOPAMAX

Lab Data: diagnostic procedure - spectrascopy test: normal

History: Headache; Migraine

Prex Illness: Convulsion; Brain lesion

Prex Vax Illns:

Vaers Id: **314662-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		03-Jun-2008	04-Jun-2008	FR	WAES0805USA05462	04-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Headache, Herpes zoster, Malaise, Nerve injury, Pain, Rash

Symptom Text: Information has been received from the health authority agency (ref. # PEI2008006875) concerning a 14 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL (lot # not reported). On an unspecified date, the patient was vaccinated with a second dose of GARDASIL (lot # not reported). Subsequently, after the first vaccination with GARDASIL, the patient felt unwell and experienced dizziness, headache, and body pain. The outcome was not reported. These events were reported as non-serious. After the second dose of GARDASIL, on an unknown date, the patient developed severe skin rash, facial herpes zoster (twice), body pain and severe "nerve impairment in the knee" as reported by the patient's mother. She was hospitalized for several weeks. At the time of reporting, the patient had not yet recovered. Treatment with antiepileptic garbapentin was started on an unknown date. Other business partner numbers included: E2008-04768 and E2008-04680. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 314663-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	08-May-2007	18-May-2007	10	03-Jun-2008	04-Jun-2008	FR	WAES0805USA05464	04-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister, Erythema, Paraesthesia, Pruritus, Rash

Symptom Text: Information has been received from a physician concerning a 22 year old female, with no relevant history reported, who on 08-MAY-2007 was vaccinated with the first dose of GARDASIL, lot #, route and site not reported. Ten days post vaccination (18-MAY-2007), the patient developed relapsing genital exanthema with blisters, redness and severe itching. Additionally she complained about underbelly paresthesia. The second dose of GARDASIL, was given 02-JUL-2007, and the third dose of GARDASIL was given on 03-NOV-2007. The patient had been examined by several gynecologists and dermatologists who obtained diagnostic testing. Allergological tests (not otherwise specified) were carried out with no pathological findings. Relevant laboratory test data revealed the following: Herpes Simplex Virus Type 1/2 IgM was equal to 1.05 (slightly positive); serum immunoglobulin G (IgG) was negative; c-reactive protein was 39 mg/dl; varicella zoster immunoglobulin G antibody test (VZV IgG) was increased; and a vulvular biopsy on an unspecified date showed non-specific signs of inflammation. No cause was found for the patients experiences. Treatment with (acyclovir) was started on an unknown date with no improvement of symptoms. At the time of reporting the patient has not yet recovered. The reporting physician determined the genital rash and paresthesia to be an other important medical event and assessed the relation to GARDASIL as unlikely, he pointed out, just the temporal relation. The file has been closed. Other business partner numbers include E20080-04739. No further information is available.

Other Meds: Unknown

Lab Data: vulvar biopsy, non-specific signs of inflammation; allergy test, no pathological findings; diagnostic laboratory test, VZV IgG Ab; HSV type 1 and/or 2 identification PCR, 1.05, slightly positive; serum C-reactive protein, 39 mg/l; serum imm

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **314664-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Feb-2008	01-Feb-2008	0	03-Jun-2008	04-Jun-2008	AL	WAES0805USA05641	04-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction, Memory impairment, Urinary incontinence, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning a female patient (age not reported) who on an unspecified date was vaccinated with a first 0.5 mL dose of GARDASIL. Immediately after, she experienced a seizure and urinary incontinence. In approximately February 2008 ("past few months"), the patient experienced a seizure and urinary incontinence immediately after receiving the second dose of GARDASIL. The nurse reported that the patient recovered within a minute or two with no memory of what had happened. No treatment was required. Upon internal review, the patient's seizures were considered other important medical events. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 314665-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Nov-2007	Unknown		03-Jun-2008	04-Jun-2008	FR	WAES0805USA06160	04-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Asthenia, Condition aggravated, Dizziness, General physical health deterioration, Headache, Loss of consciousness, Post lumbar puncture syndrome, Speech disorder

Symptom Text: Information has been received from an agency (Ref. #PEI2008006874) via a letter from the mother of a 15 year old female patient with a history of Epstein-Barr Virus (EBV) infection (2005) and reduced general condition who on 21-AUG-2007 was vaccinated with the first dose of GARDASIL. On 14-NOV-2007, the patient was vaccinated with the second dose of GARDASIL. Concomitant medication was not reported. It was worth noting that the patient already had a reduced general condition since the EBV infection and often felt asthenic and dizzy. In approximately November 2007 (exact date was not reported), the patient was treated for borreliosis (although Borrelia was not detected) with rifampicin after the second vaccination. Since the second vaccination the patient often experienced a loss of consciousness and sudden speech disorder attacks and she was admitted to the hospital (dates not reported). All examinations performed (EEG, MRI and CSF) were normal. Symptoms did not improve and the patient was again hospitalized in December 2007 with the same results. From December 2007 until mid February 2008, the patient's condition was good. On 19-FEB-2008, the patient developed again attacks of dizziness and she felt asthenic. She also experienced headache which was probably caused by the lumbar puncture. On 21-FEB-2008, the patient was not able to walk, although she had no sensory disorder nor paresis and was again hospitalized. A neurological examination was performed which was normal and psychosomatic disorder was suspected. The causality and outcome of the events were not reported. Other business partner numbers included: E2008-04673. Additional information is not expected.

Other Meds: Unknown

Lab Data: electroencephalography, ??Nov?07, normal; magnetic resonance imaging, ??Nov?07, normal; neurological examination, 21?Feb08, normal; cerebrospinal fluid analysis, ??Nov?07, normal

History: Epstein-Barr virus infection

Prex Illness: Asthenia; Dizziness; Reduced general condition

Prex Vax Illns:

Vaers Id: **314674-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-Aug-2007	21-Aug-2007	0	23-May-2008	29-Jul-2008	TN	WAES0708USA04069	29-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB186AA	0	Right leg	Intramuscular	
MNQ	SANOFI PASTEUR	U2391BA	0	Left leg	Intramuscular	
HPV4	MERCK & CO. INC.	0469U	0	Right leg	Intramuscular	
VARCEL	MERCK & CO. INC.	658178/1013U	1	Left leg	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024AA	4	Right leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site erythema, Injection site induration, Injection site mass, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a registered nurse concerning a 11 year old female with peanut allergy who on 27-SEP-1996 was vaccinated with a dose of varicella virus vaccine live (Oka/Merck) (Lot # 658178/1013U). On 21-AUG-2007, the patient was vaccinated subcutaneously in the left thigh with a 0.5 mL dose of varicella virus vaccine live (Oka/Merck), a dose of meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA, lot # 62391BA, mfr. Sanofi Pasteur) "in the same thigh but many inches apart", a dose of GARDASIL vaccine (yeast) (lot # 0469U), diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (lot# AC52B024AA, mfr. GSK) and hepatitis A virus vaccine (unspecified) (lot# AHAVB186AA, mfr. GSK). The registered nurse reported that within 20 minutes post vaccination the patient experienced an injection site reaction with redness 1 to 1.5 inches in diameter. The patient sought unspecified medical attention. No treatment required. There was no product quality complaint involved. Follow-up information was received on 05-SEP-2007. Follow-up information was received via a telephone call with a registered nurse who stated she did not know if the patient had recovered. Follow-up information was received on 13-SEP-2007. Follow-up information was received via a telephone call with a registered nurse who updated the varicella virus vaccine live (Oka/Merck) lot number (658178/1013U). Follow-up information was received on 25-SEP-2007 from a registered nurse concerning a 11-year-old (also reported as 12 years old) white female with a peanut allergy who on 27-SEP-1996 was vaccinated with her first dose of varicella virus vaccine live (Oka/Merck) and her second subcutaneous 0.5 ml dose administered in her left thigh on 21-AUG-2007 (lot # 658178/1013U). There were no illnesses at the time of the report. Concomitant vaccines administered on 21-AUG-2007 (lot # 658178/1013U). There were no illnesses at the time of the report. Concomitant vaccines administered on 21-AUG-2007 included a first intramuscul

Other Meds:

Lab Data: None

History:

Prex Illness: Peanut allergy

Prex Vax Illns:

Vaers Id: **314721-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	23-Apr-2008	23-Apr-2008	0	03-Jun-2008	11-Jun-2008	CA		02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Blister, Burning sensation, Disturbance in attention, Erythema, Fungal infection, Herpes zoster, Pain, Rash, Sleep disorder, Vaginal infection, Vulvovaginal pruritus

Symptom Text: GARDASIL given 4-23-08 - That evening developed red patch upper chest -> blistered -> 4/20 spread along T3 dermatome. By 4-27-08. Pain along rash. 4-28-28 Treated with acyclovir 800 mg 5x/day x10days. 06/23/2008 MR received from OBGYN. Pt presented to office with red, blistery rash on R side of chest in T3 dermatome and itching and burning in vaginal area. DX: Shingles. Yeast vaginitis. Seen again 5/5/08 with rash better. C/o difficulty sleeping and concentrating.

Other Meds: Ortho Tri-Cyclen Lo

Lab Data: HSV culture negative. Labs: HSV cx (-).

History: PCN allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **314734-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	27-Feb-2008	27-Feb-2008	0	03-Jun-2008	11-Jun-2008	NY		11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB242AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1518U	1	Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	0930U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest discomfort, Dyspnoea, Throat irritation

Symptom Text: Four hours after HPV mother stated child developed throat irritation, shortness of breath. Next day chest discomfort.

Other Meds: Claritin PRN

Lab Data: None

History: Seasonal

Prex Illness:

Prex Vax Illns:

Vaers Id: **314741-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-May-2008	27-May-2008	0	03-Jun-2008	11-Jun-2008	LA		11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB253BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0063X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2549AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1781U	0	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Immediate post-injection reaction, Pallor, Syncope

Symptom Text: At 2:35 PM immediately after receiving HPV vaccine, pt became pale, diaphoretic and fainted. Easily aroused after approximately 2-3 sec. Cool wash cloth to neck and monitored for 25 min with mother present. Pt left clinic ambulatory with difficulty.

Other Meds: Zyrtec; Zoloft

Lab Data: None

History: Depression

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **314749-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-May-2008	Unknown		03-Jun-2008	11-Jun-2008	CA		11-Jun-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0930U	1	Right arm	Unknown	
MNQ	SANOFI PASTEUR	U2419AA	1	Left arm	Unknown	
TDAP	SANOFI PASTEUR	C2720AA	0	Left arm	Unknown	
VARCEL	MERCK & CO. INC.	1799U	1	Left arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB175AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inflammation

Symptom Text: Local inflammation to (L) arm.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **314768-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	05-May-2008	05-May-2008	0	03-Jun-2008	04-Jun-2008	IA		04-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site pain, Pain in extremity

Symptom Text: Pt c/o extremely sore arm, tenderness at injection site, and inability to lift arm above head since receiving 3rd Gardasil injection. Injection was given 5/05/08 and patient continued to c/o symptoms 5/20/08. Patient tried ice and ibuprofen with very minimal relief.

Other Meds: Citalopram Hydrobromide 20mg, Mircette, Valtrex

Lab Data:

History: Ehlers-Danlos Syndrome, Dysmenorrhea, Depression

Prex Illness: None

Prex Vax Illns:

Vaers Id: 314769-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Jun-2008	02-Jun-2008	0	03-Jun-2008	04-Jun-2008	MI		04-Jun-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2562AA	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2688AA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB114AH	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0067X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Heart rate, Loss of consciousness, Pallor, Respiratory rate, Syncope

Symptom Text: Administered Tdap, Hep A, and then HPV4. Within 5-10 seconds following the HPV4 client fainted, was unconscious for approx 15-20 seconds, woke up with ammonia inhalents. Color pale but pulse at approx 60/min and resp from 12-14/minute. Assisted to exam table, remained in clinic for 30 minutes under observation. Grandmother with client--states has hx of being "woozy". Menactra given after recovery.

Other Meds: None

Lab Data: none

History: None, no allergies noted.

Prex Illness: None

Prex Vax Illns:

Vaers Id: 314786-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-May-2008	23-May-2008	0	03-Jun-2008	09-Jun-2008	CA		11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB268DA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0667X	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2889AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2552AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness

Symptom Text: Patient had her 4 immunization given on both arms. Passed out right after (sitting on chair) for few seconds, recovered right away. VS taken, kept in bed for observation. MD notified & evaluated, later discharged to mother.

Other Meds: None

Lab Data: well care/immunization

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: **314834-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		23-May-2008	29-Jul-2008	PA	WAES0708USA05223	29-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	0778U	1	Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a 17 year old female who was vaccinated with varicella virus vaccine live (Oka/Merck) (657718/0778U). Concomitant therapy included human papillomavirus vaccine (MSD). Subsequently, the patient developed a rash after receiving her second dose of varicella. Additional information has been requested.

Other Meds:

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **314876-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Apr-2008	01-Apr-2008	0	04-Jun-2008	06-Jun-2008	FR	WAES0805USA04959	06-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Multiple sclerosis relapse, Paraesthesia oral

Symptom Text: Information has been received from a physician concerning a 22 year old female with multiple sclerosis (since 2001 following a hepatitis B vaccine) (manufacturer unknown) who in April 2008, was vaccinated with a first dose of GARDASIL. Three to four weeks after the vaccination with GARDASIL, the patient experienced a new flare of multiple sclerosis associated with circumoral paraesthesia and a left upper limb paresthesia. She was given 80 mg of PREDNISOLON and 15 days later she recovered from paraesthesia except mild circumoral paresthesia. It was also reported that in 2001, a lumbar puncture revealed an inflammatory CSF, an magnetic resonance imaging (MRI) showed hypersignals and evoked potentials that were normal. From 2001 to 2004, she was prescribed AVONEX but it was not well tolerated, then from June 2006 to March 2007 she was prescribed COPAXONE but she had allergic problems. In 2006 she had 4 flares of sensitivity to corticotherapy. In the beginning of 2007 she was prescribed IMUREL. A new flare of multiple sclerosis without any stimulus in 2007 was treated with corticosteroids. Upon internal review, multiple sclerosis relapse was considered an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: spinal tap, ??01, inflammatory CSF; magnetic resonance imaging, ??01, hypersignals

History:

Prex Illness: Multiple sclerosis

Prex Vax Illns:

Vaers Id: 314878-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	Unknown	01-Jul-2007		04-Jun-2008	06-Jun-2008	NY	WAES0805USA06228	06-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypoaesthesia, Inappropriate schedule of drug administration, Multiple sclerosis, Optic neuritis

Symptom Text: Information has been received from a physician concerning a 29 year old female with no pertinent medical history or drug reactions/allergies who in July 2007, was vaccinated with a first dose of GARDASIL. There was no concomitant medication. In September and December 2007 the patient was vaccinated with a second and third dose of GARDASIL respectively. The physician reported that on an unspecified date the patient was diagnosed with multiple sclerosis and it may be related to GARDASIL. The patient has had optic neuritis and numbness on half of her body. At the time of reporting the patient had not recovered. No additional information has been reported by the physician. The physician felt that multiple sclerosis was considered to be disabling. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 314879-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Jan-2008	01-Jan-2008	0	04-Jun-2008	06-Jun-2008	DC	WAES0805USA06185	14-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Cataplexy, Dizziness, Dysarthria, Dyspnoea, Fatigue, Hallucination, Hypersomnia, Loss of control of legs, Movement disorder, Narcolepsy, Sleep disorder, Syncope, Tremor

Symptom Text: Information has been received from a physician concerning an 11 year old female with penicillin allergy and no pertinent medical history who in January 2008, was vaccinated with a third dose of GARDASIL. There was no concomitant medication. In January 2008, the patient developed cataplexy 1 to 3 days after vaccination. About 2 months later in March 2008, the patient developed narcolepsy with hallucinations and a limb movement disorder. The patient was seen in the physician's office and was treated with an unknown stimulant. On unspecified dates the patient had a computed axial tomography, poly sleep latency tests and an magnetic resonance imaging (MRI) was ordered. At the time of reporting the patient had not recovered. The physician considered the patient's cataplexy and narcolepsy with hallucinations and limb movement disorder were considered to be disabling and other medical events. Additional information has been requested. 8/13/2008 Outpatient records received from 3/2008 to 6/2008 with fnal dx: narcolepsy. Pt initially developed sx of dizziness, fatigue, decreased energy, interupted sleep and episodes offalling asleep/losing bodily control but not fully passing out following 3rd HPV shot in 1/2008. Initially thought to be vasodepressive sx tx'd with increased salt and fluids without improvement. Seen once in ER in 2/2008 for episode of shuddering, weakness, excessive sleepines/syncope without dx. Seen by neuro with w/u WNL. Has had episodes of slurred speech and difficulty catching breath. Picture more c/w cataplexy/narcolepsy.

Other Meds: None

Lab Data: computed axial; sleep study, poly sleep latency tests; magnetic resonance, ordered. Labs and Diagnostics: Brain MRI WNL. CT scan WNL. TSH, T3 and T4 WNL.

History: PMH: Allergy to PCN.

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **314880-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	16-Jan-2008		04-Jun-2008	06-Jun-2008	FR	WAES0805USA06158	06-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Acute febrile neutrophilic dermatosis, Chillblains, Erythema multiforme, Leukocytoclastic vasculitis

Symptom Text: Information has been received 28-MAY-2008 from a health authority from a health care professional concerning a 16 year old female who was vaccinated with a dose of GARDASIL date, site and route of administration, lot number are unknown). On 16-JAN-2008 the patient experienced Sweet's syndrome, an erythema exsudativum multiforme, pernio and an urticarial vasculitis. The patient fully recovered on 01-FEB-2008. The health care professional made a biopsy to confirm the pernio. The health care professional also took a blood test and the abnormal results were a decreased hemoglobin, iron and ferritin. Additional information has been requested. The reporter felt the events were considered to be an other medical event. Other business partners included are: E2008-04909.

Other Meds: Unknown

Lab Data: biopsy, confirmed pernio; hemoglobin, decreased; urine iron test, decreased; serum ferritin assay, decreased

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 314881-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Mar-2008	26-Mar-2008	9	04-Jun-2008	09-Jun-2008	FL	WAES0805USA06024	30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Dyskinesia, Gait disturbance, Headache, Motor dysfunction, Paraesthesia, Paralysis, Quadriparesis, Sensory loss

Symptom Text: Information has been received from a nurse practitioner concerning a female (age not reported) who on an unspecified date was vaccinated with her first and only dose of GARDASIL 0.5 mL. There was no concomitant medication. Subsequently "one week after vaccination" the patient developed total body paralysis and was hospitalized and all the lab tests which included a complete blood cell count came back negative. Several days after the hospitalization, the patient got better and was released. The reporter considered that total body paralysis to be disabling. Additional information has been requested. 6/25/2008 MR received for ER visit 3/26/2008 with DX: Quadriparesis-resolved. Pt developed a h/a, took a nap and awoke with inability to move all 4 extremities. Parent reports that this is the 3rd episode of these sx. During triage, unable to move 4 extremities. 1 hr later continued to have some motor and sensory deficits. Tingling reported in legs. Able to move toes after several hours and ambulating with slow unsteady gait and jerky movements in several more. D/C with resolution of sx in ~6 hrs from arrival.

Other Meds: None

Lab Data: diagnostic laboratory, negative; complete blood cell, negative. Labs and Diagnostics: CT Brain scan unremarkable. MRI cervical spine w/ straightening of cervical lordosis and incidental adenoidal hypertrophy. CXR WNL. CBC, UA and Chem WNL.

History: Unknown. PMH: asthma.

Prex Illness:

Prex Vax Illns:

Vaers Id: **314917-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Aug-2007	01-Aug-2007	0	23-May-2008	30-Jul-2008	AZ	WAES0709USA01012	30-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Injection site erythema, Injection site swelling, Nausea

Symptom Text: Information has been received from a physician concerning an 11 year old female consumer who "about one month ago" was vaccinated with a second dose of varicella virus vaccine live (Oka/Merck). Additional suspect therapy included a second dose of Gardasil (MSD). Other concomitant vaccination may have included Menactra. " Soon after vaccination" the patient developed nausea, dizziness, injection site redness and injection site swelling. The patient was examined by the physician. Subsequently, the patient recovered. No further information was provided. There was no product quality complaint involved. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 314918-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-May-2008	30-May-2008	3	04-Jun-2008	09-Jun-2008	TN		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2406AA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB264CA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1757U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood product transfusion, Decreased appetite, Diarrhoea, Eczema, Excoriation, Gingival bleeding, Idiopathic thrombocytopenic purpura, Immune system disorder, Infectious mononucleosis, Lymphadenopathy, Nausea, Pain, Petechiae, Pruritus, Purpura, Pyrexia, Tonsillar disorder

Symptom Text: Dx with ITP. 6/10/08 Reviewed PCP medical records of 5/27-6/6/08. FINAL DX: Idiopathic thrombocytopenic purpura; mononucleosis Records reveal that on day of vaccination patient experienced low grade fever, decreased appetite, nausea, hands itching x 1 day. Exam revealed excoriated area of left hand between thumb & 1st digit appearing like eczema. Returned to office 5/30 w/petechial rash all over except hands & feet & diarrhea. Referred to hematology. Tx w/IVIG. Returned to office 6/2 w/improved purpura. Returned to clinic 6/4 w/continued improvement but new erythematous exudate & enlarged tonsills & cervical lymphadenopathy. Referred to heme for additional IVIG. By 6/6 platelets & rash had improved considerably. To continue f/u in 10 days for labs. 7/4/08 Reviewed heme/onc clinic medical records of 5/30/08 FINAL DX: immune mediated type thrombocytopenia. Records reveal patient experienced fever, achiness, nausea & diarrhea approx 8 days prior to onset of symptoms which resolved; gum bleeding & lower extremity petecchial rash on day of consult. Seen by PCP & referred emergently to heme/onc. Tx w/IVIG while in clinic & serial labs followed.

Other Meds:

Lab Data: Dx with ITP (5-30-08) LABS: SGOT 90, SGPT 87. UA w/occult blood. LABS: Initial plts 7K (L). Final plts 75. Monospot (+).

History: Dx ITP PMH: allergies PCN, cephapir

Prex Illness:

Prex Vax Illns:

Vaers Id: **314963-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Jun-2008	03-Jun-2008	0	04-Jun-2008	12-Jun-2008	LA		12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1226U	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2549AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Xanthopsia

Symptom Text: client experienced lightheadedness and visual changes in which everything appeared yellow within 5 minutes of the injection. vital signs remained stable w/o resp distress. Denied any dizziness or nausea. Client observed on unit for 40 minutes w/o any worsening changes. Client left unit w/o apparent distress with improvement in vision.

Other Meds:

Lab Data:

History:

Prex Illness: none

Prex Vax Illns:

Vaers Id: **314964-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	02-Jun-2008	02-Jun-2008	0	04-Jun-2008	12-Jun-2008	NC		12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye pruritus, Eye swelling, Rash, Urticaria

Symptom Text: APPROXIMATELY 3 HOURS AFTER GARDASIL GIVEN PATIENT NOTICED "RASH" ON ARM AND EYES BEGAN TO ITCH. 30 MINUTES LATER PATIENT TOOK HER MEDICINES FOR A SINUS INFECTION - ZPACK/FLONASE AND WITHIN ANOTHER 30 MINUTES EYES BEGAN TO SWELL AND AND HIVES ON CHEST BEGAN. WENT TO URGENT CARE WHO THEN SENT PATIENT TO E.R. PATIENT WAS GIVEN PREDNISONE, PEPCID AC AND BENADRYL. ALSO THAT MORNING PATIENT HAD TAKEN MUCINEX AND SUDAFED PE.

Other Meds: MUCINEX; SUDAFED PE; CONCERTA; NUVARING; CALCIUM; MULTI VIT; VIT C; IMIPRAMINE HCL; PROMETHAZINE PRN; MAXALT PRN; VICODIN PRN

Lab Data:

History:

Prex Illness: SINUS INFECTION

Prex Vax Illns:

Vaers Id: 314975-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	03-Jun-2008	03-Jun-2008	0	04-Jun-2008	05-Jun-2008	TX		06-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2407AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	M1758U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dysphonia, Fall, Headache, Heart rate decreased, Loss of consciousness, Malaise, Musculoskeletal stiffness

Symptom Text: ADMINISTERED AN HPV AND MENINGOCOCCUS AS FIRST TIME DOSES TO 21 YEAR OLD FEMALE. ADVISED CLIENT THAT IF SHE DID NOT EAT LUNCH SHE MAY FAINT AS IT IS A SIDE EFFECT OF BOTH VACCINES. SHE STATED SHE DID NOT EAT LUNCH. ADVISED CLIENT TO WAIT 15 MINUTES IN CASE SHE DID FEEL FAINT. AFTER RECEIVING THE IMMUNIZATIONS THE CLIENT STAYED IN THE CHAIR AND DID NOT GET UP. AFTER 5 MINUTES TELLS NURSE SHE IS FEELING BAD. I TELL HER IF SHE IS FEELING BAD TO STAY IN THE CHAIR. A FEW SECONDS AFTER STATING THIS SHE STARTS TO MOVE AND BECAME STRAIGHT AS A BOARD AND STARTED TO TURN FACE DOWN TOWARD THE CHAIR THEN FELL OFF THE CHAIR TO THE FLOOR LANDING ON HER LEFT SIDE OF HER BODY. SHE MADE A GROWLING SOUND AS SHE WAS MOVING. ON THE FLOOR SHE DID NOT MOVE AND I WENT TO SHAKE HER TO SEE IF SHE WAS BREATHING. I TOLD THE CLERK TO CALL 911 AND WAS CALLING HER NAME AND SHE STARTED TO MOVE AND TOLD ME "I AM ALL RIGHT". I ASKED HER AGAIN TO BE SURE AND SHE STARTED TO SIT UP AND SAID AGAIN "I AM ALL RIGHT". I TOOK HER PULSE AND IT WAS SLOW AND SLIGHTLY IRREGULAR. I ASKED HER IF SHE EVER HAD HER HEART CHECKED AND SHE SAID SHE DID WHEN SHE WAS YOUNGER BUT THEY DID NOT FIND ANYTHING. I ASKED HER IF SHE EVER HAD THIS HAPPEN BEFORE AND SHE TOLD ME WHEN SHE WAS LITTLE IT HAPPENED BUT THE LAST TWO TIMES SHE WAS IMMUNIZED NOTHING HAPPENED. SHE TOLD ME THEY USUALLY GAVE HER IMMUNIZATIONS WHEN SHE WAS LYING DOWN. SHE TOLD ME RECENTLY SHE WAS HAVING BLOOD DRAWN AND SHE PASSED OUT. I ASKED HER IF SHE SAW LIGHTS OR ANYTHING AND SHE TOLD ME SHE SAW A CARTOON LIKE THE ONE SHE WAS WATCHING IN THE WAITING ROOM BEFORE SHE WAS IMMUNIZED THEN EVERYTHING WENT BLACK THEN SHE SAW MY FACE. SHE SAID SHE DID NOT REMEMBER WHAT HAD HAPPENED. SHE SAID THAT HER LEFT UPPER FOREHEAD HURT BUT THAT WAS ALL. NOTHING ELSE HURT. SHE WAS ABLE TO SIT UP ON HER OWN AND FINALLY WAS ABLE TO STAND AND GET INTO THE CHAIR. THE CLIENT WAS VERY LARGE AND IT WAS NOT POSSIBLE TO KEEP HER FROM FALLING OUT OF THE CHAIR TO THE FLOOR BECAUSE OF HER SIZE. I GAVE HER A WET TOWEL AND SHE RUBBED I

Other Meds: UNKNOWN

Lab Data:

History: DENIED

Prex Illness: DENIED

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **314988-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Jan-2008	31-Jan-2008	0	05-Jun-2008	12-Jun-2008	VA		12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	11448U	0	Gluteous maxima	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure, Heart rate normal, Loss of consciousness, Pallor

Symptom Text: NURSE'S NOTES: Pt given first Hpv shot and got to check out window and pt passed out. Pt did not hit her head or any other areas of the body.Pt was pale in color. Bp 110/70 P- 80 .Pt given sips of water and stated that she felt fine. Taken to exam room for observation for any other symptoms. Bp 108/ 70 P- 84. Pt continuing taking water. Pt with mother and waited in room. Pt left with mother and was not dizzy, light headed or having any other symptoms.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **314994-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-May-2008	01-Jun-2008	5	05-Jun-2008	16-Jun-2008	VA		16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	1	Left arm	Intramuscular	
	TYP	SANOFI PASTEUR	A0446	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site urticaria, Injection site warmth

Symptom Text: red, itching, wheel at site of injection, warm to touch, treated with Benadryl gel, symptoms lasted x1 week. observed upon waking up in the morning of 6/1/08.

Other Meds: N/A

Lab Data: N/A

History: allergy to Amoxicillin

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: 315002-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	10-Dec-2007	05-Jan-2008	26	05-Jun-2008	16-Jun-2008	NH		23-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contraception, Dizziness, Paraesthesia, Stress, Vitreous floaters

Symptom Text: One month after 2nd vaccine in Gardasil series (in Dec. 2007), began having tingling and numbness on and off in the hands, feet, arms, and legs, including right arm (site of injection). After third vaccine (in April 2008), immediately noticed an abundance of eye "floaters," including a dark, shadowy floater. Tingling has continued intermittently through the present date (June 5, 2008). I have seen numerous doctors, a neurologist, an ophthalmologist, and counselors to deal with the stress of the ordeal. I have received clean tests for Lyme, B12 deficiency, rheumatoid arthritis, high cholesterol/diabetes, anti-nuclear antibodies, TSH RPR, and segmentation westergreen. I have also had an EMG, a full battery evoked potentials test, and an MRI. All test have come back normal, but symptoms are persisting. 6/6/08 Patient w/numbness & tingling of hands/feet. BCP changed. 6/20/08 Reviewed PCP medical records of 1/9/08-5/8/08 which included neurology consult. FINAL DX: sporadic paresthesias Records reveal patient experienced hand tingling & numbness for 2-3 days, more on the right, in early January. Developed dizzy spells w/lightheadedness intermittently. Referred for second neuro opinion.

Other Meds: Sprintec

Lab Data: Blood tests (all came back clean/no detection of): Lyme, B12, rheumatoid arthritis, diabetes, anti-nuclear antibodies, TSH RPR, Segmentation Westergreen. Also had an EMG, full battery evoked potentials, and an MRI. All results normal. L

History: Seasonal and pet allergies, benign functional heart murmur PMH: asthma, BCP

Prex Illness: None

Prex Vax Illns:

Vaers Id: **315009-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	05-Jun-2008	05-Jun-2008	0	05-Jun-2008	12-Jun-2008	TX		12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye movement disorder, Fall, Head injury, Heart rate normal, Hypotonia, Injection site pain, Loss of consciousness, Respiratory rate

Symptom Text: Patient came to pharmacy to recieve the third in a series of Gardasil Shots. She confirmed she had no ill responses from her first two shots (I had asked her as I had not given the first two shots). I administered the vaccination, applied a bandaid to the injection site, and massaged the site briefly. We stood there for a few minutes, so I could observe the patient, talking about her work. After a few minutes she started to rub her arm, I asked her if it was bothering her more then the first two shots, and she said yes, that it was stinging a little more then the first two. Her eyes began to flutter so I grabbed her by her wrists. She begain to buckle at the knees and was falling towards the counter. I caught her head with my forearms, then she went completly limp. She then went backwards as she landed in a sitting position. i tried to lay her out softly but lost my grip, falling the rest of the way and hitting the back of her head on the floor. We raised her feet and called 911. She had normal breaths and pulse until emergancy help arrived a few minutes later. She came to and was coherent shortly after she had passed out.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **315019-1** **Related reports:** 315019-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	28-May-2008	29-May-2008	1	04-Jun-2008	10-Jun-2008	MA		06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Blindness transient, Bradycardia, Dizziness, Fatigue, Headache, Migraine, Orthostatic hypotension, Presyncope, Pupils unequal, Syncope vasovagal

Symptom Text: 05/29/08 - 8 pm - notice different size pupils, headache. 5/30/08 - 1 pm - dizziness, 30 second loss of vision, headache, uneven pupils. 6/4 uneven pupils, headache. 8/26/08 Reviewed ER medical records of 6/05/2008. FINAL DX: probable migraine HA Records reveal patient experienced HA, transient visual disturbance & intermittent unequal pupils. Referred to neuro & neuro-opthalmologist & those reports are included. Neuro exam was WNL. Neuro-Ophtho exam of 6/19/08 revealed significant orthostatic blood pressure changes with normal neuro/eye exam. Recommended additional cardiology w/u to include transesophageal echocardiogram, tilt table test & catecholamine blood test. 6/6/08 Reviewed PCP medical records. FINAL DX: vasovagal syncope Records reveal patient experienced good health on day of vax. Only complaint re BCP which caused nausea. Seen in ER on 5/30 w/episode of bilateral loss of vision that day. Had seen chiropractor & also exercised earlier that day. While stretching her neck during exercise, felt lightheaded & weak then lost vision in both eyes & felt faint. Symptoms resolved spontaneously in approx 20 seconds. Seen by PCP & sent to ER. Neuro consult done. Continued to feel lightheaded while in ER otherwise asymptomatic. Placed in cervical collar. F/U visit to PCP on 6/2 for continued vision difficulties & dizziness. Optho eye examination WNL. Eye exam on 6/2 revealed PERL. Concured w/ER diagnosis 6/13/08 Reviewed ER medical records of 5/30/2008. FINAL DX: near syncope Records reveal patient had seen chiropractor 5/30 for neck manipulation then went to gym for work out. While stretching neck laterally, had lightheadedness & felt weak then gradually lost vision in both eyes & became very light headed & felt like she was going to pass out. In ER, placed in cervical collar & felt better. 7/11/08 Reviewed opthamologist & neurologist medical records of 6/2-6/19/2008. FINAL DX: transient vision loss Records reveal patient experienced sudden onset dizziness & loss of visio

Other Meds: None

Lab Data: CAT scan 5/30/08, X-rays 5/30/08, heart EKG 5/30/08, MRI 6/3, MRA 6/3. LABS:cervical x-rays WNL. CT angiogram WNL. EKG sinus bradycardia. CBC, chemistry & UA all WNL. MRI/MRA WNL. CBC, chemistry & UA all WNL.

History: None PMH: tumor on heel, sepsis left calf, immune deficiency, metrorrhagia & dysmenorrhea, lazy eye as child. ETOH use.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **315019-2** **Related reports:** 315019-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	19-May-2008	21-May-2008	2	10-Jun-2008	11-Jun-2008	MA	WAES0606USA00293	11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness, Convulsion, Fatigue, Headache, Pupils unequal, Tunnel vision

Symptom Text: Information has been received from a health professional concerning a 22 year old female patient with a history of dysmenorrhoea and metrorrhagia who on approximately 19-MAY-2008, past week or two, was vaccinated IM with a 0.5ml dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified) and MICROGESTIN FE. On approximately 21-MAY-2008, 2 days after the vaccination, the patient experienced unequal pupils. She saw a chiropracter. The next day she had total blindness for 30 seconds and darkness and tunneling of vision. The patient was taken to the emergency room the weekend of 30-MAY-2008 to 01-JUN-2008. The following day she had a headache with fatigue. The patient's mother questions whether this was a seizure from GARDASIL. On 02-JUN-2008, the patient saw an opthamologist. At the time of this report, the patient's outcome was unknown. Upon internal review, total blindness and seizure were considered to be an other important medical event. Additional information has been requested.

Other Meds: MICROGESTIN FE; hormonal contraceptives

Lab Data: Unknown

History: Dysmenorrhoea; Metrorrhagia

Prex Illness:

Prex Vax Illns:

Vaers Id: 315128-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		06-Jun-2008	06-Jun-2008	FR	WAES0805USA06368	09-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Autoimmune disorder, Chemotherapy, Condition aggravated, Wegeners granulomatosis

Symptom Text: Information has been received from a physician concerning an 18 year old female with an unspecified autoimmune disorder (onset 4 years ago) who in January 2008, was vaccinated with the third dose of GARDASIL. In February 2008, the patient developed the autoimmune disease, Wegener's granulomatosis, and was hospitalized for an unknown period of time. The patient was treated with two unspecified chemotherapies. At the time of this report, the patient was not recovered. Neither the reporter nor the treating physicians of the hospital suspect any correlation between GARDASIL and the disease. No further information is available. Other business partner numbers include E2008-04932.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Autoimmune disorder

Prex Vax Illns:

Vaers Id: 315134-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	09-Apr-2007	Unknown		06-Jun-2008	09-Jun-2008	NC	WAES0704USA04780	09-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse through a Merck Pregnancy Registry concerning a 22 year old female with a drug reaction to erythromycin (vomiting) with no pertinent medical history. The patient had done a few home pregnancy tests prior to the administration of the GARDASIL. On 09-APR-2007 prior to vaccination, the patient had a pregnancy test in the physician's office and was vaccinated intramuscularly, into the left arm with a 0.5 mL dose of GARDASIL, (Lot # 657617/0384U). There was no concomitant medication. It was reported that the patient was pregnant after receiving the vaccine. Follow up phone call information obtained from a registered nurse reported that the patient had an early termination of pregnancy. No complications were reported, and the patient subsequently finished the GARDASIL series. Upon internal review, early termination of pregnancy was considered to be an other important medical event. No further information is expected.

Other Meds: Unknown

Lab Data: Beta-human chorionic, performed in office prior to vaccination.

History: Vomiting

Prex Illness: Pregnancy NOS (LMP = Unknown); Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: 315135-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Feb-2007	24-Feb-2007	23	06-Jun-2008	09-Jun-2008	--	WAES0805USA04530	10-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U1892AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0962F	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Central venous catheterisation, Chemotherapy, Chills, Fatigue, Hodgkins disease, Lymphadenopathy

Symptom Text: Information has been received from a pharmacist concerning a female (age unknown) who, on an unspecified date, was vaccinated with a first dose of GARDASIL. Subsequently, the patient was diagnosed with Hodgkin's lymphoma. The patient was seen at the office. At the time of the report, the patient was in remission. No product quality complaint was involved. Upon internal review Hodgkin's lymphoma was considered to be an other important medical event. This is an amended report. The serious criteria of other important medical event was changed to yes for Hodgkin's lymphoma. Additional information has been requested. 06/09/2008 MR received from oncologist which include PCP records as well as outside consultant records. Pt seen by pediatriction 2/27/07 with lymphadenopathy at the base of the neck. Initially thought to be r/t recent dx of mono in November 2006. RTO 4/10/07 with same, as well as chills and fatigue. Refered to oncologist and seen 5/2/2007. Dxd with Hodgkin's Disease following excisional lymph node bx. Staged at level IIA. Port placed for chemo-6 cycles of ABVD, which was successful in achieving remission. No evidence of recurrence at f/u visits.

Other Meds: Unknown

Lab Data: Unknown. Labs and Diagnostics: Lymph node bx (+) for nodular sclerosing Hodgkin's Disease. CT scan (+) for supraclavicular mass and multiple enlarged lymph nodes in the mediastinum. Bone marrow bx- no evidence of hodgkin's. ESR 29. CMP

History: Unknown. PMH: Innocent murmur. Infectious mono 11/2006. Chicken pox Allergy to Amoxicillin-rash/hives

Prex Illness:

Prex Vax Illns:

Vaers Id: **315136-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		06-Jun-2008	09-Jun-2008	--	WAES0805USA04887	09-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician who reported to the company representative that she heard multiple patients who received GARDASIL and experienced seizure after the vaccination. In a follow up telephone call to the physician she reported that "there was a little problem". "This was all from rumors from her patients who heard kids at their school were receiving GARDASIL and having seizures." The physician reported that not all the kids at the high school who had the seizures even received the GARDASIL vaccination. The physician said "again a rumor going around." She mentioned that she called the high school principal requesting further information about the events but she had not got any more information about patients and the events. She reported that she had no problems with GARDASIL. The physician would fax the local newspaper that talked about this incidence. No further information was available at the time of this report. The outcome was unknown. Upon internal review seizure was determined to be an other important medical event. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **315137-1** **Related reports:** 315137-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	23-May-2008	23-May-2008	0	06-Jun-2008	09-Jun-2008	PA	WAES0805USA05094	09-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Information has been received from a physician concerning a 21 year old female with acne who on 23-MAY-2008 was vaccinated IM with a first 0.5 ml dose of GARDASIL (lot # 659437/1266U). Concomitant therapy included BENZACLIN. On 23-MAY-2008, immediately after vaccination, the patient seizure, fainted and lost consciousness while in the physician's office. The patient sought medical attention in the physician's office. There were no laboratory or diagnostic tests performed. At the time of the report, the patient was recovering. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: BENZACLIN

Lab Data: None

History:

Prex Illness: Acne

Prex Vax Illns:

Vaers Id: **315137-2** **Related reports:** 315137-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	23-May-2008	28-May-2008	5	09-Jun-2008	16-Jun-2008	PA		16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope, Unresponsive to stimuli

Symptom Text: Syncope with possible seizure like activity immediately after IM injection of GARDASIL. Pt unresponsive approx. 10 seconds. Dr. was notified, vitals obtained & normal, pt given cool cloth, soda & crackers. Monitored for 45 minutes prior to leaving office.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **315138-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-Sep-2007	Unknown		06-Jun-2008	09-Jun-2008	NY	WAES0805USA05608	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Conversion disorder, Headache, Muscular weakness, Postictal state, Sensory disturbance, Syncope, Tremor

Symptom Text: Information has been received from a physician concerning a 17 year old female with no specified pertinent medical history, who on 07-SEP-2007 was vaccinated with the first dose of GARDASIL, lot # 654510/0962F, and she was reported as fine. Subsequently, sometime later on an unspecified date, the patient experienced seizures. On 17-NOV-2007, the client received her second dose of GARDASIL, lot # 657006/01884, and she is still experiencing some sporadic seizures/epilepsy activity. The patient is recovering and is being seen by a neurologist for follow-up. Upon internal review, seizures were considered to be an other important medical event. Additional information has been requested. 7/4/08 Vaccination record reveals patient received HPV #1, lot #0962F, on 5/29/2007; and HPV #2, lot #0188U, on 9/7/2007. 7/15/08 Reviewed hospital medical records of 11/17-11/20/2007. FINAL DX: Conversion disorder Records reveal patient experienced syncope, right arm shaking, postictal confusion. Seen by PCP w/o treatment. Presented to ER w/right arm/leg weakness & unable to get OOB. On exam, c/o right temporal HA, RUE & RLE slightly weak w/decreased sensory. Gait was normal. Neuro & psych consults done.

Other Meds: Unknown

Lab Data: LABS: CT & CTA of head, EEG WNL. Blood work WNL.

History: Unknown PMH: asthma. Anxiety. On BCP.

Prex Illness:

Prex Vax Illns:

Vaers Id: 315139-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Mar-2008	26-May-2008	86	06-Jun-2008	09-Jun-2008	FR	WAES0805USA06366	09-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute myeloid leukaemia

Symptom Text: Information has been received from a general practitioner concerning a 15 year old female who in March 2008, was vaccinated with the second dose of GARDASIL. The first vaccination was administered in January 2008. On 26-MAY-2008, the patient was diagnosed with acute myeloid leukemia and was hospitalized. At the time of this report, the patient had not recovered. No further information is available. Other business partner numbers include E2008-04900.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 315140-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		06-Jun-2008	09-Jun-2008	FR	WAES0806AUS00010	09-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Oedema peripheral, Throat tightness

Symptom Text: Information has been received from a physician concerning a 16 year old female with asthma who was vaccinated with her second dose of GARDASIL (date not reported). Concomitant therapy included DTaP which was administered at the same time as GARDASIL. Subsequently, ten hours following vaccination with her second dose of GARDASIL and DTaP, the patient developed hand swelling and a sensation of tightness in her throat. Subsequently, the patient was taken to emergency department of hospital and was admitted for treatment. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: 315185-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	02-Jul-2007	03-Jul-2007	1	23-May-2008	01-Aug-2008	CO	WAES0707USA01455	01-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	MERCK & CO. INC.	0442U	0	Unknown	Unknown	
HPV4	MERCK & CO. INC.	0522U	0	Unknown	Unknown	
VARCEL	MERCK & CO. INC.	0609U	1	Left arm	Unknown	
TDAP	SANOFI PASTEUR	C2734AA		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contusion, Erythema, Nodule, Tenderness

Symptom Text: Information has been received from a health professional concerning an 11 year old female with no medical history or allergies who on 02-JUL-2007 was vaccinated on left arm with a dose of varicella virus vaccine live (Oka/Merck) (lot # 657715/0609U). The concomitant therapy on the same day included Gardasil (MSD) (Lot # 657737/0522U), and dose of Adacel (lot # C2734AA) and a first dose of hepatitis A virus vaccine inactivated (MSD) (Lot # 657307/0442U). There was no illness at the time of vaccination. On 03-JUL-2007, the patient developed a 2X4 cm nodule that was red and tender. It was reported that the nodule looked like a bruise. On 5-JUL-2007, the patient was recovering. No diagnostic laboratory tests were undertaken. There were no adverse events following prior vaccination. Additional information has been received from the health professional stating the patient developed a 2X4 cm nodule which was red and tender. There was no infection. The patient had recovered on 09-JUL-2007. No further information is expected.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **315237-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	05-Jun-2008	05-Jun-2008	0	06-Jun-2008	12-Jun-2008	NJ		12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure, Fall, Head injury, Syncope

Symptom Text: Pt fainted after GARDASIL vaccine injected. Pt fell to the floor. Pt helped back on table. Pt. c/o head injury, ice applied to bump in back of head, water, juice given. BP prior injection 106/60 and after injection 110/70 x 2. Pt to ER for evaluation and follow up.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 315248-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Jun-2008	03-Jun-2008	0	06-Jun-2008	12-Jun-2008	CA		12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypotension, Pallor, Syncope

Symptom Text: Pt received HPV vaccine then attempted to leave clinic after 10 mins and had syncopal episode, pale low blood pressure - was back to normal in 15 min.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **315250-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Jun-2008	04-Jun-2008	0	06-Jun-2008	11-Jun-2008	FL		11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Right leg	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2569AA	0	Left leg	Subcutaneously	
	VARCEL	MERCK & CO. INC.	1584U	1	Left leg	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Fainting, layed down, BP taken, pulse taken. Stable.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **315253-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Jun-2008	Unknown		06-Jun-2008	10-Jun-2008	CO		10-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHAVB519AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	1	Right arm	Intramuscular	
	IPV	SANOFI PASTEUR	A0169	1	Right arm	Intramuscular	
	MMR	MERCK & CO. INC.	1672U	1	Left arm	Subcutaneously	
	VARCEL	MERCK & CO. INC.	1807U	1	Right arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C2927AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: I accidentally administered Tdap instead of Td for dose #2 of primary series. (Received Tdap on 4-3-08). 6-4-08 - TC to mom - denies fever or swelling L arm.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 315257-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Jun-2008	03-Jun-2008	1	06-Jun-2008	11-Jun-2008	MO		11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	42567AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Chest pain, Dizziness, Nausea, Pain, Sleep disorder

Symptom Text: Patient describes immediate "sharp" pain to entire right shoulder and into right armpit. Awoke from sleep after 3 - 4AM next morning from sharp, stabbing pain rotating down from right armpit and across low chest/upper abdomen. Temperature 102, had nausea and was dizzy. No further episodes after time of follow-up exam on 6/3/08 in office. No source of fever, very painful to light touch on right side of chest (axillary line). Received Reoprasin, Orservation.

Other Meds: None

Lab Data: None

History:

Prex Illness: Sunburn over arms/shoulders

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **315262-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Jun-2008	03-Jun-2008	0	06-Jun-2008	12-Jun-2008	MS		12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2770AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1448U	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB268AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Head injury, Pallor, Syncope, Unresponsive to stimuli

Symptom Text: Walked out of room and 25 yards experienced a syncopal episode/hit head/unresponsive and large jerk one time for 30-40 seconds. Pale afterwards.

Other Meds:

Lab Data:

History: None

Prex Illness: None/Plantars Wart

Prex Vax Illns:

Vaers Id: **315280-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	05-Jun-2008	05-Jun-2008	0	06-Jun-2008	16-Jun-2008	TX		16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Syncope

Symptom Text: unusual pain at time of shot; fainted with 15 minutes of shot

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **315281-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Jun-2008	06-Jun-2008	0	06-Jun-2008	12-Jun-2008	FL		12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB222AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Syncope

Symptom Text: PT GIVEN TWO INJECTIONS. HEP A GIVEN IM/LD. HPV GIVEN IM/RD. PT. FAINTED ABOUT 2 MIN AFTER HPV WAS GIVEN. PT START TO SWEAT COOL TOWEL WERE PUT ON FOREHEAD AND NECK. AMMONIA INHALANT WAS USE. PT STAYED IM ROOM FOR 30 MINUTES AND FELT FINE. TIME START 11:15 AM-11:45AM.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **315303-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-May-2008	30-May-2008	3	06-Jun-2008	09-Jun-2008	NY	A0731566A	09-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB222AA	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1486U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Liver function test abnormal, Pyrexia

Symptom Text: This case was reported by a physician and described the occurrence of elevated liver function test in a 15-year-old female subject who was vaccinated with HAVRIX (GlaxoSmithKline). Concurrent vaccination included GARDASIL given on 27 May 2008. There were no concurrent medications. On 27 May 2008 at 16:45 the subject received 2nd dose of HAVRIX in the left arm. On 30 May 2008, 3 days after vaccination with HAVRIX, the subject developed a fever of 102 degrees. On 02 June 2008, the subject's fever had not resolved and the reporting physician sent the subject for blood work. Her CBC was 6300, epstein barr test was negative, all chemistries were normal with the exception of the following elevated liver function tests: GGT: 104, AST: 428, ALT: 352, LD: 786, bilirubin was 0.6 and her alkaline phosphatase was 92. This case was assessed as medically serious by GSK. At the time of reporting the subject fever was resolved (June 2008) and the outcome of the other events was unspecified. The physician considered the events were possibly related to vaccination with HAVRIX.

Other Meds: No concurrent medication

Lab Data: Alanine aminotransferase, 02Jun2008, 352; Alkaline phosphatase, 02Jun2008, 92; Aspartate aminotransferase, 02Jun2008, 428; Bilirubin, 02Jun2008, 0.6; Body temperature, 30May2008, 102; CBC, 02Jun2008, 6300; Epstein-Barr virus test, 02Jun2008

History: It was reported that the subject was sick in January 2008, but her liver function tests were normal. The subject has no history of adverse events following previous vaccinations.

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: 315326-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-Jun-2008	06-Jun-2008	1	06-Jun-2008	11-Jun-2008	PA		11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea

Symptom Text: Complained of nausea lasting a few days after receiving GARDASIL #1 4/3/08 and #2 6/5/08.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None known

Prex Vax Illns: Nausea~HPV (Gardasil)~1~13~In Patient

Vaers Id: **315331-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Jul-2007	10-Jul-2007	0	23-May-2008	01-Aug-2008	--	WAES0707USA02353	01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Subcutaneously	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received through the Merck pregnancy registry from a nurse practitioner concerning a 20 weeks pregnant 14-year-old female whose last menstrual period was 19-Jun-2007 (she had a full period throughout) with a concurrent condition of asthma and has no known allergies. On 10-JUL-2007 she was vaccinated at an unknown site with a subcutaneous injection of 0.5 milliliters varicella virus vaccine live (Oka/Merck). Suspected vaccinations included Gardasil (MDS), (duration and dose not reported), hepatitis A virus vaccine inactivated (manufactured unspecified), (duration and dose not reported) and Menactra. On 14-JUL-2007, the patient found out she was 20 weeks pregnant. Medical attention was sought. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: urine culture - slight urinary tract infection; hematology - HIV blood work non-reactive; total serum human chorionic gonadotropin test blood work - results not back; Rapid plasma reagin card - results not back

History:

Prex Illness: Pregnancy NOS (LMP=Unknown) Asthma

Prex Vax Illns:

Vaers Id: 315371-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Jun-2007	19-Jun-2007	1	23-May-2008	05-Aug-2008	--	WAES0707USA04075	05-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MEN	UNKNOWN MANUFACTURER	NULL		Right arm	Unknown	
VARCEL	MERCK & CO. INC.	NULL		Right arm	Subcutaneously	
HPV4	MERCK & CO. INC.	NULL		Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Mass, Skin warm

Symptom Text: Information has been received from a consumer concerning her 15 year old female daughter, with no pertinent medical history, drug reaction or allergies, who on 18-JUN-2007 was vaccinated subcutaneously into the right arm with 0.5 mL varicella virus vaccine live (Oka/Merck). Concomitant therapy that same day included meningococcal vaccine (unspecified) and Gardasil. The following day, on 19-JUN-2007, the patient developed a large knot, the size of a baseball, on right arm. The right arm was the arm the patient received both varicella virus vaccine live (Oka/Merck) and meningococcal vaccine (unspecified). It was very hot to touch and looked like a huge red mound, which ran in a oblong pattern down her arm to two inches from her elbow. She received the human papillomavirus vaccine in her left arm. At the time of reporting the patient was considered recovered as of 25 JUN 2007. Unspecified medical attention was sought. There were no diagnostic studies performed. There was no product quality complaint. Additional information is not expected.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 315394-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	29-Jun-2007	30-Jun-2007	1	23-May-2008	05-Aug-2008	NC	WAES0706USA01199	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0186U	0	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	0531U	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site oedema, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a registered nurse concerning a 13 year old white female with phenylketonuria who on 29 JUN 2007 at 9:00 was vaccinated subcutaneously into the left arm with a second dose of varicella virus vaccine live (Oka/Merck) (Lot # 657405/0531U). Concomitant therapy that same day included an intramuscular first dose vaccination of hepatitis A vaccine (inactive) (Lot # "0282F") and intramuscular first dose vaccination of human papillomavirus vaccine (GARDASIL), (Lot # 655618/0186U). There was no illness at the time of vaccination. On 30-JUN-2007 the patient developed a three inch area of redness, swelling and pain at the injection site of "Varivax" (left arm) the patient's guardian elected to have the patient seen in the emergency room. On 02 JUL 2007 the site was observed to be only slightly red and tender to touch, with slight edema. No treatment was given. The patient was recovered on 02 JUL 2007. There were no lab diagnostic studies performed. There were no known adverse events following prior vaccinations. There was no product quality complaint. This is one of several reports received from the same source. Additional information has been requested.

Other Meds:

Lab Data: None

History:

Prex Illness: Phenylketonuria

Prex Vax Illns:

Vaers Id: 315398-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Jul-2007	16-Jul-2007	0	23-May-2008	05-Aug-2008	--	WAES0707USA04383	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site rash, Injection site warmth, Pain, Pyrexia

Symptom Text: Information has been received from a nurse practitioner concerning an 11 year old female who on 16-JUL-2007 was vaccinated subcutaneously with a second single dose of varicella virus vaccine live (Oka/Merck) (Lot# 657620/0536U). Additional suspect vaccination included Gardasil vaccine (MSD). Other concomitant therapy included Menactra and diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (manufacturer unknown). Within 12 hours of being vaccinated the patient developed a severe injection site reaction that continued to become "more severe." The injection site rash was about 7 inches in diameter and wrapped around the patients arm, was warm, hard to touch in the middle and was less red on the outside of the rash. On a follow-up visit to the doctor the next day (on 17-JUL-2007) the patient had a low grade fever and a general feeling of achiness. Nurse practitioner was concerned that the patient might have cellulitis. On the third day following vaccination the patient returned for another follow up visit, the rash had stabilized. It was noted that the nurse practitioner treated the patient with Benadryl. Lab studies for a white blood cell count were normal. No other information was provided. There was no product quality complaint involved. Additional information has been requested. This is one of several reports from the same source.

Other Meds:

Lab Data: WBC count 07/16/07 Norma; body temp 07/17/07 - low grade fever

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 315412-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	05-Jul-2007	05-Jul-2007	0	23-May-2008	05-Aug-2008	NC	WAES0707USA04709	09-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
MNQ	SANOFI PASTEUR	U2327AA	0	Left leg	Unknown	
DTAP	UNKNOWN MANUFACTURER	AC52B005CA	0	Right arm	Unknown	
HEPA	MERCK & CO. INC.	NULL	0	Right arm	Unknown	
HPV4	MERCK & CO. INC.	0523U	0	Right leg	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Herpes zoster, Injection site erythema, Injection site swelling

Symptom Text: Follow up information has been received from a health professional concerning an 18 year old black female student, with no medical history on drug allergies, who on 05-JUL-2007 was vaccinated with her second dose of varicella virus vaccine live (Oka/Merck). Concomitant vaccinations administered on that same day included the first dose of hepatitis A vaccine virus (inactive) (MSD) (Lot# 656966/0018U) in the right arm, the first dose of GARDASIL vaccine (yeast) (MSD) (Lot# 657868/0523U) in the right thigh, diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (AC52B005CA) in the right arm and the first dose of meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA) (Lot# U2327AA) in the left thigh. There was no illness at the time of vaccination. On that same day, the patient developed a local reaction with 4.5 x 3.5 cm injection site swelling and 4.5 x 3.5 cm redness (left arm). It was also noted that the patient also developed zoster after vaccine earlier in life. It was unknown whether medical attention was sought. Subsequently, the patient recovered. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 315500-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-May-2008	29-May-2008	1	09-Jun-2008	10-Jun-2008	FR	WAES0806USA00564	10-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1147U		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Loss of consciousness, Nausea, Syncope, Vomiting

Symptom Text: Information has been received from a health professional concerning a 16 year old female patient with no relevant medical history reported, who on 28-MAY-2008 was vaccinated intramuscularly with a dose of GARDASIL (Lot # 1147U, batch # NH06740). On 29-MAY-2008, 24 hours after the vaccination, the patient experienced two syncopal episodes in which one of the episodes was associated with a loss of consciousness for several minutes. The patient went to the emergency room where clinical examination and biological tests performed were normal. Then the patient had epigastric pain with nausea and vomiting. She was hospitalized under surveillance during 24 hours. At the time of reporting, the patient's outcome was unknown. Other business partner numbers include: E200805037. Additional information is not expected. The case is closed.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, 29May08, normal; Physical examination, 29May08, normal.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 315501-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	22-Jun-2007	Unknown		09-Jun-2008	10-Jun-2008	TX	WAES0806USA00640	10-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed visiting nurse (L.V.N) through the Merck pregnancy registry, concerning a female who on 22-JUN-2007 was vaccinated with the first dose of GARDASIL (lot#, route and dose not reported). On 22-AUG-2007 the patient received the second dose of GARDASIL (lot#, route and dose not reported). The nurse reported that the patient then became pregnant and miscarried at 7 weeks gestation. The patient sought unspecified medical attention. On 03-JUN-2008, the third dose of GARDASIL vaccine (lot#, route and dose not reported) was given. No additional information was provided. Upon internal review, the patient's miscarriage was considered an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 315502-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-Mar-2008	28-Mar-2008	7	09-Jun-2008	10-Jun-2008	FR	WAES0806USA00741	10-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Balance disorder, Dysarthria, Pyramidal tract syndrome

Symptom Text: Information has been received from a neurologist concerning a 16 year old female with a history of hyperactivity who on 21-MAR-2008 was vaccinated with the first dose of GARDASIL via intramuscular route. Concomitantly, an unspecified treatment was taken. Approximately one week after vaccination, occurred balance disturbance with dysarthria. On an unspecified date, the patient was hospitalised. Clinical examination was performed on an unspecified date and showed pyramidal syndrome. Magnetic resonance imaging performed on an unspecified date showed several hypersignal located at brain among which one took the contrast. Lumbar puncture was performed on an unspecified ate, results were pending. Diagnosis pending as further examinations were on going and multiple sclerosis was suspected. According to the physician, the vaccination was not the cause of the symptoms. Other business partner numbers included E2008-05107. Additional information has been requested.

Other Meds: [therapy unspecified]

Lab Data: physical examination, pyramidal syndrome; magnetic resonance imaging, several hypersignal located at brain among which one took the contrast; spinal tap, results pending

History: Hyperactivity

Prex Illness:

Prex Vax Illns:

Vaers Id: 315503-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Jul-2007	28-Jul-2007	1	09-Jun-2008	10-Jun-2008	WI	WAES0805USA06000	10-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	0	Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Pain in extremity, Pyrexia, Syncope, Visual acuity reduced

Symptom Text: Information has been received from a physician concerning a 14 year old female, who on 27-JUL-2007 was vaccinated with a first dose of GARDASIL (Lot# 658100/0525U) and a dose of VARIVAX. Concomitant vaccination included diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid. On 28-JUL-2007 the patient called the physician's office to report that she experienced a fever of 101F, a sore arm (unspecified where), and a headache. The patient was treated with over the counter TYLENOL. On 26-SEP-2007 the patient was vaccinated with a second doe of GARDASIL (Lot # 0530U). There was no concomitant therapy. On 17-OCT-2007 the patient went to the emergency room. The patient's "eyes were getting dark" and her vision was fading. The patient experienced syncope. An EKG was performed with normal results except for borderline prolonged QT. The patient was referred to see a pediatric cardiologist on 15-NOV-2007. Another EKG was performed and was normal, and the QTC was also normal. The patient had been monitored. On 20-FEB-2008 the patient was vaccinated with her third dose of GARDASIL (Lot# 659962/1740U). There were no adverse reactions after the third dose. At the time of the report, the outcome of the patient was unknown. Upon internal review "eyes getting dark" vision fading was considered to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: electrocardiogram, 10/17?/07 - normal results except for borderline prolonged QT; electrocardiogram, 11/15/07 - normal and QTC was also normal; body temp, 07/28/07, 101F

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 315507-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	20-Apr-2007	17-Jun-2007	58	09-Jun-2008	10-Jun-2008	MT	WAES0708USA03050	10-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Inappropriate schedule of drug administration

Symptom Text: Information has been received through the Merck pregnancy registry concerning a 29 year old female with no pertinent medical history or no drug reactions/allergies who on approximately 20-APR-2007 was vaccinated with a first dose of GARDASIL (lot # unknown) injection. On 20-JUN-2007 the patient was vaccinated with a second dose of GARDASIL. There was no concomitant medication used. The consumer reported that she had a positive pregnancy test on 10-AUG-2007 (home pregnancy test and blood test). Her last menstrual period date was 17-JUN-2007, and the estimated due date was 23-MAR-2008. At the time of the report, the patient reported she had not had any reactions. Initial and follow up information has been received from the nurse practitioner who indicated that the patient did not carry the pregnancy to term. She indicated that the patient "had significant problems and miscarried the pregnancy." No other records were available. Upon internal review, the patient's miscarriage was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: serum beta-human, 08/10/07 - (HPT and Blood test) positive

History:

Prex Illness: Pregnancy NOS (LMP = 6/17/2007)

Prex Vax Illns:

Vaers Id: 315508-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	28-Feb-2007	28-Feb-2007	0	09-Jun-2008	10-Jun-2008	--	WAES0703USA04792	10-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0187U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received from a registered nurse for the manufacturing registry of GARDASIL concerning a 20 year old female with bipolar disorder, depression, anxiety, polycystic ovaries and thalassaemia minor who on 28-FEB-2007 was vaccinated with first dose of GARDASIL (Lot #656049/0187U, expiration date 29-SEP-2009). There was no concomitant medication (client told the nurse she was not taking any medications at the time). Prior to vaccination on 28-FEB-2007, urine pregnancy test was performed and was negative. Client presented to the office of 23-MAR-2007 and urine pregnancy test performed was positive for pregnancy. The patient's last menstrual period was 28-JAN-2007. Estimated date of delivery was 04-Nov-2007. Follow-up information indicated that the patient had a miscarriage at approximately 9 weeks gestation on an unspecified date. It was reported that the pregnancy was a spontaneous triplet pregnancy. There were three empty gestational sacs. No fetal heart tones were ever detected and there was no further progression of development. It was reported that the gestational sac sizes were about three to four weeks of development. At the time of the report the patient was pregnant again (WAES# 0806USA00961). The outcome of the patient was unknown. Upon internal review the miscarriage was considered to be an other important medical event. This is one of two reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: Urine beta-human, 02/28/07, urine pregnancy test negative; Urine beta-human, 03/23/07, urine pregnancy test positive.

History:

Prex Illness: Pregnancy NOS (LMP = 1/28/2007); Bipolar disorder; Depression; Anxiety; Polycystic ovaries; Thalassaemia minor

Prex Vax Illns:

Vaers Id: 315509-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	15-Oct-2006	30-Dec-2006	76	09-Jun-2008	10-Jun-2008	--	WAES0703USA01568	10-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Labour complication

Symptom Text: Initial and follow-up information has been received through the Merck pregnancy registry from a consumer concerning her 19 year old daughter with no pertinent medical history who on approximately 15-OCT-2006 was vaccinated with a first dose of GARDASIL. There were no concomitant medications. On 18-DEC-2006, the patient was vaccinated with a second dose of GARDASIL. On 30-DEC-2006, the patient found out she was pregnant. Unspecified medical attention was sought. In September 2007, the patient gave birth to a healthy female via primary cesarean section because she "just couldn't push that baby out." The baby weighed 9 pounds and 1 ounce. At the time of the report, both mother and baby were well without any problems. Upon internal review, "just couldn't push that baby out" was considered to be an other important medical event. Additional information is not expected.

Other Meds: None

Lab Data: diagnostic laboratory, "OB panel"

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 315510-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	25-Mar-2008	25-Mar-2008	0	09-Jun-2008	10-Jun-2008	FR	WAES0805USA06370	10-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abnormal behaviour, Amenorrhoea, Breast swelling, Bronchospasm, Dysphonia, Dyspnoea, Fluid retention, Injection site pain, Injection site swelling, Laryngeal oedema, Laryngospasm, Myocardial ischaemia, Pyrexia, Sinusitis, Stridor, Thyroiditis, Tracheal oedema

Symptom Text: Information has been received from an adult female dermatologist (probably older than 26 years old) with no allergies and no relevant medical history who on an unspecified date was vaccinated with a first dose of GARDASIL and on 25-MAR-2008 was vaccinated with a second dose of GARDASIL (batch number, route and site of administration not reported). She reported that on the day of vaccination (25-MAR-2008) she developed severe injection site pain and slight injection site swelling. She could not lie upon the spot. The pain lasted two weeks. One day after vaccination on 26-MAR-2008 she developed high fever and was almost hallucinating. After a few days, when she felt slightly better, her temperature was 39.6 centigrade. Since one day after vaccination she seemed to develop bronchospasm: shortness of breath and hoarseness developed, which increased in the days after that. She visited the General Practitioner (GP) after three days because she suspected upper respiratory tract infection, pneumonia or bronchitis. The GP said that her lungs were clean, but he prescribed ATROVENT. She visited a lung specialist who diagnosed that she did not have asthma but he did prescribed SYMBICORT and nasal spray. She received antibiotics as well as telephonic consultation with the GP. A few weeks after vaccination she developed sinusitis, which caused aggravation of the shortness of breath and hoarseness. She received a second time antibiotics and dexamethasone for ten days and a second nasal spray. She left to a foreign country on 24-APR-2008 and developed shortness of breath during the night, for which she was taken to the emergency room (ER) on 25-APR-2008. Her trachea was almost completely closed. Her diagnosis was stridor, tracheal oedema. An electrocardiogram (ECG) showed cardiac ischaemia. She received SOLUMEDROL 125 milligram, epinephrine and BENADRYL. She was monitor guarded in the hospital for five days (in the coronary care unit). On 30-APR-2008 she developed again laryngeal oedema and laryngeal spasms. The Ear Nose Throat

Other Meds: Unknown

Lab Data: electrocardiogram, 24Apr08, Comment: showed cardiac ischaemia; body temp, 27?Mar08, 39.6 Centigrade

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 315511-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		09-Jun-2008	10-Jun-2008	NY	WAES0805USA05997	10-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL. Subsequently the patient experienced a seizure. At the time of the report the patient's outcome was unknown. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 315512-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	25-Jul-2007	25-Jul-2007	0	09-Jun-2008	10-Jun-2008	PA	WAES0709USA04219	10-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature baby

Symptom Text: Initial and follow up information has been received from a licensed practical nurse and a nurse through the Pregnancy Registry for GARDASIL vaccine regarding a 24 year old female with von Willebrand's disease, seasonal allergies, hypertension, allergies to BENADRYL and aspirin and migraines who on 25-JUL-2007 was vaccinated intramuscularly with her first dose of GARDASIL (Lot # 658094/0524U). Concomitant therapy included OVCON 35, BENICAR and ALLEGRA. The OVCON 35 was discontinued on 24-AUG-2007. On 24-AUG-2007, the patient took a home pregnancy test (test not specified) which was positive (LMP = 20-JUL-2007). No symptoms have been reported. The patient was scheduled for an office visit on 26-SEP-2007. On 25-MAR-2008, the patient delivered a pre-term baby at 35 weeks gestation (not further specified). The baby had some respiratory difficulty at birth and was placed in the ICU, otherwise appeared healthy. No other details available at this time. Additional information is not available.

Other Meds: OVCON 35; ALLEGRA; BENICAR

Lab Data: beta-human chorionic, 08/24/07, positive

History:

Prex Illness: Pregnancy NOS (LMP = 7/20/2007); Von Willebrand's disease; Seasonal allergy; Hypertension; Drug hypersensitivity; Migraine

Prex Vax Illns:

Vaers Id: **315513-1** **Related reports:** 315513-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Aug-2007	01-Aug-2007	0	09-Jun-2008	10-Jun-2008	WI	WAES0708USA04006	30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Umbilical cord around neck

Symptom Text: Information has been received from the pregnancy registry for GARDASIL, via a registered nurse concerning a 19 year old female who on 01-AUG-2007 was vaccinated with her first dose of GARDASIL, (lot # 658094/0524U) 0.5ml, IM. Subsequently, a pregnancy test (blood test) was positive (LMP 25-JUN-2007, EDD 30-MAR-2008). The patient was placed on therapy with a prenatal vitamin, and amoxicillin 500mg for dental work, on an unspecified date. Follow up information from a physician reported that on 15-APR-2008, the patient delivered a 7.2 pound, normal, baby girl with an Apgar score of 6 and 8. The baby was delivered with a nuchal cord that was reduced and the baby was sent to the neo-natal intensive care unit for retractions. It was not reported if the baby was admitted to the NICU. No treatment or outcome information has been reported. Upon internal review, nuchal cord reduction was considered an other important medical event. Additional information has been requested.

Other Meds: amoxicillin; hormonal contraceptives; vitamins (unspecified)

Lab Data: beta-human chorionic, positive blood test

History: Dysmenorrhoea

Prex Illness: Pregnancy NOS (LMP = 6/25/2007); Dental examination

Prex Vax Illns:

Vaers Id: 315576-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Oct-2007	04-Dec-2007	43	09-Jun-2008	10-Jun-2008	TX		10-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	2	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Confusional state, Congenital central nervous system anomaly, Grand mal convulsion, Laceration, Loss of consciousness, Partial seizures, Postictal state

Symptom Text: Grand mal seizure occurred 1 month after GARDASIL #3. 8/22/08 Reviewed ER medical records of 12/2/2007. FINAL DX: seizures Records reveal patient experienced seizure in car (passenger) on way to school w/LOC & laceration of tongue. Was postictal & confused. no incontinence. Neuro consult by phone. Loaded w/anti-seizure med & was to be seen in neuro office next day. 4/8/09 Received Neuro consult 6/9-12/15/2008. FINAL DX: idiopathic generalized tonic-clonic & partial seizure disorder Records reveal patient experienced recurrent seizures 4/08 & had stopped antiseizure meds prior. Meds changed. Again stopped meds 6/08 & had partial seizure.

Other Meds: none

Lab Data: Normal MRI; EEG pending 6/17/08 Reviewed hospital labs. CBC WNL. Chemistry WNL except calcium 8.5(L). Urine drug screen (-). UA w/(+)ketones. CT head WNL. MRI brain WNL but w/ linear right lateral temporal anomaly thought to be ins

History: none PMH: had seizure 1 yr prior, neuro w/u inconclusive. Former meth & marijuana use. Psoriasis, eczema, HA, dizziness, blurred vision, confusion, difficulty concentrating, lethargy, slurred speech, dry eyes, poor handwriting. PE tubes in childhood. Family hx: alzheimer's, parkinson's, DM.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **315600-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-May-2008	27-May-2008	0	09-Jun-2008	18-Jun-2008	MS		18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Left arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB520AA	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Pruritus

Symptom Text: Vaccines administered at 2 PM. At 2:20 PM reported intense itching right arm. Vital signs stable. BENADRYL liquid given at 2:25 PM orally. At 2:35 reports itching redness right upper thigh.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **315644-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Jun-2008	05-Jun-2008	2	09-Jun-2008	16-Jun-2008	MD		17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2965BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cellulitis

Symptom Text: Pt developed small 4 cm cellulitis in left arm

Other Meds:

Lab Data:

History:

Prex Illness: None-

Prex Vax Illns:

Vaers Id: 315648-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Jun-2008	07-Jun-2008	1	09-Jun-2008	16-Jun-2008	TX		17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DT	SANOFI PASTEUR	U2024BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1757U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Injection site irritation, Injection site pain, Injection site swelling

Symptom Text: Irritation, swelling, pain to injection site left deltoid area duration 2 days today slight erythema

Other Meds: none

Lab Data: n/a

History:

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **315656-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-Jun-2008	09-Jun-2008	0	09-Jun-2008	16-Jun-2008	VA	VA08:009	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling cold

Symptom Text: Patient reported her throat was 'cool" and her left arm felt cool, also. She felt "light-headed" five minutes after vaccination. Dr. Day assessed patinet lying down in exam room. Dr. Day reported that patient spoke without difficulty, no swelling or edema, no wheezing. VS - WNL. Patient consented to lay down for 20 minutes, then sat in chair for 10 minutes, left with her mother without having any additional problems.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **315669-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-May-2008	16-May-2008	0	09-Jun-2008	19-Jun-2008	CO		19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2425AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash

Symptom Text: Pt reported to school health office 1:45 pm, 5/16/08, 3h after iz, with rash on (L) arm - HPV side. 3 areas on arm, 1 the size of a silver dollar, 2" below injection site. 2 smaller spots near elbow, each 1cm in size; Tx with itch relief; parent contacted. Observed for 40 min; sent home; f/u 5/19: no hives; patient reported they resolved after 4 hours.

Other Meds: None

Lab Data: N/A

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **315672-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	29-May-2008	29-May-2008	0	09-Jun-2008	18-Jun-2008	NV		18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2405AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0338U	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Nausea

Symptom Text: Child nauseated, lightheaded, dizzy immediately after injection. Needed to lie down for 30 min. Eventually recovered with no other effects.

Other Meds: clindamycin HCl 300 mg TID

Lab Data: 4:35PM-Pulse Ox-94% P-55 / BP-88/56 left arm; 4:50PM-Pulse Ox-97% P-70 / BP 92/62 left arm; 5:05PM-Pulse Ox-98% P-64 / BP-98/64 left arm; 5:25PM-Pulse Ox-98% P-65 / BP 92/62 left arm

History: None

Prex Illness: Strep pharyngitis on Abx tx

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 315674-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	03-Jun-2008	03-Jun-2008	0	09-Jun-2008	18-Jun-2008	MD		18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Cold sweat, Disturbance in attention, Dizziness, Feeling cold, Heart rate normal, Hyperhidrosis, Pallor

Symptom Text: 6-3-08 pt. received HPV #1, L delt. via biojector at 2:30 pm. 2:45 pm pt. became pale lightheaded & unable to concentrate. Placed head between legs . At 3 pm given juice, cool cloth to head & laid her back in chair. Approx 3:15 diaphoretic, P 71, BP 120/76. 3:30 pm ambulated to bathroom became lightheaded again. Laid back down cold clammy, diaphoretic, pale. 4 pm pt. states she felt better. Color pink, skin warm to touch.

Other Meds: ORTHOTRICYCLEN

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 315702-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	10-Mar-2008	10-Mar-2008	0	09-Jun-2008	19-Jun-2008	PA		19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Concussion, Head injury, Loss of consciousness, Skull fractured base

Symptom Text: 3/10/08, patient was given her 2nd GARDASIL vaccine, initially tolerated well. She was standing at the checkout area approximately 10 minutes after injection and passed out hitting her head on counter. She had a concussion, was sent to ER. While in ER CT scan which revealed 2 hair line fractures of occipital bone.

Other Meds:

Lab Data: CT scan noted 2 hair line fractures of occipital bone.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 315710-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Jun-2008	05-Jun-2008	1	09-Jun-2008	19-Jun-2008	WV		19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Pyrexia

Symptom Text: Fever: 0100AM Chills: 0100AM - Temp 103.6 oral; Taken to ER at 0230. While in ER was given; Two bags of IV fluids. Motrin 400mg and Zofram 2mg

Other Meds: None

Lab Data: CBC - Normal, BMP - Normal, Urinalysis - Normal, Strep screen - Negative, Chest XRay Normal, Tests to rule out bacterial or viral infection.

History: Seasonal Allergies

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 315712-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Jun-2008	03-Jun-2008	0	09-Jun-2008	19-Jun-2008	WV		19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Body temperature increased, Fatigue, Headache, Hypersensitivity, Injection site pain, Rash, Sinus congestion

Symptom Text: 3rd GARDASIL injection given at 8:15. Went home with baby sitter. Felt fine. Laid down @ 2:45 and woke up @ 3-3:15. Complained of severe abdominal pain, pain in injection site and H/A. Temperature 101 F. Baby sitter gave 2 Tylenol. Fever went down. At 7:30 rash on face, temperature of 99.9. Saw doctor. Had sinus drainage. Was given teaspoon Zantac and 2 Tylenol. 6/4/08, still has rash. Feels tired.

Other Meds: No

Lab Data: Dx: Allergic reaction to HPV

History: None known

Prex Illness: None known

Prex Vax Illns:

Vaers Id: 315717-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	05-Jun-2008	05-Jun-2008	0	09-Jun-2008	19-Jun-2008	GA		19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	2	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1891U	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Loss of consciousness, Musculoskeletal stiffness, Urinary incontinence

Symptom Text: The patient had just received her immunizations and PPD when she slumped over and lost consciousness. Her body was stiff (particularly her arms) and she lost bladder. She became alert after approximately 60 seconds and answered all questions appropriately but does have some amnesia surrounding the event. We kept her in the office for an additional 30 minutes for monitoring.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 315730-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Jun-2008	06-Jun-2008	0	09-Jun-2008	19-Jun-2008	NM		19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Cold sweat, Dizziness, Heart rate decreased, Oxygen saturation decreased, Pallor, Syncope

Symptom Text: Patient got clammy and dizzy with paleness at 1:32PM. At 1:33PM patient fainted. Blood pressure dropped to 80/41, O2 saturation dropped to 89%, Heart rate dropped to 51. Patient recovered after O2. Patient left office with stable vitals with mother at 2:20PM

Other Meds: None

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 315849-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	30-Apr-2007	30-Apr-2007	0	10-Jun-2008	11-Jun-2008	UT	WAES0705USA02699	11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0210U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Foetal malposition

Symptom Text: Information has been received from a physician and a 20 year old female consumer through a Merck pregnancy registry with no allergies and a history of 1 pregnancy and 1 live birth who on 30-APR-2007 was vaccinated with the first dose of GARDASIL (lot #0210U), 0.5 ml. Concomitant therapy included ALDARA. In approximately April 2007, it was determined that the patient was pregnant. The date of last menstrual period was 10-APR-2007 and estimated delivery date was reported as 15-JAN-2008. It was reported that the patient has had no ill effects. On 15-JAN-2008, the patient reported that she delivered a healthy baby girl weighing 7 lbs. 13 oz. via primary cesarean due to fetal malposition (baby was transverse). At the time of reporting, it was noted that mother and baby are both well, "without any problems." No further information is available.

Other Meds: ALDARA

Lab Data:

History:

Prex Illness: Pregnancy NOS (LMP = 4/10/2007)

Prex Vax Illns:

Vaers Id: 315850-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	12-Jun-2007	01-Aug-2007	50	10-Jun-2008	11-Jun-2008	NC	WAES0806USA00295	30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	03896	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Condition aggravated, Gallbladder disorder, Malaise

Symptom Text: Information has been received from a nurse practitioner concerning her 27 year old daughter with haemolytic anaemia (requiring blood transfusions every 10 to 12 weeks) and drug hypersensitivity to codeine and a history of splenectomy at 18 months of age and cholecystectomy (December 2007) who on 17-APR-2007, 02-JUN-2007 and October 2007 was vaccinated IM with a first, second and third 0.5 ml dose of GARDASIL. Concomitant therapy included YASMIN, folic acid, PAXIL and vitamins (unspecified). In August 2007, the patient required blood transfusions every 2-3 weeks until March 2008. Since March 2008, the patient has required blood transfusions every 5 to 6 weeks. Laboratory diagnostic studies include a complete blood cell count, liver function tests and reticulocyte count. At the time of this report, the patient had not recovered. Frequent blood transfusions was reported as an other important medical event. Additional information has been requested. 6/20/08-records received-10/05/07-declined tranfusion. LFTs normal. 10/5/07-Feeling sick. Scheduled for cholecystectomy for problems with gall stones and abdominal pain.

Other Meds: YASMIN; folic acid; PAXIL; vitamins (unspecified) 6/20/08-records received- Yasmin for birth control switching to NuvaRing. 4/2/08-remains on Yasmin.

Lab Data: complete blood cell; hepatic function tests; blood reticulocyte

History: Splenectomy; Cholecystectomy 6/20/08-records received- PMH: Pyruvate kinase deficiency hemolytic anemia. Splenectomy, inguinal hernia repair, breast reduction. Allergy to codeine, latex and betadine.

Prex Illness: Haemolytic anaemia; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **315854-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Mar-2008	09-Apr-2008	26	10-Jun-2008	11-Jun-2008	FR	WAES0805USA06367	11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1148U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pharyngitis, Purpura

Symptom Text: Information has been received from a physician concerning a 15 year old female with a history of overweight and appendicectomy who on 14-MAR-2008 was vaccinated with GARDASIL (lot# 1146U; batch number NH00410) by intramuscular route in the deltoid. The patient had no concomitant treatment. On 09-APR-2008 i.e. approximately 3 weeks after vaccination the patient developed pharyngitis. The test for streptococcus was negative. On 22-APR-2008 i.e. approximately 5 weeks after vaccination, the patient developed purpura on the legs. The patient was seen at the emergency room, however she was not hospitalised. The events were reported as moderate. As of 24-APR-2008, the patient had fully recovered. No further information was available. The reporter considered the events of purpura and pharyngitis were other medical events. The other business partners included are: E2008-04902.

Other Meds: None

Lab Data: Diagnostic laboratory test, streptococcus, negative.

History: Overweight; Appendicectomy

Prex Illness:

Prex Vax Illns:

Vaers Id: 315855-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Dec-2007	01-Mar-2008	79	10-Jun-2008	11-Jun-2008	FR	WAES0805USA06159	11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0253U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraception, Gait disturbance, Muscular weakness, No reaction on previous exposure to drug, Paraesthesia, Peripheral vascular disorder, Systemic lupus erythematosus

Symptom Text: Information has been received from a physician concerning a 17 year old female patient on 13-DEC-2007 was vaccinated IM into the left upper arm with a second dose of GARDASIL (Lot # 0253U; Batch# NF58540). Concomitant therapy included hormonal contraceptives (unspecified). In the beginning of March 2008, the patient experienced peripheral circulatory disorder, paraesthesia of the forearms and hands, muscle weakness and gait disorder. On 08-APR-2008, the diagnosis of systemic lupus erythematous was established. Treatment with PREDNISOLON was started. at the time of this report, the patient's symptoms were ongoing. It was also reported that the patient was vaccinated on 25-OCT-2007, with a first dose of GARDASIL (Lot# 1539F; Batch# NF42170) and it was well tolerated. Lupus erythematous, peripheral vascular disorder, paraesthesia, muscle weakness and gait disorder were considered other important medical events. Other business partners numbers include: E2008-04875. No further information is available.

Other Meds: hormonal contraceptives (unspecified), Unk - Unk

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 315857-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	26-May-2008		10-Jun-2008	11-Jun-2008	FR	WAES0806USA00529	11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chest pain, Dyspnoea, No reaction on previous exposure to drug

Symptom Text: Information has been received from a general practitioner concerning an 18 year old female who in May 2008, was vaccinated with the third dose of GARDASIL (lot no. not reported) via intramuscular route. Site of injection was not reported. On 26-MAY-2008 the patient experienced dyspnoea and chest pain and was hospitalized. She was treated with VOLTAREN and recovered on 29-MAY-2008. First and second vaccinations were well tolerated. Other business partner numbers include E2008-04983. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 315858-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	26-May-2008		10-Jun-2008	11-Jun-2008	FR	WAES0806USA00530	11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT No reaction on previous exposure to drug, Pain in extremity, Paraesthesia

Symptom Text: Information has been received from a general practitioner concerning an 23 year old female who in May 2008, was vaccinated with the third dose of GARDASIL (lot no. not reported) via intramuscular route. Site of injection was not reported. On 26-MAY-2008 the patient experienced pain in legs and paraesthesia of both arms and legs. The patient was admitted to hospital on 29-MAY-2008. Outcome was not reported. First and second vaccinations were well tolerated. Other business partner numbers include E2008-04984. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 315859-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Mar-2008	Unknown		10-Jun-2008	11-Jun-2008	FR	WAES0806USA00525	11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Nausea, Weight decreased

Symptom Text: Information has been received from a pediatrician concerning a 17 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL (lot number, injection site and route not reported). In March 2008, the patient was vaccinated with a second dose of GARDASIL (lot number, injection site and route not reported). Subsequently the patient lost weight, and complained about nausea and dizziness. She was admitted to hospital on an unspecified time. Outcome was not reported. Other business partner numbers include E200804942. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 315860-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-Dec-2007	14-Jan-2008	34	10-Jun-2008	11-Jun-2008	FR	WAES0806USA00523	11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0276U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Diarrhoea, Weight decreased

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 11-DEC-2007 was vaccinated with a first dose of GARDASIL (lot number 0276U, batch number NF58550) I.M. into the upper arm. Since 14-JAN-2008 the patient experienced stomach pain, diarrhoea and lost weight of 8 kg. She was admitted to hospital on 26-MAY-2008 for in-patient examinations. Gastroscopy, duodenoscopy, abdominal sonography and laboratory tests including blood count and inflammatory parameters showed no pathological finding. A psychological check-up is planned. Symptoms were ongoing at the time of reporting. Other business partner numbers include E200804923. Additional information has been requested.

Other Meds: Unknown

Lab Data: gastroscopy, no pathological findings; duodenoscopy, no pathological findings; abdominal ultrasound, no pathological findings; laboratory test, blood count no pathological findings; laboratory test, inflammatory parameters no pathological f

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **315861-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		10-Jun-2008	11-Jun-2008	FR	WAES0806USA00492	11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chills, Dizziness, Nausea

Symptom Text: Information has been received from a pharmacist concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (lot number, injection site and route not reported). Subsequently the patient experienced dizziness, nausea and chills since 6 months. The patient was hospitalized but no pathological findings were shown. The patient's symptoms were ongoing at time of reporting. Other business partner numbers include E200804922. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 315862-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	02-Apr-2007	01-May-2007	29	10-Jun-2008	11-Jun-2008	FR	WAES0806USA00405	11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1019F	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Depression, Mental disorder, Pain, Suicide attempt

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter who on 02-APR-2007 was vaccinated IM, into the deltoid, with a first dose of GARDASIL (lot #655635/1019F; batch NF03290). In the beginning of May 2008, the patient experienced depression. In November 2007 she had a "nervous breaking." She complained of pain in the whole body and attempted suicide. She was admitted to a psychiatric hospital on 09-APR-2008. Despite ongoing symptoms, the patient was vaccinated with a second dose of GARDASIL (lot #654948/0903F; batch NE47410) on 02-JUN-2007 and third dose of GARDASIL (lot #1536F; and batch NG01520). Other business partner included E2008-04868. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 315864-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	12-Mar-2008	Unknown		10-Jun-2008	11-Jun-2008	PA	WAES0805USA06371	11-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Genital haemorrhage, Intra-uterine death, Muscle spasms, Uterine dilation and curettage

Symptom Text: Information has been received from the pregnancy registry for GARDASIL from a nurse concerning a 21 year old female with no known pertinent medical history, or drug reactions/allergies who on 12-MAR-2008 was vaccinated with the first dose of GARDASIL (lot # 659657/1487U), 0.5ml, IM to the left deltoid. Concomitant therapy included FEMCON FE and prenatal vitamins (unspecified). On 18-APR-2008 the patient had a positive home pregnancy test. Her last menstrual period was 11-MAR-2008. She was seen for her first prenatal examination on 20-MAY-2008. The patient developed cramping and vaginal spotting on 28-MAY-2008 and was diagnosed by ultrasound on 30-MAY-2008 with fetal demise of twins. The patient was scheduled to have dilation and curettage and evacuation procedure. No other symptoms or treatment were reported. Upon internal review fetal demise of the twins was considered to be an other important medical event. Additional information has been requested.

Other Meds: FEMCON FE; vitamins (unspecified)

Lab Data: Ultrasound, 05/30/08, fetal demise of twins; Beta-human chorionic, 04/18/08, positive home pregnancy test.

History:

Prex Illness: Pregnancy NOS (LMP = 3/11/2008)

Prex Vax Illns:

Vaers Id: 315872-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-May-2008	29-May-2008	0	10-Jun-2008	19-Jun-2008	TX		19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Blood pressure, Dizziness, Heart rate, Pallor

Symptom Text: Vaccine adm 1838 after approx 2 minutes, pt feel week, pale and dizzy c/o fainting like sensation, pt alert and oriented x3. Ammonia inhalers given, PCP informed, pt placed in examination table for recovery. BP 90/58, SPO2 98-99 at room air pulse 66 bpm. Pt recovered and d/c home in good condition. 12 minutes - total - recovery time.

Other Meds: ADVAIR DISKUS, SINGULAIR, XOPHENEX, NASONEX, ZYRTEC

Lab Data: None

History: Asthma/allergies

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **315880-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-May-2008	28-May-2008	0	10-Jun-2008	19-Jun-2008	CA		19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	17404	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	1796U	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2358AA	0	Right arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	B222AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C2904AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Syncope, Tooth fracture

Symptom Text: Pt. fainted after receiving vaccines she hit head on counter and chipped her tooth.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **315885-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Mar-2007	Unknown		10-Jun-2008	19-Jun-2008	MS		19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain lower, Alopecia, Chest discomfort, Diarrhoea, Vomiting

Symptom Text: After receiving the GARDASIL vaccine, pt is losing lots of hair. It has been a year and she is still losing hair. She has diarrhea often and vomits weekly. She has also been experiencing lower right ab pain. She has also been hurting in her chest right side.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **315886-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Mar-2007	Unknown		10-Jun-2008	19-Jun-2008	--		19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthma exercise induced, Trichorrhexis

Symptom Text: Patient was given the GARDASIL vaccine and now her hair is breaking off. She has always had very healthy hair. She has also developed asthma induced by exercise.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **315899-1 (S)** **Related reports:** 315899-2; 315899-3; 315899-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Feb-2008	04-Feb-2008	-1	10-Jun-2008	11-Jun-2008	PA		16-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anxiety, Chest pain, Convulsion, Costochondritis, Diarrhoea, Dystonia, Gastrointestinal disorder, Muscle rigidity, Postictal headache, Postictal state, Tonic clonic movements, Tremor, Unresponsive to stimuli, Vomiting

Symptom Text: My daughter has been having seizures since she had her second Gardasil vaccination. She also had intestinal problems for approximately four weeks immediately after vaccination. She continues to have seizures. 6/16/2008 MR received for 2 ER visits 3/31 and 4/10 2008 with DX: Dystonic Reaction, Anxiety (3/31) and Seizure, Costochondritis (4/10). Initially presented with uncontrollable shaking and stiffness episodes several times/hr. Some diarrhea/ vomiting recently. MD observed tonic-clonic motions of the neck muscle. Pt remained awake. Seen again 4/10 with c/o of seizure with sharp chest pain. Tremors noted of the upper body. Recently started on Topamax for Seizure 7/15/2008 MR received for DOS 5/14-19/2008 with D/C DX: Non-epileptic seizures. Pt presented with ~6 week hx of episodes of unresponsiveness, jaw tremors with arm flexing which began 6 weeks after 2nd Gardasil vax. Pt has no recollection of events. Episodes down from 15-25/day to 1-2/day after starting Topamax and Keppra. Pt c/o post-ictal h/a and confusion. Pt had multiple events without EEG changes during hospitalization. Weaned from Keppra and Topamax and d/c.

Other Meds:

Lab Data: MRI, EEG, MRA, CT SCAN. Labs and Diagnostics: Head CT WNL. EEG WNL. CXR WNL.

History: none. PMH: anemia. abcess foot. Allergy to sulfa.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **315899-2** **Related reports:** 315899-1; 315899-3; 315899-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Feb-2008	31-Mar-2008	55	16-Jul-2008	17-Jul-2008	PA	WAES0807USA01607	27-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 21-NOV-2007 was vaccinated with the first dose of GARDASIL. On 05-FEB-2008, the patient was vaccinated with the second dose of GARDASIL. On 31-MAR-2008 the patient experienced her first seizure. The physician did not stated if the patient had had additional seizures. The patient had had a CT scan of brain and MRI of brain, both were negative. The patient had been seen by 3 different neurologists. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: head computed axial, negative; magnetic resonance, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **315899-3** **Related reports:** 315899-1; 315899-2; 315899-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		12-Mar-2009	13-Mar-2009	PA	WAES0903USA01142	27-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from an immunization coordinator at the physician's office concerning a female who was vaccinated IM with GARDASIL (Lot# not reported). And the patient developed seizure symptoms. Therapy with GARDASIL was discontinued. The outcome of adverse event was unknown. It was reported that the patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **315899-4 (S)** **Related reports:** 315899-1; 315899-2; 315899-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Feb-2008	07-Feb-2008	2	01-Apr-2009	02-Apr-2009	PA		02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	1	Right arm	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Amnesia, Arthralgia, Back pain, Confusional state, Convulsion, Diarrhoea, Dyspnoea, Eye pain, Facial palsy, Fatigue, Feeling abnormal, Hypoaesthesia, Migraine, Monoplegia, Mood swings, Muscle twitching, Nausea, Neck pain, Oropharyngeal pain, Paraesthesia, Regressive behaviour, Staring, Syncope, Tremor, Vomiting

Symptom Text: non-epileptic seizures, migraines, fainting, tremors, twitches, numbness, intermittent leg paralysis and facial paralysis, tingling, staring or blank episodes, eye pain, joint pain, neck pain, back pain, memory loss, confusion, brain fog, regression, mood swings and chronic fatigue; bouts of nausea, vomit, and diarrhea; throat pain accompanied by occasional difficulty breathing; nausea, nausea, diarrhea and vomitting began several days after; first seizure on 3/31/08; currently still has all symptoms

Other Meds: None

Lab Data: MRI, MRA, CT SCAN, BLOOD WORK MANY TIMES, EEG (MANY), VIDEO EEG (TWO WEEKS),

History: sulfa allergy

Prex Illness: None

Prex Vax Illns:

Vaers Id: **315914-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Jun-2008	10-Jun-2008	0	10-Jun-2008	18-Jun-2008	PA		18-Jun-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0368U	1	Right arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAUK324BA	1	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0063X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypotonia, Pallor, Syncope, Unresponsive to stimuli

Symptom Text: Patient became limp unresponsive,pale,slumped in chair, ammonia ampule used to gain responsiveness.Positioned verticle on exam table, vital signs taken. Responded quickly to ammonia ampule. No history of fainting with other vaccines. discharged from DOH alert, talking, walked to car. Episodelasted about 8 seconds.

Other Meds:

Lab Data: Vital signs at 19:45 B/P 94/62 tongue thrust 11:00 AM resting on exam table, alert, pink color to lips and face.

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **315916-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	09-Jun-2008	09-Jun-2008	0	10-Jun-2008	18-Jun-2008	TN		18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: At time when administrating the shot she fainted for about 30 seconds.

Other Meds:

Lab Data: n/a

History: ADHD

Prex Illness: refill on medication

Prex Vax Illns:

Vaers Id: **315917-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	10-Jun-2008	10-Jun-2008	0	10-Jun-2008	18-Jun-2008	PA		18-Jun-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0063X	1	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAU3215AAA	1	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	03686	1	Right arm	Subcutaneously	
TDAP	SANOFI PASTEUR	C2927AA	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypotonia, Pallor, Unresponsive to stimuli

Symptom Text: Patient became limp upon the administration of the fourth vaccine, nonresponsive, slumped in chair,pale color. ammonia ampule immediately used, patient immediately responded,alert,color improved(pink), able to sit, drink juice, talk. Episode lasted about 10 seconds. Left DOH talking,alert, walked to car.

Other Meds:

Lab Data: Observed at DOH for about 15 minutes following episode.

History: Mother reports patient had similar episode when under stress but not with previous vaccines.

Prex Illness:

Prex Vax Illns:

Vaers Id: 315920-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	10-Jun-2008	10-Jun-2008	0	10-Jun-2008	19-Jun-2008	MO		19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Fatigue, Nausea, Urticaria

Symptom Text: Five minutes after gardasil shot administration client c/o weakness, fatigue, light headedness, nausea. Approximately 45 minutes after administration client contacted office stating she now has hives on back, b/l arms, waist line and bra line.

Other Meds: n/a

Lab Data: n/a

History: n/a

Prex Illness: n/a

Prex Vax Illns: Faintness, low b/p~HPV (Gardasil)~1~19~In Patient

Vaers Id: 315934-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Jun-2008	09-Jun-2008	0	10-Jun-2008	19-Jun-2008	MA		19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2564AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0387U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope vasovagal

Symptom Text: Patient had a vasovagal attack in office. EMTs were called but patient denied to go to hospital as she was feeling fine and patient was monitored in office for half an hour.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **315936-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Apr-2008	Unknown		10-Jun-2008	19-Jun-2008	TX		19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2888AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Parent of child called me on 6/4/08 to state that unbeknown to her patient was pregnant when she received shots on 4/24/08. No known ill effects reported per parent.

Other Meds: None

Lab Data: N/A

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **315938-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
6.0	F	05-Jun-2008	Unknown		10-Jun-2008	19-Jun-2008	NY		19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1248U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Nurse gave GARDASIL to this 6 yr old female by mistake.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **315939-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
8.0	F	05-Jun-2008	Unknown		10-Jun-2008	19-Jun-2008	NY		19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Nurse gave GARDASIL to this 6 yr old by mistake.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 315980-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	18-Jul-2007	18-Jul-2007	0	11-Jun-2008	12-Jun-2008	CT	WAES0708USA05232	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0954F	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Caesarean section, Drug exposure during pregnancy, Fungal infection, Placenta praevia haemorrhage, Premature labour

Symptom Text: Initial information has been received for the Pregnancy Registry for GARDASIL from a physician concerning a 20 year old female who was a smoker and allergic to peanuts who on 16-JUL-2007 was vaccinated with a first dose of GARDASIL. The physician reported that the patient was pregnant when she was given the first dose of GARDASIL vaccine. It was unknown if patient sought any medical attention. The outcome was unknown. Follow up information from the doctor's office received concerning a 21 year old (previous reported as 20 years old) female patient who was a smoker (one pack per day), had one Pregnancy and one elective termination (date and year not reported). The patient also had concurrent condition of peanut allergy, attention deficit disorder, questionable bipolar disorder (off therapy x 6 months), "asthma rare", thalassaemia trait ("B thal trait") and was rhesus antibodies negative. On 18-JUL-2007 (previous reported as 16-JUL-2007) she was vaccinated with a second dose of GARDASIL, lot # 653938/0954F. It was reported that on 22-AUG-2007 patient was treated with VITAFOL +DHA for prenatal care and on 18-JAN-2008 she was treated with REPLIVAA 21/7) for anemia. On 20-FEB-2008 she was treated with MONISTAT 7) for yeast infection. It was also reported that she was off of therapy CONCERTA, ABILIFY and KLONOPIN for six months. In follow up information from the physician's office it was reported that patient had an ultrasound on 14-SEP-2007 for validity and dating. The result showed intrauterine pregnancy and fetal heart was positive. On 01-NOV-2007 the maternal serum alpha-fetoprotein test was done and the result was within normal. On 15-NOV-2007 a diagnostic test level 11 was done which showed placenta previa anatomic evaluation was within normal limit. On 21-NOV-2007, 04-FEB-2008 and on 03-MAR-2008 patient received three doses of globulin, RHOGAM x1 for Rh negative bleeding. In follow up it was reported that patient had routine pregnancy laboratory tests and in November 2007 she had "MSQS" laboratory test and the r

Other Meds:

Lab Data: ultrasound, 09/14/07, IUP (intrauterine pregnancy) + fetal heart (validity detecting); ultrasound, 11/15/07, label 11 ultrasound showed placenta previa placenta previa; diagnostic laboratory, 11/07, "MSQS" test results was within normal ran

History:

Prex Illness: Pregnancy NOS (LMP = 7/3/2007) Smoker; Peanut allergy; Attention deficit disorder; Bipolar disorder; Asthma; Thalassaemia trait;

Prex Vax Illns:

Vaers Id: 315981-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	26-Jul-2007	26-Jul-2007	0	11-Jun-2008	12-Jun-2008	--	WAES0708USA00777	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received from the Merck Pregnancy Registry via a nurse practitioner concerning a 17 year old female who on 26-JUL-2007 was vaccinated with a third dose of GARDASIL. Subsequently, the patient became pregnant. The patient's last menstrual period was on 15-Jun-2007 and the estimated date of delivery is 21-Mar-2008. No adverse reactions were reported. In August 2007 the patient had an elective termination. At the time of the report the patient's outcome was unknown. Upon internal review elective termination was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 6/15/2007)

Prex Vax Illns:

Vaers Id: **315982-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Sep-2007	01-Jan-2008	96	11-Jun-2008	12-Jun-2008	FR	WAES0806USA00442	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0354U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Type 1 diabetes mellitus

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who on 27-SEP-2007 was vaccinated intramuscularly into the upper arm with the third dose of GARDASIL (Lot #0354U, batch #NF58150). In January 2008 diabetes mellitus type I was diagnosed. At the time of this report, the patient's outcome was unknown. It was reported that the first and second vaccination with GARDASIL were were well tolerated. The reporter considered diabetes mellitus type I to be an other important medical event. Other business partner numbers include: E200804927. Additional information is not expected. The file is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: **315983-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		11-Jun-2008	12-Jun-2008	FR	WAES0806USA00526	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a gynaecologist concerning a female patient who in her 10th week of pregnancy, was vaccinated with a third dose of GARDASIL (lot number, injection site and route not reported). No detailed information was provided about the first and second dose of vaccination. In the 17th week of pregnancy the patient experienced a spontaneous abortion with a foetus who had a gastroschisis. The patient was hospitalized. Due to pathological findings of the fetus in ultrasonography, an amniocentesis was performed. The karyotype of the child was normal. The outcome was not reported. Other business partner numbers include E200804946. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, pathological findings in fetus; amniocentesis, karyotype was normal

History:

Prex Illness: Pregnancy NOS (LMP =Unknown)

Prex Vax Illns:

Vaers Id: **315984-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	28-Dec-2007	01-Apr-2008	95	11-Jun-2008	12-Jun-2008	FR	WAES0806USA00565	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0311U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Gastrectomy, Nausea, Perforated ulcer, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a physician concerning a 21 year old female who on an unspecified date was vaccinated with the first dose of GARDASIL. Subsequently the patient experienced nausea and vomiting on an unspecified date. On 28-DEC-2007 the patient was vaccinated intramuscularly with the second dose of GARDASIL (Batch # NG14100/Lot # 0311U) (site not reported). In April 2008, (4 months after vaccination), the patient experienced nausea, vomiting and epigastric pain all of moderate intensity. The patient was diagnosed with a perforated ulcer, hospitalized, and underwent a gastrectomy. Aetiology work-up of the ulcer was on-going. At the time of this report, the patient had not recovered. Additional information has been requested. Other business partner numbers include E2008-05053.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 315985-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	14-Jan-2008	20-Feb-2008	37	11-Jun-2008	12-Jun-2008	FR	WAES0806USA00713	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Colour vision tests abnormal, Eye pain, Headache, Hemianopia, Optic neuritis retrobulbar, Papilloedema, Scotoma, Visual acuity reduced, Visual disturbance

Symptom Text: Information was received from a local Health Authority (reference # NT20080226), concerning a 17 year old (also reported as 16 year old) female with a history of migraine, who on 14-JAN-2008 received a second dose of GARDASIL via IM route (injection site not reported). On 17-FEB-2008 (one month after vaccination) the patient experienced ocular pain cephalgia-like of moderate intensity more when mobilizing the eye. Then 72 hours after i.e. on 20-FEB-2008 she had visual acuity decreased and feeling of white spots. There was decreased visual acuity and papillary oedema with scotoma in the left inferior temporal face. On 31-MAR-2008 during her hospitalization neurological clinical examination was normal and biological test was normal, there was no cellular reaction, cerebrospinal (originally reported as cecervicospinal) fluid proteins were normal, electrophoresis revealed that there were no oligoclonal bands, inflammatory parameters and viral serologies were normal. Encephalic MRI showed no hypersignals. Evoked potentials were a little bit increased but still in normal ranges with no anomaly as to the amplitude. She was diagnosed an optic neuritis retrobulbar. She was prescribed SOLU-MEDROL IV during 3 days. On 17-APR-2008 examination revealed visual acuity of 6/10 for left eye and 10/10 for right eye. There was no diplopia. Examination with slit-lam was normal, pupillary reflex was normal. Mobilization of eyeball was normal and without any pain. Visual field TG2 found some nasal deficiencies on the right and a left nasal quadranopsia. Vision of colours was unsaturated and normal on the right and showed some anomalies of tritan type on the left. Fundus oculi showed bilateral papillary oedema decreasing. In May the patient was improving. Patient was recovering. Other business partner numbers included: E2008-05044. No further information is available. The file is closed.

Other Meds: Unknown

Lab Data: neurological examination, 31Mar08, normal; diagnostic laboratory test, 31Mar08, normal; magnetic resonance imaging, 31Mar08, normal; visual evoked potential, 31Mar08, A little bit increased but still in normal ranges with no anomaly as to t

History: Migraine

Prex Illness:

Prex Vax Illns:

Vaers Id: 315986-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-May-2008	23-May-2008	1	11-Jun-2008	12-Jun-2008	FR	WAES0806USA00905	12-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Paraplegia

Symptom Text: Information has been received from a physician concerning a 15-year-old female who received her first and second dose of GARDASIL (no information about the dates, sites, routes of administration and lot number available) and no adverse event was reported. On 22-MAY-2008, the patient received the third dose of GARDASIL (lot number unknown) by IM on her deltoid. On 23-MAY-2008, she experienced a paraplegia of her two legs. The patient's experience has been confirmed by a neurologist who confirmed that this patient has been hospitalized from 23-MAY-2008 until 30-MAY-2008 and completely recovered. In the beginning, he had some suspicion about a GBS case or mononucleosis but the results of the exams didn't confirm these hypothesis. The neurologist assessed the event as not related to the vaccine. The patient just had sessions of kinesitherapy since 30-MAY-2008 which are still ongoing. Other business partner numbers include E200805170.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316007-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Nov-2007	Unknown		11-Jun-2008	23-Jun-2008	MI		23-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265V	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dysarthria, Headache, Menstruation irregular, Pelvic pain, Urinary incontinence, Vaginal discharge, Vulvovaginal disorder

Symptom Text: Irregular menstruation; urinary incontinence-sporadic/episodic; headaches, especially left-sided; stomach pain after meals; slurring words; excessive vaginal discharge, itching; pelvic pain; vulvar pain; vulvar bumps.

Other Meds: YAZ

Lab Data: None

History: NKDA; Anxiety/Depression; GERD; Dysmenorrhea

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316014-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	27-May-2008	27-May-2008	0	11-Jun-2008	23-Jun-2008	TX		23-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1965U		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Fatigue, Joint stiffness

Symptom Text: PATIENT WITH RHEUMATOID ARTHRITIS NOTICED AFTER IMMUNIZATION STIFFNESS IN JOINTS ALONG WITH FATIGUE

Other Meds:

Lab Data:

History: RHEUMATOID ARTHRITIS

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **316023-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	23-May-2008	24-May-2008	1	11-Jun-2008	23-Jun-2008	MA		23-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	0	Unknown	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B015BA		Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	1585U	1	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Local reaction, Swelling

Symptom Text: LOCALIZED ERYTHEMA AND SWELLING

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 316033-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	06-Jun-2008	07-Jun-2008	1	11-Jun-2008	13-Jun-2008	VA		20-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB224BA		Left arm	Unknown	
HPV4	MERCK & CO. INC.	1967U		Left arm	Unknown	
IPV	SANOFI PASTEUR	A0805		Left arm	Subcutaneously	
MMR	MERCK & CO. INC.	0040X		Left arm	Subcutaneously	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Blepharospasm, Dyskinesia, Dysphonia, Excessive eye blinking, Eyelid oedema, Facial spasm, Headache, Lip swelling, Muscle spasms, Muscle twitching, Rash, Swelling face, Visual disturbance

Symptom Text: The morning after vaccine receipt, she woke up with a round area of red and raised rash in the center of the forehead. She then noticed her left upper eyelid was swollen and it was hard for her to see. Shortly after that she noticed spasms around left periorbital area. She had a very mild HA. Her family reported facial swelling and mild hoarseness developed on 6/7/08, together with twitching/blinking of the eyes (rt more than lt) and occasional jerking of the arms. She was seen in the ED on 6/7/08 and the ED physician noted twitching of left eyelid and right shoulder. She was given Valium 10mg po and SOLUMEDROL 125mg IV. Twitching decreased and as she was getting d/c paperwork she started having more twitching. Eyes were closing Invot, R >L UE and LE were "twitching". This lasted 45 min and she received SOLUMEDROL 125mg, Valium 2mg IV and BENADRYL 25mg IV. This decreased the movements. She was then admitted for further evaluation and observation. She states the movements are not painful. She is able to stop them briefly but they recur and are more intense. She is still able to voluntarily use the extremities during these episodes.. Other than this episode, movements like this never occurred before. She does not have a h/o ticks or OCD traits. No recent fever, chills, SOB, CP, GI or GU sx, arthralgias. She denied any respiratory symptoms, coughing, nausea, etc. During hospitalization, she continued to have intermittent right or right and left eye twitching with occasional twitching of bilateral mouth. Sx are not painful. Pt felt like she could suppress these but felt uncomfortable during the suppressive episodes. 2 Episodes of jerking to involve right arm and leg, the last one was on the night 6/8/08. Right sided twitching did not last long or as severe as initial presentation. Baseline eye twitching also some what decreased. No further swelling of eye and lips. Pt was discharged on CONGENTIN and BENADRYL to be taken as needed. 08/19/2008 MR received for DOS 6/7-9/2008 with D/C DX: Twitching of eye and limbs.

Other Meds: Thuja oxydentralis tab (took 1 tab on 6/7/08 while in ED), Nature's defense for heavy metal cleansing (took 1 tab on day of vaccines, o/w did not take regularly

Lab Data: 09 Jun 2008:Copper 78 mcg/dL 70-155; Streptolysin O Ab 389 (H) IU/mL <=200; Ceruloplasmin 18.3 mg/dL (17.9-53.3); 8 June 2008: C-Reactive Protein 0.102 mg/dL; Thyroxine Free 0.871 (L) ng/dL (1.01-1.79); Thyrotropin 0.368 mcIU/mL (0.27-4.20)

History: Migraines (between ages 5 and 10, throbbing HA x 20 minutes, plus photophobia); hay fever; NKDA; PSH: Left shoulder surgery. PMH: migraines age 5-10, hay fever, shoulder surgery. NKDA

Prex Illness:

Prex Vax Illns:

Vaers Id: 316036-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	09-Jun-2008	09-Jun-2008	0	11-Jun-2008	20-Jun-2008	RI		20-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0802U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oedema peripheral, Rash pruritic, Urticaria

Symptom Text: Patient developed hand & feet swelling, pruritic rash with urticaria over limbs and torso. She was treated with PO prednisone and PO hydroxyzine.

Other Meds: ORTHO TRICYCLEN LO

Lab Data: none

History: penicillin allergy

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316041-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Jun-2008	10-Jun-2008	1	11-Jun-2008	23-Jun-2008	RI		23-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	62610	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Urticaria

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **316053-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	11-Mar-2008	13-Mar-2008	2	11-Jun-2008	09-Jul-2008	CA	200801455	09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	AHAVE215AA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	14887U		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2546A		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Dizziness, Fatigue, Headache, Palpitations

Symptom Text: Initial report received on 06 May 2008 from a Nurse Practitioner in the United States. A 13 year-old-patient, with past medical history of mild depression, had received on 11 March 2008 an intramuscular right deltoid injection of MENACTRA (lot # U2546AA); a left deltoid dose of GARDASIL (Lot # 1487U); and a right deltoid dose of VAQTA vaccine (Lot # AHAVE215AA) The route and site of administration was not provided for the VAQTA and GARDASIL vaccines. Two days post-vaccination, the patient complained of lightheadedness, dizziness, headache, fatigue, tightness in her chest, and on episode of heart palpitations lasting about two minutes. The patient required evaluation by a physician, but no relevant diagnostic tests or laboratory data were performed. Treatments received were not reported. At the time of this report, the patient had recovered.

Other Meds: NONE

Lab Data: None were performed

History: The patient was not ill at the time of the vaccinations on 11 March 2008. Past medical history includes mild depression. The patient had not received any other vaccinations within four weeks of 11 March 2008.

Prex Illness:

Prex Vax Illns:

Vaers Id: 316055-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	15-May-2008	Unknown		11-Jun-2008	09-Jul-2008	PA	200801655	09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2568AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1967U		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Body temperature increased, Flushing, Headache, Musculoskeletal stiffness, Nausea

Symptom Text: Initial report was received 17 May 2008 from a health care professional. A 22-year-old female patient had received an intramuscular right deltoid injection of MENACTRA, lot number U2568AA and an intramuscular left deltoid injection of GARDASIL (manufacturer Merck), lot number 1967U and on the evening of vaccination, she developed a low grade temperature, general weakness, headache, stiff neck, nausea and her face appeared flushed. At the time of vaccination, the patient had a history of mild asthma and seasonal allergies but no concurrent illnesses. Concomitant therapies included and Albuterol inhaler prn. According to the reporter, the patient had a temperature of 98.6 degrees Fahrenheit at the time of the report. The patient had not recovered from the event.

Other Meds: ALBUTEROL INHALER

Lab Data: None

History: At the time of vaccination, the patient had a history of mild asthma and seasonal allergies but no concurrent illness.

Prex Illness:

Prex Vax Illns:

Vaers Id: 316058-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	11-Apr-2008	07-May-2008	26	12-Jun-2008	16-Jun-2008	GA		15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0314U		Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Abdominal pain, Apallic syndrome, Autonomic nervous system imbalance, Blood pressure fluctuation, Blood product transfusion, Cardiac arrest, Cerebral infarction, Choreoathetosis, Coma, Diarrhoea, Dizziness, Dyskinesia, Dystonia, Encephalitis, Escherichia infection, Fall, Gastrointestinal tube insertion, Headache, Hemiparesis, Hypoaesthesia, Hypotonia, Intensive care, Lacunar infarction, Left ventricular hypertrophy, Lumbar puncture, Mechanical ventilation, Meningitis aseptic, Mental status changes, Nausea, Pyrexia, Renal cyst, Staphylococcal infection, Steroid therapy, Tracheostomy, Urinary incontinence, Urinary tract infection, Vomiting

Symptom Text: 21 y/o female seen in ER 13 May with C/O it hand & lt. foot numbness approximately 1 month post GARDASIL vaccine. She also C/O of nausea, vomiting and diarrhea. A heat CT demonstrated bilateral basal ganglion infarcts and a MRI showed with similar results with no acute process. She was admitted 20 May with left hemiballsmus. On 22 May her mental status declined. She received many doses of HALDOL and ATIVAN for agitation and was intubated on 28 May. She was transferred to medical center 28 may for w/u for encephalitis and has since become comatose. Symptoms: Nausea w/vomiting, Diarrhea, Nausea w/o vomiting, Numbness. 7/11/08 Reviewed hospital medical records for 6/11-6/23/2008. FINAL DX: aseptic meningo-encephalitis; choreoathetosis r/t meningo-encephalitis; paroxysmal autonomic instability w/dystonia; e. coli UTI. Records reveal pt transferred from military hospital. Military deployment 1-3/2008. On leave 5/2008 developed n/v/d, abd pain & bifrontal HA which continued to worsen. Sought medical help but no dx given. Developed left side weakness, flaccidity & several falls. Found 5/12 unable to ambulate & incontinent of urine. Taken to ER where MRI revealed possible basalganglia infarct. To ICU where subsequent MRIs were WNL. Ventilated & remains in persistent vegetative state. LPs done. PICC , trach & PEG tubes. Intermittently febrile, labile BP, asystole x2. Tx in multiple hospitals w/multiple meds including steroids, IVIG, antibiotics & antivirals. 12/11/08 Reviewed additional medical records of 5/08-7/08. FINAL DX: Records reveal patient experienced nausea/vomiting/diarrhea, dizziness & HA, left hand/foot numbness x 4-5 days. Seen in ER on 5/13 where labs were WNL but CT of brain revealed lacunar infarcts, bilateral basal ganglia & cavum verge. Numbness continued & developed involuntary jerking of LEs & difficulty walking. Admitted to MICU 6/08 w/encephalitis. Tx w/IVIG & steroids. Transferred to higher level of care & then to inpatient rehab program.

Other Meds: None Known

Lab Data: LABS: MRI of head & spine WNL. CT angiogram of head WNL. PET scan abnormal. Right side craniotomy for biopsy of right frontal lobe. EEGs slow but WNL. CSF: WBC 14 monos, protein 17, glucose 68, cytopathlogy revealed mostly normal lymph

History: None PMH: smoker.

Prex Illness: None Known

Prex Vax Illns:

Vaers Id: 316069-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	14-Feb-2007	14-Feb-2007	0	12-Jun-2008	13-Jun-2008	IL	WAES0702USA02856	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Initial and follow-up Information has been received through the Merck pregnancy registry from a physician concerning a 17 year old female with no pertinent medical history, no known allergies or adverse drug reactions and one prior pregnancy and child with no complication or problems. On 14-FEB-2007, the patient was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL (Lot# 655619/1427F). There were no concomitant medications reported. The physician reported that after the administration, the patient reported that she was pregnant. It was reported that the patient had a prenatal mid trimester sonogram performed and "slanted eyes" were noted. At that time it was suggested to the patient that the baby might have Down's syndrome. On 24-JUL-2007 the patient had a full term vaginal delivery. Her baby was diagnosed with Down's syndrome confirmed by chromosome analysis. The baby had been evaluated by a cardiologist for a patent ductus arteriosis which has closed and a "tiny" patent foramen ovale. The baby had an unspecified thyroid problem for which an endocrine follow-up was scheduled. At the time of the report, the outcome of the atrial septal defect, thyroid disorder and trisomy 21 were unknown. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound, prenatally-"slanted eyes"; chromosomal analysis, Confirmed Down's syndrome (baby)

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **316070-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Jan-2008	01-Jan-2008	0	12-Jun-2008	13-Jun-2008	FR	WAES0806CAN00053	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from a physician concerning a 20 year old female who in June 2007, was vaccinated with the first dose of GARDASIL, lot #not available. In August 2007 the patient was vaccinated with the second dose of GARDASIL, lot # not available and in January 2008 the patient was vaccinated with the third dose of GARDASIL, lot # not available. In approximately May 2008, the patient experienced multiple sclerosis. In approximately May 2008, the MRI suggested that this patient had developed multiple sclerosis. Upon internal review, multiple sclerosis was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, ??May?08, suggests this patient has developed multiple sclerosis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316071-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Mar-2008	19-Mar-2008	1	12-Jun-2008	13-Jun-2008	--	WAES0806USA00082	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a consumer (mother) concerning her 11 year old daughter who on an unspecified date was vaccinated with the first dose of GARDASIL. On 18-MAR-2008 the patient was given the second dose of GARDASIL, (lot # not reported), IM. One day after receiving the vaccination 19-MAR-2008 the daughter experienced a seizure. She was taken to the emergency room where a CT scan and blood work were performed with normal results. The patient was released that same day and reportedly recovered on an unspecified date. Upon internal review, seizures were considered an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, 03/19/08 - normal; computed axial, 03/19/08 - normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316073-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	05-May-2008	08-May-2008	3	12-Jun-2008	13-Jun-2008	FR	WAES0806USA00566	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Pelvic venous thrombosis

Symptom Text: Information has been received from a health authority concerning a 19 year old female who on 05-MAY-2008 was vaccinated IM with a second dose of GARDASIL (site not reported). The patient's concomitant suspect therapy included: JASMINE from 25-MAR-2008 to 08-MAY-2008. On 08-MAY-2008, 3 days after vaccination she had bilateral iliofemoral iliac thrombosis of the right internal iliac, left external iliac and left internal iliac with upgoing to the inferior vena cava. There was no dyspnea or intermittent claudication. She was hospitalized and treated with PREVISCAN and LOVENOX and "retaining of lower limbs." Blood pressure was 105/65 mmHg. At the time of the report the patient had not recovered. Other business partners numbers included: PO20080225 and E2008-05059.

Other Meds: JASMINE

Lab Data: blood pressure measurement, 105/65 mmHg

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316074-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Jan-2008	28-Jan-2008	20	12-Jun-2008	13-Jun-2008	FR	WAES0806USA00567	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Erythema nodosum

Symptom Text: Information has been received from a Health Authority concerning a 17 year old female with allergy to ALAFATIL and a history of left ankle sprains and ankle fracture (2001) who on 08-JAN-2008 was vaccinated IM with a dose of GARDASIL (site not reported). On 28-JAN-2008, 20 days after vaccination, the patient experienced an erythema nodosum with arthralgia of the lower limbs and subcutaneous nervures. She was hospitalized and treated with diclofenac. Complementary examinations were performed: radiography of thorax, "tubertest." sero D hepatitis C and B, lactate dehydrogenase, streptococcus and were all normal. By the end of February 2008, symptoms disappeared. At the time of the report, the patient had recovered. Other business partners numbers included: E2008-05065 and LL20080204

Other Meds: Unknown

Lab Data: X-ray; normal, thorax; tuberculin skin test, "tubetest" normal; diagnostic laboratory test, streptococcus normal; serum LDH, normal; serum hepatitis B Ab, normal; serum hepatitis D Ab, normal; serum hepatitis C antibody test, normal

History: Ankle fractures; Ankle sprain

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **316075-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jun-2008	02-Jun-2008	0	12-Jun-2008	13-Jun-2008	MD	WAES0806USA00594	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Injection site pain, Pruritus, Syncope

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter who on 02-JUN-2008 was vaccinated with a first dose 0.5 mL of GARDASIL. Concomitant therapy included tuberculin purified protein derivative and meningococcal vaccine (manufacturer unknown). The mother reported that on 02-JUN-2008 her daughter fainted after she was vaccinated with her first dose of GARDASIL. She also developed itching on her hand and soreness at the injection site. The patient sought unspecified medical attention. The patient's blood pressure was obtained (results not reported). A telephone call was placed to the doctor's office to obtain more information. At this time no additional information was available. The patient was recovering. The reporter considered the events syncope, patient experienced itching on her hand and soreness at the injection site to be disabling. Additional information has been requested.

Other Meds: tuberculin purified protein

Lab Data: blood pressure, 06/02/08 - result not reported

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316076-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	02-Jun-2008	02-Jun-2008	0	12-Jun-2008	13-Jun-2008	CA	WAES0806USA00634	02-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	1740U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness

Symptom Text: Information has been received from a physician concerning a 12 year old female with a history of an elbow injury and passing out, who on 02-JUN-2008 was vaccinated with the first 0.5 ml dose of GARDASIL (Lot # 659962/1740U). Concomitant therapy included a dose of MENACTRA and a dose of DTAP. On 02-JUN-2008 the patient passed out after receiving the first dose of GARDASIL. The patient was already in the clinic. The physician also reported that the patient "might have experienced a minor seizure because her hands were kind of rigid and were tightened up." No diagnostic laboratory testing was performed. The physician noted that the patient had recovered. No product quality complaint was involved. Upon internal review, minor seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: None

History: Elbow injury; Passed out

Prex Illness:

Prex Vax Illns:

Vaers Id: 316077-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	10-Nov-2007	10-Nov-2007	0	12-Jun-2008	13-Jun-2008	FR	WAES0806USA00729	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	CNE26610	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Back pain, Condition aggravated, Drug administered at inappropriate site, Immediate post-injection reaction, Impaired driving ability, Injection site pain, Myalgia, Neck pain, Serum sickness

Symptom Text: Information has been received from a health professional and a physician concerning a 22 year old female with a family history of rheumatoid arthritis (great-aunt and great-grandmother) who on 10-NOV-2007 was vaccinated with GARDASIL (lot #, batch #"ONE26610") IM in the left buttock. Vaccination with GARDASIL was performed by the reporter in the absence of any pathological condition. Immediately after vaccination, she experienced intense pain at the site of injection. In the evening, she experienced arthralgia and myalgia in the vaccinated side of the body. The physician reported that the patient experienced very intense and disabling arthralgia and myalgia since vaccination. Work-up performed by an internist showed positive antinuclear antibodies at 1:640. Nothing was found on rheumatology and infectious fields. The physician added that the patient had no medical history and was convinced that the patient's events were related to the vaccine. Pain was increasing and prevented the patient from driving. Treatment with morphinic analgesic was implemented. Biological testing confirmed the absence of a biological inflammatory syndrome. Bone scintigraphy showed a few focal areas of increased radiotracer uptake. Hospital report concluded to probable serum sickness disease possibly secondary to vaccination. The reporting physician added that the patient had experienced violent pain at the site of injection at the moment of vaccination and that the first adverse events occurred a few days after vaccination. The physician reported that nocturnal pain regressed. He confirmed that the patient never experienced fever after the vaccination. Work-up showed non-specific antinuclear antibodies. MRI scan of sacro-iliac joints was planned. The physician reported a marked clinical improvement of her condition even though she was still hampered in her daily activities. Morphinics were replaced by level 3 analgesics on an unspecified date. It was noted that with in the hours following vaccination, pain that occurr

Other Meds: None

Lab Data: diagnostic laboratory test, ??Nov07, normal protein profile with no dysglobulinemia; diagnostic laboratory test, ??Nov07, negative circulating immune complex; diagnostic laboratory test, Biological testing confirmed the absence of a biologi

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316078-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	07-Dec-2006	08-Dec-2006	1	12-Jun-2008	13-Jun-2008	PA	WAES0701USA04393	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0954F		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Induced labour, Postpartum state

Symptom Text: Initial and follow-up information has been received through the pregnancy registry from a 25 year old female office manager with no pertinent medical history who on 07-DEC-2006 was vaccinated with a 0.5 ml dose of GARDASIL (lot #653938/0954F). There was no concomitant medication. On 29-DEC-2006 the patient learned that she was pregnant. Unspecified medical attention was sought. On an unspecified date the patient underwent "blood work" and an ultrasound. There was no adverse experience. At the time of the initial report, the patient was 9.5 weeks gestation. It was reported that the patient was induced at 41 weeks estimated gestational age for a low amniotic fluid index. The patient had a primary cesarean section due to a non-reassuring fetal heart rate and failure to descend with minimal cervical dilation. She delivered a healthy normal female weighing 7 pounds and 2 ounces on 24-AUG-2007. It was reported that the mother had some difficulty "mentally" postpartum. At the time of the report, the mother and baby were "well." Upon internal review, non-reassuring fetal heart rate and failure to descend with minimal cervical dilation were considered to be other important medical events. Additional information is not expected.

Other Meds: None

Lab Data: Ultrasound; Diagnostic laboratory

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 316079-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Mar-2008	Unknown		12-Jun-2008	13-Jun-2008	FR	WAES0806USA00742	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Optic neuritis, Scotoma

Symptom Text: Initial information has been received from a general practitioner concerning a 15-year-old female patient with no relevant medical history who received the first dose of GARDASIL on 14-MAR-2008 via intramuscular route in her left deltoid. On an unspecified date the patient experienced a central scotoma, therefore she consulted a neurologist who performed a MRI which resulted normal. She was diagnosed with an inflammatory optic neuritis and link with vaccination was not excluded. The patient had recovered on an unspecified date. No further information is available. Other business partner numbers included E200805112.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **316080-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		12-Jun-2008	13-Jun-2008	MD	WAES0806USA00853	13-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Paralysis

Symptom Text: Information has been received from a physician, who heard from another physician, that a female (age unreported) who was vaccinated with a dose of GARDASIL, became paralyzed. The reporter considered the paralysis to be disabling. It was reported that the patient has not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316081-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	27-Dec-2007	Unknown		12-Jun-2008	13-Jun-2008	PA	WAES0806USA00805	23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from a registered nurse concerning an approximate 22 year old female who in December 2007, was vaccinated with the first dose of GARDASIL. Concomitant therapy included YAZ. Subsequently the patient experienced numbness and tingling in both feet. The second dose of GARDASIL, 0.5 ml, IM was given between January 2006 and May 2008. The patient was seen by a neurologist who recommended that the patient not receive the third dose. The reporter felt that numbness and tingling in both feet was considered to be an other important medical event. Additional information has been requested.7/18/08-record received for DOS 6/27/08-neurology consultation for C/O numbness involving lower part of body present since January 2008 possibly due to Gardasil. PE: free of any objective abnormality.

Other Meds: YAZ

Lab Data: 7/18/08-records received- MRI no abnormalities, minor degenerative changes correlate with chronic back back and a probablye right renal cyst. EMG and nerve conduction studies normal. ESR 31. Impression: myelopathy possible as an adverse eff

History: Unknown 7/18/08-records received-PMH:chronic low back pain and scoliosis.

Prex Illness:

Prex Vax Illns:

Vaers Id: 316084-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-Apr-2008	13-Apr-2008	7	12-Jun-2008	17-Jun-2008	FR	WAES0806USA00740	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Erythema nodosum, Oedema, Pain, Skin plaque

Symptom Text: Initial information has been received from health authorities concerning a 20-year-old female patient with medical history of appendicectomy was vaccinated with a dose of GARDASIL on 06-APR-2008, via intramuscular route. On 08-APR-2008 the patient stopped oral hormonal contraceptives JASMINELLE and had implant of hormonal contraceptives IMPLANON. On 13-APR-2008 i.e. 7 days after vaccination the patient had erythemato-oedematous plaques hot on right knee and then on the right leg and on left elbow which developed with same colours of bruise. She also had pain burn-like worsened by chances of position and which were not resolved by analgesics. There was no significant change in her way of life. Clinical examination: temperature was at 37.5 degree centigrade. Hemodynamic revealed pulse normal. Blood pressure was at 138/88 mmHg. Heart rate was at 101/min. Vigilance was normal. Glasgow was at 15. Breathing was normal. On 23-APR-2008, cardiovascular examination, pulmonary examination, digestive examination, neurological examination, urologic examination, rheumatology were all normal. There was no arthralgia. There was no general signal. Dermatological examination was abnormal: erythematous nodules of different ages for both lower limbs and 2 nodules on elbows. There was no tonsillitis. There was no transit trouble. There was no adenopathy. There was no other particular functional anomaly. On 17-APR-2008 biological tests were performed: RP was normal. There was an inflammatory syndrome: ESR was increased at 44 mm the first hour. CRP was increased at 107 mg/L. Antibodied ASD and ASLO were negative. SGOT, SGPT and TSH were normal. Moderate leukocytosis at 12.85. Plasma protein electrophoresis showed a slight increase in Alpha-1 globulin. Tuberculin intradermal reaction was negative. She was prescribed DOLIPRANE in case of pain and she had to raise up her lower limbs. On 25-APR-2008 at 7 a.m. leukocytes were at 5.17 G/L, hemoglobin were at 11.7 g/dL, platelets at 318G/L, polynuclear neutrophilic leukocyte at 1.94 G/L, lymp

Other Meds: IMPLANON, 08Apr08 - UNK; drospirenone (+) ethinyl estradiol, UNK - 08Apr08

Lab Data: diagnostic laboratory test, 17Apr08, Antibodied ASD was negative; diagnostic laboratory test, 17Apr08, Antibodied ASLO was negative; diagnostic laboratory test, 17Apr08, Moderate leukocytosis at 12.85; cardiovascular evaluation, 23Apr08, no

History: Appendicectomy

Prex Illness:

Prex Vax Illns:

Vaers Id: 316085-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	29-May-2008	29-May-2008	0	12-Jun-2008	16-Jun-2008	MS		24-Jun-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEP	MERCK & CO. INC.	0672R	1	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1208F	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2613AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B020AA	0	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Convulsion, Dizziness, Oedema peripheral, Paraesthesia, Syncope, Vaccination complication

Symptom Text: Syncopal episode about 10 min after injection, possible seizure activity for 15-20 seconds. Then generalized weakness, tingling, and dizziness. The patient responded poorly to fluids, Benadryl, Epinephrine, and Decadron. 6/13/08-DC summary received for DOS 5/29-5/31/08. DC DX: Adverse reaction to vaccination. Day of vaccines developed swelling of right arm, felt dizzy and weak. Continued to feel weak for day or 2. Arm swelling and tingling continued as well as weakness of grip on right arm.

Other Meds:

Lab Data: 6/12/08-records received-Chemistries within normal limits. WBC 7.7, H and H 11.3 and 32.5. UA within normal limits.

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316089-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Jun-2008	05-Jun-2008	0	12-Jun-2008	20-Jun-2008	WI		20-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Injection site pain, Paraesthesia

Symptom Text: Approximately 5 min. after receiving the HPV vaccine client complained of pain at the injection site followed by tingling & numbness of her right hand & fingers. This continued for the next 24 hours. Client has since recovered.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316131-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Apr-2008	08-Apr-2008	1	12-Jun-2008	23-Jun-2008	OH		23-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	H0188U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Oxygen saturation normal, Wheezing

Symptom Text: Client went to emergency room approximately 24 hours after receiving first dose of HPV vaccine with complaints of difficulty breathing (wheezing). Denied itching, rashes or history of asthma. Denied sensation of throat closing. Pulse ox was 99%. Client was treated at the ER with Prednisone PO 60 mg; Pepcid PO 20 mg and Benadryl PO 50 mg with good results. Discharged to home with instructions to follow up at Health Dept in 2-4 days.

Other Meds: none

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: 316159-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-May-2008	29-May-2008	1	13-Jun-2008	16-Jun-2008	FR	WAES0806USA00727	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1147U		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Loss of consciousness, Nausea, Syncope, Vomiting

Symptom Text: Information has been received from a health professional concerning a 16 year old female with no medical history who on 28-MAY-2008 was vaccinated with a dose of GARDASIL (lot # 1147U, batch # NH06740) IM. On 29-MAY-2008, i.e. 24 hours after vaccination, she experienced 2 episodes of syncope and 1 of these was associated with loss of consciousness of several minutes. She went to emergency where clinical examination and biological tests performed were normal. Then she had epigastric pain with nausea and vomiting. She was hospitalized under surveillance during 24 hours. At time of reporting, outcome was unknown. Other business partner numbers included: E2008-05037. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, biological tests were normal.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 316160-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	28-Apr-2008	01-May-2008	3	13-Jun-2008	16-Jun-2008	FR	WAES0806USA01181	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0513U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dermatitis allergic, Dyspnoea

Symptom Text: Information has been received from a physician concerning a 23 year old female with coeliac disease who on an unspecified date was vaccinated with a dose of GARDASIL which was well tolerated. Concomitant therapy included hormonal contraceptives (unspecified). On 28-APR-2008, the patient was vaccinated with another dose of GARDASIL (lot #0513U/Batch # NG34780), IM. On 01-MAY-2008, the patient experienced an allergic rash and complained about dyspnea. First she was treated in an emergency department and then she was admitted to hospital (23-MAY-till 29-MAY-2008) because symptoms were ongoing. Her liver values (unspecified), c-reactive protein, and leukocytes were increased (not otherwise specified). The patient recovered completely on an unspecified date. File is closed. Other business partner numbers include E2008-05054. Additional information is not expected.

Other Meds: Hormonal contraceptives (unspecified), unk, unk

Lab Data: WBC count, increased; Serum C-reactive protein, increased; Hepatic function tests, liver values increased.

History:

Prex Illness: Coeliac disease

Prex Vax Illns:

Vaers Id: **316161-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-May-2008	01-May-2008	0	13-Jun-2008	16-Jun-2008	FR	WAES0806USA01182	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Concussion, Fall, Syncope

Symptom Text: Information has been received from a health authority concerning a 15 year old female with no reported relevant medical history, who on an unspecified date in May 2008, was vaccinated with the first dose of GARDASIL, batch # not reported. Immediately after vaccine administration with GARDASIL, the patient had a syncope (described as severe by the reporter), due to syncope the patient fell ending up with a concussion. The patient was brought to hospital emergency room where she recovered. BP after syncope 90/50. It was reported that the patient recovered on the same day. Events were considered as medically relevant by the reporter. Case is closed. Other business partner numbers include E2008-05040. Additional information is not expected.

Other Meds: Unknown

Lab Data: blood pressure measurement, ??May08, 90/50

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316205-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	03-May-2008	03-May-2008	0	13-Jun-2008	23-Jun-2008	--		23-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0094G		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Patient was to receive HPV vaccine. The bottle that was available did not look like the usual vaccine that is given. Consult made with medical director of immunization and technician instructed by MD to give the immunization. It was discovered the next day that this was in fact HPV antibody reagent given to the patient. Patient was by the medical director and had no symptoms. Unable to contact manufacturer until the next business day. Manufacturer contacted and MSDS obtained. Poison Control Center contacted. Per Poison Control, no adverse effects are expected.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **316210-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	29-May-2008	29-May-2008	0	13-Jun-2008	23-Jun-2008	NC		23-Jun-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB233AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1968U	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B020AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Rash, Rash macular

Symptom Text: Red splotchy rash appeared on face, neck, and shoulders. She had cried before and during immunization injections. Rash appeared approximately 3-5 minutes after administration of vaccines. No respiratory distress, she stated she had no problem breathing. She was monitored for 30 minutes at the office. After 15 minutes rash on face had disappeared and only light reddish on neck and shoulders. Released after 30 minutes with only one red spot below left ear approximately 1 1/2 circular inch.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316229-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Jun-2008	11-Jun-2008	0	13-Jun-2008	23-Jun-2008	WI		23-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1977U	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Confusional state, Dysarthria, Dysphonia, Eye swelling, Fall, Limb injury, Nervousness, Pallor, Speech disorder, Swelling face

Symptom Text: Patient received her vaccine then sat in a chair while her 14 year old brother got his second chicken pox shot, she was laughing and goofing around with her 12 year old brother. Then within minutes she was on the floor, her body started shaking and she started making noises. The nurse stated that this never happened before and ran out of the room to get Dr. After he was in the room a short time patient came to and he helped her back into the chair. He tried telling me that it was probably 'cause her blood sugar was low from not eating, not true she ate two hours before she got her vaccine. She was pale, confussed and talking slowly. Dr. then gave her some water and put an ice pack on the back of her neck, told me she'd be fine. For the next three hours at home patient was hoarse, had slurred speech and responded to everything very slowly. Her face ended up swollening as did her eyes, her face and eyes are still somewhat swollen today. She hurt her right thumb when she fell, Dr. said it is probably sprained, but never took an x-ray. We went back to see Dr. yesterday, patient still swollen and slow. She stated that maybe Patient just fainted because of being worked up about getting a shot but she has no idea why her speech would be slurred or why she would be hoars. I tried to explain to her that patient was not worked up about the shot and her and her brother were goofing around when patient ended up on the floor but she wouldn't listen. She said that when people have a siezure they will pee and poop their pants, however I have friends that have siezures and they never have done that. The paper I received after patient's reaction states that a reaction can happen within minutes to a few hours of the vaccine and the doctor keeps telling me it can't happen that fast. Patient is still swollen this morning,she just got up so I am not sure how her reactions are. Patient gets almost all staight A+'s in school I am worried how this will effect her.

Other Meds: zyrtec 10 mg daily

Lab Data: none was done and I did not receive any information on any possible side effects of the vaccine until after patient had a problem and we were ready to leave Dr. is our family doctor even though there were no doctors present when patient re

History: seasonal allergies, born a month early, five pounds at birth

Prex Illness: none

Prex Vax Illns: none~ ()~~0~In Sibling|none~ ()~~0~In Patient|none~ ()~~0~In Sibling

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316232-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-May-2007	Unknown		13-Jun-2008	16-Jun-2008	--	WAES0806USA02312	16-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Peripheral vascular disorder, Sleep disorder, Thrombosis, Weight decreased

Symptom Text: This case is poorly documented. Information has been received from a consumer report which appeared in a television bulletin on 27-MAY-2008. It was reported by the mother of the patient that her 18 year old daughter was vaccinated with the first dose of GARDASIL on an unspecified date and was well tolerated. The second dose of GARDASIL, lot #, route and administration site not reported, was given in May-2007. Subsequently on an unknown date, the patient developed a thrombosis (not otherwise specified) and complained about weight loss, sleeping and circulatory disorder. Outcome was not reported. The reporter considered thrombosis, insomnia, circulatory disorder peripheral, and weight loss to be other important medical event. Additional information has been requested. Other business partner numbers include E2008-05381.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316238-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Jun-2008	10-Jun-2008	0	13-Jun-2008	23-Jun-2008	MI		23-Jun-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB235BA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1967U	0	Right leg	Intramuscular	
MNQ	SANOFI PASTEUR	U2365AA	0	Left leg	Intramuscular	
TDAP	SANOFI PASTEUR	C2844AA	0	Right arm	Intramuscular	
HEP	MERCK & CO. INC.	1610U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Headache, Loss of consciousness, Posturing, Thirst

Symptom Text: Client states to have felt light headed after recieving all 5 injections. Client passed out within 30 seconds, started posturing then had a Seizure. Posturing and seizure last about 45 seconds. Ammonia snapped under nose and client came became alert with 15 seconds. Client was very thirsty and had a headache following event. Ambulance was called to have client evaluated. Mother was also called. Client evaluated 6/13 and client states to have had no further symptoms.

Other Meds: tuberculin test with other injections

Lab Data:

History: Shellfish allergy

Prex Illness: none

Prex Vax Illns:

Vaers Id: 316245-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Jun-2008	13-Jun-2008	0	13-Jun-2008	23-Jun-2008	AK		23-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	0389U	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	U2552AA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor

Symptom Text: Pt became pale and stated "I feel really light headed". Had her lie down and drink juice.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 316286-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Mar-2008	19-Mar-2008	1	16-Jun-2008	17-Jun-2008	--	WAES0806USA00950	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, No reaction on previous exposure to drug

Symptom Text: Information has been received from a consumer concerning her 11 year old daughter, who, on an unspecified date, was vaccinated with a first dose of GARDASIL. The first dose was well tolerated. On 18-MAR-2008 at 11:00 the patient was vaccinated with a second dose of GARDASIL. On 19-MAR-2008 the patient experienced a seizure at school. The patient was taken to the hospital from school. A computed axial tomography (CAT) scan and blood work were performed and were both "good." The patient was seen by a neurologist who performed a computed axial tomography (CAT) scan and a magnetic resonance image (MRI) and both "turned out fine." The mother believed that the patient had the seizure due to the vaccination. It was reported that the patient was very healthy with no problems before the shot and has had no problems since the shot. The patient recovered on an unspecified date. Upon internal review the seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: computed axial, "was good"; diagnostic laboratory, "was good"; computed axial, "turned out fine"; magnetic resonance, "turned out fine"

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **316287-1** **Related reports:** 316287-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	15-May-2008	20-May-2008	5	16-Jun-2008	17-Jun-2008	MO	WAES0806USA00815	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Right arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Adverse drug reaction, Contusion, Convulsion, Grand mal convulsion, Loss of consciousness, Neurological examination normal, Tremor, Unresponsive to stimuli, Vaccination complication

Symptom Text: Information has been received from a nurse concerning a 25 year old female who was vaccinated intramuscularly with the third dose of GARDASIL. Subsequently, five days post vaccination, the patient experienced seizures. The patient was taken to the emergency room. It was reported that the patient cannot drive according to state law for a while. Computed tomography scan and magnetic resonance imaging were performed with no results reported. It was reported that the patient is fine now. On an unspecified date, the patient recovered. No product quality complaint was involved. The reporter considered seizures to be disabling. Additional information has been requested. 2/24/09 Received Neuro medical records of 5/28-10/2/2008. FINAL DX: single gen tonic-clonic seizure secondary to Gardasil injection Initial examination & subsequent office visit both revealed neuro exam WNL. Referred for EEG & MRI brain which were WNL. No further records available. 6/19/08-ER records received for DOS 05/20/08-presented with after episode of shaking all over, loss of consciousness, unresponsive. Contusion on back due to sliding out of chair.Seizure probably secondary to Drixoral, coffee and cigarette took second dose only 8 hours after first dose. Impression probable drug reaction. 12/31/08 Reviewed GYN office records. FINAL DX: none provided Records reveal patient experienced good health on vax dates.

Other Meds: Unknown

Lab Data: Computed axial, no results reported; Magnetic resonance, no results reported6/19/08-records received- Drug screen positive for amphetamines. CT head normal with slightly symmetric region in posterior limb of internal capsule in left. LAB

History: Unknown PMH: abnormal Pap smears. Allergic: PCN.

Prex Illness:

Prex Vax Illns:

Vaers Id: **316287-2** **Related reports:** 316287-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	15-May-2008	15-May-2008	0	15-Dec-2008	16-Dec-2008	--	WAES0812USA02167	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Right arm	Unknown	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Grand mal convulsion

Symptom Text: Information has been received from a 24 year old female patient with penicillin allergy who on unspecified dates was vaccinated with the first and second doses of GARDASIL and in May 2008, was vaccinated with the third dose of GARDASIL (lot number not available). In May 2008, the patient experienced a grand mal seizure shortly after receiving the third dose of the vaccine. She was rushed to the emergency room in an ambulance but was not admitted to the hospital. An electroencephalography and magnetic resonance imaging were performed, results not provided. She had not had another seizure but was still seeking treatment from a neurologist. At the time of reporting, the patient was recovering. Upon internal review, grand mal seizure was determined to be an important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: 316288-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Apr-2008	11-May-2008	26	16-Jun-2008	17-Jun-2008	NY	WAES0806USA00675	21-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Benign intracranial hypertension, Condition aggravated, Eye pain, Headache, Nausea, Oral contraception, Phonophobia, Photophobia, Vomiting

Symptom Text: Information has been received from a consumer concerning her 18 year old daughter with pseudotumor cerebri and scoliosis and no drug reactions or allergies, who on 15-APR-2008 was vaccinated with the first dose of GARDASIL. Concomitant therapy included YAZ and acetazolamide (MSD). The patient's mother stated that her daughter has the condition known as pseudotumor cerebri. As a result of this condition, she sometimes has a build up of intercranial and spinal pressure which causes severe headaches and problems with her eyes, such as pain and sensitivity to light. Prior to receiving the vaccine on 15-APR-2008, her last episode of this increase and build up of intercranial and spinal pressure took place in March 2007. On 11-MAY-2008 the patient had another one of these episodes which caused her to have severe headaches, and problems with her eyes such as pain and sensitivity to light. She was hospitalized for one day so that her physician could do a spinal tap. Subsequently, the patient recovered. No product quality complaint was involved. Additional information has been requested.7/21/08-records received for 5/16/08-DC DX: Pseudotumor cerebri. Presented to ED with 5 day history of intermittent headache and 1 day of nausea and vomiting. Headache worse at night and associated with phot and phonophobia. Nauseated and vomiting times two.

Other Meds: DIAMOX; YAZ

Lab Data: diagnostic laboratory, 05/11?/08, no results reported; spinal tap, 05/11?/08, no results reported 7/21/08-records received-LP normal. WBC increased 12.8, PT 14.8 and INR 1.2.

History: 7/21/08-records received-PMH:scoliosis. Seasonal allergies. Diagnosed with PTC March 2007 well controlled until day of admission.

Prex Illness: Pseudotumor cerebri; Scoliosis

Prex Vax Illns:

Vaers Id: 316289-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	05-Jul-2007	05-Jul-2007	0	16-Jun-2008	17-Jun-2008	VA	WAES0709USA00536	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1208F		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received through the Merck Pregnancy Registry from a registered nurse concerning a 21 year old female who on 05-JUL-2007 was vaccinated IM in the left deltoid with a 0.5 ml dose of GARDASIL (lot # 654741/1208F). Concomitant therapy included hormonal contraceptives (unspecified), ibuprofen, cough, cold, and flu therapies (unspecified). On an unspecified date the patient took herself off of these modification due to financial difficulty, albuterol, metformin, and WELLBUTRIN. On an unspecified date the patient went to the emergency room (unspecified reason) and found out she was 3 weeks pregnant. She had an OB/GYN appointment on 05-SEP-2007, results not reported. Her last menstrual period was 14-Aug-2007, with an estimated date of delivery was 20-MAY-2008. In September 2007 the patient experienced a miscarriage. Upon internal review the miscarriage was considered to be an other important medical event. Additional information has been requested.

Other Meds: Albuterol; WELLBUTRIN; Cough, Cold, and Flu therapies; Hormonal contraceptives; Ibuprofen; Metformin

Lab Data: Beta-human chorionic, 3 weeks pregnant.

History:

Prex Illness: Pregnancy NOS (LMP = 8/14/2007)

Prex Vax Illns:

Vaers Id: 316290-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Jan-2007	23-Jan-2007	0	16-Jun-2008	17-Jun-2008	IL	WAES0702USA00083	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received from a certified medical assistant and an other health professional through a Merck pregnancy registry concerning a 16 year old female with depression and a history of "female problems" (unspecified) and miscarriage (prior to 1st GARDASIL), who on 23-JAN-2007 was vaccinated intramuscularly with a 0.5 mL first dose of GARDASIL. Concomitant therapy included PAXIL. Subsequently the patient had a positive home HCG test. The patient was examined by her obstetrician on 29-JAN-2007 who ordered a serum HCG test. At the time of this report, results of test were pending. In early 2007, it was reported that at approximately 5-6 weeks gestation the patient had an "early" spontaneous abortion. On an unspecified date, the patient received the second dose of GARDASIL and subsequently she had another miscarriage (dates not reported). Subsequently on an unspecified date, the patient received the third dose of GARDASIL and conceived again (date not reported). The patient's last menstrual period was approximately November 2007 and her estimated delivery date August 2008. It was reported that the patient was doing well with no adverse events. The reporter stated that she did not think any of the events were related to GARDASIL. After internal review, abortion was considered to be an other important medical event. Additional information has been requested.

Other Meds: PAXIL

Lab Data: beta-human chorionic, 01/??/07, positive; total serum human, 01/29/07, results pending

History: Reproductive tract disorder; Miscarriage

Prex Illness: Pregnancy NOS (LMP = Unknown); Depression

Prex Vax Illns:

Vaers Id: 316291-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	24-Apr-2007	24-Apr-2007	0	16-Jun-2008	17-Jun-2008	FL	WAES0705USA00602	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received through a pregnancy registry from a 21 year old female with penicillin allergy who on 24-APR-2007 was vaccinated with a third dose 0.5 mL of GARDASIL. There was no concomitant medication. On 24-APR-2007 the patient experienced vaccine exposure during pregnancy. The patient's last menstrual period was 24-MAR-2007 and the estimated due date was 29-DEC-2007. A blood test was positive for pregnancy. Follow up information has been received from the nurse who reported that the patient had a spontaneous abortion during her pregnancy. The nurse could not confirm the estimated gestational age at the time of the "miscarriage". Upon internal review, the patient's spontaneous abortion was considered to be an other important medical event. This patient experienced another adverse event reported in WAES# 806USA002235. Additional information has been requested.

Other Meds: None

Lab Data: serum beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = 3/24/2007); Penicillin allergy

Prex Vax Illns:

Vaers Id: 316292-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	12-Jun-2007	12-Jun-2007	0	16-Jun-2008	17-Jun-2008	--	WAES0706USA04188	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0211U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Gestational diabetes

Symptom Text: Information has been received from a Nurse Practitioner concerning a 26 year old female with a history of 0 pregnancies and 0 live births and a history of ventricular tachycardia and Papanicolaou smear abnormal who on 12-JUN-2007 was vaccinated with her first dose GARDASIL (lot#0211U). Concomitant therapy included ORTHO TRI-CYCLEN LO). The patient later found out that she was pregnant with an LMP of 15-MAY-2007. The patient also had an HPV test which tested negative. Medical attention was sought. Follow-up information was received on 27-May-2008 from a nurse who indicated that the patient delivered a healthy baby girl on 15-FEB-2008. The baby was normal and healthy with no congenital anomalies. Follow-up information was received from an outcome pregnancy questionnaire. The patient weighed 8 pounds 4 ounces. The Apgar score was 9 and 9. The patient was 39 and 1/2 weeks from LMP. The infant was not normal and she had mild metatarsus adductus and mild curly toe deformities. On an unspecified date the patient had OB testing and labs revealed gestational diabetes which was under diet control. During pregnancy the patient received OBTREX for pregnancy. Medical records were received from the physician's office for the baby. On 10-APR-2008 the baby had a 6 week follow-up visit with the physician. The baby has a bilateral foot. The baby is almost 2 months of age. Overall the baby was doing well. Her mother does not have any new concerns or complaints. The baby has not had any recent fevers or other systemic signs of illness. The baby was well developed, well nourished, alert and no acute distress. An exam of the bilateral lower extremities reveals full range of motion of all joints, neurovascularly intact through out. Leg lengths were equal. Skin folds were symmetric. Barlow, Ortolani and Galeazzi tests were negative. Exam of the feet does reveal mild metatarsus adductus deformities. The calcancovalgus deformities are already correcting. Mildly curly toe deformities exist of the 4th toes bilate

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: physical examination, 04/10/08 - Barlow, Ortolani and Galeazzi tests were negative; diagnostic radiology, 04/10?/08 - see narrative; cervix HPV DNA assay - negative

History: Ventricular tachycardia; Papanicolaou smear abnormal

Prex Illness: Pregnancy NOS (LMP = 5/15/2007); Contraception

Prex Vax Illns:

Vaers Id: 316293-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Jul-2007	19-Jul-2007	1	16-Jun-2008	17-Jun-2008	IL	WAES0708USA05332	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Oligohydramnios

Symptom Text: Initial and follow-up information has been received for the Merck Pregnancy Registry from a medical assistant concerning an 18 year old female who on 18-JUL-2007 was vaccinated IM in the left deltoid with a 0.5 ml dose of GARDASIL (Lot# 657868/0523U). It was reported that the patient experienced no adverse symptoms. On 28-AUG-2007 the patient's urine beta-human chorionic gonadotropin test reported positive for pregnancy. On 28-AUG-2007 the patient had an ultrasound that showed no evidence that the patient was pregnant. At that time, the patient's HCG level was reported to be only 55. It was reported that it was "too soon to see anything." The patient's last menstrual period was 21-JUL-2007, the estimated conception date was 05-AUG-2007, and the estimated date of delivery was 28-APR-2008. The patient did not have any previous pregnancies. At the time of the report, the patient was 10 weeks pregnant. On an unspecified date the patient underwent an ultrasound which revealed oligohydramnios. On 14-APR-2008, the patient delivered a healthy, normal baby boy via caesearean section due to fetal intolerance to labor and nuchal cord at 38 weeks. The birth weight was 5 pounds 11 ounces, and the infant's apgar score was 9/9. The infant was normal with no congenital anomalies. Other medications that were taken during the pregnancy were unspecified prenatal vitamins and PROMETRIUM, 200 mg for low progesterone from 05-SEP-2007 to 05-OCT-2007. At the time of the report, the outcome of the patient was unknown. Upon internal review caesarean section due to fetal intolerance to labor and nuchal cord was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: ultrasound, 08/28/07 - no evidence of pregnancy, HCG was only 55; ultrasound - oligohydraminios; urine beta-human, 8/28/07 - positive; total serum human, 08/28?/07, 55

History:

Prex Illness: Pregnancy NOS (LMP = 7/21/2007)

Prex Vax Illns:

Vaers Id: 316294-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	12-Sep-2007	12-Sep-2007	0	16-Jun-2008	17-Jun-2008	NJ	WAES0710USA03349	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received from a physician concerning a 19 year old female with a penicillin allergy who on 12-SEP-2007 was vaccinated with GARDASIL. On 08-OCT-2007 the patient was found to be pregnant. The patient plans to terminate the pregnancy for non medical reasons. The patient's outcome is unknown. On 20-OCT-2007 the patient had an elective termination 8 7/8 weeks from her last menstrual period. Upon internal review the elective termination was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: urine beta-human, 10/08/07, positive

History: Penicillin allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **316295-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Jul-2007	09-Jul-2007	0	16-Jun-2008	17-Jun-2008	--	WAES0711USA05500	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Haemorrhage

Symptom Text: Initial and follow up information has been received from a registered nurse concerning a 19 year old female who on 09-JUL-2007 was vaccinated IM (site not reported) with a first 0.5ml dose of the GARDASIL (lot# 657736/0389U). The patient was not pregnant at the time of the 1st dose of the GARDASIL. The patient missed her second dose of the GARDASIL. The nurse contacted the patient in November 2007, to let her know she needed to come in for her second dose but the she never came. In December 2007 the patient called the office and said she needed to be seen for pregnancy. Last menstrual period listed in the office chart was "September or October 2007." On 12-DEC-2007 the patient called the office with bleeding. On 13-DEC-2008 the patient had a spontaneous abortion. The nurse reported that the patient has not resumed the series even though they had attempted many times to contact her. Upon internal review the spontaneous abortion was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 316296-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	19-May-2008		16-Jun-2008	17-Jun-2008	FR	WAES0806USA00561	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Acute myeloid leukaemia, Ascites, Back pain, Blast cell count increased, Blood creatinine increased, Blood urea increased, Breath sounds abnormal, Computerised tomogram abnormal, Contusion, Dyspnoea, Fibroadenoma of breast, Full blood count, Haemoglobin decreased, Hepatosplenomegaly, Lymphadenopathy, Monocyte percentage increased, Pelvic mass, Petechiae, Platelet count decreased, Platelet transfusion, Pleural effusion, Pyrexia, Ultrasound abdomen abnormal

Symptom Text: Information has been received from a physician concerning a 15 year old female patient, with no relevant history, who in January 2008 and March 2008 received the first and second doses of GARDASIL, respectively. On 20-MAY-2008 the patient was diagnosed with acute myeloid leukemia and was hospitalised. On 02-JUN-2008 follow-up information was received from her general practitioner. The physician transmitted the hospital records of the patient from her hospitalization from 26-MAY-2008 to 27-MAY-2008. She was admitted for acute myeloid leukemia, questionable level IV. Around 20-MAY-2008 the patient had dorsal pain. On 23-MAY-2008 she had abdominal pain. When she was admitted for hospitalization her blood pressure was 128/83, heart rate was 120 and she had fever of 38C. Examination of her abdomen confirmed the pelvic mass and hepatosplenomegaly. Pulmonary examination revealed reduced vesicular whispering on the right base. Cardiac test was normal. Hyperhemia with adenopathies submandibular (it must be mentioned that she had surgical extraction of the left inferior third molar last week with concomitant lymphadenopathy submandibular). She also had inguinal lymphadenopathy, diffuse petechiae and bruising on her lower limbs. Right mammary examination showed tumourous infiltration with a hard lesion on the superficial level, with a depth of 6 centimeters at the level of the right inferior and superior interior quadrant. On 26-MAY-2008, during the night, she had increased blood pressure and breathing difficulty. She received treatment with FASTURTEC and a platelet transfusion. On 26-MAY-2008 the following diagnostic procedures were performed: echography of the abdomen revealed pelvic mass with abdominal adenopathies with ascites, with bilateral pleural effusion and hepatosplenomegaly. There was also an adenofibroma on the right breast of 2x1 centimeters; Computed Tomography scan of the thorax, abdomen and pelvic was performed and revealed a bilaterally pleural effusion of mild abundance and of more import

Other Meds: None

Lab Data: Blood pressure measurement, 26May08, 128/83 (value); Physical examination, 26May08, pelvic mass and hepatosplenomegaly; Diagnostic procedure, 26May08, pulmonary exam: reduced vesicular whispering on the right base; Diagnostic procedure, 26M

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 316297-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Mar-2008	30-Mar-2008	15	16-Jun-2008	17-Jun-2008	FR	WAES0806USA00568	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0484U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Gastroenteritis, Oedema peripheral, Pain, Pyrexia, Rash, Rash maculo-papular, Skin plaque, Vomiting

Symptom Text: Information has been received from a health professional (local health authorities on 03-JUN-2008 under reference number PC20080124) concerning an 18 year old female with no medical history who on 15-MAR-2008 was vaccinated with GARDASIL (lot# 0484U; batch number NG29170) in the left arm via intramuscular route. On 30-MAR-2008 the patient experienced vomiting and abdominal pain which evoked a non febrile gastroenteritis picture. On 01-APR-2008 the patient was presented with arthralgia in the ankle. On 02-APR-2008 joint symptoms worsened leading to 3 days hospitalisation: pain increased, oedema occurred to legs maculo-papular-oedematous skin eruption occurred (violine aspect), with the form of plaque at lower limbs and trunk and fever at 39 degrees Celsius with no chills. On an unspecified date, further examinations were performed and found: absence of leukocytosis: C-reactive protein at 84 mg/l with erythrocyte sedimentation rate at 38mm at first hour; serum rheumatoid factor test (latex waler rose) was negative, cyclic citrullinated antipeptide antibody test, antineutrophil cytoplasmic antibody test, type 2 serum antimitochondrial antibody test were negative; hepatitis A, B and C serologies were ongoing; B19 Epstein-Barr virus and Cytomegalovirus (CMV) parvovirus serologies were negative; chlamydia and salmonella serologies were negative and syphilis (results not provided) and chest X-ray was normal. Corrective treatment with analgesics was given and it was observed that the outcome was slowly favorable. On 08-APR-2008, standing was still painful at the feet. The case is closed. No further information is available. Other business partners included are: E2008-05064.

Other Meds: Unknown

Lab Data: chest X-ray, normal; body temp, 02Apr08, 39 C; Epstein-Barr virus antibodies, negative; parvovirus B19 PCR, negative; serum ANCA, negative; serum C-reactive protein, 84 mg/l; serum cyclic citrulline peptide IgG Ab, negative; serum rheumatoi

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316298-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Apr-2008	18-Apr-2008	1	16-Jun-2008	17-Jun-2008	FR	WAES0806USA01727	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0467U	1	Left arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Disorientation, Dizziness, Headache, Pulse pressure decreased, Shock, Unresponsive to stimuli, Vomiting

Symptom Text: Information has been received from a physician concerning a 13 year old female with a history of recurrent headaches (suspicion of migraine) who on 17-APR-2008 was vaccinated with a second dose of GARDASIL (Lot #0467U, Batch #NG14290) IM in the left arm. Concomitant medication was not reported. Previous vaccination with GARDASIL (Lot #0483U, Batch #NG20170) on 07-FEB-2008 was well tolerated. The morning of 18-APR-2008, the patient complained of headache and dizziness. Her pulse was "hardly palpable", the patient vomited and experienced a "circulatory shock." The patient was unresponsive for verbal stimuli and disorientation. Nothing was reported about any therapy. The same evening symptoms had resolved (exact duration not reported) except for headache which lasted for a few days. The patient recovered completely. File closed. Headaches, vomited, circulatory shock, disoriented and nausea were considered to be immediately life-threatening by the reporter. Other business partner numbers included E2008-05186. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Headache recurrent

Prex Illness:

Prex Vax Illns:

Vaers Id: 316299-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Feb-2008	01-Apr-2008	45	16-Jun-2008	17-Jun-2008	FR	WAES0806USA01723	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0278U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chest pain, Dyspnoea, Laparoscopy, Pleural effusion

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who on 16-FEB-2008, was vaccinated into the deltoid muscle with a third dose of GARDASIL (Lot# 0278U; Batch# NF56940). In April 2008, the patient experienced dyspnea and was hospitalized due to the event. A laparoscopy was carried out on an unspecified date and showed bilateral pleural effusion with chest pain. A CT scan showed no pathological findings. On an unspecified date the patient recovered. It was also reported that on 02-AUG-2007 the patient was vaccinated IM into the deltoid muscle with a first dose of GARDASIL (Lot# 1518F; Batch# NF32800) and on 04-OCT-2007, she was vaccinated IM into the deltoid muscle with a second dose of GARDASIL (Lot# 0354U; Batch# NF58150). No reactions occurred. Other business partner's numbers include: E2008-05207. No further information is available.

Other Meds: Unknown

Lab Data: laparoscopy, ??Apr08, showed bilateral pleural effusion; computed axial tomography, ??Apr08, no pathological findings

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316300-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	13-May-2008	13-May-2008	0	16-Jun-2008	16-Jul-2008	FR	WAES0806USA01719	16-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1358F	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Conversion disorder, Fall, Grand mal convulsion, Malaise, Syncope

Symptom Text: Information has been received from an health authority concerning a 19 year old female patient, with no previous medical history reported, who on 13-MAY-2008 was vaccinated intramuscularly with the first dose of GARDASIL (lot # 1358F, batch # NG13640). On 13-MAY-2008, the same day, after about fifteen minutes, she slumped to the ground and complained about feeling unwell. She also experienced tonic clonic seizures to the trunk and upper limbs that lasted 10-20 seconds. During the entire episode her pulse rate was normal. According to the reporter, she probably experienced a lipothynic episode of hysterical crisis. The patient was assisted and monitored. The outcome was completely recovered on 13-MAY-2008. The case was reported as not serious by both the health authority and the reporter. It was reported that upon internal review tonic-clonic seizures were considered a medically significant event and the case was upgrade to serious. Other business partners numbers include: E200805108, 85720 and IT22108. Additional information is not expected. The case is closed.

Other Meds: Unknown

Lab Data: diagnostic procedure, 13May08, pulse rate = normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 316301-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	16-Nov-2007	30-Nov-2007	14	16-Jun-2008	17-Jun-2008	FR	WAES0806USA01398	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0253U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Aphasia, Contraception, Headache, Hyperreflexia, Paraesthesia, Sensation of heaviness

Symptom Text: Information has been received from a gynecologist concerning a 22 year old female with a history of migraine, food allergy, unilateral right leg pain and back pain since MAY-2007 who on 16-NOV-2007 was vaccinated with the first dose of GARDASIL, (lot # 0253U/batch # NF58540) into the left upper arm. Concomitant therapy included hormonal contraceptives (unspecified). Two weeks post vaccination on approximately 30-NOV-2007, with GARDASIL, the patient experienced paraesthesia of fingers and feet, headache, aphasia and heavy feeling of both legs. MRI of lumbar spine on 13-NOV-2007 showed intervertebral disc protrusion. The patient was hospitalized from 30-NOV-2007 to 06-DEC-2007. Neurological examinations including magnetic resonance imaging (MRI) of the crania and cervical spine, visual evoked potential (VEP), somatosensory evoked potential (SEP), MEP, lumbar puncture, extracranial doppler sonography and doppler of A. carotis and A. temporalis showed normal results. Physical examination showed hyperreflexia of all extremities. Inflammatory disease of CNS was assumed "although this could not be verified currently". The patient was treated with Soludecortin H and symptoms improved. On 06-JUN-2008 the reporter was contacted by phone. The patient recovered except for ongoing slight increase of reflexes. Exact duration of symptoms was unknown. Despite ongoing symptoms the second vaccination with GARDASIL, was given on 14-JAN-2008. The third vaccination with GARDASIL, (lot # 0467U/batch # NG14290) was given on 09-MAY-2008. No additional information is available. Other business partner numbers include E2008-05133.

Other Meds: hormonal contraceptives (unspecified), Unk - Unk

Lab Data: magnetic resonance imaging, 13Nov07, lumbar spine-intervertebral disc protrusion; magnetic resonance imaging, ??Dec07, cranial - normal; magnetic resonance imaging, ??Dec07, cervical spine - normal; visual evoked potential, ??Dec07, normal;

History: Migraine; Food allergy; Unilateral leg pain; Back pain

Prex Illness: Intervertebral disc protrusion

Prex Vax Illns:

Vaers Id: **316302-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	03-Jun-2008	04-Jun-2008	1	16-Jun-2008	17-Jun-2008	ME	WAES0806USA01004	17-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blindness transient, Headache, Pupils unequal, Vision blurred

Symptom Text: Information has been received from a consumer concerning a 22 year old female who on approximately "03-JUN-2008 or 04-JUN-2008" was vaccinated IM with a first 0.5 ml dose of GARDASIL. There was no concomitant medication. On 04-JUN-2008, the patient's mother noticed that one of the patient's pupils "was large and the other was small." The next day "they switched and the small one was large and the other was small." It was reported that sometimes "both are huge." Her vision was blurry and she had a steady headache since receiving the vaccine. "At one point" she "lost her vision for 30 seconds and it came back." Diagnostic studies performed included: MRI and carotid artery test" (results not reported). The patient will not be continuing the series. At the time of the report, the patient had not recovered. Upon internal review, transient blindness was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: magnetic resonance, result not reported; carotid artery, results not reported

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316337-1 (S)** **Related reports:** 316337-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-Jun-2008	10-Jun-2008	1	16-Jun-2008	20-Jun-2008	CO		03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Grand mal convulsion

Symptom Text: At midnight on the day she received the vaccine, she experienced a seizure and was taken by ambulance to the ED. She was then stable and was discharged home. She had a second seizure at 6am and was again taken by ambulance to the ED. She was then kept for 48 hr. observation. 7/2/08-records received for DOS 6/10-6/11/08-DC DX: Seizures, new onset. Status post Gardasil vaccination. Neurologically intact. Evening of vaccination started seeing bright lights, generalized tonic-clonic seizure, seen in ED without incident. Following morning had second seizure, generalized tonic-clonic seizure with eyes rolled up.

Other Meds: None

Lab Data: CT scan, MRI, Lab tests, and EEG were all within normal limits. 7/2/08-records received- MRI, CT negative. EEG:abnormal indicated possible abnormality in left frontotemporal region, probably slowing secondary to seizure.

History: None 7/2/08-records received-PMH: migraines. Severe concussion 4 1/2 years ago when patient hit a tree while skiing.

Prex Illness: None. Had normal physical exam that day.

Prex Vax Illns:

Vaers Id: **316337-2 (S)** **Related reports:** 316337-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-Jun-2008	09-Jun-2008	0	18-Jun-2008	19-Jun-2008	CO	WAES806USA01993	19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a 14 year old female patient who on 09-JUN-2008, was vaccinated with a second dose of GARDASIL (Lot reported as "0070X"). About 12 hours later, by midnight, the patient had a seizure and went to the emergency room (ER). She had a CT scan and bloodwork done while in the ER and the results came back normal for both tests, so the patient was sent home. On 10-JUN-2008 at 0600, the patient experienced a second seizure and this time the ER chose to admit the patient for a 48 hour observation. The patient had an EKG, an MRI and a neurology consult while in the hospital. At the time of this report, the patient's outcome was unknown. It was also reported that the patient received her first dose of GARDASIL on 07-APR-2008. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: computed axial, 06/09/08 - normal; electrocardiogram, 06/10?/08; magnetic resonance, 06/10?/08; laboratory test, 06/09/08 - blood work - normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316341-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-May-2008	28-May-2008	8	16-Jun-2008	25-Jun-2008	NJ		25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Fatigue, Head injury, Headache, Loss of consciousness

Symptom Text: Patient passed out in doctors office after receiving 3rd dose of HPV Vaccine on 05/20/08. Landed face down on floor and received bump on head from fall. On 05/28/08 began feeling light-headed. Then started having headaches and experiencing general fatigue. Was seen by Dr. Sless twice and the local hospital emergency room twice. Also, went to The Children's Hospital of Philadelphia. All blood tests and urine tests came back normal. EKG was normal. CT scan of the head with and without contrast was normal. As of today, 06/16/08 patient still experiencing headaches and general fatigue.

Other Meds:

Lab Data: CT Scan of head with and without contrast came back normal. All blood tests and urine tests came back normal. EKG was normal

History: Patient referred to Pediatric Cardiologist in Jan. 2008 for border line hypertension

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316370-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jun-2008	Unknown		16-Jun-2008	25-Jun-2008	GA		25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2423AA	0	Right leg	Intramuscular	
	HPV4	MERCK & CO. INC.	0802U	1	Right leg	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB443BA	1	Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect dose administered, No adverse event

Symptom Text: None-Client was given an adult dose of Hepatitis B-instead of Ped./adol. dose.

Other Meds: None

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 316389-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Jun-2008	16-Jun-2008	0	17-Jun-2008	25-Jun-2008	SC		25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Injection site urticaria, Injection site warmth, Urticaria

Symptom Text: DIFFUSE HIVES COVERING ENTIRE BODY & FACE, MORE CONCENTRATED ON ARM WERE INJECTION GIVEN, PAIN AT SITE, WARM TO TOUCH. HIVES STARTED AT APPROX. 5PM AND GOT WORSE AS THE NIGHT WENT ON. TX- BENDRYL ZANTAC, PRELONE.

Other Meds: NONE

Lab Data:

History: NKA, HEALTH CHILD

Prex Illness: ADD, INSECT BITES

Prex Vax Illns: NONE~ ()~NULL~~In Sibling1|NONE~ ()~NULL~~In Sibling2|NONE~ ()~NULL~~In Patient

Vaers Id: **316390-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Jun-2008	17-Jun-2008	0	17-Jun-2008	25-Jun-2008	TX		25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB233AA	2	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1968U	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2573AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted and quickly recovered. The fainting spell lasted approximately 15 seconds. Patient was monitored for 20 minutes after fainting spell occurred. No further incidents were monitored during that time.

Other Meds: Folic Acid

Lab Data: None

History: Thalassemia

Prex Illness: None

Prex Vax Illns:

Vaers Id: **316404-1** **Related reports:** 316404-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Jun-2008	17-Jun-2008	0	17-Jun-2008	25-Jun-2008	PA		25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	18960	3	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt given HPV vaccine IM injection as well as Varicella SQ injection. Pt had syncope at check out desk and required staff intervention.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **316404-2** **Related reports:** 316404-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Jun-2008	16-Jun-2008	0	19-Jun-2008	30-Jun-2008	PA		09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1896U	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: PATIENT FAINTED 5 MINUTES AFTER HPV ADMINSTRATION. RECOVERED AFTER AMONIA SALTS BROKEN. SEEN BY PHYSICIAN. STAYED IN OFFICE FOR 40 MINUTES FOR OBSERVATION AND RECOVERY. PATIENT WAS ABLE TO AMBULATE AND STAND ON HER OWN BEFORE LEAVING THE OFFICE.

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NO

Prex Vax Illns:

Vaers Id: 316417-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Apr-2008	08-May-2008	37	17-Jun-2008	18-Jun-2008	FR	WAES0806USA02351	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Pulmonary embolism

Symptom Text: Information has been received from a health professional concerning a 17 year old female who in April 2008, was vaccinated via intramuscular route with the first dose of GARDASIL (batch#, dose and site not reported). On 08-MAY-2008, i.e. 1 month after vaccination, the patient had pulmonary embolism of moderate intensity. The reporter noted that the patient was hospitalized for 15 days, and had anticoagulant treatment of PREVISCAN. Medical history was not reported. There was no etiology found. At the time of reporting, the patient had fully recovered. Other business partner numbers included: E2008-05311. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316418-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Jul-2007	Unknown		17-Jun-2008	18-Jun-2008	WV	WAES0710USA00505	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MMR	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HEP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1208F		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Labour complication, Smear cervix abnormal

Symptom Text: Information has been received from a physician assistant concerning a female (age not reported) with a history of abnormal Papanicolaou smear (CINI) who on 25-JUL-2007 was vaccinated with a dose of GARDASIL (lot # 654741/1208F) and was 5 weeks pregnant. The patient's last menstrual period was reported to be on 24-JUN-2007 and an estimated delivery date of 30-MAR-2008. Concomitant therapy vaccination included MMR, vitamins (unspecified), hepatitis B virus vaccine (unspecified) and meningococcal vaccine (unspecified). On 23-AUG-2007 an ultrasound was performed with normal results. A "full prenatal panel" was also performed with an abnormal PAP smear. The patient's status was reported as "good". Follow up information received on 09-JUN-2008. The physician assistant reported that the patient gave birth to a baby boy at 40 weeks gestation. He was 8lbs 8oz and Apgars were 7 and 8. He is healthy and normal and there were no gross anomalies listed. It was reported that the mother did have a c-section for failure to progress and no dilation, but there were no complications. Upon internal review c-section for failure to progress and no dilation was considered to be an other medical event. Additional information is not expected.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 08/23/2007, normal - reason for test: dating

History: Papanicolaou smear abnormal

Prex Illness:

Prex Vax Illns:

Vaers Id: 316419-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-May-2008	04-May-2008	0	17-Jun-2008	18-Jun-2008	FR	WAES0805USA03564	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1113U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Haematoma, Head injury, Immediate post-injection reaction, Loss of consciousness, Syncope, Tympanic membrane perforation

Symptom Text: Initial and follow-up information has been received from a physician concerning a 17 year old female, who on 04-MAY-2008 was vaccinated IM in the left deltoid with a first dose GARDASIL (Lot# 1113U; Batch# NH08990). There was no concomitant medication. Four minutes post vaccination the patient experienced sudden syncope of severe intensity. Loss of consciousness induced a fall, which caused head trauma and a haematoma behind the ear. The physician did not describe the event as a vasovagal syncope. The syncope lasted a "few minutes." The patient experienced a head injury and a perforated ear-drum. The patient stayed at home for 48 hours under the physician's surveillance, who was also her mother. A consultation with a ear-nose-throat specialist was scheduled to check the patient's condition. The ear, nose, and throat surveillance was ongoing for the perforated eardrum. It was reported that the patient felt better. At the time of the report, the patient was recovering. The reporter thought that syncope was not of vagal aetiology. No complementary examinations were performed to document the syncope. It was reported that the patient had no adverse reaction to other unspecified vaccines. The physician considered syncope, head injury, and perforated eardrum to be an other important medical event. Other business partner numbers included: E200804340. Additional information is not available.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316420-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Jun-2008	06-Jun-2008	0	17-Jun-2008	18-Jun-2008	FR	WAES0806USA02182	18-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0513U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Immediate post-injection reaction, Pallor, Syncope

Symptom Text: Information has been received from a pediatrician concerning a 17 year old female, who on 06-JUN-2008 was vaccinated IM into the left upper arm with a first dose of GARDASIL (Lot# 0513U; Batch# NG34780). At the time of the vaccination the patient had her menstruation. A few minutes post vaccination the patient became pale and experienced a convulsive syncope. The patient's blood pressure was 120/70mmHg and her pulse was 97/min. The patient was put in Trendelenburg positioning and recovered after a "short time." The patient was hospitalized as a precaution. Other business partner numbers included: E2008-05222. Additional information is not available.

Other Meds: Unknown

Lab Data: blood pressure measurement, 06Jun08, 120/70 mm/Hg; total heartbeat count, 06Jun08, 97

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316430-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Jun-2008	16-Jun-2008	0	17-Jun-2008	26-Jun-2008	AZ		04-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2583AA	0	Left arm	Unknown	
HPV4	MERCK & CO. INC.	1968U	0	Right arm	Unknown	
TDAP	SANOFI PASTEUR	C2966AA	0	Left arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB280AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pallor

Symptom Text: Patient left exam room after waiting 20 minutes past vaccinations. Medial assistant found patient laying down in front of exit door with mom. Patient was alert and oriented, however, patient pale and reported dizzy, nauseated. Patient ambulated with assistance to exam room. Patient laid down on exam table. Vitals checked. Physician notified. Patient kept an additional 25 mins and physician discharged patient.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 316438-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	25-Mar-2008	25-Mar-2008	0	17-Jun-2008	26-Jun-2008	PA		26-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hot flush, Pain, Pain in extremity, Palpitations, Paraesthesia

Symptom Text: Painful arm and entire side of body, leg hurt x 24 hrs. Hot flashes, tingling in arm, onset of palpitations. ? arrhythmia about 2 months post vaccine.

Other Meds:

Lab Data: EKG, ECHO, Holter Monitor

History: Seasonal Allergies; Br asthma

Prex Illness: None

Prex Vax Illns:

Vaers Id: 316442-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	04-Feb-2008	05-Feb-2008	1	17-Jun-2008	26-Jun-2008	CA		26-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0930U	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Headache

Symptom Text: Severe headaches and temp 104 axillary after 1 day HPV #2 given 2/4/08.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **316446-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	29-Aug-2007	29-Aug-2007	0	17-Jun-2008	26-Jun-2008	WI		26-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness

Symptom Text: Passed out immediately for approximately 5 minutes.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 316452-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	05-Jun-2008	06-Jun-2008	1	17-Jun-2008	25-Jun-2008	CO		25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash pruritic

Symptom Text: Pruritic rash lower extremities and distal upper extremities. Not raised. Started 1 day after 1st HPV shot.

Other Meds:

Lab Data: Will refer to allergist for allergy testing for yeast.

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **316492-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Aug-2007	01-Aug-2007	0	18-Jun-2008	19-Jun-2008	AL	WAES0711USA00586	19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal growth retardation, Intra-uterine death, Placental disorder

Symptom Text: Information has been received through the Merck pregnancy registry for GARDASIL through a nurse concerning a 23 year old female with an allergy to FLAGYL who in August 2007, was vaccinated with her first dose of GARDASIL. There was no concomitant medication. The reporter stated that the patient received her first dose of GARDASIL while pregnant in another office (LMP = 11-JUL-2007). It was reported that the patient had an ultrasound (no additional information provided). The patient sought unspecified medical attention by seeing the physician. Follow-up phone call information from a nurse reported that the patient had a intrauterine fetal demise (IUFD) at 25 weeks gestation on 08-JAN-2008. There were placental abnormalities and severe intrauterine growth retardation (IUGR). No other information was provided. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound

History:

Prex Illness: Pregnancy NOS (LMP = 7/11/2007); Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **316493-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Nov-2007	01-May-2008	153	18-Jun-2008	19-Jun-2008	FR	WAES0806USA02188	19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Migraine, No reaction on previous exposure to drug, Paraesthesia, Weight decreased

Symptom Text: Information has been received from a physician (who received the information from a patient's mother) concerning a 14 year old female who on 30-NOV-2007 was vaccinated with the first dose of GARDASIL (lot# not reported), which was well tolerated. On 03-JAN-2008 the patient was vaccinated intramuscularly into the upper arm with the second dose of GARDASIL (lot# not reported). In the beginning of May 2008, the patient developed paresthesia, migraine and weight loss and was hospitalized for diagnostics. No reports on findings were made available to the reporter. The events were ongoing at the time of reporting. The physician noted that according to the patient's mother "the symptoms improve while her daughter listens to loud music via an MP3 player". The reporting physician does not see a causal relationship to the vaccination. Other business partner numbers included: E2008-05224. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316494-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	10-Mar-2008	25-Mar-2008	15	18-Jun-2008	19-Jun-2008	FR	WAES0806USA02352	19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Butterfly rash, Systemic lupus erythematosus

Symptom Text: Information has been received from a dermatologist concerning a 20 year old female patient with no relevant medical history reported, who on 10-MAR-2008 was vaccinated with a first dose of GARDASIL. On approximately 25-MAR-2008, 15 days after the vaccination, the patient developed a butterfly rash. A cutaneous biopsy showed lupus band at indirect fluorescent antibody test. From a biological point of view, it was reported that antinuclear antibodies were positive and at 1/320 without any anti-DNA and anti RNA antibodies. Urine culture showed no proteinuria. Clinical examination revealed no arthralgia and no neurological signs. She was diagnosed with a disseminated lupus erythematous. She was prescribed PLAQUENIL. At the time of reporting, the patient had not recovered. The reporter considered disseminated lupus erythematosus to be an other important medical event. Other business partners numbers include: E200805196. No further information is available.

Other Meds: Unknown

Lab Data: physical examination, no arthralgia; no neuro signs; skin biopsy, skin: lupus band at indirect fluorescent antibody test; serum ANA, 1:320, positive and without any anti-DNA and anti RNA; urine culture, no proteinuria

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316495-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-May-2008	01-May-2008	0	18-Jun-2008	19-Jun-2008	FR	WAES0806USA02356	19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Incorrect route of drug administration, Loss of consciousness

Symptom Text: Information has been received from a general practitioner concerning a female patient with anxiety, who in May 2008, was vaccinated subcutaneously with the first dose of GARDASIL. A few seconds after the vaccination, the patient experienced loss of consciousness and convulsive movements. The patient spontaneously recovered in a few minutes. It was specified that the patient was anxious because of the vaccination. The reporter considered loss of consciousness and convulsive movements to be other medically important events. Other business partners numbers include: E200805165. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Anxiety

Prex Vax Illns:

Vaers Id: **316496-1 (S)** **Related reports:** 316496-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	16-Apr-2008	18-Apr-2008	2	18-Jun-2008	19-Jun-2008	UT	WAES0806USA01573	19-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Injected limb mobility decreased, Laboratory test, Pain in extremity, X-ray

Symptom Text: Information has been received from a nurse concerning a 25 year old female who on 16-APR-2008 was vaccinated in the left arm with a dose of GARDASIL (uncertain if it was the first dose). Concomitant therapy included YAZ for birth control. On 18-APR-2008 the patient experienced persistent pain in the left arm that prevented the arm from being raised. There was no swelling and no induration. The patient still had the arm pain as of 06-JUN-2008 when the patient was seen in the office. The patient was told to use ice therapy, but the ice was reported to make the pain worse. The patient had been placed on DIFLUCAN and VOLTAREN. On an unknown date, x-ray and unspecified lab tests were performed and no result was provided. The patient's persistent pain in the left arm was considered to be disabling. Additional information has been requested.

Other Meds: YAZ

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316496-2** **Related reports:** 316496-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	16-Apr-2008	18-Apr-2008	2	17-Jul-2008	18-Aug-2008	UT	WAES0806USA07939	18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a registered nurse concerning a 25 old female who on 16-APR-2008 was vaccinated with a first dose of GARDASIL in the left deltoid. On 18-APR-2008, the patient complained of a sore left arm. On 02-MAY-2008, the sore left arm was treated with heat. On 06-MAY-2008, the arm was still very sore and was treated with ice, heat and ibuprofen. On 12-MAY-2008, the sore left arm was not improving and the patient was referred for an x-ray. The x-ray showed a normal result. On 27-MAY-2008, the patient still complained of a sore left upper arm and was referred to orthopedics for an evaluation of possible unrelated bursitis. It was reported the patient did not go for the evaluation. On approximately 16-JUN-2008, the left arm starting to not be as sore. At the time of the report the outcome of the sore left arm was recovering. The outcome of the possible unrelated bursitis was unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: X-ray 05/12/2008 normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 316510-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Oct-2007	01-Oct-2007	0	18-Jun-2008	30-Jun-2008	--		09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0755U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Arthralgia, Fatigue, Headache, Hot flush, Hypoaesthesia, Insomnia, Irritability, Laboratory test normal, Lymphadenopathy, Malaise, Mononucleosis heterophile test negative, Musculoskeletal discomfort, Myalgia, Paraesthesia, Pharyngolaryngeal pain, Streptococcal identification test negative, Tinnitus, Viral infection

Symptom Text: Pt states that for the past 5-6 days she has had a HA in mid forehead. HA always present to some degree but does vary considerably in intensity. Pt also c/o anterior neck discomfort earlier in day (not necessarily worse w/ swallowing) that has improved on its own. She denies stiff neck or posterior neck pain. She also c/o generalized fatigue, numbness and tingling in both her legs, "hot flashes", and sore muscles throughout her body. She states her skin feels very sensitive to touch. She states she has had increased anxiety in recent days (unsure why) and has been very irritable. She adamantly denies any suicidal or homicidal thoughts/plans. LMP 1 1/2 weeks ago > normal. This 18-year-old has been in a couple of times now for this complaint. She has seen Dr. All of these symptoms started directly after her HPV vaccination. This is discussed in detail in Dr's notes. The patient's current symptoms include numbness, malaise, swollen glands, joint pain, muscle pain, fatigue, increase in her headache frequency and hot flashes. She even noticed that her right ear clicks after the injection. In general, she does not feel well. The respite from school has helped somewhat. She is less stressful, but still, according to her and her mother, continues to be very anxious with lots of mood irritability. She still does go to the gym daily and run. She enjoys visiting with her friends. Her sleep is still quite poor. The AMBIEN has helped. This recent episode was overlaid with a viral illness. I reviewed her blood work from a couple of weeks ago with them again and that all looked normal. This 18-year-old was seen by me last week in the same-day clinic. I felt she might be depressed. She was reacting to sore throat, fatigue, and insomnia. Her lab studies are all perfectly normal. Her strep screen was negative. Her monotest was negative as well as a CBC and thyroid testing. Today, she presents with her mother and history is more complete in that she had GARDASIL vaccine in October and then in December

Other Meds:

Lab Data: 18Jan08, Weight (Kilograms), 70 KG; BP, 118/70 MMH; Pulse, 88 BPM; Respirations, 16; Pain Scale (0-10 and Nonverbal), 8; Pain Location - Specify, TOOTH; 01/11/08, TSH, 0.917 uIU/mL; 01/11/08, sodium, 139 mEq/L, potassium, 4.0 mEq/L, chlorid

History: No known drug allergies.

Prex Illness:

Prex Vax Illns:

Vaers Id: **316528-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Jun-2008	18-Jun-2008	0	18-Jun-2008	26-Jun-2008	WI		26-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall

Symptom Text: Administered HPV vaccine to patient at approx 8:30 am. Within 5 minutes she became dizzy and dropped to the floor but remained consious throughtout. Laid patient on floor with legs elevated for approx 10 min. Alert and Oriented x3. Shortly thereafter she was able to come to seated position, drinking fluids, sat for another 15 minutes in office and then felt much better. Released at approx. 9:00am w/mother.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 316540-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Jun-2008	15-Jun-2008	5	18-Jun-2008	26-Jun-2008	NY		26-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	2	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2558AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Nausea

Symptom Text: Pt had some nausea. Had clinically evaluation and blood screen. No tx. Pt had sx after we discovered that the 3rd dose of HPV was given too early. First dose was on 2/12/08, 2nd dose was on 4/8/08, and the most current dose was 6/10/08.

Other Meds:

Lab Data: CBC and chem were neg.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 316546-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-Feb-2008	15-Feb-2008	1	18-Jun-2008	27-Jun-2008	WI		27-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2541AA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B019AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1775U	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1287U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rectal haemorrhage, Vaccine positive rechallenge

Symptom Text: Rectal bleeding x 1 episode after both doses of Gardasil (2-14-2008 and 04-17-2008)

Other Meds: Strattera,Lactaid,Respirdol,Zyrtec

Lab Data: none

History: none

Prex Illness: Allergic Rhinitis

Prex Vax Illns:

Vaers Id: 316548-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Apr-2008	18-Apr-2008	1	18-Jun-2008	27-Jun-2008	WI		27-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	7	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rectal haemorrhage

Symptom Text: Rectal bleeding x 1 episode following Gardasil administration

Other Meds: Nasocort,Zyrtec,Strattera,Lactaid, Respirdol

Lab Data: none

History: Allergic Rhinitis

Prex Illness: none

Prex Vax Illns:

Vaers Id: 316564-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Jun-2008	17-Jun-2008	0	18-Jun-2008	25-Jun-2008	FL		25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Labia enlarged

Symptom Text: Labia minora swelling.

Other Meds:

Lab Data: UA negative

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316566-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Jun-2008	16-Jun-2008	0	18-Jun-2008	26-Jun-2008	FL		14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	1566U	1	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2417AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Muscular weakness, Pain in extremity

Symptom Text: Pain in both arms, headache, dizziness and weak legs and arms.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **316568-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Mar-2008	18-Mar-2008	0	18-Jun-2008	26-Jun-2008	PA		26-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dysarthria, Memory impairment

Symptom Text: Patient reported to Dr. office on 6/10/08 and reported dizziness, slurred speech and forgetfulness after first vaccine on 3/18/08, no report prior to 6/10/08.

Other Meds: Ibuprofen; Midol

Lab Data:

History: Severe dysmenorrhea

Prex Illness:

Prex Vax Illns:

Vaers Id: **316569-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	14-May-2008	Unknown		18-Jun-2008	26-Jun-2008	WI		26-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Local swelling, Lymphadenopathy

Symptom Text: Patient phoned student health clinic on 6/11/08. She was back home and says she had a reaction to the HPV vaccine, which she got on 5/14/08. Says got "swollen lymph nodes" in the groin area which were biopsied. Says developed swollen nodes a few days after vaccine, but did not go to get seen until back home over 1 wk later. Is due to have other nodes biopsied soon.

Other Meds: Desogen

Lab Data: Says bx showed "dead cells".

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316570-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jun-2008	16-Jun-2008	0	18-Jun-2008	25-Jun-2008	CA		25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B013AA		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site pruritus, Injection site swelling

Symptom Text: Developed redness, swelling, pain & itching at injection site where she received varicella vaccine the night she received it.

Other Meds:

Lab Data: Well child check

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **316584-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-Jun-2008	18-Aug-2008	AL	WAES0805USA02852	19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Guillain-Barre syndrome

Symptom Text: Initial and follow-up information has been received from a physician concerning a female (age unknown), who, on an unspecified date, was vaccinated with a first dose of GARDASIL. Subsequently, the patient experienced arthralgia. On an unspecified date the patient was vaccinated with the third dose of GARDASIL. Subsequently, the patient experienced symptoms of GUILLAIN-BARRE SYNDROME. The patient sought unspecified attention. At the time of the report, the patient had not recovered. No product quality complaint was involved. Follow-up information indicated that the physician did not know the name of the patient. The physician reported that he received information on the event through a contact of a friend and he did not have additional information on the patient. The physician considered the symptoms of GUILLAIN-BARRE SYNDROME and arthralgia to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316585-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-Jun-2008	18-Aug-2008	AL	WAES0805USA02386	18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Guillain-Barre syndrome

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a third dose of GARDASIL. Subsequently, the patient experienced symptoms of GUILLIAN BARRE SYNDROME. The patient is not under the care of the reporting physician. The reporting physician stated the event was relayed to him by another physician. At the time of this report, the patient had not recovered. No product quality complaint was involved. The physician considered the symptoms of GUILLAIN-BARRE SYNDROME to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316586-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Apr-2008	28-Apr-2008	0	19-Jun-2008	18-Aug-2008	--	WAES0805USA01442	18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female patient with seasonal allergies who on 28-APR-2008 was vaccinated intramuscularly with a 0.5 mL dose of GARDASIL (Lot #660387/1967U). On 28-APR-2008, the patient experienced hives all over. On 30-APR-2008, the patient recovered. Hives were considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Seasonal allergy

Prex Vax Illns:

Vaers Id: **316588-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Apr-2008	24-Apr-2008	0	19-Jun-2008	19-Aug-2008	--	WAES0805USA01266	19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Malaise, Nausea, Pallor

Symptom Text: Information has been received from a mother, for the Pregnancy Registry for GARDASIL vaccine (yeast), concerning her 15 year old daughter with a history of latex allergy and tonsillectomy who on 24-APR-2008 was vaccinated with her first dose of GARDASIL vaccine (yeast) (Lot #, size, and route not reported). There was no concomitant medication. On 24-APR-2008 the patient "became pale, and she was nauseous and sick for one day". On an unspecified date, the patient took a pregnancy test which was positive (not further specified) (LMP approximately 05-FEB-2008, "estimated date of conception is 27-Feb-2008"). On 25-APR-2008, the patient fully recovered from paleness, nausea and being sick. The patient sought unspecified medical attention. No additional information was provided. Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic - positive

History: Tonsillectomy, LMP = 02/05/2008

Prex Illness: Pregnancy NOS, Latex allergy

Prex Vax Illns:

Vaers Id: **316589-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
35.0	F	01-May-2008	01-May-2008	0	19-Jun-2008	19-Aug-2008	FL	WAES0805USA01277	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Fatigue, Injection site pain, Myalgia

Symptom Text: Initial and follow up information has been received from a physician, nurse and a 35 year old female with a shell fish allergy, and a history of abnormal PAP test (February 2008), colposcopy (April 2003), biopsy (April 2003), and low grade CIN 1, who on 01-MAY-2008 was vaccinated intramuscularly in the lateral part of the thigh (unspecified which thigh) with her first dose of GARDASIL vaccine (yeast) (Lot # 660387/1967U). On 01-MAY-2008 the patient experienced injection site pain. On approximately 03-MAY-2008, also reported as "a couple of days later", the patient experienced leg muscle pain, muscle pain in the hands, knees and ankles, joint pain in the hands, knees and ankles and general tiredness. On 08-MAY-2008, the patient called the doctor's office and was treated with over the counter ibuprofen. The patient was to call the office if symptoms did not improve. At the time of the report, the patient had not contacted the doctor's office again. Subsequently on an unspecified date, the patient recovered from the injection site pain, arthralgia, fatigue, leg muscle pain, and muscle pain in the hands, knees and ankles. No further information was provided. Additional information has been requested.

Other Meds: None

Lab Data: colposcopy - 04/??/03, biopsy - 04/??/03, Pap test - 02/??/200 - abnormal

History: Cervical intraepithelial neoplasia I, Papanicolaou smear abnormal, Biopsy, Colposcopy

Prex Illness: iodine allergy

Prex Vax Illns:

Vaers Id: 316590-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		19-Jun-2008	19-Aug-2008	--	WAES0805USA01289	19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Information has been received from a certified nurse midwife concerning five or six 18 to 19 year old females, concomitant medications and pertinent medical histories not specified, who were vaccinated (dates unspecified) with the first doses of GARDASIL vaccine (yeast) (Lot #'s, and routes unspecified). It was reported that several weeks after receiving the GARDASIL vaccine (yeast) 5 or 6 patients unfortunately came back with hundreds of genital warts. At first they thought it may be just a chance occurrence not only did the nurse midwife see these , the doctor saw a few of these instances as well. The patients came in and had a pap, the pap smears came back and after that the first dose of GARDASIL vaccine (yeast) was administered, and after that they saw these outbreaks of genital warts come back. "It was so bad that these girls needed laser therapy and sometimes they continued laser therapy and even after that continued laser therapy. The patients still had genital warts." Some continued to receive the second and third dose and some may not, but at least some did finish the doses. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test - results not reported

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316591-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-May-2007	25-May-2007	1	19-Jun-2008	19-Aug-2008	CA	WAES0805USA01295	19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Syncope

Symptom Text: Information has been received from a physician concerning a 16 year old female with concomitant medications and pertinent medical history reported as unspecified, who on 24-MAY-2007 was vaccinated with her first dose of GARDASIL vaccine (yeast) (Lot # not reported). On 25-MAY-2007, the patient felt weak, dizzy and fainted, and sought unspecified medical attention. The patient recovered completely a short time later (date unspecified). No product quality complaint was involved. Additional information is not expected.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316592-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	08-Apr-2008	08-Apr-2008	0	19-Jun-2008	19-Aug-2008	MD	WAES0805USA01308	19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site pain

Symptom Text: Information has been received from a registered nurse concerning a 24 year old female with a sulfonamide allergy and no medical history, who on 08-APR-2008 was vaccinated intramuscularly with the first dose of GARDASIL vaccine (yeast). There was no concomitant medication. On 08-APR-2008 the patient developed a hard lump with pain at the injection site. It was reported that the patient called the physician's office. No diagnostic laboratory studies were performed. At the time of this report the patient had not recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: sulfonamide allergy

Prex Vax Illns:

Vaers Id: **316593-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-Jun-2008	19-Aug-2008	--	WAES0805USA01344	19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a nurse practitioner concerning a female with a history of asthma who was vaccinated intramuscularly on an unspecified date with her first dose of GARDASIL vaccine (yeast) (lot# not reported). Subsequently the patient experienced a headache 10 minutes after the dose. The patient still had the headache 4 hours later. The patient was instructed to take diphenhydramine hydrochloride (BENADRYL) and go to bed. Subsequently, the patient recovered from the headache the next morning. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: 316594-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	02-May-2008	03-May-2008	1	19-Jun-2008	19-Aug-2008	--	WAES0805USA01381	19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lip swelling, Swollen tongue, Tongue disorder

Symptom Text: Information has been received from a nurse practitioner concerning a 19 year old female with pertinent medical history reported as unspecified, who on 02-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast), 0.5 ml, (Lot # and route not specified). Concomitant therapy included hormonal contraceptives (unspecified). On 03-MAY-2008 the mother of the patient called the office and reported that her daughter's lip swelled and there were sores and bumps on her upper and lower lip and on her tongue. The patient was told to take diphenhydramine HCL (BENADRYJ for the reactions. At the time of report the patient had not recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316595-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	29-Apr-2008	29-Apr-2008	0	19-Jun-2008	19-Aug-2008	FL	WAES0805USA01390	19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a health professional concerning a 17 year old female who on 29-APR-2008 was vaccinated intramuscularly with her first dose of GARDASIL vaccine (yeast) (lot# 0152X). On 29-APR-2008, about 3 hours after vaccination, the patient experienced a rash on her face. The patient was instructed to use over the counter diphenhydramine hydrochloride (BENADRYL) to treat rash. Subsequently, the patient recovered from the rash on her face. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316596-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-Jun-2008	19-Aug-2008	--	WAES0805USA01393	19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site bruising

Symptom Text: Information has been received from a health professional concerning herself who was vaccinated intramuscularly with her second dose of GARDASIL vaccine (yeast) (lot# not reported). There was no concomitant medication. Subsequently the patient experienced bruising at the injection site. The patient's bruising at the injection site persisted. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316597-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		19-Jun-2008	19-Aug-2008	NJ	WAES0805USA01413	19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning two 14 year old females who were vaccinated intramuscularly with their first dose of GARDOSIL vaccine (yeast) (lot#'s not reported). Subsequently the patients experienced syncope and their outcome was not reported. The practice does not want to be contacted regarding this report. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316598-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Apr-2007	14-May-2007	35	19-Jun-2008	20-Jun-2008	TX	WAES0705USA04331	20-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	NULL		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1424F		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed visiting nurse through the Merck pregnancy registry concerning a 17 year old female patient with no history or allergies to medication, who on 09-APR-2007 was vaccinated intramuscularly into the right deltoid, with a dose of GARDASIL (Lot# 654885/1424F). Concomitant therapy administered into the left deltoid on included a dose of MENACTRA and a dose of VAQTA (MSD). It was noted the patient was not taking other medications. On 13-MAY-2007, a home pregnancy test was performed. On 14-MAY-2007, the patient was determined to be two months pregnant via information from the patient's mother. In June 2007, the patient had a miscarriage and was reported to be approximately 2 months pregnant at the time of the miscarriage. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Upon internal review, miscarriage was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: beta-human chorionic, 05/13/07

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 316599-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-Jan-2008	21-Jan-2008	0	19-Jun-2008	20-Jun-2008	--	WAES0806USA02446	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	12670	1	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Alcohol abuse, Depression, Drug abuse, Neck pain

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female with pertinent medical history and drug reactions/allergies reported as unspecified, who on 19-NOV-2007 was vaccinated IM with the first dose of GARDASIL. Concomitant medications were reported as none. It was reported that the second dose of GARDASIL was given IM on 21-JAN-2008, and subsequently the patient experienced neck pain. The patient did not notify the nurse practitioner of this experience until she went in to received her third dose of GARDASIL on 11-JUN-2008. The patient did not go on to complete the series and was waiting till more information was available regarding this. The patient sought medical attention at the hospital on an unspecified date, where she was observed and then released. No treatment information had been provided. The neck pain healed "on its own". Additional information has been requested. 10/10/08 Hospital medical records reviewed for 6/2008. FINAL DX: alcohol & cannabis abuse, possible recurrent depression.

Other Meds: None

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 316600-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	31-Jul-2007	31-Jul-2007	0	19-Jun-2008	20-Jun-2008	PA	WAES0710USA01474	20-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour, Premature separation of placenta

Symptom Text: Initial and follow-up information has been received from a health professional through the Merck pregnancy registry concerning a 23 year old female smoker with no drug allergies, who on 30-JAN-2007 was vaccinated intramuscularly with a 0.5mL first dose of GARDASIL. On 30-MAR-2007 the patient was vaccinated with a second dose of GARDASIL. On 31-JUL-2007 the patient was vaccinated with a third dose of GARDASIL (Lot# 658222/0927U). There was no concomitant medication. Subsequently, the patient was pregnant and reported to be in her first trimester. The patient took a home pregnancy test that was positive. On 10-SEP-2007 prenatal blood work was taken and an ultrasound was performed that was normal. The patient's last menstrual period was 03-JUL-2007 and her estimated delivery date was 09-APR-2007 (also reported as 11-APR-2008). The patient called the office. The patient had one previous pregnancy that resulted in a spontaneous abortion. At the time of the report, the patient's outcome was unknown. No product quality complaint was involved. On 02-MAR-2008 the patient went into pre-term labor at 34 weeks with abruptio placenta and delivered a male baby that weighed 2175 grams. It was reported that the baby was in the hospital NICU on oxygen and was receiving unspecified antibiotics. The mother was bottle-feeding the baby. The length of stay in the NICU, and the reason for the infant being treated with oxygen and unspecified antibiotics was not reported. No further information was available on the baby's condition. This is an amended report. The serious criteria for hospitalization has been changed to yes for premature baby and birthweight low. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound, 09/10/07, normal; serum beta-human, 09/10/07; beta-human chorionic, positive

History: Pregnancy; Miscarriage

Prex Illness: Pregnancy NOS (LMP = 7/3/2007); Smoker

Prex Vax Illns:

Vaers Id: 316611-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Aug-2007	02-Apr-2008	224	19-Jun-2008	20-Jun-2008	CA	200801981	05-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2330A		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1060U		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea, Dysaesthesia, Guillain-Barre syndrome, Hypoaesthesia, Nausea, Pain, Pain in extremity, Paraesthesia, Peripheral sensory neuropathy, Pharyngitis streptococcal, Viral infection

Symptom Text: Initial information received from a health care professional on 11 June 2008. A 17-year-old female patient with a past history of Bell's palsy and asthma, received an intramuscular injection of MENACTRA, lot number U2330AA, in the left deltoid, and an intramuscular injection GARDASIL (manufacturer Merck), lot number 1060U, in the right deltoid on 22 August 2007. 224 days later, on 02 April 2008, the patient presented to the physician's office with painful dysesthesias in her feet and legs. She also complained of numbness and tingling in her feet, which was reported to have been "going on for awhile". The numbness and tingling had progressed to her fingers and forearm. She was treated with gabapentin with no success. Subsequently, she was seen by a neurologist and was diagnosed with Guillain-Barre syndrome. Laboratory work was completed on an unspecified date and showed a sed rate of 30 and Rheumatoid factor greater than 15. At the time of this report, the patient had not recovered from the events. 11/4/08-records received-office visit 4/9/08-C/O numbness in both feet for 2-3 weeks progressively worse. Present in bottoms of feet only with pins and needles sensation and sharp stabbing pain. Able to walk and run without any problems. Assessment:sensory polyneuropathy subacute onset-probably Guillain-Barre syndrome. Office visit 4/11/08-more pain in feet and numbness is a little bit worse, denies weakness. Presented 4/15/08 with C/O either a viral syndrome or streptococcal pharyngitis, diarrhea, nausea and purulent pharyngitis. Impression: subacute sensory polyneuropathy of undetermined etiology, possibly Guillain-Barre variant.Office visit 5/20/08-largely asymptomatic since 4/21/08-working diagnosis is sensory variant of Guillain-Barre syndrome resolving.

Other Meds: ALBUTEROL, NASONEX

Lab Data: Sed rate 30, Rheumatoid factor greater than 15. 11/4/08-records received-4/11/08-EMG and nerve conduction studies consistent with mild predominantly sensory neuropathy. Motor conduction studies normal but motor distal latencies prolonged

History: The patient had a past medical history of asthma and Bell's palsy. On 07/Feb/2007, she presented to the physician's office with left sided facial numbness and swelling, and was diagnosed with Bell's palsy. 11/4/08-records received-PMH: breast infection, chicken pox and reactive airway disease.

Prex Illness:

Prex Vax Illns:

Vaers Id: 316623-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-Jun-2008	13-Jun-2008	2	19-Jun-2008	25-Jun-2008	IN		25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2408AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Nausea, Vomiting

Symptom Text: N/V h/a dizziness.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 316624-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	26-Jul-2007	27-Jul-2007	1	19-Jun-2008	26-Jun-2008	AL		03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Erythema, Inappropriate schedule of drug administration, Incorrect route of drug administration, Induration, Nausea, Pruritus, Pyrexia

Symptom Text: Patient reports 2" x 3" knot, redness, itching at intradermal test site. No symptoms/signs at intramuscular site. (Intradermal test done secondary to fever, chills, nausea after 1st injection). Patient was instructed to use Benadryl, hydrocortisone cream and ice. This reaction occurred 24 hours after injection. 1st reaction occurred approximately 8 hours following injection.

Other Meds: Lo Ovral 28; Singulair PRN; Valtrex PRN

Lab Data: N/A

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: 316644-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	17-Jun-2008	17-Jun-2008	0	19-Jun-2008	30-Jun-2008	TX		30-Jun-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEP	MERCK & CO. INC.	0723F	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1968U	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2573AA	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2937BA		Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB236AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling

Symptom Text: Immediately after administering the Hepatitis B vaccine in the left arm, which was the second vaccine administered in the left arm, the patient and I noticed swelling in the arm. No redness was noted in the left arm, but the patient did complain of some discomfort and pain. I asked the patient to wait in the waiting room for 15 minutes so that I could monitor any further swelling or reactions. After 15 minutes the swelling was not as significant as first noted. Yet, slight swelling remained. The patient was given two 200mg tablets of Ibuprofen.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316657-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Jun-2008	19-Jun-2008	0	19-Jun-2008	30-Jun-2008	IA		30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2537AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1976U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypotonia, Pallor

Symptom Text: pt received menactra and gardasil. Within 30-60 seconds she was pale around the mough and then limp in her chair. Assisted her to the floor and fanned her. Recovery began within the next 1-2 minutes. Allowed her to lay, then sit on floor, then to chair before leaving at approx 15 mins. Denied any reoccuring feelings, and insisted she felt ok at that time.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 316675-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	18-Jun-2008	19-Jun-2008	1	19-Jun-2008	26-Jun-2008	MD		26-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Axillary pain, Lethargy, Musculoskeletal chest pain, Pain

Symptom Text: Pt. received HPV #2 in left deltoid via biojector, approx. 10:00AM 6/18/08. On 6/19/08, 10:30AM, pt. telephoned RN to report pain from left armpit to left rib area, and lethargy. Pt. advised to see PMD for continued pain or if pain worsens.

Other Meds: DEPO PROVERA

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **316676-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Jun-2008	17-Jun-2008	1	19-Jun-2008	26-Jun-2008	OK		26-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1471U	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0063X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Swelling, Tenderness, Urticaria

Symptom Text: Urticarial swelling 1 inch diameter 24 hours later. Swelling 4 inches in diameter with central tenderness 48 hours after immunization, pruritic - no fever or systemic illness.

Other Meds:

Lab Data:

History:

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 316677-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	17-Jun-2008	17-Jun-2008	0	19-Jun-2008	26-Jun-2008	SC		26-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Feeling hot, Throat tightness

Symptom Text: C/O feel faint, throat closing up, but eased somewhat after drinking water. Also c/o feeling really hot.

Other Meds:

Lab Data: none

History: seasonal allergies

Prex Illness: none

Prex Vax Illns:

Vaers Id: 316690-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jul-2007	01-Jul-2007	0	20-Jun-2008	23-Jun-2008	--	WAES0709USA00326	23-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arrested labour, Caesarean section, Drug exposure during pregnancy, Foetal distress syndrome, Foetal heart rate decreased

Symptom Text: Initial and follow up information has been received from a certified nurse midwife and a nurse for the Pregnancy Registry for GARDASIL concerning a female (age not reported) who in July 2007, was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL. The certified nurse midwife reported that the patient was already pregnant (about 20 weeks gestation) when she received her first dose of GARDASIL. The patient sought unspecified medical attention. No other symptoms were noted. There was no product quality complaint involved. On 06-JUN-2008 a follow up telephone call was made to the doctor's office to know the patient's pregnancy outcome information and a telephone message was left. ON 11-JUN-2008 a nurse called back and reported that the patient had a primary cesarean section at term on 31-JAN-2008 and delivered a healthy and normal male baby weighing 7 lb, 10 oz. The baby's apgar score was 9/9. It was reported that the reason for the C-section was arrested descent in second stage with fetal intolerance to labor resulting in multiple deep variable decelerations. No complication was reported. Upon internal review patient having arrested descent in second stage of labor and fetal intolerance to labor resulting in multiple deep variable decelerations which required a cesarean section delivery were determined to be other important medical events. Additional information is not expected.

Other Meds: Unknown

Lab Data: Apgar score, 01/31/08, 9/9

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316691-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	04-Feb-2008	04-Feb-2008	0	20-Jun-2008	23-Jun-2008	KS	WAES0805USA02352	23-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from the Merck Pregnancy Registry for GARDASIL via a 25 year old female with depression, on CELEXA 20 mg daily, who on 29-OCT-2007 was vaccinated with the first dose of GARDASIL, 0.5 ml, injection form (lot# not specified). The second dose of GARDASIL, (Lot# not specified) was administered on 04-FEB-2008, and the third dose of GARDASIL, (Lot# not specified) was administered on 05-MAY-2008. On an unspecified date, she sought medical attention and had blood and urine tests performed (dates, test names and results were not noted). The patient reported that she was pregnant and her last menstrual period was 10-APR-2008, her estimated due date was calculated to be 16-JAN-2009. Follow-up information reported on 20-MAY-2008, 4 to 6 weeks from her last menstrual period, the patient had a spontaneous abortion. It was reported that the products of conception were not examined and it was unknown if the fetus was normal. Upon internal it was reported that spontaneous was an other important medical event. Additional information has been requested.

Other Meds: CELEXA mg

Lab Data: diagnostic laboratory - no results; diagnostic urinalysis - no results

History:

Prex Illness: Pregnancy NOS (LMP = 4/10/2008); Depression

Prex Vax Illns:

Vaers Id: 316693-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Jun-2008	06-Jun-2008	1	20-Jun-2008	23-Jun-2008	FL	WAES0806USA01531	07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Confusional state, Convulsion, Dehydration, Hypothyroidism, Syncope vasovagal

Symptom Text: Information has been received from a certified medical assistant concerning a 17 year old female with no drug reactions/allergies who on 05-JUN-2008 was vaccinated with GARDASIL (lot number 659962/1740U) 0.5 mL IM. Concomitant therapy included SYNTHROID, LEXAPRO and LUNESTA. On 06-JUN-2008 at about 4 AM the patient experienced 2 seizures a few minutes apart. The patient was taken to the emergency room (ER), evaluated, released and referred to a neurologist. On an unspecified date a magnetic resonance imaging (MRI) and electroencephalography (EEG) was performed but results were not available. No other information was available. Upon internal review seizure was considered to be an other medical event. Additional information has been requested. 6/24/08 Reviewed PCP vax rec & medical record of 6/5/08 which reveal pt w/dysmenorrhea & on Yasmin. Otherwise in usual state of good health. 7/4/08 Reviewed ER medical records of 6/6/08. FINAL DX: weakness, dehydration & hypothyroidism & vasovagal syncope. Records reveal patient experienced syncope x 2 followed by seizure activity & then confusion while at home. No further seizure activity while in ER & d/c to home.

Other Meds: LEXAPRO; LUNESTA; SYNTHROID

Lab Data: magnetic resonance, results not available; electroencephalography, results not available LABS: CT, CXR, EKG WNL. EEG abnormal. Urine drug screen (+) benzodiazepines. TSH 19.3(H).

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316694-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	26-Nov-2007	08-Feb-2008	74	20-Jun-2008	23-Jun-2008	FR	WAES0806USA02386	23-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0233U	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chest pain, Dyspnoea, Heart rate increased, Pulmonary embolism, Venous thrombosis

Symptom Text: Information has been received from a general practitioner concerning a 17 year old female who on 03-APR-2007 and 24-MAY-2007 was vaccinated with a first and second dose of GARDASIL (batch#NF12410/lot#1341F), which was well tolerated. On 26-NOV-2007 the patient was vaccinated into the upper arm with a third dose of GARDASIL (batch#NF46740/lot#0223U). Concomitant therapy included hormonal contraceptives (unspecified). On 08-FEB-2008 the patient complained of a sharp pain in chest, increased pulse frequencies and unusual dyspnea after easiest exposures. Based on massive increasement of D-Dimer and increased pulmonary artery pressure showed on echocardiogram, a diagnosis of severe pulmonary embolism (both sides) was established, and she was hospitalized. Diagnosis was confirmed by computerized tomography (spaces of contrast medium in both main pulmonary arteries). The beginning of the pulmonary embolism was found in a thrombosis of the left superficial femoral vein. Therapy with heparin and MARCUMAR was started. The patient also experienced venous thrombosis and coagulation factor VIII level increased and was hospitalized. A factor V Leiden mutation and a APC-resistance as factor II were ruled out. On 08-APR-2008 the following lab tests and diagnostic tests were performed: D-Dimer: 3.88mg/mL; CRP: 3.38 mg/dl; fibrinogen:632 mg/dl; leukocytes:13.0; There was massive increasement of TSH (up to 11micg/dl). An echocardiogram showed increased pulmonary artery pressures; computerized tomography showed spaces, openings of contrast medium in both main pulmonary arteries. Factor VIII activity was slightly increased and Factor VIII associated antigen (Von Willenbrand-antigen) activity was increased. The patient was discharged on 15-FE-2008. On 09-APR-2008 the patient underwent lab tests which included: fibrinogen: 4.8g/l (normal range: 1.8-3.5g/l); Factor VIII: 215% (normal range: 50-175%); D-Dimer: 0.30mg/L (normal range: 0.0.5mg/l); lipoprotein: 79.5 mg/dl (normal range: 0-30 mg/dl); FT3: 5.7 pmol/l (N: 2.7-7.6); FT4: 16.2 p

Other Meds: hormonal contraceptives (unspecified), Unk - Unk

Lab Data: echocardiography, 08Feb08, Increasement of pulmonary artery pressure; computed axial tomography, 08Feb08, spaces, openings of contrast medium in both Pulmonary Arteries; ultrasound, Thyroid gland-without pathological findings; WBC count, 08

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316695-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Jan-2007	01-Jun-2008	517	20-Jun-2008	23-Jun-2008	FR	WAES0806USA02387	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Alopecia areata, Condition aggravated, No reaction on previous exposure to drug

Symptom Text: Information has been received from a gynaecologist concerning a 19 year old female with alopecia areata who at the end of 2007 was vaccinated with a first dose of GARDASIL (lot #, route and dose not reported), and no adverse effect occurred. At the beginning of 2008, the patient was vaccinated with a second dose of GARDASIL (lot #, route and dose not reported). The patient had a known alopecia areata which was aggravated. According to the patient's mother, the whole head was affected and the patient was hospitalized (date of hospitalization not reported). Other business partner numbers included: E2008-05292. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Alopecia areata

Prex Vax Illns:

Vaers Id: 316696-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Dec-2007	01-Jun-2008	183	20-Jun-2008	23-Jun-2008	FR	WAES0806USA03280	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Alopecia areata, Condition aggravated, No reaction on previous exposure to drug

Symptom Text: Information has been received from a gynaecologist concerning a 19 year old female with alopecia areata who was vaccinated with a 2nd dose of GARDASIL at the beginning of 2008. The patient had a known alopecia areata which aggravated. According to the patient's mother the whole head was affected and the patient was hospitalized (date of hospitalization not reported). The outcome was unknown. The patient was vaccinated with a first dose of GARDASIL at the end of 2007. No adverse effect occurred. Other business partner numbers included E2008-05292.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Alopecia areata

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316724-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jun-2008	16-Jun-2008	0	20-Jun-2008	30-Jun-2008	CA		30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	19784	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling abnormal, Gaze palsy, Headache, Hyperventilation, Hypotonia, Musculoskeletal stiffness, Pallor, Syncope, Syncope vasovagal, Tremor, Vaccine positive rechallenge

Symptom Text: FIRST EVENT 4/9/08: RECEIVED HPV 1, TDAP, MCV4 - FAINTED SEVERAL SECONDS AFTER VACCINES GIVEN, EYES ROLLED BACK AND PT STIFFENED AND SHOOK FOR A FEW SECONDS, THEN RECOVERED QUICKLY. THOUGHT TO BE VAGAL EPISODE. WITNESSED BY MOM AND ASSISTED BY NURSE AND NICOLE FABRIS, MD. SECOND EVENT 6/16/08: NERVOUS BEFORE SHOTS BC FAINTED LAST TIME. RECEIVED HPV 2. A FEW SEC LATER, FELT DIZZY AND UNABLE TO SEE, HEAD HURT THEN WENT LIMP, LEANED TO RIGHT AND STIFFENED AND ARMS AND LEGS SHOOK A LITTLE FOR APPROX 15 SEC, THEN PT WAS PALE, HYPERVENTILATING, EYES OPEN. SHE EVENTUALLY BECAME LUCID AND RESPONSIVE OVER ABOUT 3-5 MIN. BP STABLE THROUGHOUT. LUCID AND CONVERSATIONAL AFTER 5 MIN BUT QUIET AND STILL FELT "BAD". SHE RECOVERED COMPLETELY WITHIN 10 MINUTES. THIS ALSO WAS THOUGHT TO BE A VAGAL RESPONSE.

Other Meds:

Lab Data:

History:

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316733-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Jun-2008	20-Jun-2008	0	20-Jun-2008	30-Jun-2008	PA		30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: PT received HPV # 2. Pt reported to mother that she felt dizzy while waitng to check out. Pt assisted back to exam room . Vitals monitored. Pt discharged to home accompanied by mother when stable.

Other Meds: n/a

Lab Data: N/a

History:

Prex Illness: Pharnigitis

Prex Vax Illns:

Vaers Id: **316738-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	20-Jun-2008	20-Jun-2008	0	20-Jun-2008	30-Jun-2008	WA		30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	2	Left arm	Intramuscular	
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	AHABB108AA	2	Right arm	Intramuscular	
	TYP	SANOFI PASTEUR	A0522	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure systolic, Bradycardia, Dizziness

Symptom Text: Pt felt woozy after recieving 3rd vaccine(HPV). MD present,SBP70's, Bradycardia HR 50's. Amonia inhalent administered. Pt taken to urgent care via wheelchair

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **316747-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Jun-2008	20-Jun-2008	0	22-Jun-2008	30-Jun-2008	NH		30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	
	VARCEL	GLAXOSMITHKLINE BIOLOGICALS	NULL	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness

Symptom Text: Mini Seizure and loss of consciousness (for about a minute) in response to first shot of Gardasil (HPV Vaccine)

Other Meds: Birth Control (Tri-Sprintec)

Lab Data:

History: none known

Prex Illness: none known

Prex Vax Illns:

Vaers Id: **316760-1 (S)** **Related reports:** 316760-2; 316760-3; 316760-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-May-2008	16-May-2008	11	20-Jun-2008	24-Jun-2008	FL		15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Diplopia, Fatigue, Hypoaesthesia, Nerve injury, Paraesthesia, Sensation of heaviness, Tremor, VIth nerve paralysis

Symptom Text: About 10-14 days after receiving 2nd dose of HPV vaccine patient complained of double vision, numbness in hands & feet, tremors, abdominal pain, heaviness in arms, fatigue. She was seen by doctor Dx-sixth nerve palsy, abnormal MRI, admitted to hospital. 7/14/08-PCP note seen in office 6/2/08-for C/O double vision, 15 days prior seen by ophthamologist. 8/6/08-records received for DOS 6/10-6/13/08-DC DX: ADEM. Presented with diplopia a few weeks prior to admission, seen by optometrist and diagnosed with 6th nerve palsy. Two weeks prior to admission presented with paresthesias involving all extremities. Diplopia somewhat improved.

Other Meds:

Lab Data: MRI; lumbar puncture; blood 2nd dose; diagnosed with ADEM 8/6/08-records received for DOS 6/10-6/13/08-DC DX: ADEM. CSF albumin increased 5120, olig bands increased 11. EBV VCA IGG positive. MRI abnormal .with left periventricular white ma

History: none

Prex Illness: dizziness, sight, numbness

Prex Vax Illns:

Vaers Id: **316760-2 (S)** **Related reports:** 316760-1; 316760-3; 316760-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-May-2008	01-Jun-2008	27	24-Jun-2008	26-Jun-2008	FL		07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB222AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1448U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diplopia, Leukoencephalomyelitis, Paraesthesia, Paralysis

Symptom Text: Mom states that as a result of the child receiving the HPV vaccine her child began with double vision and was hospitalized and diagnosed with ADEM-Acute Disseminated Encephalomyelitis. 8/6/08-records received for DOS 6/10-6/13/08-DC DX: ADEM. Presented with diplopia a few weeks prior to admission, seen by optometrist and diagnosed with 6th nerve palsy. MRI abnormal. Two weeks prior to admission presented with paresthesias involving all extremities. Diplopia somewhat improved.

Other Meds: None

Lab Data: MRI 5-23-08 7/6/08-records received-MRI spine normal. MRI brain abnormal with left periventricular white matter lesion. CSF albumin increased 5120, olig bands increased 11. EBV VCA IGG positive.

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **316760-3** **Related reports:** 316760-1; 316760-2; 316760-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Mar-2008	Unknown		17-Jul-2008	22-Jul-2008	FL		05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB222AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diplopia, Leukoencephalomyelitis

Symptom Text: Mom states that as a result of the child receiving the HPV vaccine her child began with double vision and was hospitalized and diagnosed with ADEM - Acute Disseminated Encephalomyelitis.

Other Meds: None

Lab Data: MRI 5-23-08

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **316760-4 (S)** **Related reports:** 316760-1; 316760-2; 316760-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-May-2008	Unknown		15-Aug-2008	18-Aug-2008	--	WAES0807USA05058	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB222AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1448U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Diplopia, Fatigue, Hypoaesthesia, Leukoencephalomyelitis, Sensation of heaviness, Tremor, VIth nerve paralysis

Symptom Text: This report was identified from line listings obtained on request by the Company from the agency under the an Act. A 14 year old female with a previous illness of dizziness, "sight" and numbness was vaccinated with the second dose (also reported as 0 previous doses) of GARDASIL (lot # 659653/1448U), IM into the left arm, on 05-MAY-2008. Concomitant therapy included HAVRIX (unspecified) (lot # AHAVB222AA). On 16-MAY-2008, the patient complained of double vision, numbness in hands & feet, tremors, abdominal pain, heaviness in arms and fatigue. She was seen by the doctor who diagnosed sixth nerve palsy. The patient was admitted to the hospital. An MRI was performed on 23-MAY-2008. A lumbar function was also performed. The patient was diagnosed with Acute Disseminated Encephalomyelitis (ADEM). The listing indicated that one or more of the events required hospitalization, were considered to be disabling, and were considered to be immediately life-threatening. The original reporting source was not provided. The VAERS ID# is 316760. A standard lot check investigation was performed. All in-process quality checks for the lot in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the center and was released. No further information is available.

Other Meds:

Lab Data: magnetic resonance, 05/23/08, ABNORMAL MRI; spinal tap, ?/?/08, diagnosed with ADEM

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316768-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-Jun-2008	20-Jun-2008	1	20-Jun-2008	30-Jun-2008	--		30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1596U	0	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2613AA	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0654F	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site induration, Injection site swelling

Symptom Text: 3 inch red raised indurated non-tender area around inoculation site. Benadryl PRN left arm SQ injection site.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 316781-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-May-2008	01-May-2008	0	16-Jun-2008	10-Jul-2008	--	WAES0805USA00615	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site pain, Vaccine positive rechallenge

Symptom Text: Information has been received from a pharmacy student concerning a 17 year old female who on 01-MAY-2008 was vaccinated with her third dose of GARDASIL (Lot #, site and route not reported). On 01-MAY-2008 the patient experienced an increased level of pain when the third dose of GARDASIL was administered. The patient noted that pain during administration of the third dose was much greater than the pain associated with the first two doses. The dates of the prior two doses of GARDASIL were not reported and the onset of pain related to these injections was not reported. The patient sought unspecified medical attention by contacting the pharmacy. On an unspecified date, the patient recovered from the increased level of pain during vaccine administration. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316782-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-May-2008	01-May-2008	0	16-Jun-2008	10-Jul-2008	CA	WAES0805USA00631	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a physician concerning a female who on 10-MAY-2008 was vaccinated with her first dose of GARDASIL (lot number unspecified). On 01-MAY-2008 the patient fainted immediately after receiving the dose. She hit the floor and hit her head and "it wasn't good". The patient sough unspecified medical treatment in the office. No additional information at this time. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316783-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	CT	WAES0805USA00634	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site anaesthesia, Injection site pain

Symptom Text: Information has been received from a nurse concerning females who were vaccinated on unspecified dates with a dose of GARDASIL (lot#'s not reported). Subsequently the patients experienced injection site pain and numbness. Additional information has been requested. A phone call was placed on 07-MAY-2008 to obtain more information; however the phone call has not been returned.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316784-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	22-Apr-2008	22-Apr-2008	0	16-Jun-2008	10-Jul-2008	HI	WAES0805USA00652	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus generalised, Rash generalised

Symptom Text: Information has been received from a health professional concerning a 25 year old Native Hawaiian female with asthma, a history of hydrocephalus, no drug reactions/allergies and no illness at the time of the vaccination who on 22-APR-2008 was vaccinated with GARDASIL (lot # 659964/1978U) in the right deltoid at 2:30 PM. Concomitant therapy included DEPO-PROVERA. On 22-APR-2008 at 2:33 PM the patient developed itching and rash over the entire body from face to feet. The patient was given 10 CC's of BENADRYL. Additional information is not expected.

Other Meds: DEPO-PROVERA

Lab Data:

History: Hydrocephalus

Prex Illness: Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316785-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	--	WAES0805USA00667	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a health professional concerning a female in her early 20's who was vaccinated on an unspecified date with a dose of GARDASIL. Subsequently the patient called the office and reported her period was delayed following vaccination. Subsequently, the patient recovered from a delay in her menstrual period. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316786-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	--	WAES0805USA00669	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a health professional concerning a 15 year old female who was vaccinated on an unspecified date with a dose of GARDASIL (lot# not reported). The patient's mother called and stated her daughter's menstrual period was delayed following vaccination. Subsequently, the patient recovered from her menstrual period being delayed. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 316787-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Mar-2008	12-Apr-2008	27	16-Jun-2008	10-Jul-2008	--	WAES0805USA00757	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthma, Dyspnoea, Hypoaesthesia, Loss of consciousness, Panic attack, Paraesthesia, Syncope, Tonic clonic movements

Symptom Text: Information has been received from a nurse practitioner (N.P.) concerning a 14 year old female with no pertinent medical history or drug reactions/allergies who on 16-MAR-2008 was vaccinated with a first dose of GARDASIL (lot# 659437/1266U) 0.5 mL IM. There was no concomitant medication. The N.P. mentioned that after receiving her first dose of GARDASIL on 16-MAR-2008 the patient has been experiencing episodic syncope with shortness of breath, numbness and tingling of the arms and then she passes out. The patient's teachers have reported that she has limb movement similar to a seizure. The episodes last about 5 to 10 minutes. The N.P. mentioned that the patient has had 10 or more of these episodes since 12-APR-2008. All the episodes have been witnessed at school, the episodes that occur at home have not been witnessed. On 19-Apr-2008 a spirometry test was performed and demonstrated a mild obstruction consistent with mild asthma. The patient was then placed on an albuterol inhaler. Additional laboratory and diagnostic tests were performed the same day. A chest X-ray, liver enzyme test, a kidney function and thyroid function test were normal. The patient's blood lymphocyte count was slightly decreased and blood monocyte percent was slightly elevated. The patient was seen in the emergency room the last week of April 2008 and was diagnosed with panic attacks. The patient was sent to a cardiologist who stated that there was no cardiac underlying reason for the episodes and he believes that the patient was having panic attacks. The patient was going to be sent to see a neurologist. At the time of reporting the patient was recovering from syncope, shortness of breath, numbness of the arm, panic attack, tingling of the arm and tonic-clonic movements and the outcome of asthma was unknown. No additional information was available. Additional information has been requested.

Other Meds: None

Lab Data: spirometry, 04/19/08, demonstrated mild obstruction consistent with mild asthma; chest X-ray, 04/19/08, normal; renal function study, 04/19/08, normal; hepatic function tests, 04/19/08, normal; thyroid function test, 04/19/08, normal; lymph

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316788-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	02-May-2008	03-May-2008	1	16-Jun-2008	10-Jul-2008	--	WAES0805USA00773	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash vesicular

Symptom Text: Information has been received from a nurse practitioner concerning a 19 year old female patient with no medical history and no allergies reported who on 02-MAY-2008 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (Lot # 660387/1967U). Concomitant therapy included hormonal contraceptives (unspecified). On 03-MAY-2008, approximately 24 hours after the vaccination, the patient developed a vesicular rash on her lower lip and on the tip of her tongue. The patient was seen in the office on 05-MAY-2008. No diagnostic laboratory testing was performed. At the time of this report, the patient's outcome was not recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **316789-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	CA	WAES0805USA00799	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with two doses of GARDASIL. On an unspecified date, the patient tested positive for Papilloma viral infection (HPV), type unspecified. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervix HPV DNA assay, positive.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316790-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	22-Apr-2008	25-Apr-2008	3	16-Jun-2008	10-Jul-2008	--	WAES0805USA00841	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Heart rate increased

Symptom Text: Information has been received from a nurse practitioner concerning a teenage female with no medical history and no drug allergies, who on 22-APR-2008 was vaccinated IM with a first dose of GARDASIL. On 25-APR-2008 the patient experienced shortness of breath, elevated pulse, and breathing issues. The patient was taken to the emergency room but the specifics were unknown. The patient recovered on an unspecified date. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pulse oximetry

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 316791-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Jul-2007	27-Jul-2007	0	16-Jun-2008	10-Jul-2008	MI	WAES0805USA00856	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Complication of pregnancy, Drug exposure during pregnancy

Symptom Text: Information has been received for the Merck Pregnancy Registry for GARDASIL from a 17 year old female with no drug reactions/allergies who maybe a diabetic who in April 2007 was vaccinated with a first dose of GARDASIL. There was no concomitant medications. On 27-JUL-2007 the patient was vaccinated with a second dose of GARDASIL injection and was pregnant. The gestation period was 7 months. The patient has had a lot of complications with the pregnancy. Unspecified medical attention was sought. On an unspecified date blood work and an ultrasound was performed. No additional information was provided. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory; ultrasound

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 316792-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	LA	WAES0805USA00861	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Immediate post-injection reaction, Pain

Symptom Text: Information has been received from a 13 year old female with bipolar disorder and an allergic reaction to azithromycin who on an unspecified date was vaccinated with a first dose of GARDASIL and experienced stinging. At the time of reporting it was unknown if the patient had recovered from stinging. There was no concomitant medication. In December 2007, the patient was vaccinated with a second dose of GARDASIL 0.5mL injection. "Immediately after receiving the vaccine" the patient experienced numbness. At the time of reporting the patient recovered "after about a week". Medical attention was not sought. No further information was provided. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Bipolar disorder; Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **316793-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-Mar-2008	11-Mar-2008	0	16-Jun-2008	10-Jul-2008	MD	WAES0805USA00889	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Pallor

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who on 11-MAR-2008 at 04:30 PM was vaccinated IM with a first dose of GARDASIL (lot # 659182/1757U). The physician reported that on 11-MAR-2008 after receiving the injection the patient became pale and sweaty. She recovered in five to ten minutes with normal blood pressure of 90/60. Her heart rate was 70 per minute which was same as check in before the injection was administered. The patient reported as recovered on 11-MAR-2008. Additional information is not expected.

Other Meds: Unknown

Lab Data: blood pressure, 03/11/08, 90/60; total heartbeat count, 03/11/08, 70 per, After patient recovered from adverse event; total heartbeat count, 03/11/08, 70 per, before getting injection

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316794-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	TX	WAES0804USA05323	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Initial and follow up information has been received from a medical assistant concerning an 18 year old female who in approximately February 2008 (also reported as 2 months ago), was vaccinated with her first dose of GARDASIL (Lot #, site and route not reported). On 24-APR-2008 the patient was at the physician's office for her second vaccination with GARDASIL and noted that she was one day late for her menstrual period. A urine pregnancy test was performed which was negative. The patient was not pregnant, so the second dose of GARDASIL (Lot #, site and route not reported) was administered. The patient sought unspecified medical attention when she was seen by the physician. The patient's outcome was not reported. No further information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Urine beta-human, 04/24/08, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316795-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	--	WAES0805USA00187	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Syncope

Symptom Text: Information has been received from the authors of the above entitle published literature article concerning a 16 year old female patient who was vaccinated with a dose of GARDASIL. It was reported that the patient felt dizzy and had pallor within five minutes of receiving an GARDASIL vaccination. While being escorted back to an examination room, she fainted, but the physician caught her as she fell. She was observed for thirty minutes in the clinic and recovered completely. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316796-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	GA	WAES0805USA00408	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pyrexia, Rash

Symptom Text: Information has been received from a physician concerning a female who was vaccinated on an unspecified date with a dose of GARDASIL (lot# not reported). The patient developed a fever of 103F and red spots on her body after receiving a dose of GARDASIL. The patient's mother took her to the ER and she was released. The patient was recovering from the fever and red spots on her body. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316797-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.3	F	Unknown	14-Apr-2008		16-Jun-2008	10-Jul-2008	--	WAES0805USA00413	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy, Neck mass

Symptom Text: Information has been received from a mother concerning her daughter who in approximately 2007 was vaccinated with her first dose of GARDASIL (lot# not reported). Concomitant therapy included hormonal contraceptives (unspecified). The patient received the second dose of GARDASIL (lot# not reported) between September 2007 and February 2008. During the week of 14-APR-2008 the patient experienced a lump on the side of her neck. The doctor said it was an enlarged lymph node, cause unknown. She was treated with 2 antibiotics. She also saw a dentist for 2 impacted wisdom teeth but the dentist did not think it was connected with the lymph node. However the 2 impacted teeth were removed on 25-APR-2008 because they may have caused the lymph nodes to become infected. The patient's lump on the side of her neck persisted. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: dental X-ray; red blood cell count; hepatic function tests

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316798-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	15-Apr-2008	15-Apr-2008	0	16-Jun-2008	10-Jul-2008	PA	WAES0805USA00420	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a physician concerning a female who on approximately 15-APR-2008 was vaccinated intramuscularly with her first dose of GARDASIL (lot# not reported). Three minutes after vaccination the patient experienced syncope and fell down and hit her head. An ice pack was used for treatment, after which she was awake, oriented and alert. Subsequently, the patient recovered from syncope and falling down and hitting her head. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316799-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	29-Feb-2008	01-Apr-2008	32	16-Jun-2008	10-Jul-2008	--	WAES0805USA00439	29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Foreign travel, Urticaria

Symptom Text: Initial information and follow up has been received from a health professional concerning a 21 year old female with allergic rhinitis, gastroesophageal reflux disease and drug reactions/allergy to STRATTRA who on 29-FEB-2008 was vaccinated with her first dose of GARDASIL (lot# not reported). Concomitant therapy included a topical antifungal drug (unspecified) and hormonal contraceptives (unspecified). In the beginning of April 2008, the patient experienced hives. The hives appeared after certain activities such as after taking a shower, and then disappeared. However, the hives appeared again a few days later. The patient was seen by the nurse practitioner and was recovering. The patient was also recently tested for tuberculosis and the PPD test was positive, but the chest x-ray was negative. The patient had recent travel out of the country and recent foot fungus.

Other Meds: antimicrobial (unspecified); hormonal contraceptives

Lab Data: chest X-ray, negative; Mantoux test, positive

History:

Prex Illness: Rhinitis allergic; Gastroesophageal reflux disease; Hypersensitivity

Prex Vax Illns:

Vaers Id: 316800-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	15-Apr-2008	25-Apr-2008	10	16-Jun-2008	10-Jul-2008	--	WAES0805USA00467	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a certified medical assistant concerning a 26 year old female patient who on 15-APR-2008 was vaccinated with a first dose of GARDASIL (no lot # provided). Concomitant therapy included YASMIN. The patient experienced a hives outbreak 10 days after the first dose was given. The patient sought medical attention through speaking with the medical assistant. No further information was available from the medical assistant. The patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: Yasmin

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316801-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	--	WAES0805USA00490	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthritis, Pain

Symptom Text: Information has been received from a consumer concerning her daughter, a 17 year old female with a history of drug hypersensitivity to PEDIAZOLE, who sometime in 2007 was vaccinated with all three doses of GARDASIL (lot numbers and dates unspecified) and has been diagnosed with arthritis. Sometime after receiving the first dose, her daughter developed pain all over her body including ankles, knees, and elbows. Right before receiving the third dose her symptoms started to improve but still existed. The consumer is wondering if her daughter's symptoms will worsen after receiving dose #3. The consumer did not want to provide the physician's information or provider's name. No other details. The patient's arthritis and pain all over her body persisted. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Drug hypersensitivity

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316802-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Feb-2008	13-Feb-2008	0	16-Jun-2008	10-Jul-2008	PA	WAES0805USA00506	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crying, Dizziness, Oedema peripheral, Pain, Pain in extremity, Sensation of heaviness, Skin discolouration

Symptom Text: Information has been received from a physician concerning a 14 year old female patient who on 13-FEB-2008 at 12:45 was vaccinated into the left arm with the first dose of GARDASIL (Lot # 659655/1486U). On 13-FEB-2008, immediately after the shot was administered, the patient developed pain in the left arm. She cried for about seven minutes and began to complain of heaviness in her arm and stinging and aching. She then became dizzy and had to lie supine for fifteen minutes. She left the office in stable condition. Within one to two hours she developed swelling and discoloration of all fingers of the left hand. This lasted twenty-four hours and resolved spontaneously. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316803-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	PA	WAES0805USA00512	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with GARDASIL (lot number and dates unspecified). Subsequently the patient experienced a rash on the opposite arm from injection site. No additional information was provided. The patient sought unspecified medical treatment. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316804-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	--	WAES0805USA00531	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received from a female consumer who was vaccinated with a dose of GARDASIL (Lot# not reported). The patient reported that she developed a fever after receiving a dose and then she was fine the next day. The patient's outcome is recovered. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316805-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	FL	WAES0805USA00534	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Information has been received from a physician concerning an unspecified number of female patients who were experiencing pain from vaccination with GARDASIL (Lot# not reported). It is unknown if the patients sought medical attention. The patients' outcomes are unknown. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316806-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	26-Dec-2007	26-Dec-2007	0	16-Jun-2008	10-Jul-2008	KS	WAES0805USA00611	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Infectious mononucleosis

Symptom Text: Information has been received from a physician concerning a patient currently diagnosed with infectious mononucleosis who on 26-JUN-2007 was vaccinated with the first dose of GARDASIL (lot number unspecified). On 26-DEC-2007 the patient was vaccinated with the second dose of GARDASIL (lot number unspecified). The patient called the physician's office to schedule the third dose but is now diagnosed with infectious mononucleosis. No other symptoms reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Infectious mononucleosis

Prex Vax Illns:

Vaers Id: **316807-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Aug-2007	29-Aug-2007	0	16-Jun-2008	10-Jul-2008	TX	WAES0805USA00612	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0930U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Fatigue, Menstrual disorder, Menstruation irregular, Pain, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 29-AUG-2007 was vaccinated intramuscularly with her first dose of GARDASIL (Lot # 658488/0930U) (site not reported). The patient has experienced pain and irregular menstrual cycles since administration. On 30-OCT-2007, the patient was vaccinated intramuscularly with her second dose of GARDASIL (Lot # 657006/0188U) (site not reported). On 03-MAR-2008, the patient was vaccinated intramuscularly with her third dose of GARDASIL (Lot # 6659657/1487U) (site not reported). On an unspecified date(s) the patient had a CBC, TSH and glucose test performed, no results reported. On 29-APR-2008, the patient had an office visit where she informed the physician that she was still experiencing weakness, fatigue and menstrual problems. The patient was treated with PONSTEL (not further specified). Additional information has been requested.

Other Meds: Unknown

Lab Data: complete blood cell; plasma TSH; blood glucose

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316808-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	01-Mar-2007	15-Mar-2007	14	16-Jun-2008	10-Jul-2008	IL	WAES0805USA01769	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysuria, Erythema, Pruritus, Vaginal infection

Symptom Text: Information has been received from a registered nurse concerning a 12 year old female with anxiety disorder and reflux oesophagitis and no drug reactions/allergies who on 03-JAN-2007 was vaccinated with a first dose of GARDASIL 0.5 mL IM. Concomitant therapy included LEXAPRO and PREVACID. On 01-MAR-2007 the patient was vaccinated with a second dose of GARDASIL in her pediatrician's office. The patient has not received a third dose. On 15-MAR-2007 the patient developed persistent recurrent vaginitis, severe dysuria with itching and redness in the genital area. Medical attention was sought. On an unspecified date urinalysis and vaginal cultures were negative. The patient was treated with multiple courses of oral DIFLUCAN, MYCOLOG cream, MONISTAT cream, an estrogen vaginal cream and one of course of VALTREX. The symptoms recurred when treatment was discontinued. At the time of reporting it was unknown if the patient had recovered. No further information was provided. Additional information has been requested.

Other Meds: LEXAPRO; PREVACID

Lab Data: Urinalysis, negative; Vaginal culture, negative.

History:

Prex Illness: Anxiety disorder; Reflux oesophagitis

Prex Vax Illns:

Vaers Id: 316809-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	27-Feb-2007	27-Feb-2007	0	16-Jun-2008	10-Jul-2008	CO	WAES0703USA02156	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0243U		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Delivery, Drug exposure during pregnancy

Symptom Text: Information has been received through the pregnancy registry for GARDASIL from a medical assistant concerning a 26 year old female with erythromycin hypersensitivity who on 27-FEB-2007 was vaccinated with a dose of GARDASIL (Lot# 656372/0243U), 0.5 ml. Concomitant therapy included NUVARING. The patient received GARDASIL while being pregnant (LMP 05-FEB-2007). Follow-up phone call information has been received from a nurse who reported that the patient delivered an 8 pound male, at 39 weeks EGA, with Apgars of 8 and 9. Thick mecomium was noted after artificial rupture of membranes during labor. The baby was healthy, normal and there were no complications. No additional information is expected.

Other Meds: NUVARING

Lab Data: diagnostic laboratory

History:

Prex Illness: Pregnancy NOS (LMP = 2/5/2007); Drug hypersensitivity

Prex Vax Illns:

Vaers Id: 316810-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	02-Feb-2007	02-Feb-2007	0	16-Jun-2008	10-Jul-2008	--	WAES0703USA05278	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0014U		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Gestational diabetes, Live birth, Postpartum haemorrhage, Urinary tract infection

Symptom Text: Initial and follow-up information has been received from a nurse practitioner concerning a 26 year old female with a history of 2 pregnancies, 2 elective terminations and 0 live births and a history of scoliosis who on 02-FEB-2007 was vaccinated with GARDASIL (Lot number 653776/0014U). Subsequently, the patient discovered she was pregnant. On 06-MAR-2007, the patient underwent an ultrasound because she was unsure of her last menstrual period which revealed an intrauterine pregnancy, 9 weeks, 2 days. Her last menstrual period was determined to be 28-DEC-2006, with an expected delivery date of 07-OCT-2007. On 20-MAR-2007 the patient developed a urinary tract infection and was treated with KEFLEX qid x 7 days. On an unspecified date it was reported that the patient had a 3 hour glucose tolerance test performed, which showed elevated value. The patient's gestational diabetes mellitus did not require insulin therapy. On 02-OCT-2007 the patient delivered a normal, healthy baby girl with no congenital anomalies weighing 6 lbs 4 oz (length not reported). Apgar scores were 7 and 9. The patient experienced a post partum hemorrhage (not further specified). Additional information is not expected.

Other Meds: Unknown

Lab Data: ultrasound, 03/06/07, intrauterine pregnancy, 9 wk 2 day; beta-human chorionic; glucose tolerance test, 3 hr; 1 elevated value

History: Scoliosis

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316811-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	09-Mar-2007	Unknown		16-Jun-2008	10-Jul-2008	NJ	WAES0707USA03730	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Live birth, Pregnancy induced hypertension

Symptom Text: Initial and follow-up information has been received from the Merck Pregnancy Registry via physician concerning a 26 year old female with a history of Epstein-Barr virus infection, who on 09-MAR-2007 was vaccinated with a first dose of GARDASIL. On 10-MAY-2007 the patient was vaccinated with the second dose of GARDASIL. Subsequently the patient became pregnant. The patient's last menstrual period was on 22-JUN-2007. The estimated date of delivery is on 28-MAR-2008. Unspecified medical attention was sought. Ultrasounds were performed on 14-AUG-2007, 17-SEP-2007, and 13-NOV-2007 and were all within normal limits. At the time of the report patient's outcome was unknown. Follow-up information indicated that 37 1/7 weeks from her last menstrual period on 09-MAR-2008 the patient gave birth to a female infant. The infant weighed 7 pounds 3 ounces, and her apgar score was 9/9. The infant was normal with no congenital anomalies. The patient had no previous pregnancies and one full term delivery. Complications were possible mild pre-eclampsia and mild shoulder dystocia during labor and delivery. During pregnancy the patient experienced pregnancy induced hypertension (PIH). Diagnostic tests performed during pregnancy were a 24 hour urine every 6 weeks and NST's every week at starting at 32 weeks. Additional information is not expected.

Other Meds: Unknown

Lab Data: ultrasound, 08/14/07 - within normal limits; ultrasound, 09/17/07 - within normal limits; ultrasound, 11/13/7 - within normal limits

History: Epstein-Barr virus infection

Prex Illness:

Prex Vax Illns:

Vaers Id: 316812-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	29-Mar-2007	28-Aug-2007	152	16-Jun-2008	10-Jul-2008	OH	WAES0707USA03800	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1424F	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Live birth, Placenta praevia, Small for dates baby

Symptom Text: Initial and follow-up information has been received from a certified medical assistant concerning a 22 year old female who had one previous pregnancy and one full term delivery, who on 31-JAN-2007 was vaccinated intramuscularly with a 0.5mL first dose of GARDASIL (Lot# 654540/0800F). On 29-MAR-2008 the patient was vaccinated with a second dose of GARDASIL (Lot# 654885/1424F). In July 2007 the patient was determined to be pregnant. Her third dose of GARDASIL will be delayed until after completion of the pregnancy. No problems were reported. The patient sought unspecified medical attention. On 28-AUG-2007 an ultrasound was performed for dating and the results were placenta previa. On 28-NOV-2007 a repeat ultrasound revealed small gestational age and on 24-JAN-2008 an ultrasound revealed placenta previa resolved. At the time of the report, the patient's outcome was unknown. No product quality complaint was involved. Follow-up information indicated that 40.5 weeks from her last menstrual period on 13-MAR-2008 the patient gave birth to a male infant. The infant weighed 7 pounds and had an Apgar score of 9/9. The infant was normal with no congenital anomalies and no abnormalities. The complication of marginal placenta previa took place during the pregnancy. Other medication taken during the pregnancy starting on 23-JUL-2007 included prenatal vitamins once daily. Additional information is not expected.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 08/28/07, result-placenta previa; ultrasound, 11/28/07, small gestational age; ultrasound, 01/24/08, placenta previa resolved

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 316813-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	22-Feb-2007	22-Feb-2007	0	16-Jun-2008	10-Jul-2008	--	WAES0707USA04686	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Live birth

Symptom Text: Information has been received from the Pregnancy Registry for GARDASIL from a 23 year old female with a latex allergy and no pertinent medical history who on 22-FEB-2007 was vaccinated with a dose of GARDASIL (lot # unknown) injection. Concomitant therapy included "CHANPIX" [therapy unspecified]. On 22-FEB-2007 the patient received GARDASIL when she was 5 weeks pregnant. The date of the last menstrual period was approximately 01-JAN-2007. Medical attention was sought. On an unspecified date a pregnancy test was performed to confirm the results. The patient is currently 6 months pregnant. The estimated date of delivery is 08-OCT-2007. No further information is provided. Follow-up information was received from the patient. The patient called and advised that she will be in 90-95% range to have a high birth weight baby. (9lbs +). Patient advised that she may require a c-section. Follow-up information was received from the LPN and reported that the baby had a full-term live birth (female) weighing 7 pounds 3 ounces. The LPN had no further information. Follow-up was also received from the patient who reported her baby is now 7 months old and has a right hip "click". The baby was evaluated by a specialist (not specified) who told her the baby was normal. No further information was provided about the baby. Additional information has been requested.

Other Meds: [therapy unspecified]

Lab Data: beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/1/2007); Latex allergy

Prex Vax Illns:

Vaers Id: 316814-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	02-Jul-2007	Unknown		16-Jun-2008	10-Jul-2008	--	WAES0708USA01526	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0245U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Herpes zoster

Symptom Text: Initial and follow up information has been received for the Pregnancy Registry for GARDASIL from a Registered Nurse (R.N.) concerning a 22 year old female patient who on 02-JUL-2007 was vaccinated with a first dose of GARDASIL lot #656050/0245U. The nurse reported that patient received the injection during pregnancy. No adverse reactions were reported. Unspecified medical attention was sought by the patient. In follow up information the doctor's office reported that patient had shingles approximately at 26 weeks of her pregnancy. She had ultrasound x3 was done and they were reported as normal. On 28-FEB-2008 she delivered a female normal baby 39 weeks from her last menstrual period. The baby weighed 6 lb 8 oz and was 21 inches in length. Her Apgar score was 8/9. There was no congenital abnormalities reported. Additional information is not expected.

Other Meds: Unknown

Lab Data: ultrasound, X 3 normal; Apgar score, 02/28/08, 8/9

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 316815-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Aug-2007	Unknown		16-Jun-2008	10-Jul-2008	--	WAES0709USA04289	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0930U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amniotic fluid volume decreased, Drug exposure during pregnancy, Induced labour

Symptom Text: Initial and follow-up information has been received from a certified nurse midwife through the Merck pregnancy registry concerning a 16 year old white female that was positive for papilloma viral infection in August 2007 and no drug allergies, who on 08-AUG-2007 was vaccinated intramuscularly with a 0.5mL first dose of GARDASIL (Lot# 658488/0930U). Concomitant therapy included prenatal vitamins (unspecified), 1 tablet once daily. Subsequently, the patient was pregnant. The patient's last menstrual period was 06-JUN-2007 and her estimated date of delivery was 15-MAR-2007. The patient was reported to be 15 weeks pregnant. The patient had an office visit. Prenatal labs were performed and the results were unknown. On 18-OCT-2007 an ultrasound was performed for anatomy and the results were within normal limits "primary change discrepancy dates." The patient had no previous pregnancies. There was no adverse experience related to this event. At the time of the report, the patient's outcome was unknown. No product quality complaint was involved. Follow-up indicated that the patient gave birth to a normal baby with no congenital anomalies via vaginal delivery on 02-APR-2008. It was noted that the patient had to be induced due to low amniotic fluid. Additional information is not expected.

Other Meds: Vitamins (unspecified) dose

Lab Data: Diagnostic laboratory, prenatal labs - results unknown; Ultrasound, 10/18/07, reason-anatomy, results - within normal limits "primary change discrepancy dates".

History:

Prex Illness: Pregnancy NOS (LMP = 6/6/2007); Papilloma viral infection

Prex Vax Illns:

Vaers Id: **316816-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Sep-2007	04-Sep-2007	0	16-Jun-2008	10-Jul-2008	FL	WAES0710USA01433	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Rhesus antibodies negative

Symptom Text: Information has been received for the Pregnancy Registry for GARDASIL from a physician concerning a 16 year old female patient who on 04-SEP-2007 was vaccinated with a first dose of GARDASIL (lot # unknown) injection. The physician was reported by the patient's mother and it was reported that the patient found out that she was pregnant on 06-SEP-2007. Medical attention was sought. No other information provided. In follow up information it was reported that patient had prenatal vitamins (unspecified) therapy. She was Rhesus (Rh) antibody negative and globulin, immune (RHOGHAM) was given to her at 30 weeks of her pregnancy. On 07-MAY-2008 she delivered a normal male baby 39-40 weeks from her last menstrual period. The baby was 21 inch in length and weighed 7lb 13.4 oz. Her Apgar score was 9/10. There was no congenital anomalies with the baby. Additional information is not expected.

Other Meds: Unknown

Lab Data: beta-human chorionic, 09/06/07, Positive for pregnancy; Apgar score, 05/07/08, 9/10

History:

Prex Illness: Pregnancy NOS (LMP = 8/5/2007)

Prex Vax Illns:

Vaers Id: 316817-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	14-May-2007	20-Jul-2007	67	16-Jun-2008	10-Jul-2008	WI	WAES0710USA05811	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0014U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pregnancy induced hypertension, Premature baby, Premature labour, Streptococcal identification test positive

Symptom Text: Initial and follow up information has been received through the Merck pregnancy registry through a health care professional concerning a 21 year old female with nausea and pain, with a history of 1 pregnancy and 0 live births and a history of alcohol abuse, Papanicolaou smear abnormal, who had a colposcopy and a loop electrosurgical excision procedure performed in April 2007. On 13-Mar-2007 the patient was vaccinated with her first dose of GARDASIL (lot number 655617/1447F) and on 14-May-2007 the patient received the second dose of GARDASIL (lot number 653736/0014U). Concomitant therapy included NUVARING until May 2007, VITRUM PRENATAL, PHENERGAN and ADVIL. the patient had on OB panel on 13-Sep-2007 and a Pap on 09-Oct-2007, results reported as "abnormal". Patient is now pregnant (LMP=20-Jul-2007) estimated delivery date of 26-April-2007. As of 10-Sep-2007 the patient is taking prenatal vitamins and PHENERGAN. The patient's obstetric history included 1 previous pregnancy which ended in an elective termination at an unknown number of weeks from LMP. A prenatal ultrasound was done on 04-DEC-2007 which showed to be normal. The estimated delivery date was mentioned as 25-APR-2008 (previously reported as 26-APR-2007). The patient sought medical attention with an office visit. No adverse experience related to this event. In follow up information from the doctor's office it was reported that mother had pregnancy induced hypertension and preterm labor (no onset dates reported). It was also reported that she was positive for group B streptococcus agalactiae (+GBs) (date of onset not reported). On 25-MAR-2008 she delivered a normal male baby 35 weeks 3 days from her LMP. The baby weighed 7 lb 1 oz and his length was 19.5". His Apgar score was 7/8 and head circumference was 12.6". No complication or abnormalities were reported. Additional information is not expected.

Other Meds: VITRUM PRENATAL, NUVARING, ADVIL 200mg, PHENERGAN (PROMETHAZINE) 25mg

Lab Data: diagnostic laboratory, 09/13/07; ultrasound, 12/04/07, Normal OB screening; Pap test, 10/09/07, abnormal; Apgar score, 03/25/08, 7/8

History: Alcohol abuse; Papanicolaou smear abnormal; Loop electrosurgical excision procedure; Colposcopy; Termination of pregnancy - elective

Prex Illness: Pregnancy NOS (LMP = 7/20/2007); Nausea; Pain

Prex Vax Illns:

Vaers Id: 316818-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	08-Jun-2007	17-Apr-2007	-52	16-Jun-2008	10-Jul-2008	VA	WAES0711USA00139	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pre-eclampsia, Prolonged labour

Symptom Text: Information has been received from a licensed practical nurse for the Merck pregnancy registry for GARDASIL concerning an 18 year old female who on 08-JUN-2007 was vaccinated intramuscularly with the third dose of GARDASIL (lot# not reported). Per the nurse, the patient received the third dose of GARDASIL while pregnant (LMP=17-Apr-2007). The pregnancy was confirmed by a urine pregnancy test. The reporter did not know when the patient received the first or second dose of GARDASIL. The patient sought unspecified medical attention in the physician's office. The reporter requested that all correspondence take place via mail as opposed to fax and that the mailing envelope be marked "CONFIDENTIAL". Additional information received from pregnancy questionnaire and telephone memo (27-MAY-2008): On 15-FEB-2008 the patient gave birth to a normal, female baby (7.5 pounds, 20 inches long). The patient developed pre-eclampsia at full-term and had a long "30-hour" labor. Both the mother and baby are doing well. Additional information is not expected.

Other Meds: Unknown

Lab Data: ultrasound; urine beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = 4/17/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316819-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Oct-2007	04-Oct-2007	0	16-Jun-2008	10-Jul-2008	AZ	WAES0712USA05639	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Delivery, Drug exposure during pregnancy

Symptom Text: Information and follow up has been received from a physician for the Pregnancy Registry for GARDASIL concerning a 14 year old Caucasian female who on approximately 04-OCT-2007 was vaccinated with her first dose of GARDASIL (lot# not reported). Subsequently the patient was about 16 weeks pregnant (estimated LMP was 05-JUN-2007) with a due date of 13-MAR-2008. On 07-DEC-2007 the patient had a level 2 ultrasound for mild cerebral dilated ventricles in the fetus. The patient is taking prenatal vitamins (unspecified) daily. The patient was seen in the office and her outcome was not reported. Additional information has been requested. The patient delivered a healthy female baby on 10-MAR-2008 by vaginal delivery. There were no complications during the delivery and no known abnormalities in the baby. The nurse practitioner indicated that the lateral ventricle dilation found on ultrasound had gotten smaller prior to delivery. The babies birth weight was 7lbs. 5oz.

Other Meds:

Lab Data: Ultrasound, 12/07/07, lateral ventricle dilation.

History:

Prex Illness: Pregnancy NOS (LMP = 6/5/2007); Low grade squamous intraepithelial lesion

Prex Vax Illns:

Vaers Id: **316820-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	30-Jul-2007	15-Aug-2007	16	16-Jun-2008	10-Jul-2008	SC	WAES0802USA02753	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0388U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Delivery, Drug exposure during pregnancy, Infectious mononucleosis

Symptom Text: Information and follow-up information has been received from a physician's office worker and a nurse practitioner for the Pregnancy Registry for GARDASIL, concerning an 18 year old female who on 29-MAY-2007, 30-Jul-2007 and 02-Jan-2008 was vaccinated with her 0.5 ml first (lot# 657622/0388U), second (lot# 657622/0388U) and third (lot#659055/1522U) doses, respectively, of GARDASIL. Nurse reported that it was the patient's daughter or her friend, who told her about patient's pregnancy. Nurse noted that the patient was approximately 7 months pregnant (LMP approximately 15-Aug-2007). Unspecified medical attention was sought by contacting nurse. In September 2007, it was reported that the patient had mononucleosis, and was treated with AMOXIL, 500 mg BID. It was reported that on 30-Apr-2008 (40 weeks from LMP), the patient delivered a normal male baby. The baby weighed 7 lbs 6 oz and was 20.5 inches long. The patient had no complications during pregnancy and labor. No additional information is available.

Other Meds:

Lab Data:

History:

Prex Illness: Pregnancy NOS (LMP = 8/15/2007)

Prex Vax Illns:

Vaers Id: 316821-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Jul-2007	21-Aug-2007	22	16-Jun-2008	10-Jul-2008	IL	WAES0803USA03958	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1447F	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Ear pain, Impetigo, Inappropriate schedule of drug administration, Pain in jaw

Symptom Text: Information has been received through the Merck pregnancy registry concerning a 16 year old female, with no medical history or allergies reported, who on 30-JUL-2007 and 30-NOV-2007 was vaccinated with the first and second doses of GARDASIL, respectively (Lot # first dose 655617/1447F; second dose 657617/0384U). Concomitant medication included BACTRIM DS and ibuprofen. It was reported that the patient is now pregnant. On 22-AUG-2007 the patient complained of jaw pain. On 16-JAN-2008 the patient complained of ear pain. On 25-JAN-2008 to 4-FEB-2008 the patient had impetigo. On 01-APR-2008 an ultrasound was performed in the third trimester due to no prior obstetrical care. Results were not reported. No problems were reported. On 01-MAY-2008 the patient delivered a 7 pound 6 ounce male infant, length 21 inches, a head circumference of 38 centimeters and Apgar scores 9/9. There were no congenital anomalies or other complications or abnormalities noted. There were no complications reported during the pregnancy or during labor/delivery. No product quality complaint was involved. No further information is available.

Other Meds: ibuprofen, ibuprofen, BACTRIM DS TABLETS

Lab Data: ultrasound, 04/01/08, normal; 3rd trimester assessment, no prior OB care

History:

Prex Illness: Pregnancy NOS (LMP = 8/21/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316822-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	--	WAES0804USA01269	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a registered nurse concerning approximately eleven college-aged females who on unspecified dates, were vaccinated with the first, second and third doses of GARDASIL. Subsequently the patient's were experiencing abnormal pap smears since receiving GARDASIL. Prior to receiving the GARDASIL, the patient's had normal pap smears. The patient's sought unspecified medical attention. Follow up information from the registered nurse indicated that she has no medical records for these patients and that the girls live in three separate states. At the time of the report, the patient's outcomes were unknown. No product quality complaint was involved. No further information is available.

Other Meds: Unknown

Lab Data: Pap test, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316823-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Dec-2007	17-Dec-2007	0	16-Jun-2008	10-Jul-2008	OH	WAES0805USA01788	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Thyroid disorder

Symptom Text: Information has been received from a certified medical assistant concerning a 17 year old female who on 20-AUG-2007 was vaccinated intramuscularly with a first dose of GARDASIL (Lot# not reported). On 17-DEC-2007, the patient was vaccinated intramuscularly with a second dose of GARDASIL (Lot# not reported). On 25-FEB-2008, the patient was vaccinated intramuscularly with a third dose of GARDASIL (Lot# not reported). Concomitant therapy included multivitamins (unspecified). The patient is now experiencing thyroid problems and on 25-APR-2008 was started on Synthroid 25 mcg po once daily. It was reported that the patient had no thyroid problems in the past. The patient's status was reported as not recovered. Additional information has been requested.

Other Meds: Vitamins (unspecified)

Lab Data: Total plasma, normal; Plasma TSH, normal; Total serum thyroxine, low; Free serum thyroxine, low.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **316824-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-May-2008	07-May-2008	0	16-Jun-2008	10-Jul-2008	VA	WAES0805USA01791	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Panic attack, Paraesthesia

Symptom Text: Information has been received from a nurse concerning an 18 year old female with a history of a panic attack not related to GARDASIL who on 11-FEB-2008 was vaccinated intramuscularly with her first dose of GARDASIL (lot # not reported). On 07-MAY-2008 the patient was vaccinated intramuscularly with her second dose of GARDASIL (lot# reported as 657706/1439U). Following the vaccination on 07-MAY-2008, the patient experienced a panic attack, tingling in fingers, dizziness, felt faint and clammy. The patient's blood pressure prior to injection was 100/80 and her temperature was 98.8F. The patient was assisted to supine position and rested in office. The patient felt better after resting and was instructed to see her primary care physician. On 08-MAY-2008 the patient recovered from the panic attack, tingling in fingers, dizziness, feeling faint and clammy. Additional information has been requested.

Other Meds: Unknown

Lab Data: blood pressure, 05/07/08, 100/8, prior to injection; body temp, 05/07/08, 98.8F, prior to injection

History: Panic attack

Prex Illness:

Prex Vax Illns:

Vaers Id: **316825-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	--	WAES0805USA01836	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a health professional concerning a female who was vaccinated on unspecified dates with the first and second dose of GARDASIL (lot#'s not reported). Subsequently the patient fainted after her first dose of the vaccine. She did not faint after the second dose was given. Subsequently, the patient recovered from fainting and sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316826-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-May-2007	21-May-2007	0	16-Jun-2008	10-Jul-2008	--	WAES0805USA01908	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0960F	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Headache

Symptom Text: Information has been received from a nurse, for the Merck pregnancy registry, concerning a 15 year old female with no previous medical history or no known drug allergies who on 21-MAY-2007 was vaccinated intramuscularly in the left deltoid with a 0.5 ml first dose of GARDASIL (Lot # 654535/0960F). On 21-MAY-2007, the patient developed a headache and took over the counter ibuprofen. On 16-JAN-2008, the patient was vaccinated intramuscularly in the right deltoid with a 0.5 ml second dose of GARDASIL (Lot# 658558/1061U). On 26-MAR-2008, the patient was vaccinated intramuscularly in the right deltoid with a 0.5 ml third dose of GARDASIL (Lot# 659657/1487U). On 13-MAR-2008, the patient had a pre natal check up and lab work, blood test, and a pregnancy test. It was reported that the patient is now pregnant with a LMP of 15-Dec-2007. Unspecified medical attention was sought in the office. The patient's outcome was unknown. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory, 03/13/08; beta-human chorionic, 03/13/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = 12/15/2007)

Prex Vax Illns:

Vaers Id: **316827-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	IL	WAES0805USA01916	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Excoriation, Furuncle, Skin discolouration

Symptom Text: Information has been received from a physician concerning 3 females who were vaccinated on unspecified dates with a dose of GARDASIL (lot#'s not reported). In approximately March-April 2008 the patient's experienced boils. Each patient had the boil in a different location. One patient's boil was under the arm: another patient's was in the groin area and the third patient's was on the outside of the calf. The one on the calf was reddish gray with an abrasion below it. One patient received the second dose of GARDASIL and has refused to get the 1st dose. A phone call was placed on 13-MAY-2008 to obtain more information, but the call has not been returned. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316828-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	AZ	WAES0805USA01928	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a physician concerning an 11 year old female who was vaccinated on an unspecified date with a dose of GARDASIL (lot# not provided). Subsequently a couple days after the vaccination, the patient experienced a rash all over her body. The patient was not hospitalized and no medication. The patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316829-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	27-Nov-2007	27-Nov-2007	0	16-Jun-2008	10-Jul-2008	NY	WAES0805USA01961	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site pain, Scar

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 25-MAY-2007 was vaccinated with the first dose of GARDASIL (lot# 656051/0244U). On 27-JUL-2007 the patient was vaccinated with the second dose of GARDASIL (lot# 658100/0525U). On 27-NOV-2007 the patient was vaccinated with the third dose of GARDASIL (lot# 655327/1287U). On 08-May-2008 the office manager reported that the patient experienced pain and decreased movement in the injection site arm on the same day of vaccination with the third dose of GARDASIL, 27-NOV-2007. The patient was seen in the office on 20-DEC-2007 and was referred to a neurologist (outcome unspecified). On 08-May-2008, the office manager reported that the patient was still having pain in the injection site arm, but it was improving. The arm had no redness, no numbness, no tingling or masses and the arm had normal capillary appearances. A scar was noted (not clear if the scar was related to vaccination). There was no other information to report. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316830-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Feb-2008	24-Mar-2008	27	16-Jun-2008	10-Jul-2008	KY	WAES0805USA02037	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hepatitis C antibody, Pyrexia

Symptom Text: Information has been received from a medical assistant concerning a 13 year old female who on 06-AUG-2007 was vaccinated intramuscularly with her first dose of GARDASIL (Lot # reported as 0903U"). On 25-OCT-2007, the patient was vaccinated intramuscularly with her second dose of GARDASIL (Lot # 659435/1265U) On 26-FEB-2008, the patient was vaccinated intramuscularly with her third dose of GARDASIL (Lot # 660387/1967U). There was no concomitant medication. On an unspecified date, the patient had "blood work for hepatitis C". The medical assistant reported that the patient has a "reported elevated Hepatitis C blood result" (not further specified). Since 24-MAR-2008, the patient has had elevated fevers (not further specified). The patient denied recreational drug use or sexual activity. The patient was reporting to be recovering. The patient sought unspecified medical attention with a phone call to the office. No additional information is available. Additional information has been requested.

Other Meds: None

Lab Data: serum hepatitis C

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 316831-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	14-Dec-2007	23-Apr-2008	131	16-Jun-2008	10-Jul-2008	--	WAES0805USA02039	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0089U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection, Sickle cell anaemia, Smear cervix abnormal

Symptom Text: Information has been received from a nurse practitioner concerning a 25 year old female, with a family history of sickle cell anemia (Father), lupus (mother) and stroke due to lupus (mother), who on 02-APR-2007 was vaccinated intramuscularly in the left deltoid with her first dose of GARDASIL (Lot # not reported). On 12-JUN-2007, the patient was vaccinated intramuscularly in the right deltoid with her second dose of GARDASIL (Lot # reported as "0089O"). On 14-DEC-2007, the patient was vaccinated intramuscularly in the left deltoid with her third dose of GARDASIL (Lot # 655324/0089U). The nurse practitioner reported that the three GARDASIL doses were given at another office. Concomitant therapy included hormonal contraceptives (unspecified). The reporter stated "birth control started on 26-MAR-2007 (Patient was on birth control prior to this date but stopped at an unspecified time due to family reasons)". On 23-APR-2008 the patient had a thin prep PAP smear "(a high risk HPV test gets done goes along with thin prep PAP)." On 01-MAY-2008, the results of the PAP smear and HPV test were reported and the HPV test was positive. Previous pap smears performed on 09-JUN-2006 and 26-MAR-2007 were negative for lesions and malignancy. On an unspecified date, the patient was found to be positive for sickle cell anemia and will be going to a specialist. The patient will be going for a colposcopy for the abnormal PAP results. No further information was provided. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Pap test, 06/09/06 - negative for intraepithelial lesion and malignancy; Pap test, 03/26/07 - negative for interferential lesion and malignancy; hemoglobin S test - positive

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **316832-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	23-Apr-2008	23-Apr-2008	0	16-Jun-2008	10-Jul-2008	--	WAES0805USA02040	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Herpes zoster

Symptom Text: Information has been received from a nurse practitioner concerning a female (age unknown), who on 23-APR-2008 was vaccinated IM with a 0.5mL first dose of GARDASIL (Lot# 0152X). Concomitant therapy included ORTHO TRI-CYCLEN LO. On 23-APR-2008 several hours post vaccination the patient developed an outbreak of shingles on her chest. The patient was seen at the office and was treated with acyclovir. No laboratory diagnostics were performed. At the time of the report, the patient was recovering. No product quality complaint was involved. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316833-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	29-Mar-2008	01-Apr-2008	3	16-Jun-2008	10-Jul-2008	--	WAES0805USA02053	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acne

Symptom Text: Information has been received from a 25 year old female consumer who on 29-MAR-2008 was vaccinated with her first dose of GARDASIL (Lot #, site and route not reported). There was no concomitant medication. In "early April 2008", the patient experienced a severe acne breakout on her cheeks and forehead. The patient sought medical treatment in the office. She was initially treated with one month supply of doxycycline (unspecified), but the acne did not improve. On 09-MAY-2008, the patient was switched to prednisone (not further specified). At the time of this reporting the severe acne breakout has persisted. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **316834-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	--	WAES0805USA02055	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site erythema, Injection site pain

Symptom Text: Information has been received from a consumer concerning a 13 year old granddaughter who, on an unspecified date was vaccinated with her second dose of GARDASIL (Lot #, site and route were not reported). Concomitant therapy included antibiotics (unspecified) for a cold and nasal spray (unspecified) for allergies. "Soon after receiving the shot", the patient experienced redness and soreness at the injection site. "This effect disappeared, but soon afterward a brown spot appeared at the injection site (like a birthmark), and is still present". The patient sought unspecified medical attention. No additional information was provided. Additional information has been requested.

Other Meds: antimicrobial (unspecified); cough, cold, and flu therapies

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316835-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	07-Mar-2008	07-Mar-2008	0	16-Jun-2008	10-Jul-2008	--	WAES0805USA02060	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypokinesia, Injected limb mobility decreased, Pain in extremity, Presyncope, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female who on 07-MAR-2008 was vaccinated IM with the first dose of GARDASIL (659964/1978U). Per the reporter, the patient experienced extreme pain in her arm after receiving the first dose of GARDASIL. The pain was experienced in the same arm that the vaccine was administered and the patient noted that the pain made it difficult for her to move her arm. It was also noted that the patient nearly fainted at the office on the day of administration and that the patient had experienced vomiting in the evening of the date of administration. The patient sought unspecified medical attention in the physician's office. Subsequently, the patient recovered from her extreme pain, decreased mobility, near fainting and vomiting. No further information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316836-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Jan-2008	15-Jan-2008	0	16-Jun-2008	10-Jul-2008	MA	WAES0805USA02089	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0187U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, No reaction on previous exposure to drug, Pyrexia, Vomiting

Symptom Text: Initial information and follow up has been received from a nurse practitioner concerning a 13 year old white female who on 14-NOV-2007 was vaccinated intramuscularly in the left arm with her first dose of GARDASIL (lot# 659437/1266U). There was no concomitant medication. On 15-JAN-2008 the patient was vaccinated intramuscularly in the left arm with her second dose of GARDASIL (lot# 656049/0187U). On 15-JAN-2008 the patient experienced headaches, vomiting and a fever. Subsequently the patient recovered from headaches, vomiting and a fever several days after the vaccination. She had no symptoms after the first GARDASIL. The patient sought medical attention by calling the office. On 16_MAY-2008 the patient was vaccinated intramuscularly in the left arm with the third dose of GARDASIL (lot# 659657/1487) with less reaction. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **316837-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	22-Apr-2008	22-Apr-2008	0	16-Jun-2008	10-Jul-2008	TN	WAES0805USA02104	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discolouration, Vaccine positive rechallenge

Symptom Text: Initial information and follow up has been received from a nurse concerning a 26 year old female who on 22-APR-2008 was vaccinated in the left deltoid with her third dose of GARDASIL (lot# 659964/1978U0. On 22-APR-2008 the patient stated that she developed a white area around the injection site from the last two injections. The nurse did see a vague white area- half circle to the left of what looks like the needle stick. Also looks like white vague outline of a bandaid. The patient sought unspecified medical attention and her outcome was not reported. On 14-SEP-2007 the patient was vaccinated in the left deltoid with her first dose of GARDASIL (lot# 658554/0928U). On 16-NOV-2007 the patient was vaccinated in the left deltoid with her second dose of GARDASIL (lot# 659437/1266U).

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316838-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	07-May-2008	07-May-2008	0	16-Jun-2008	10-Jul-2008	NC	WAES0805USA02271	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Incorrect route of drug administration, Injection site erythema, Injection site irritation

Symptom Text: Information has been received from a health professional concerning a 19 year old female with an allergy to DEMEROL, morphine and penicillin who on 11-OCT-2007 was vaccinated with her first dose of GARDASIL (lot# 658563/1063U). On 03-JAN-2008 the patient was vaccinated with her second dose of GARDASIL (lot# 659439/1267U). On 07-MAY-2008 the patient was vaccinated with her third dose of GARDASIL (lot# 660389/1968U). The third dose may have been administered subcutaneously. Concomitant therapy included YASMIN. On 07-MAY-2008, within 15 minutes of the dose, the patient experienced burning and redness at the injection site. The patient was being treated with BENADRYL, antibiotics and cool compresses applied to the injection site. The patient was seen in the office and her outcome was unknown. Additional information has been requested.

Other Meds: YASMIN

Lab Data: brachial artery, within normal limits

History:

Prex Illness: Drug hypersensitivity; Drug hypersensitivity; Penicillin allergy

Prex Vax Illns:

Vaers Id: **316839-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	CA	WAES0805USA02303	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning two female patients who were vaccinated with their second dose of GARDASIL (lot number unspecified) and developed urticaria. The patients are not patients of the reporting physician and no patient specific information was provided. The physician asked not to be contacted. No other information to report.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316840-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	CA	WAES0805USA02303	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning two female patients who were vaccinated with their second dose of GARDASIL (lot number unspecified) and developed urticaria. The patients are not patients of the reporting physician and no patient specific information was provided. The physician asked not to be contacted. No other information to report. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316841-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	10-Jul-2008	--	WAES0805USA02313	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a caller concerning her daughter who missed her menstrual period after receiving the second dose of GARDASIL (lot# not reported). The caller did not want to report any additional information. Additional information is not expected.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316842-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	05-May-2008	05-May-2008	0	16-Jun-2008	14-Jul-2008	CO	WAES0805USA02331	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a registered nurse concerning a 23 year old female with a history of papilloma viral infection and abnormal pap test (NOV-2007), with no known allergies, and no concomitant medications, who on 05-MAY-2008 was vaccinated with the first dose of GARDASIL, 0.5 ml, IM to the right deltoid, (Lot# 0152X). That same evening when the patient arrived home she had a rash on both arms, on her trunk, and descending down to her thighs. The patient telephoned the office and was treated with over the counter Benadryl, she recovered on an unspecified date. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, 11/??/07, + HPV

History: Papilloma viral infection

Prex Illness:

Prex Vax Illns:

Vaers Id: **316843-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Feb-2008	Unknown		16-Jun-2008	14-Jul-2008	KS	WAES0805USA02333	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a registered nurse concerning a female who on 07-FEB-2008 was vaccinated IM in the left deltoid with the first dose of GARDASIL (lot# 655327/1287U). In approximately March 2008, the patient developed irregular menstrual cycles. In the last couple of months, the patient has been having about 2 periods a month compared to her usual 1 cycle monthly. The patient sought unspecified medical attention by contacting her physician's office. The patient's irregular menstrual cycles have persisted. There are no other details. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316844-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	09-May-2008	09-May-2008	0	16-Jun-2008	11-Jul-2008	CT	WAES0805USA02339	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea

Symptom Text: Information has been received from a licensed practical nurse concerning a 22 year old female with no concomitant medications or pertinent medical history, who on 09-MAY-2008 was vaccinated with the first dose of GARDASIL, 0.5ml, IM, (Lot # 659182/1757U). Later that same day she developed diarrhea, was afebrile and had no nausea or vomiting. The patient sought medical attention over the phone and was advised by the doctor to take IMODIUM as needed. As of the date of the report (12-MAY-2008), she continued with diarrhea, and had not recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316845-1** **Related reports:** 316845-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	26-Dec-2007	Unknown		16-Jun-2008	11-Jul-2008	OH	WAES0805USA02344	08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	UNKNOWN MANUFACTURER	0874U	2	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C904AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1267U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Dyspnoea, Exfoliative rash, Grip strength decreased, Joint swelling, Pain in extremity, Rash erythematous, Rheumatoid arthritis

Symptom Text: Information has been received from a nurse (patients mother) concerning her 19 year old daughter, with no concomitant medications, no drug allergies, and no pertinent medical history, who in July 2007 (date unreported), was vaccinated with the first single dose, injection, of GARDASIL (Lot # not specified). The second single dose injection of GARDASIL, (Lot # not specified) was approximately two months later in SEP-2007, (date unreported), and the third single dose injection of GARDASIL, (Lot # not specified) was in DEC-2007; (date unreported). One week following the third dose of GARDASIL the patient initially complained of pain in both knees and then subsequently she had pain in her hands. She also experienced shortness of breath. The patient sought unspecified medical attention and had blood tests, thyroid studies and x-rays (no dates, test names or results were reported). Subsequently, she was diagnosed with rheumatoid arthritis. As of the date of the report 12-MAY-2008, the patient has not recovered. No product quality complaint was involved. Additional information has been requested. 7/4/08 Reviewed rheumatology office notes of 5/1/08-5/19/2008 FINAL DX: rheumatoid arthritis Records reveal patient experienced scaly erythematous rash on dorsum of feet 9/2007 followed by joint pain & swelling. Joint pain persistent daily & worse in AM. Had been tx in 3/2008 w/tapering steroids w/dramatic improvement. NSAIDS not helpful. On exam, had decreased grip strength bilaterally. 8/5/08 Reviewed PCP medical records & vax records. VAX: 5/24/2007: HPV #1, 0389U, IM, LA Hep B #1, 0039U, IM RA 7/27/07: HPV #2, 0802U, IM RA Hep B #2, 0007U, IM LA Menactra, U2367AA, IM LA 12/26/07: HPV #3, 1267U, IM LA Hep B #3, 0874U, IM LA Adacel, C904AA, IM RA Records reveal patient c/o stiff hands in AM on 5/24/07 visit & had just started acne meds. 8/5/08 Reviewed ur

Other Meds: Unknown Proactive acne med BCP

Lab Data: X-ray, results not reported; diagnostic laboratory, results not reported; thyroid function test, results not reported LABS: 2/2008 Sed rate 27(H), monospot & Lyme serology (-). 5/1/08 Sed rate 18 (N), anti-CCP >200(H). CRP 1.2(H). RF

History: Unknown PMH: on BCP. Acne.

Prex Illness: stiff hands in AM

Prex Vax Illns:

Vaers Id: **316845-2 (S)** **Related reports:** 316845-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	26-Dec-2007	28-Dec-2007	2	03-Jul-2008	07-Jul-2008	OH		05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	2	Left arm	Intramuscular	
	HEP	UNKNOWN MANUFACTURER	0874U	2	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C904AA		Right arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Oedema peripheral, Pain in extremity

Symptom Text: On 12-28-07 pt came home from work c/o severe bilateral knee pain. Increasing in severity with stair climbing. Some improvement with rest, ice and Ibuprofen. In Feb she began to c/o hand and wrist pain, bil. Hands were swollen. Minimal improvement with ice and Ibuprofen. Evaluated by physician at school. Blood work done. c/o of constant physician at school Blood work done. c/o of constant joint pain and states "I feel 85 yrs. old".

Other Meds:

Lab Data: R/A Factor increased 59.9; Refer to Dr's report

History: None

Prex Illness: None

Prex Vax Illns: RA~HPV (Gardasil)~3~19~In Patient

Vaers Id: **316846-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Nov-2007	01-May-2008	170	16-Jun-2008	14-Jul-2008	KS	WAES0805USA02854	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a healthcare worker concerning a 17 year old female with concomitant medications, allergies, and pertinent medical history reported as none, who on 13-NOV-2007 was vaccinated with the first dose of GARDASIL. A second dose of GARDASIL (Lot # 659657/1487U), 0.5ml, IM was given on an unspecified date. The patient is experiencing hair loss, reportedly starting "two weeks ago" (01-MAY-2008). The patient sought medical attention over the telephone. No outcome information was reported. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316847-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-May-2008	07-May-2008	1	16-Jun-2008	11-Jul-2008	MI	WAES0805USA02867	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Rash macular

Symptom Text: Information has been received from a nurse concerning a 20 year old female with pertinent medical history, allergies and concomitant medications reported as none, who on 06-MAY-2008 was vaccinated with the first dose of GARDASIL, 0.5ml, IM, (lot# 659964/1978U). On 07-MAY-2008, one day after receiving GARDASIL, the patient developed red, blotchy areas on both arms. The areas of redness were intermittent, reappearing at night. Unspecified medical attention was sought via the telephone and and resolved completely on 09-MAY-2008 without treatment. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316848-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-May-2008	12-May-2008	0	16-Jun-2008	11-Jul-2008	GA	WAES0805USA02871	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Medical device complication, Pharmaceutical product complaint, Syncope

Symptom Text: Information has been received from a healthcare worker concerning a 15 year old female who on 07-NOV-2007 was vaccinated with a first dose of GARDASIL (lot # not reported). On 10-JAN-2008 the patient was vaccinated with a second dose of GARDASIL (lot # not reported). On 12-MAY-2008 the patient was vaccinated with a third dose of GARDASIL (lot # 0152X). It was reported that "when attempting to administer the GARDASIL syringe, the plunger would not depress. According to the medical assistant, the white plastic tray was crushed at the end. The plastic seal was loose and up at the damaged end. The carton was not damaged. The syringe was removed from the package and the needle was placed on the syringe. The needle was in the patient's arm and the plunger would not depress. When the needle was removed from the arm, the safety device activated. The syringe was discarded because the patient fainted and the medical assistant needed to put the syringe in a safe place." It was also reported that "they have been using the syringe for a while and are familiar with its use. The product was ordered directly from Merck. This was a product quality complaint. The patient was vaccinated successfully with another prefilled syringe. There were no problems reported. The SR# is 13050492422. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316849-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	17-Oct-2007	21-Oct-2007	4	16-Jun-2008	14-Jul-2008	PA	WAES0805USA02878	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Menstruation irregular, Metrorrhagia

Symptom Text: Information has been received from a Licensed Practical Nurse for the Pregnancy Registry for GARDASIL, concerning her 19 year old daughter with asthma and scoliosis who on 17-OCT-2007 was vaccinated intramuscularly with a first dose of GARDASIL (lot # not reported). The nurse reported that her daughter received her first dose of GARDASIL and afterwards experienced irregular period with spotting. On 23-JAN-2008 the patient was vaccinated intramuscularly with her second dose of GARDASIL (lot # not reported) and the patient reported that her period was "not right". The patient believes her LMP was 21-FEB-2008. Concomitant therapy included YAZ, ascorbic acid, cyanocobalamin, omega-3 marine triglycerides and iron (unspecified). The patient also reported that she took YAZ at night time and she forgot to take it one night but then took it the next morning. The patient's mother believes that the birth control failed because of GARDASIL. The mother also reported that the patient was taking YAZ while she was pregnant. An ultrasound on 13-MAY-2008 showed that the patient was 8 weeks 4 days pregnant. Additional information has been requested.

Other Meds: ascorbic acid; cyanobobaalamin; YAZ; iron (unspecified); omega-3 marine triglyercides

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 2/21/2008); Asthma; Scoliosis

Prex Vax Illns:

Vaers Id: 316850-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	--	WAES0805USA02905	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia facial

Symptom Text: Information has been received from a health department administrator concerning a female in her "early twenties" who was vaccinated on an unspecified date with a "second dose" of GARDASIL (lot # not reported). The administrator reported that the patient received the second dose of HPV rL1 6 11 16 18 VLP vacine (yeast) and later the same day, the patient called to report that she was experiencing numbness on one side of her face. The administrator also reported that the patient was advised to go the emergency room. The patient was not admitted to the hospital. The patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316851-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		16-Jun-2008	11-Jul-2008	FL	WAES0805USA02927	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Injection site pain, Vaccine positive rechallenge

Symptom Text: Initial and follow up information has been received from a physician's office and an 18 year old female consumer for the pregnancy registry for GARDASIL with breast pain while on YAZ who in early December 2007 was vaccinated with her first dose of GARDASIL (lot number unknown). Concomitant therapy included YAZ. On the same day in early December, the patient experienced pain at injection site. Subsequently, by the next day, the patient recovered from pain at the injection site. On 14-FEB-2008 the patient was vaccinated with her second dose of GARDASIL (lot number unknown). On 14-Feb-2008 the patient experienced pain at the injection site. Subsequently, by the next day, the patient recovered from pain at the injection site. In early April 2008 the patient found out she was 3-4 weeks pregnant (LMP = 27-FEB-2008) and "will not be getting her third dose". The consumer also reported breast pain while on YAZ from October 2007 until approximately 20-Feb-2008 to the manufacturer. Blood tests for hepatitis and to confirm pregnancy were performed. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: YAZ

Lab Data: serum beta-human, posit

History:

Prex Illness: Pregnancy NOS (LMP = 2/27/2008); Breast pain

Prex Vax Illns:

Vaers Id: **316853-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
32.0	F	Unknown	29-Apr-2008		16-Jun-2008	14-Jul-2008	IL	WAES0805USA02942	06-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Accidental exposure, Limb injury

Symptom Text: Information has been received from a health professional that on approximately 29-Apr-2008, a vial of GARDASOL (lot # 659182/1757U) shattered when she opened it. She cut her left hand on the broken glass. Subsequently, the health professional experienced accidental exposure. The patient flushed her hand with running water and cleaned it with alcohol. The patient sought unspecified medical attention in the office. Subsequently, the patient recovered from the cut on her left hand in about a week. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316854-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	11-Jun-2008	11-Jun-2008	0	23-Jun-2008	26-Jun-2008	NY		26-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2568AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1740U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt fainted after receiving GARDASIL (within 30 seconds). Also received MENACTRA prior to GARDASIL.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 316861-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	18-Jun-2008	18-Jun-2008	0	23-Jun-2008	30-Jun-2008	MI		30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	9725102	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: After received HPV vaccine, 8 min later - up walking and talking in hallway, then passed out for approx 10-15 sec. Then awake, alert, responsive. No complaints. Vital signs stable.

Other Meds:

Lab Data: Observed for 30 min. Mother did not want to wait for child to be examined by doctor - stated she just needed to go home and eat.

History: Home meds - Singulair, Advair, Albuterol inhaler

Prex Illness:

Prex Vax Illns:

Vaers Id: **316862-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	MO	WAES0805USA02965	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a female who on unspecified dates was vaccinated with her first and second doses of GARDASIL (Lot #s not reported). On an unspecified date, after receiving the third dose of GARDASIL, the patient had "an abnormal PAP". The patient sought unspecified medical attention. The patient outcome is unknown. No further information was provided.

Other Meds: Unknown

Lab Data: Pap test, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316863-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-Jun-2008	19-Jun-2008	0	23-Jun-2008	30-Jun-2008	ME		30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB223AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1978U	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2425AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0175X	1	Left arm	Subcutaneously	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B020AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Pt received vaccines at 1420. At 1425 pt c/o feeling dizzy and nauseated. No vomiting. After laying pt down, giving fluids and taking frequent vital signs, pt was brought down to ER at 1520.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 316864-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	Unknown	Unknown		16-Jun-2008	11-Jul-2008	MI	WAES0805USA02968	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pneumonia primary atypical, Weight increased

Symptom Text: Information has been received from a consumer concerning her 10 year old granddaughter who in "late 2007" was vaccinated with her first dose of GARDASIL (Lot #, site and route not reported). In "early 2008", the patient was vaccinated with her second dose of GARDASIL (Lot #, site and route not reported). Subsequently the patient experienced weight gain after the first dose of GARDASIL. It was reported that the weight gain started "within months of the first dose". The patient "now has walking pneumonia" for which she is taking DELSYM. The patient sought unspecified medical attention. The patient's weight gain and walking pneumonia persisted. No additional information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316865-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Apr-2008	25-Apr-2008	0	16-Jun-2008	14-Jul-2008	MO	WAES0805USA02969	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal stiffness, Syncope

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 25-APR-2008 was vaccinated intramuscularly in the deltoid with her second dose of GARDASIL (Lot # not reported). On 25-APR-2008 the "patient's body felt very stiff" and she fainted after receiving her second dose of GARDASIL. The patient sought unspecified medical attention. On an unspecified date, the patient recovered from the "body felt very stiff" and fainting. No additional information was provided. Additional information has been requested.

Other Meds: unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 316866-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		16-Jun-2008	11-Jul-2008	NY	WAES0805USA03355	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site bruising

Symptom Text: Information has been received from a physician concerning a 13 year old female with no previous medical history or no known drug allergies, who in April 2008, was vaccinated IM in the left arm with a 0.5 ml first dose of GARDASIL (lot# 658094/0524U). There was no concomitant medication. For the first week after the vaccination the patient would develop a "bruised area" at the injection site after someone touches or hits the area. Unknown medical attention was sought via telephone. The bruising resolved one week after the injection. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316867-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	03-Oct-2007	03-Oct-2007	0	16-Jun-2008	14-Jul-2008	FL	WAES0805USA03369	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Arthritis, Joint swelling, Musculoskeletal stiffness, Oedema peripheral, Pain in extremity, Rheumatoid arthritis, Steroid therapy, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 21 year old female with Asthma who on 03-OCT-2007 was vaccinated IM in deltoid with a first dose of GARDASIL (Lot# 658556/1060U). On 05-Dec-2007 the patient received IM deltoid the second (lot# 659435/1265U) and IM deltoid the third dose on 31-Mar-2008 (lot# 659964/1978U). The patient experienced arthritis like symptoms after receiving each of the three doses. The patient experienced pain and stiffness in both hands, feet and her right knee. The patient first experienced the symptoms after the first dose. The symptoms improved by the time the patient was due for the second dose but never completely resolved. When the patient received the second dose the symptoms returned and the same pattern of improvement and return of symptoms was experienced when the patient received the third. It was noted that the symptoms improved but never completely resolved. The patient was treated with anti-inflammatory medications VENTILAN and NAPROXEN. The patient was seen by a physician. The patient was recovering. Follow up information received indicated that on 10-Oct-2007, the patient experienced bilateral, symmetric joint pain and swelling in hands and feet. The patient was being evaluated by Rheumatology for rheumatoid arthritis. Diagnostic laboratory tests were pending. At the time of reporting the patient had not recovered. Additional information has been requested. 7/4/08 Reviewed GYN office records of 3/31/2008. Requested additional vax records & office records. Records reveal patient experienced usual state of good health w/o complaints on day of final vaccination. 7/11/08 Received vax records & GYN office records. No complaints noted on any vaccination dates. 5/12/2008 pt presented w/joint pain. Stated 1 wk after initial injection, developed stiffness & swelling of right hand w/limited ROM of fingers & stiff throughout the day. Also had bilateral foot pain & swelling, unable to wear high heel shoes. Right knee pain. Stated symptoms worsened after eac

Other Meds: Unknown

Lab Data: diagnostic laboratory - pending LABS: ESR 20(N), RF 15(N), ANA 1:80(H).

History: PMH: asthma HPV #2, 12/5/2007, RA, Lot # 1265U HPV #3, 3/31/2008, RA, Lot # 1978U

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **316868-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	13-May-2008	13-May-2008	0	16-Jun-2008	14-Jul-2008	OH	WAES0805USA03392	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash, No reaction on previous exposure to drug, Rash

Symptom Text: Information has been received from a medical assistant concerning an 18 year old female with allergies and pertinent medical history reported as none, who on 18-MAR-2008 was vaccinated with the first dose of GARDASIL (lot # 659055/1522U), 0.5ml, IM to the left arm and no reaction developed. Concomitant therapy included YAZ. On 13-MAY-2008 the patient was vaccinated with the second dose of GARDASIL (lot # 659182/1957U, 0.5ml, IM to the left arm). Following vaccination, the patient was observed for 15 minutes and no reaction was experienced. Per the patient's mother who is a nurse, a rash developed three hours afterwards. The rash started at the injection site, spread to the right arm, the patient's stomach and face, the patient took BENADRYL. The next morning, 14-MAY-2008, the patient's rash resolved and the patient's mother telephoned the doctor's office to report the event. No product quality complaint was involved. Additional information has been requested.

Other Meds: YAZ

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316869-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	14-Nov-2007	14-Nov-2007	0	16-Jun-2008	11-Jul-2008	--	WAES0805USA03483	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1210U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Vaccine positive rechallenge, Weight increased

Symptom Text: Information has been received from a physician assistant concerning a 20 year old female with pertinent medical history reported as none and drug allergies not specified, who on 14-NOV-2007 was vaccinated with the first dose of GARDASIL (lot # 655154/1210U). Concomitant therapy included YAZ. The second dose of GARDASIL (lot # 655327/1287U) was given on 16-JAN-2008. Between these two doses the patient gained 15 pounds. The third dose of GARDASIL (lot # 0152X), was given on 07-MAY-2008. Between the second and third dose the patient gained 25 pounds. She gained a total of 40 pounds in about 5 to 6 months. On an unspecified date, the patient sought medical attention by her primary care provider and had thyroid tests completed which were reported as negative. At the time of reporting, the patient had not recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: YAZ

Lab Data: thyroid function test, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316871-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	--	WAES0805USA03493	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menorrhagia

Symptom Text: Information has been received from a consumer reported on behalf of her daughter, concerning a 12 year old female with a history of "sugar goes down a little low" (hypoglycaemia), who was vaccinated on unspecified dates with 2 doses of GARDASIL. The mother reported that after her daughter started receiving her first and second doses of GARDASIL her menstrual cycle became severely heavy and required her to take birth control pills, ORTHO-NOVUM 1/35. The patient sought unspecified medical attention and had an MRI performed with no abnormal results found. The patient reportedly recovered. No product quality complaint was involved. Additional information is not expected.

Other Meds: Unknown

Lab Data: magnetic resonance - no abnormal results found

History: Hypoglycaemia

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316872-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Jun-2008	18-Jun-2008	0	23-Jun-2008	30-Jun-2008	OH		30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Dizziness, Heart rate, Respiratory rate

Symptom Text: 1022 Immunisation given, sat in chair with nurse until 1027. Walked with nurse and father - she felt lightheaded, legs buckled, escorted to chair, smelling salts used, assisted to bench in lying position, legs elevated, cold compress and cold drink given. BP 110/50, P 56, R 20 assessed by doctor. Color returned, sitting up for 5 min. Escorted out by father.

Other Meds: Robitussin CF for cough

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **316873-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-May-2008	Unknown		16-Jun-2008	11-Jul-2008	VA	WAES0805USA03496	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female (age not reported), who was vaccinated in approximately MAY 2008, with a dose of GARDASIL. The physician reported that within 15 minutes after she was vaccinated she fainted. Subsequently the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316874-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	--	WAES0805USA03507	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Pruritus generalised

Symptom Text: Information has been received from a physician concerning a female (age unreported) with concomitant medications reported as none, allergies and pertinent medical history not specified, who on an unspecified date was vaccinated with the second dose of GARDASIL, 0.5 ml, IM. Subsequently the patient experienced warmth and itching all over her torso. Unspecified medical attention was sought and the reaction subsided within an hour after the vaccine was given. No product quality complaint was involved. Additional information is not expected.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316876-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	--	WAES0805USA03513	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician assistant concerning several female patients (ages unknown), who, on unspecified dates were vaccinated with doses of GARDASIL. Subsequently, the patient experienced fainted. The patient sought unspecified medical attention. At the time of the report, the outcomes of the patients were unknown. No product quality complaint was involved. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316877-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	17-May-2007	17-Jun-2007	31	16-Jun-2008	11-Jul-2008	CA	WAES0805USA03540	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Injection site warmth

Symptom Text: Information has been received from a physician concerning a female patient who on 17-MAY-2007 was vaccinated with a first dose of GARDASIL (lot # 657736/0389U) and on 19-JUL-2008 she was vaccinated with a second dose of GARDASIL (lot # 658222/0927U). On 19-NOV-2007 she was vaccinated IM with a third dose 0.5 mL of GARDASIL (lot # 659439/1267). The physician reported that on approximately one month after the third injection the patient experienced redness, swelling and warmth at the site of the GARDASIL administration. The patient sought medical attention from the physician. At the time of this report the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316879-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	12-May-2008	15-May-2008	3	16-Jun-2008	14-Jul-2008	MA	WAES0805USA03585	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Axillary pain

Symptom Text: Information has been received from a Medical Assistant (MA) concerning a 23 year old female patient with dysmenorrhoea, penicillin allergy and sulfonamide allergy who on 12-MAY-2008 was vaccinated IM into left deltoid muscle with 0.5 mL of GARDASIL (lot # 659055/1522U). Concomitant therapy included ATIVAN, LUPRON and ESTROGENS, PREMPRO. The MA reported that on 12-MAY-2008 the patient developed a "deep soreness" of the left axilla. There was no redness or swelling. No further information available. The patient had not recovered as of this report date. Additional information has been requested.

Other Meds: PREMPRO; LUPRON; ATIVAN

Lab Data: Unknown

History:

Prex Illness: Dysmenorrhea; Penicillin allergy; Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316880-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	--	WAES0805USA03625	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle twitching

Symptom Text: Information has been received from a nurse concerning her 15 year old daughter with a history of "zones out" who was vaccinated on an unspecified date with her second dose of GARDASIL (lot# not reported). There was no concomitant medication. In January 2008, the patient experienced twitching of her hands and feet. The patient's twitching of her hands and feet persisted. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Spaced out

Prex Illness:

Prex Vax Illns:

Vaers Id: **316881-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	PA	WAES0805USA03641	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Information has been received from a physician concerning a female who was vaccinated on unspecified dates with all three doses of GARDASIL (lot#'s not reported). Subsequently the developed condyloma after completing the three dose series. The patient's outcome was not reported and she sought unspecified medical attention in the office on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316888-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Oct-2007	23-Oct-2007	0	23-Jun-2008	27-Jun-2008	VA		27-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1424F	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nervousness, Syncope, Tremor

Symptom Text: Following the 2nd dose of GARDASIL patient had what seemed to be a fainting episode followed by shaking of body, rolling up the eyes but no sphincter relaxation. The episode lasted a few seconds, patient recovered and had no recollection of the event. Vitals were normal.

Other Meds: none

Lab Data: None

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **316892-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	15-Mar-2008	Unknown		16-Jun-2008	14-Jul-2008	--	WAES0805USA03732	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a mother concerning her daughter with pertinent medical history, allergies and concomitant medication not reported who approximately 15-MAR-2008 (two months ago) was vaccinated with a dose of GARDASIL and hasn't had her period since. The outcome and causality of the event was not reported. Additional information is not expected.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316894-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	08-May-2008	10-May-2008	2	16-Jun-2008	11-Jul-2008	PA	WAES0805USA03776	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a nurse concerning a 26 year old female with a history of an ovarian cyst in March 2008, low grade squamous intraepithelial lesion and sulfonamide allergy who on 29-FEB-2008 was vaccinated intramuscularly with her first dose of GARDASIL (lot# 655327/1287U). Concomitant therapy included ORTHO TRI-CYCLEN LO. On 08-MAY-2008 the patient was vaccinated intramuscularly with her second dose of GARDASIL (lot# 0151X). On 10-MAY-2008 the patient experienced pain at the injection site. She had relief when treated with ice and TYLENOL, but the pain at the injection site persisted when the treatment was discontinued. The patient sought medical attention by calling the office. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: diagnostic laboratory

History: Ovarian cyst; Low grade squamous intraepithelial lesion

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **316896-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		16-Jun-2008	14-Jul-2008	GA	WAES0805USA03778	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a physician concerning an unspecified number of patients who were vaccinated with a dose of GARDASIL. The patients experienced pain when they received the injection. It was unknown whether medical attention was sought. Patient outcome was not reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316899-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	15-May-2008	15-May-2008	0	16-Jun-2008	11-Jul-2008	PA	WAES0805USA03782	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Face injury, Loss of consciousness

Symptom Text: Information has been received from a secretary of a physician's office concerning a 19 year old female who on 15-MAY-2008 was vaccinated (route unknown) with a first dose of GARDASIL (Lot # 660393/0067X). On the same day the patient was vaccinated with a dose of tuberculin purified protein derivative (PPD, unspecified). On 15-MAY-2008 the patient passed out 10 to 20 seconds after vaccination and hit her face. The physician attended to the patient and the rescue squad was contacted. She was brought to the emergency room where blood work, x-rays and EKG were performed. All tests results were normal. The patient was not admitted to the hospital and released from the emergency room that same evening. It was also mentioned that this patient is "not apprehensive". Subsequently on 15-MAY-2008 the patient recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds:

Lab Data: X-ray, 05/15/08, normal; electrocardiogram, 05/15/08, normal; diagnostic laboratory, 05/15/08, normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 316901-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	11-Dec-2007	12-Dec-2007	1	16-Jun-2008	14-Jul-2008	NY	WAES0805USA03788	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia facial, Injection site pain

Symptom Text: Information has been received from a health professional from a physician's office a 25 year old female with type 2 diabetes mellitus and a history of migraines who on 18-OCT-2007 and 11-DEC-2007 was vaccinated intramuscularly with a 0.5 mL first and second dose of GARDASIL (Lot #'s 658563/1063U and 659441/1446U), respectively. Concomitant therapy included NUVARING and LEVAQUIN. The caller reported that the patient was in the office today (16-MAY-2008) to receive the third dose of GARDASIL. At that time the patient stated that "the day after receiving the second dose, on 12-DEC-2007, she experienced pain in her arm at injection site and numbness in her face lasting 4 days". The patient was seen by her family doctor for symptoms. The third dose of GARDASIL was not administered. No laboratory diagnostic studies were performed. Subsequently, on approximately 16-DEC-2007 the patient recovered. No product complaint was involved. Additional information has been requested.

Other Meds: NUVARING; LEVAQUIN

Lab Data: None

History: Migraine

Prex Illness: Type 2 diabetes mellitus

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316903-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	18-Feb-2008	18-Feb-2008	0	16-Jun-2008	14-Jul-2008	PA	WAES0805USA03825	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0755U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from a medical assistant concerning a 23 year old female with no medical history and an allergy to penicillin who on 18-FEB-2008 was vaccinated IM with the first 0.5 ml dose of GARDASIL (Lot # 658219/0755U). On 18-FEB-2008 the patient experienced joint pain, tingling and numbness in the hands bilaterally. Unknown medical attention was sought in the office. The patient's outcome was recovered on an unspecified date. Additional information has bee requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: 316905-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-May-2008	09-May-2008	6	16-Jun-2008	14-Jul-2008	AL	WAES0805USA03843	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Fatigue, Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning a 12 year old female patient with asthma and no known drug allergies, who on 03-MAY-2008 was vaccinated IM with a 0.5 ml first dose of GARDASIL (lot# not provided). Concomitant therapy included AUGMENTIN. On 09-MAY-2008 the patient experienced nausea, vomiting, fatigue, dizziness and weakness. The patient was seen by the physician. At the time of reporting the patient was feeling better. The patient was recovering. Additional information has been requested.

Other Meds: Augmentin

Lab Data: metabolic marker test - unremarkable; serum Epstein-Barr - unremarkable; urinalysis - unremarkable; complete blood cell - unremarkable

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **316907-1** **Related reports:** 316907-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	14-May-2008	17-May-2008	3	16-Jun-2008	14-Jul-2008	IN	WAES0805USA03879	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Asthenia, Insomnia, Loss of consciousness, Major depression, Syncope, Tremor

Symptom Text: Information has been received from a consumer concerning her daughter (age not reported) who on 14-MAY-2008 was vaccinated with a first dose of GARDASIL. On 17-MAY-2008, three days later the patient felt weak, was shaky, loss of consciousness and fainted. Medical attention was not sought. At the time of reporting it was unknown if the patient had recovered. Additional information has been requested. 07/04/2008 Reviewed PCP medical records of 5/14/08. Vax record included but no Lot Numbers available. Records reveal patient experienced major depression & insomnia for approx 6 mos on day of vaccination. Started on psych meds & referred for counseling. Had dropped out of school, stating financial concerns as part of depression.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316907-2** **Related reports:** 316907-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	14-May-2008	Unknown		16-Jun-2008	14-Jul-2008	IN	WAES0805USA04073	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Confusional state, Fatigue, Headache, Pain, Syncope

Symptom Text: Information has been received from a consumer concerning her 20 year old daughter, with no pertinent medical history who on 14-MAY-2008 was vaccinated with a first 0.5 ml dose of GARDASIL. There was no concomitant medication. In May 2008, a few days after vaccination, the patient experienced aches and pain, fatigue, mental confusion and headaches. It was also reported that the patient fainted while standing in line at a store. The patient did not seek medical attention. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **316908-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	U	19-Nov-2007	Unknown		16-Jun-2008	11-Jul-2008	--	WAES0805USA04009	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered nurse concerning a 17 year old patient (gender not reported) who on 19-NOV-2007 was vaccinated with a first dose of GARDASIL. The nurse reported that on an unspecified date the patient had itching after the first dose of GARDASIL that lasted until the second dose was given (date unspecified). The patient than had a rash and itching with the second dose (date unspecified). The third dose has not been given yet. At the time of reporting it was unknown if the patient had recovered. No further information was available from the nurse. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316910-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	19-Mar-2008	Unknown		16-Jun-2008	14-Jul-2008	NH	WAES0805USA04037	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Epstein-Barr virus infection

Symptom Text: Information has been received from a registered nurse concerning a 20 year old female with no pertinent medical history and no drug allergies/reactions who on 19-MAr-2008 was vaccinated with a first dose of GARDASIL (lot # 659962/1740U) 0.5 ml IM. Concomitant therapy included oral hormonal contraceptives (unspecified). Subsequently, after receiving the first dose of vaccine, the patient was diagnosed with Epstein-Barr virus. The patient sought medical attention with another physician. At the time of reporting, the outcome was unknown. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316912-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	11-Jul-2008	CO	WAES0805USA04039	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site induration, Injection site pain, Vaccine positive rechallenge

Symptom Text: Information has been received from a certified medical assistant concerning a 23 to 25 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL. Subsequently, the patient experienced a painful, indented, discolored area where the first vaccination was administered. On an unspecified date, the patient returned for the second vaccination with GARDASIL, and had a painful, white area a half dollar to dollar in size where the first vaccination was administered. When the area was palpated, an indentation in the deltoid was noted. The patient received the second dose of GARDASIL. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316913-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	08-Apr-2008	29-Apr-2008	21	16-Jun-2008	11-Jul-2008	FL	WAES0805USA04047	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Joint range of motion decreased, Malaise, Tenderness

Symptom Text: Information has been received from a physician concerning a 25 year old female with asthma, anaemia and arthritis who on an unspecified date was vaccinated with the first dose of GARDASIL. The second dose of GARDASIL was given 08-APR-2008. Concomitant therapy included montelukast sodium (MSD), daily multivitamins (unspecified), vitamin D (unspecified), iron (unspecified), B-12 injection, SYNTHROID, MOBIC and RELPAX. On 29-APR-2008 the patient called the doctor's office complaining that the injected arm was tender, she had limited range of motion in the arm, and she had feelings of malaise. The patient was seen in the doctor's office on 01-MAY-2008 and was treated with over the counter MOTRIN. No outcome information has been provided. Additional information has been requested.

Other Meds: cyanocobalamin, RELPAX, iron (unspecified), SYNTHROID 75 mg, MOBIC 7.5 mg, SINGULAIR 10 mg, vitamin D (unspecified), vitamins (unspecified)

Lab Data:

History:

Prex Illness: Asthma; Anaemia; Arthritis

Prex Vax Illns:

Vaers Id: **316915-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-May-2008	09-May-2008	8	16-Jun-2008	14-Jul-2008	--	WAES805USA04054	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, No reaction on previous exposure to drug

Symptom Text: Information has been received from a medical assistant concerning a 24 year old female who on 30-JAN-2008 was vaccinated via intramuscular route with the first dose GARDASIL, 0.5ml/once. Concomitant therapy included YAZ. The reporter stated that on 09-MAY-2008 the patient developed injection site pain after receiving a second dose of GARDASIL (Lot # 660389/1968U). The medical assistant stated that the patient called the office and complained of soreness and pain at the injection site but said there was no lump or swelling. The reporter said that the patient did not have any reactions when she received her first dose of GARDASIL. No further information was available. Additional information has been requested.

Other Meds: YAZ

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **316927-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	02-Jun-2008	02-Jun-2008	0	23-Jun-2008	30-Jun-2008	TX		30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52020AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2565AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1448U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immunisation reaction, Injection site erythema

Symptom Text: REDNESS TO (L) ARM IMM-SITE TREATMENT MOTRIN; ICE

Other Meds: 0

Lab Data: IMMUNIZATION REACTION PROBLABLY WITH TDAP

History:

Prex Illness: STUFFY NOSE

Prex Vax Illns:

Vaers Id: 316959-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	16-Nov-2007	18-Nov-2007	2	23-Jun-2008	30-Jun-2008	MN		10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1263U	1	Left arm	Intramuscular	FLU
	FLU	GLAXOSMITHKLINE BIOLOGICALS	AFLU310BA		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Anxiety, Arthralgia, Burning sensation, Chest pain, Dizziness, Dyspnoea, Ear discomfort, Fatigue, Headache, Heart rate increased, Irritable bowel syndrome, Malaise, Myalgia, Nausea, Neurological examination normal, Pain, Pain in extremity, Paraesthesia, Stomach discomfort, Toothache, Wisdom teeth removal

Symptom Text: Nausea for about a week,then felt good for about 3 week, then had burning sensation back of head and felt light headed and that lasted for about a week, then once again disappeared and then I got sick to my stomach, bad stomach pains that lasted about 6 weeks, then that went away then I had bad headaches with sharp shooting pains, burning sensations at the back and the front of the head, and had teethache even took trips to the dentist to find out everything was ok the duration of the headaches lasted about 3 1/2 months. Then had leg/muscle pains for about 3 weeks, joint pain, andchest pain, sensation of not able to get enough air that take place on in off over the past 8 months, and tireness. 7/15/08 Reviewed vax & PCP medical records. Received HPV #1, lot# 0525U, RA on 8/28/07. Records indicate patient tolerated HPV #1 well. 9/9/08 Reviewed additional PCP medical records. FINAL DX: none provided Records reveal patient experienced general good health on 8/28/07 but with bilateral ear discomfort & wisdom teeth coming in. RTC 7/15/08 & seen by Rheum c/o feeling unwell since 10/2007 w/multiple complaints of lightheadedness, nausea, HA, abdominal pain, sensitive teeth, burning ears, arthralgias, paresthesias, chest discomfort, difficulty breathing, feelings of impending doom, . Had been seen by GI & dx w/IBS. Seen by Neuro & exam was WNL. RTC 7/21/08 c/o nausea, tooth pain & increased heart rate, no diagnosis provided. RTC 8/12/08 for intermittent dizziness x several months, achy & joint pain

Other Meds: None

Lab Data: Lots of lab work and ct scans to find out nothing.I did test slighty positive on lupus and then was tested again and more in depth and then that was negative. LABS: ANA (+) w/speckled pattern. CBC & UA WNL. ESR 8 TSH 1.34. CXR, abdom

History: None PMH: never had sexual intercourse, sibling w/polymyositis, family hx of breast cancer, OA, HTN & diabetes. Occasional right side pelvic cramping near right ovary.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316960-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	11-Jun-2008		23-Jun-2008	24-Jun-2008	--	WAES0806USA02449	24-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician who stated that she heard about a 17 year old female who was vaccinated IM with a second 0.5 ml dose of GARDASIL. On 11-JUN-2008 she experienced a seizure in the physician's office. The patient sought unspecified medical attention. On 11-JUN-2008 the patient recovered. Upon internal review, seizure was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316961-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	U	Unknown	Unknown		23-Jun-2008	24-Jun-2008	TX	WAES0806USA02027	24-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epilepsy

Symptom Text: Information has been received from a representative as reported by four area physicians in different parts of the area concerning a "14-15 year old" patient who was vaccinated with a first dose of GARDASIL. Physicians reported that they heard in the newspaper and possibly the local news station that the patient experienced an epileptic seizure. At the time of reporting it was unknown if the patient had recovered. There was no lot number provided. No further information was available. Upon internal review epileptic seizure is considered to be an other medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316970-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Jun-2008	15-Jun-2008	1	23-Jun-2008	24-Jun-2008	FR	WAES0806USA03514	25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood urine present, Incorrect route of drug administration, Pyrexia, Vomiting

Symptom Text: Initial information has been received from a health professional concerning an 18-19 year old female who on 14-JUN-2008 was inadvertently vaccinated by intravenous route with a 2nd dose of GARDASIL. On 15-JUN-2008 the patient presented fever (38.6 centigrade) and vomiting. The patient took motilium to treat vomiting and after attending the physician she was administered primperan to treat the vomits and Ibuprofen to treat fever. The patient breathed and urinated well. Follow up information was received. The patient continued with fever (39.6 centigrade). On 15-JUN-2008 the patient went to the clinic, she was vaccinated and there, they indicated her to continue the treatment with Ibuprofen. A blood test showed a neutrophyls deviation (85%). Leukocytes remained at normal levels (4700). Blood in urine was observed, but was not considered relevant as subject was menstruating. An internal medicine physician examined the patient and said that she had an hyperreactivity to a strange protein. In the afternoon, after contacting patient's mother the health care professional reported that the patient did not feel worse during the night. She was being treated with Ibuprofen 600 mg/8 hour and paracetamol 500/8 hour (rotating medication every four hours). The patient presented mild fever on 15-JUN-2008 in the morning (37.5 centigrade). The health professional considered that these adverse events could also occur with the correct vaccine administration. The patient recovered. No further information is available. The case was closed. Other business partner numbers included E2008-05547.

Other Meds: Unknown

Lab Data: Neutrophil count, 15Jun08, 85%; Urinalysis, 15Jun08, blood in urine; Temperature measurement, 15Jun08, 38.6 centigrade; Temperature measurement, 15Jun08, 37.5 centigrade; WBC count, 4700; Temperature measurement, 39.6 centigrade.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316971-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Jun-2008	06-Jun-2008	4	23-Jun-2008	24-Jun-2008	FR	WAES0806USA03505	24-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1068U	2	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Contraception, Dizziness, Headache, Hypoaesthesia, Nausea, No reaction on previous exposure to drug, Paraesthesia

Symptom Text: Information has been received from a gynaecologist concerning a 15 year old female who on 02-JUN-2008 was vaccinated IM into the left upper arm with a 3rd dose of GARDASIL (lot #1068U) (Batch #NH06410). Concomitant therapy included hormonal contraceptives. On 06-JUN-2008 the patient complained of tingling, initially in both feet, in the course only in the big toe left. On 08-JUN-2008 she additionally developed numbness of right little finger, ring finger and middle finger and attacks of dizziness and nausea in the scope of headache. She was hospitalised. MRI was carried out on 10-JUN-2008, result was pending. Symptoms were ongoing at the time of reporting. On 04-DEC-2007, the patient had been vaccinated IM into the left upper arm with a first dose of GARDASIL (lot #1068U) (Batch #NG01520) and was well tolerated. On 01-FEB-2008, the patient was vaccinated IM into the left upper arm with a 2nd dose of GARDASIL (lot #1068U) (Batch #NG14290), migraine occurred. Other business partner numbers included E2008-05441 and E2008-05502.

Other Meds: hormonal contraceptives (unspecified), Unk - Unk

Lab Data: magnetic resonance imaging, 10Jun08, pending

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316972-1 (S)** **Related reports:** 316972-2; 316972-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		23-Jun-2008	24-Jun-2008	FR	WAES0806USA03493	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain lower, Vaccine positive rechallenge

Symptom Text: Information has been received from a general practitioner concerning a female who was vaccinated on an unspecified date with a 1st, 2nd, and 3rd dose of GARDASIL. The patient developed severe hypogastric pain after each vaccination. After one of the 3 vaccinations (not specified) she was hospitalized due to the adverse event. Her outcome was not reported. Other business partner numbers included E2008-05357.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316972-2 (S)** **Related reports:** 316972-1; 316972-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		25-Jun-2008	26-Jun-2008	FR	WAES0806USA07750	12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain lower, Vaccine positive rechallenge

Symptom Text: Information has been received from a company representative that a general practitioner informed her concerning a female (age not reported) who was vaccinated with 3 doses of GARDASIL (lot number and date of vaccinations not reported). The patient developed severe hypogastric pain after each vaccination. After one of the 3 vaccinations (not specified) she was hospitalized due to the adverse event. The outcome of the adverse event was not reported. No further information is available. Other business partners included are: E2008-05357.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316972-3 (S)** **Related reports:** 316972-1; 316972-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Oct-2007	15-Oct-2007	0	01-Jul-2008	02-Jul-2008	FR	WAES0806USA08237	12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1536F	0	Right arm	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain lower, Incorrect route of drug administration, Vaccine positive rechallenge

Symptom Text: Information has been received from a general practitioner concerning a 15 year old female who was vaccinated with the first dose of GARDASIL (lot # 1536F; batch NG01520) subcutaneously into the right arm on 15-OCT-2007. 10 days post vaccination, the patient developed lower abdominal pain. She was hospitalized. All examinations (not specified) were normal. She recovered completely after 5 days. The patient developed similar reactions after the following vaccinations with GARDASIL. P2 (lot # 0276U; batch NG58550) given subcutaneously into the upper arm on 20-DEC-2007, P3 (lot # 0277U; batch NG00020) subcutaneously upper arm on 28-APR-2008. File closed. Other business partner numbers included: E2008-05597. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 316973-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	19-Feb-2008	22-Feb-2008	3	23-Jun-2008	24-Jun-2008	FR	WAES0806USA03036	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Asthenia, Oligomenorrhoea, Pallor, Personality change, Pneumonia

Symptom Text: Information has been received from a mother consumer, concerning a 13 year old daughter with trisomy 21, who was vaccinated with a dose of GARDASIL (Lot #, injection route and site not reported) on 19-Feb-08. Since 22-Feb-08 the patient felt asthenic, developed prolonged menstrual cycle for more than 6 weeks, pallor, abdominal pain and a change of personality. On an unspecified date the patient was hospitalized due to pneumonia which was treated with antibiotics. Duration and outcome of this event was not reported. At the time of reporting the symptoms were still ongoing. Other business partner numbers included: E2008-05419. Additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Trisomy 21

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316974-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		23-Jun-2008	24-Jun-2008	--	WAES0806USA01959	24-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Pain in extremity

Symptom Text: Information has been received from a nurse practitioner concerning a 26 year old female who in January 2008, and February 2008 was vaccinated with the first and second doses of GARDASIL (lot#, route and dose not reported). Concomitant therapy included (oral) hormonal contraceptives (unspecified). In April 2008, the patient experienced leg pain in both legs and weakness and was hospitalized. In May 2008 the patient was vaccinated via intramuscular route with a third dose of 0.5 mL GARDASIL (lot#, not reported). No further information was provided. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316975-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Jan-2008	01-May-2008	119	23-Jun-2008	24-Jun-2008	--	WAES0806USA03277	24-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: EXTENDED HOSPITAL STAY, SERIOUS

MedDRA PT Migraine, Paraesthesia, Weight decreased

Symptom Text: Information has been received from a physician concerning a 14 year old female who was vaccinated with the first dose of GARDASIL, lot # not provided, on 30-NOV-2007. This vaccination was well tolerated. It was reported by the physician (who received the information from a patient's mother) that the 14-year-old female patient was vaccinated with a second dose of GARDASIL (lot # not reported) i.m. into the upper arm on 03-JAN-2008. In the beginning of May-2008, the patient developed paresthesia, migraine and weight loss. She was hospitalized for diagnostics; no reports on findings were made available to the reporter. The events were ongoing at the time of reporting. According to the patient's mother, "the symptoms improve while her daughter listens to loud music via an MP3-player." The reporting physician does not see a causal relationship to the vaccination (P2). Other business partner numbers included: E2008-05224. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316982-1 (S)** **Related reports:** 316982-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Apr-2007	Unknown		23-Jun-2008	26-Jun-2008	PA		08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0388U	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2225AA	0	Right arm	Unknown	
	HEPA	MERCK & CO. INC.	0017U	0	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Fibroadenoma of breast, Surgery

Symptom Text: surgical removal of giant fibroidenoma from left breast. Further plastic surgery required. Tumor was 14cm by 13cm by 6cm.

Other Meds: None

Lab Data: blood work; breast ultra sound

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **316982-2** **Related reports:** 316982-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Oct-2007	Unknown		17-Jul-2008	28-Aug-2008	PA	WAES0806USA03091	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fibroadenoma of breast, Surgery

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter with no known allergies or pertinent medical history who on 13-APR-2007 was vaccinated with a first dose of GARDASIL. On 15-JUN-2007 was vaccinated with a second dose of GARDASIL. On 16-OCT-2007 was vaccinated with a third dose of GARDASIL. Concomitant therapy also given on 13-APR-2007 included meningococcal vaccine (unspecified) (manufacturer unknown) and hepatitis A virus vaccine (unspecified) (manufacturer unknown). Mother reported an adverse experience on her daughter. In March 2008, the patient experienced large breast tumor and had it removed on 10-APR-2008 on an outpatient basis. It was a fibroadenoma which measured 14 x 13 x 6 cm. Ultrasound was performed, no result was provided. At the time of the report the patient was not recovered. The patient sought medical attention, "yes physician". There was no product quality complaint. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **316983-1 (D)** **Related reports:** 316983-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-May-2008	12-Jun-2008	15	23-Jun-2008	24-Jun-2008	NH		15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	0	Left arm	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Convulsion, Cyanosis, Death, Mydriasis, Pallor, Pulmonary oedema, Pupil fixed, Unresponsive to stimuli, Urinary incontinence

Symptom Text: Death 9/9/08 Death certificate states COD as idiopathic seizure disorder. 8/5/08 Reviewed ER medical records of 6/12/2008. Records reveal patient found unresponsive, prone on her bed when parent went to awake for school. Last seen at bedtime. Pupils fixed & dilated, cyanotic & pale, incontinent of urine, developed pulmonary edema during resuscitation. Unable to resuscitate.

Other Meds:

Lab Data:

History: Seizures PMH: 'problems w/alcohol'.

Prex Illness:

Prex Vax Illns:

Vaers Id: **316983-2 (D)** **Related reports:** 316983-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-May-2008	12-Jun-2008	15	14-Aug-2008	15-Aug-2008	--	WAES0807USA05084	15-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	0	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. on 28-MAY-2008 a 17 year old female with a history of seizures was vaccinated with her first dose of GARDASIL (lot # 658554/0928U) into the left arm. On 12-JUN-2008 she died. The cause of death is unknown. The original reporting source was not provided. The VAERS ID # is 316983. A standard lot check investigation was performed. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specification. The lot met the requirements and was released. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Convulsion

Prex Illness:

Prex Vax Illns:

Vaers Id: 316986-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	15-May-2008	15-May-2008	0	16-Jun-2008	11-Jul-2008	DE	WAES0805USA04078	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a nurse concerning a 20 year old female with eczema who on 15-MAY-2008 was vaccinated with her first dose of GARDASIL (lot# not reported). There was no concomitant medication. On 15-MAY-2008, 4 hours after vaccination, the patient experienced hives all over her neck and arm. The patient sought medical attention in the office on 19-MAY-2008 and the hives were all over her body. The patient's hives persisted. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Eczema

Prex Vax Illns:

Vaers Id: 316987-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-May-2008	15-May-2008	0	16-Jun-2008	11-Jul-2008	KY	WAES0805USA04096	11-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	1967U	0	Unknown	Unknown	
TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Immediate post-injection reaction

Symptom Text: Information has been received from a physician concerning a 15 year old female patient, with no medical history reported, who on 15-MAY-2008 was vaccinated with the first dose of GARDASIL (Lot #660387/1967U). Concomitant therapy included a dose of MENACTRA and a dose of ADACEL. On 15-MAY-2008 approximately three to four minutes after receiving the vaccine, the patient fell head first to the ground. She was taken to the emergency room but it was unknown if the patient was admitted. Diagnostic testing performed included a computed axial tomography and a cervical spine series, no results reported. At the time of this report the events had improved and the patient was recovering. No product quality complaint was involved. Additional information has been requested.

Other Meds:

Lab Data: computed axial, 05/15?/08, results not reported; spinal X-ray, 05/15?/08, results not reported

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **316988-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Apr-2008	01-Apr-2008	0	16-Jun-2008	14-Jul-2008	--	WAES0805USA04401	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, Pyrexia

Symptom Text: Information has been received from a nurse practitioner concerning a 14 year old female who in April 2008, was vaccinated a first dose of GARDASIL 0.5 mL IM. There was no concomitant medication. In April 2008, the patient experienced nausea and fever within 30 minutes of her first GARDASIL vaccination. Medical attention was sought. This was the patient's first and only dose of GARDASIL. Subsequently, the patient recovered from nausea and fever the next day. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316989-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-May-2008	19-May-2008	0	16-Jun-2008	14-Jul-2008	MD	WAES0805USA04407	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from an office manager concerning a 17 year old female who on 19-OCT-2007 was vaccinated with the first dose of GARDASIL, 0.5 ml, lot # 658563/1063U. There were no problems noted after the first dose. On 19-MAY-2008 after receiving the second dose of GARDASIL, 0.5 ml, lot # 659182/1757U, the patient fainted. It was reported that the patient sought medical attention in the office and recovered on 19-MAY-2008. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316990-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	--	WAES0805USA04469	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Condition aggravated

Symptom Text: Information has been received from a pharmacist concerning a female patient with avascular necrosis who was vaccinated with a dose of GARDASIL. Subsequently, the patient experienced worsening of her joint pain. The reporter was unable to provide the interval between the vaccine and the onset of the increased joint pain. At the time of this report, the patient has not recovered. No product quality complaint was involved. No further information is available.

Other Meds: Unknown

Lab Data:

History:

Prex Illness: Avascular necrosis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316991-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		16-Jun-2008	11-Jul-2008	CA	WAES0805USA04471	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a 21 year old female with a history of a high risk life style (behaviour disorder), who was vaccinated with the series of GARDASIL on unreported dates. Subsequently, after the completion of the GARDASIL series, on an unspecified date, the patient had an abnormal Pap test. It was reported that the patient sought unspecified medical attention, but no treatment or outcome information has been provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, abnormal

History: Behaviour disorder

Prex Illness:

Prex Vax Illns:

Vaers Id: 316992-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	20-Sep-2007	25-Sep-2007	5	16-Jun-2008	14-Jul-2008	AZ	WAES0805USA04483	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Erythema nodosum, Hypoaesthesia

Symptom Text: Information has been received from a physician concerning a 25 year old female who on 03-JUL-2007 was vaccinated intramuscularly with her first dose of GARDASIL (lot# not reported). Concomitant therapy included DEPO-PROVERA. On 20-SEP-2007 the patient was vaccinated intramuscularly with her second dose of GARDASIL (lot# not reported). On 25-SEP-2007 the patient experienced joint aches and right hip numbness and pain. She was seen by a rheumatologist and was diagnosed with erythema nodosum from GARDASIL. She was advised to not get the third dose in the series and was seen in the office on 26-MAR-2008 and she reported no problems. Subsequently, the patient recovered from joint aches and right hip numbness and pain. No further information is available.

Other Meds: DEPO-PROVERA

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 316993-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-May-2008	20-May-2008	1	16-Jun-2008	14-Jul-2008	--	WAES0805USA04488	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea, Nausea, Rash, Vomiting

Symptom Text: Information has been received from a nurse practi concerning a 17 year old female who on 19-MAY-2008 was vaccinated IM with a 0.5 ml first dose of GARDASIL (lot# 655604/0052X). On 20-MAY-2008 the patient experienced nausea, vomiting, diarrhea and "pin point" rash on her face. Unknown medical attention was sought by calling the practice. At the time of reporting the patient had not recovered from nausea, vomiting, diarrhea and pin point rash on her face. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316994-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	11-Feb-2008	11-Feb-2008	0	16-Jun-2008	11-Jul-2008	MA	WAES0805USA04491	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448J	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Acne, Diarrhoea, Headache, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered nurse concerning a 26 year old female with penicillin allergy who on 11-FEB-2008 was vaccinated intramuscularly with a first dose of GARDASIL (lot # reported as "1448J"). Subsequently the patient experienced an outbreak of large pimples on her face. On an unspecified date the patient recovered from the outbreak of large pimples on her face. Concomitant therapy included APRI. On 11-APR-2008 the patient was vaccinated intramuscularly with a second dose of GARDASIL (lot # reported as "1757J"). On 11-APR-2008 the patient experienced diarrhea, abdominal pain, fever, headache and outbreak of large pimples on her face. Subsequently, on 13-APR-2008, the patient recovered from diarrhea, abdominal pain, fever, headache, and outbreak of large pimples on her face. The patient sought unspecified medical attention by calling the physician. Additional information has been requested.

Other Meds: APRI

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **316995-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Apr-2008	30-Apr-2008	21	16-Jun-2008	14-Jul-2008	MI	WAES0805USA04541	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Genital pain, Genital tract inflammation, Vulvovaginal discomfort

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 09-APR-2008 was vaccinated with her first dose of GARDASIL (Lot #, route and site were not reported). Concomitant therapy included ALESSE. On 30-APR-2008 the patient experienced redness, soreness and swelling of the labia. The patient sought unspecified medical attention with an office visit. At the time of this report, the patient was recovering from redness, soreness and swelling of the labia. No additional information was provided. Additional information has been requested.

Other Meds: ALESSE

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 316996-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	11-Jul-2008	--	WAES0805USA04624	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Tooth avulsion

Symptom Text: Information has been received from a physician assistant concerning a female patient (age unknown), who, on unspecified date, was vaccinated with dose of GARDASIL. Subsequently, the patient fainted and her tooth fell out. The patient sought unspecified medical attention. At the time of the report, the outcome of the patient was unknown. No product quality complaint was involved. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316997-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-May-2008	20-May-2008	0	16-Jun-2008	14-Jul-2008	VA	WAES0805USA04684	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Presyncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 15 year old female who on unspecified dates was vaccinated with the first and second dose GARDASIL. On 20-MAY-2008, the patient received the third dose of GARDASIL. Following the immunizations the patient complained of feeling light-headed and dizzy; she didn't actually pass out, but looked like she would pass out. They laid her back on the table and it resolved without any serious sequelae. Additional information has been requested.

Other Meds: (therapy unspecified)

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316998-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	MI	WAES0805USA04694	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Limb discomfort

Symptom Text: Information has been received from a healthcare worker concerning a female patient who was vaccinated with a dose of GARDASIL (lot# not provided). Subsequently the patient experienced arm discomfort after receiving the vaccination, related to the vaccine feeling cold. Unknown medical attention was sought in the physician's office. The patient's outcome is unknown. No product quality complaint was involved. This is one of two case from the same source (WAES# 0805USA06180). Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **316999-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	RI	WAES0805USA04704	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Limb discomfort, Pain, Pain in extremity

Symptom Text: Information has been received from a physician concerning a female who in approximately 2007 was vaccinated IM with the first dose of GARDASIL (lot# not provided). The patient completed series of 3 doses of GARDASIL was experiencing discomfort on both arms. The patient had started GARDASIL vaccination one year ago. The patient's both arms are achy when she either lays or leans on them. She has had pain since the completion of the series. Unknown medical attention was sought by calling the physician's office. At the time of reporting the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317000-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	NJ	WAES0805USA04723	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician and office manager concerning a female who was vaccinated on an unspecified date with an unknown # of doses of GARDASIL (lot#'s not reported). Subsequently the patient developed HPV. The patient sought unspecified medical attention on an unspecified date and her outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317001-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	--	WAES0805USA04732	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Information has been received from a health professional concerning females who were vaccinated with a dose GARDASIL (lot#'s not reported). Subsequently about 20% of the patients experienced pain after vaccination and returned late for their next dose. It was also mentioned that one patient complained her arm hurt the next day. The nurse did not have any specific patient information and would not estimate the total number of patients. Attempts are being made to obtain additional identifying information to distinguish the individual patients in this report. Additional information will be provided if available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 317002-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	LA	WAES0805USA04747	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contusion

Symptom Text: Information has been received from a physician concerning a 21 year old female with rhabdomyosarcoma who was on an unspecified date was vaccinated with a second dose of GARDASIL. Subsequently a couple of days after vaccination with GARDASIL the patient developed mild bruising on both her thighs. Medical attention was sought at the office. At the time of the report the patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory, unspecified

History:

Prex Illness: Rhabdomyosarcoma

Prex Vax Illns:

Vaers Id: **317003-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		16-Jun-2008	14-Jul-2008	--	WAES0805USA04758	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypersensitivity, Pruritus generalised

Symptom Text: Information has been received from an allergist via a physician concerning a patient (age and gender not reported) who on an unspecified date was vaccinated with GARDASIL. Subsequently after the vaccination, the patient experienced itching all over the body and "other allergic reactions". No other information regarding the patient and events were known at the time. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317004-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	CA	WAES0805USA04762	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia, Rash, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 23 year old female who on approximately 01-MAR-2008 was vaccinated intramuscularly with her first dose GARDASIL (lot# not reported). The patient received the second dose of GARDASIL (lot# not reported) on an unspecified date. Subsequently the patient experienced a fever and rash on the vaccinated arm after receiving the first and second doses of GARDASIL. The patient sought medical attention on an unspecified date by calling the office. Subsequently, it was reported that the patient recovered from the fever and rash on her arm on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317005-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Nov-2007	16-Nov-2007	1	16-Jun-2008	14-Jul-2008	IL	WAES0805USA04819	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1210U	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pyrexia

Symptom Text: Information has been received from a physician concerning a 16 year old white female who on 15-NOV-2007 was vaccinated in the right deltoid with her first dose of GARDASIL (lot# 655154/1210U). There was no concomitant medication. On 16-NOV-2007 the patient suffered a severe headache and fever greater than 100F. Subsequently, the patient recovered from the severe headache and fever. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317006-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	21-Mar-2008	21-Apr-2008	31	16-Jun-2008	14-Jul-2008	PA	WAES0805USA04867	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myalgia, No reaction on previous exposure to drug, Pain

Symptom Text: Information has been received from a physician concerning an 18 year old female who was vaccinated with the first and second dose of GARDASIL on unspecified dates. It was reported that there was no problem after either dose. On approximately 21-MAR-2008, the patient was given the third dose of GARDASIL. Four weeks following the third dose, approximately 21-APR-2008, the patient complained of aches, pains, and muscle soreness. The patient sought unspecified medical attention and underwent diagnostic laboratory tests eight weeks after the third dose of GARDASIL, approximately 21-MAY-2008. "ANE" and serum rheumatoid factor test were positive. No treatment or outcome information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, 05/21/08, ANE positive; serum rheumatoid factor, 05/21/08

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317007-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	MA	WAES0805USA04883	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactic reaction, Rash, Urticaria

Symptom Text: Information has been received from a nurse concerning a female who was vaccinated with the first dose of GARDASIL (lot# Reported as"152X"). Per the nurse, the patient developed a "systemic rash with hives on her face" a week after receiving the first dose of GARDASIL. The patient sought unspecified medical attention by contacting the physician. No further information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317008-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-May-2008	Unknown		16-Jun-2008	14-Jul-2008	TN	WAES0805USA04894	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injection site pain

Symptom Text: Information has been received from a licensed practical nurse concerning a 17 year old female with a history of penicillin allergy and drug hypersensitivity who in August 2007, was vaccinated with the first dose and on 24-OCT-2007 was vaccinated with the second dose of GARDASIL (lot #'s not reported). On 22-MAY-2008 the patient was vaccinated with the third dose of GARDASIL (lot# not reported). Subsequently the patient experienced inappropriate schedule of vaccine administered. Concomitant therapy included hormonal contraceptives (unspecified). The patient also told the nurse that when receiving the previous injections, she experienced a moment of pain st the injection site. Some residual pain was present the next day. The patient's injection site discomfort resolved. Then sought unspecified medical attention in the physician's office. No additional information is available at this time. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data:

History: Penicillin allergy; Drug hypersensitivity

Prex Illness:

Prex Vax Illns:

Vaers Id: **317009-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	08-May-2008	08-May-2008	0	16-Jun-2008	14-Jul-2008	TN	WAES0805USA04907	14-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
TTOX	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 08-MAY-2008 was vaccinated with her first dose of GARDASIL (lot # unspecified). Concomitant suspect therapy included VARIVAX (lot # unspecified). Other concomitant therapy included MENACTRA and TETANUS TOXOIDS (lot#s unspecified). It was reported by physician, that the patient got really dizzy post vaccination on 08-May-2008. Physician noted that the patient came back on 12-May-2008 and still experiencing some dizziness, but has normal muscle strength. On unspecified date the neuro and glucose check were performed (results not reported). Unspecified medical attention was sought by visiting doctor's office. At the time of this report, the patient had not recovered. Per physician, the patient will not be receiving any further GARDASIL shots. No further information provided. Additional information has been requested.

Other Meds:

Lab Data: neurological; serum glucose

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317010-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		16-Jun-2008	11-Jul-2008	IL	WAES0805USA04910	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 21 year old female who in 2006 was vaccinated intramuscularly with her first 0.5 ml dose of GARDASIL (lot # unspecified). On unspecified dates the patient was vaccinated intramuscularly with her second and third 0.5 ml doses of GARDASIL (lot # s unspecified). It was reported that on unspecified date after receiving all 3 doses, the patient developed "A-typical HPV cells". On unspecified date a PAP test was performed (no results reported). Unspecified medical attention was sought. At the time of this report the patient had not recovered. No additional information was given. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 317011-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	08-May-2008	15-May-2008	7	16-Jun-2008	14-Jul-2008	ME	WAES0805USA04994	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash pruritic, Urticaria

Symptom Text: Information has been received from a nurse concerning a 26 year old female, with no pertinent medical history and no known drug reactions/allergies, who on 08-MAY-2008 was vaccinated intramuscularly with a 0.5 mL first dose of GARDASIL (Lot # 0152X). There was no concomitant medication. About one week later, approximately 15-MAY-2008, the patient developed an itchy rash and hives all over her body. The patient was treated with steroids (unspecified) and the symptoms have since resolved on an unknown date. The patient sought unspecified medical attention. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317012-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	21-May-2008	21-May-2008	0	16-Jun-2008	14-Jul-2008	--	WAES0805USA04997	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female, with unknown medical history, who on 21-MAY-2008 was vaccinated with (route unknown) with a third dose of GARDASIL (Lot# unknown). On 21-MAY-2008 the patient contacted the nurse practitioner complaining of a severe headache. The nurse practitioner reported that the patient told her that she took ADVIL and is feeling much better. No product quality

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317013-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		16-Jun-2008	14-Jul-2008	IN	WAES0805USA05015	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactic reaction

Symptom Text: Information has been received from a physician who heard from another physician in another city, concerning a patient vaccinated with a dose of GARDASIL (route, site, dose# and Lot# not provided). Subsequently the patient experienced anaphylactic reaction. The patient sought unknown medical attention. The patient's outcome is unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317014-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	07-Apr-2008	09-May-2008	32	16-Jun-2008	11-Jul-2008	MA	WAES0805USA05046	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site mass

Symptom Text: Information has been received from a physician concerning a 64 inch, 92 pound, 24 year old, generally healthy, female, witness advocate, who on an unspecified date was vaccinated with the first dose of GARDASIL, in the left deltoid. On 07-APR-2008 the patient was vaccinated with her second dose of GARDASIL, in the left deltoid, lot # 659965/1978U. On 09-MAY-2008, the patient sought medical attention for a "sick visit", she complained of a bump in the left deltoid area at the site of the injection. It was reported that the patients arm was very thin and the first and second shot were done in the deltoid of the left arm. A magnetic resonance image was taken on an unspecified date and showed possible infective etiology. The patient was treated with unspecified antibiotics. At the time of reporting, the patient was still being treated. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance, 05/09?/08, possible infective etiology

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317015-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-May-2008	21-May-2008	0	16-Jun-2008	14-Jul-2008	AL	WAES0805USA05050	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect route of drug administration, Injection site erythema, Injection site irritation, Injection site mass, Injection site swelling

Symptom Text: Information has been received from a Registered Nurse concerning a 17 year old female who on 21-MAY-2008 was vaccinated "subcutaneously below the deltoid but above the elbow (arm unspecified)" with a first dose of GARDASIL (lot # 0152X). There was no concomitant medication. It was reported that "the patient was walking out of the clinic and the nurse noticed the patient had a large knot at the injection site in which there was redness, swelling, and irritation. The patient had this reaction within 15 minutes of receiving GARDASIL. The patient was given TYLENOL and warm heat. The nurse spoke to the patient this morning and the redness was getting better." Patient outcome was reported as recovering. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317016-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	21-May-2008	22-May-2008	1	16-Jun-2008	14-Jul-2008	PA	WAES0805USA05077	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Asthenia, Back pain, Dizziness, Fatigue, Pyrexia, Syncope, Vomiting

Symptom Text: Information has been received from a nurse concerning a 13 year old female who on 21-MAY-2008 was vaccinated IM with a first 0.5 ml dose of GARDASIL. On 22-MAY-2008 the patient fainted at school after receiving her first dose the day before. It was reported the patient did not have breakfast or anything to drink before lunch and was sent home from school. The mother of the patient reported the patient continued to have symptoms of weakness, back pain, fever, fatigue, dizziness and vomited during the night. The patient required an office visit. The patient's outcome was reported as not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317017-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Apr-2008	17-Apr-2008	0	16-Jun-2008	11-Jul-2008	IL	WAES0805USA05089	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Pharyngeal oedema, Urticaria

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female who on 17-APR-2008 was vaccinated with the first dose of GARDASIL (lot # 0151X), 0.5ml, IM. Concomitant therapy included LO/OVRAL. The nurse reported that the patient received the first dose of GARDASIL, and experienced lightheadedness, dizziness and hives on the day that she received the vaccine. The patient received the vaccine early in the morning and experienced the symptoms later that day while at school. She went to the school nurse and while she was at the nurses' office she began to experience swelling of her throat. An ambulance was called and the patient was taken to the emergency room where she was given intravenous BENADRYL. The patient's symptoms improved after receiving the BENADRYL. Additional information is not expected.

Other Meds: LO/OVRAL

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317018-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		16-Jun-2008	11-Jul-2008	PA	WAES0805USA05098	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nervousness, Syncope

Symptom Text: Information has been received from a physician concerning a 13 year old female who on an unspecified date was vaccinated with a dose of GARDASIL (Dose #, lot #, site and route were not reported). The patient was "shaking a little and then collapsed" after receiving the vaccine. The patient sought unspecified medical attention by calling the office. No additional information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317019-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Dec-2007	18-Mar-2008	106	16-Jun-2008	14-Jul-2008	VA	WAES0805USA05107	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Ovarian cyst

Symptom Text: Information has been received from a registered nurse for the Pregnancy Registry for concerning a 15 year old female with no medical history and no drug reactions/allergies, who on 01-Oct-2007, 03-Oct-2007 and 08-Apr-2008 was vaccinated intramuscularly with first, second and third doses, respectively, of 0.5ml of GARDASIL (lot #'s: 658560/1062U, 658563/1063U, 659439/1267U) and became pregnant. Concomitant therapy on 01-Oct-2007, included MENACTRA. On 08-APR-2008 the patient was diagnosed with ovarian cyst. The patient sought unspecified medical attention with another physician. On unspecified date abdominal CT scan for ovarian cyst was performed (results not reported). On unspecified date the patient took urine pregnancy test that positive (LMP=18-Mar-2008). Outcome unknown. No further information available. Additional information has been requested.

Other Meds:

Lab Data: abdominal computed; urine beta-human - positive

History:

Prex Illness: Pregnancy NOS (LMP = 3/18/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317020-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	11-Jul-2008	--	WAES0805USA05108	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect route of drug administration, Injection site pain, Local reaction

Symptom Text: Information has been received from a nurse practitioner concerning an other nurse's daughter, who on unspecified date was vaccinated subcutaneously with her first dose of GARDASIL (lot# unspecified). Subsequently the patient experienced local injection site reaction with "achiness". Unspecified medical attention was sought. At the time of this report the patient's outcome was unknown. No other information provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317021-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-May-2008	22-May-2008	0	16-Jun-2008	14-Jul-2008	--	WAES0805USA05110	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Dizziness, Injection site erythema, Injection site swelling, Nausea, Paraesthesia, Pyrexia, Tremor

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female with asthma and allergy to amoxicillin, who on 22-MAY-2008 was vaccinated intramuscularly with her second 0.5ml dose of GARDASIL (lot # 659964/1978U). Shortly after being vaccinated, the patient developed tingling in her arm, swelling and redness at the injection site, low fever (101.8 F), chills, shakiness, nausea and dizziness. It was reported that the patient was seen the next day in office and the symptoms seemed to be improving. At the time of this report, the patient was still recovering. No other information was available. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Asthma; Penicillin allergy

Prex Vax Illns:

Vaers Id: **317022-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		16-Jun-2008	11-Jul-2008	MD	WAES0805USA05117	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Herpes zoster

Symptom Text: Information has been received from a physician concerning an approximately 20 year old female (twin sister), who in approximately March 2008 (date reported as "within the last two months) was vaccinated with GARDASIL (lot# unspecified). It was reported that on unspecified date after receiving GARDASIL the patient and her twin sister developed Shingles. It was also reported that "they do not live together". Unspecified medical attention was sought. At the time of this report, the outcome was unknown. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317023-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	AZ	WAES0805USA05129	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Urticaria

Symptom Text: Information has been received from a physician concerning an approximately 23 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL (lot # not reported). Subsequently the patient developed hives and a rash. It was reported that "the adverse experience lasted a couple days". On an unspecified date the patient recovered. The physician has decided to discontinue the series. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317024-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	14-May-2008	15-May-2008	1	16-Jun-2008	11-Jul-2008	--	WAES0805USA05607	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Headache, Pain

Symptom Text: Information has been received from a registered nurse concerning a female (age unreported), with no specified medical history or drug allergies, who on unspecified dates was vaccinated with the first and second dose of GARDASIL. On 14-MAY-2008, the patient received her third dose of GARDASIL, (lot # not reported). On 15-MAY-2008, the patient developed a temperature of 101 degrees Fahrenheit, a headache, and body aches. The patient went to the emergency room on an unspecified date and her temperature reached 104 degrees Fahrenheit. On an unreported date, she had laboratory tests to check for meningitis, no results were provided. No treatment information has been provided. At the time of this report the patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, 05/15?/08, check for meningitis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317025-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	11-Jul-2008	--	WAES0805USA05617	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inflammation

Symptom Text: Information has been received from a nurse practitioner concerning a female who was vaccinated with a dose of GARDASIL. She reported that the patient developed a delayed inflammatory response that started 3 days after vaccination. She did not want to provide any further information about the patient or the delayed inflammatory response. The patient's outcome was unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317026-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	28-Mar-2008	28-Mar-2008	0	16-Jun-2008	14-Jul-2008	IN	WAES0805USA05619	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a registered nurse concerning her 11 year old daughter with no pertinent medical history who on 28-MAR-2008 was vaccinated with a first dose GARDASIL (Lot # 658556/1060U). There were no concomitant medications. On 28-MAr-2008, several hours after vaccination she developed a rash. The rash covered her body except her face and neck. The patient required an office visit and was treated with BEABDRYL. The rash resolved in 3 to 4 days. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317027-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-May-2008	20-May-2008	0	16-Jun-2008	11-Jul-2008	--	WAES0805USA05625	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female who on 20-MAY-2008 was vaccinated with a third dose of GARDASIL. On 20-MAY-2008, after vaccination the patient "passed out." The patient sought unspecified medical attention. The patient outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317028-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		17-Jun-2008	15-Jul-2008	--	WAES0805USA05634	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has been received from a Hair Dresser concerning her 13 year old niece who in approximately January 2008, was vaccinated with a first dose of GARDASIL. There were no concomitant medications. She reported that a "couple of days ago" while doing her niece's hair (giving her highlights) she noticed the color bubbled up and got hot really quickly. The hair turned from brown to blond within a minute and she had to wash it off. She reported the hair was not permanently damaged. The patient did not seek medical attention. The patient's outcome was reported as recovered. Additional information is not expected.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317029-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	--	WAES0805USA05747	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 23 year old female who was "very nervous and anxious upon receiving" the first dose of GARDASIL (lot # not reported). The physician reported that he administered the first dose of GARDASIL to the patient who fainted after receiving the vaccine. The patient was given some juice and sat in a chair for 15 minutes after the first episode and then fainted again. She fell to the floor and hit her head. She did not have to go to the hospital, but the doctor reported that he felt there might be some underlying cardiac issue. The patient was referred to a cardiologist. The physician did not feel this was directly caused by GARDASIL because the patient shared that she had this same experience when receiving other vaccines. Patient outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Nervousness; Anxiety

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317030-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	11-Jul-2008	PA	WAES0805USA05811	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Therapeutic response unexpected

Symptom Text: Information has been received from a nurse concerning a female (age unknown) with warts on feet, who was vaccinated (route unknown) on an unspecified date with her first dose of GARDASIL (lot# not reported). The nurse reported that the patient had three large warts on her foot that cleared up 4-5 days after she received the vaccination. Unspecified medical attention was not sought. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Plantar warts

Prex Vax Illns:

Vaers Id: 317031-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	22-May-2008	27-May-2008	5	16-Jun-2008	11-Jul-2008	SC	WAES0805USA05948	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Discomfort, Erythema, Injection site swelling, Injection site warmth, Pain in extremity, Tenderness

Symptom Text: Information has been received from a physician concerning a 19 year old female with asthma who on 22-MAY-2008 was vaccinated intramuscularly in the left arm with her first dose of GARDASIL (Lot # 660387/1967U). Concomitant therapy included SINGULAIR. On 27-MAY-2008 the patient experienced tenderness, redness, pain in the arm, swelling at the injection site, heat at the injection site and discomfort. On 28-MAY-2008, it was reported that "the reactions are worse today". The physician recommended that the patient take TYLENOL or MOTRIN. The patient's symptoms persisted. No additional information is available. Additional information has been requested.

Other Meds: SINGULAIR

Lab Data: None

History:

Prex Illness: Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317032-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	12-May-2008	12-May-2008	0	16-Jun-2008	14-Jul-2008	--	WAES0805USA05981	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site reaction, Injection site swelling, Wrong drug administered

Symptom Text: Information has been received from a nurse midwife for the Pregnancy Registry for GARDASIL concerning a 26 year old female with an allergy to morphine, who on 12-MAY-2008 was vaccinated intradermally with GARDASIL (lot# not reported) while pregnant. There was no concomitant medication. It was reported that the patient received GARDASIL when the patient was 7 weeks 3 days pregnant (LMP = 21-Mar-2008) and the estimated date of delivery was 27-Dec-2008. The patient was to get a tuberculosis skin test and in error received GARDASIL intradermally. No product confusion was discovered, but the nurse midwife was not sure how the error was made. On 12-May-2008 after vaccination, the patient developed a local reaction at the injection site, described as itchy, raised and red 2 cm in diameter. Unspecified medical attention was sought during an office visit. At the time of this report, the patient's local reaction at the injection site, persisted. No other information available. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 3/21/2008); Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **317033-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	27-Feb-2008	28-Feb-2008	1	16-Jun-2008	11-Jul-2008	VA	WAES0805USA05984	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraception, Pruritus, Urticaria, Vaccine positive rechallenge

Symptom Text: Information has been received from a licensed practical nurse concerning a 25 year old female who on 27-FEB-2008 was vaccinated IM in the left deltoid with a first 0.5 ml dose of GARDASIL (Lot #660387/1967U). Concomitant therapy included hormonal contraceptives (unspecified). On 28-FEB-2008 the patient experienced pruritus and developed urticaria and was treated with BENADRYL. Subsequently, the patient recovered. On 23-APR-2008 she was vaccinated with a second dose of GARDASIL (Lot #660387/1967U) and on 28-APR-2008 experienced pruritus and developed urticaria and was treated with BENADRYL. The patient sought medical attention via telephone. Subsequently, the patient recovered. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317034-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-Jan-2008	Unknown		16-Jun-2008	14-Jul-2008	--	WAES0805USA05985	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Drug administered at inappropriate site, Musculoskeletal chest pain, Pain in extremity

Symptom Text: Information has been received from a nurse practitioner concerning a 13 year old female who on 05-Jan-2008 was vaccinated IM with a first dose GARDASIL (Lot #6553271/1287U) "in the glute." Shortly after vaccination the patient experienced arm pain, joint pain, and chest wall pain. On 01-MAR-2008 she was vaccinated IM with a second dose of GARDASIL in the deltoid. The patient did not inform the physician of the adverse events associated with the 1st dose until after the administration of the 2nd dose. The "pain was still there from the 1st dose when the 2nd dose was given." The patient sought unspecified medical attention. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317035-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
31.0	M	Unknown	Unknown		16-Jun-2008	11-Jul-2008	--	WAES0805USA06018	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Flushing, Inappropriate schedule of drug administration, Incorrect route of drug administration, Malaise, Tachycardia

Symptom Text: Information has been received from a 31 year old male physician who on an unspecified date in March 2008, was vaccinated with his first dose of GARDASIL (Lot #, site and route not reported). On 28-MAY-2008 the patient was vaccinated subcutaneously in the right arm using an 18 gauge needle with his second dose of GARDASIL (Lot #, site and route not reported). The physician stated that he felt a little flushed, malaise, and a little tachycardic post vaccination, "but feels fine now". On 28-MAY-2008, the patient recovered from being a little flushed, malaise and a little tachycardic. The patient sought unspecified medical attention. No additional information was provided. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317036-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		16-Jun-2008	11-Jul-2008	FL	WAES0805USA06044	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site, Hypoaesthesia

Symptom Text: Information has been received from a physician concerning a patient (age and gender unknown) who was vaccinated (route unknown) into the hip area with a dose of GARDASIL (Lot # unknown). Subsequently, on an unknown date the patient experienced numbness in the leg. It was reported that the patient is fine, numbness has resolved, no other issues. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317037-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-May-2008	Unknown		16-Jun-2008	14-Jul-2008	--	WAES0805USA06173	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning her 17 year old niece who on approximately 15-MAY-2008 was vaccinated with the second dose of GARDASIL (lot number not reported). Subsequently the patient underwent a pap smear between the first and second dose that showed stage 1 cervical dysplasia. At the time of the report the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317038-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	11-Jul-2008	MI	WAES0805USA06180	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Limb discomfort

Symptom Text: Information has been received from a healthcare worker concerning a female patient who was vaccinated with a dose of GARDASIL (lot# not provided). Subsequently the patient experienced arm discomfort after receiving the vaccination, related to the vaccine feeling cold. Unknown medical attention was sought in the physician's office. The patient's outcome is unknown. No product quality complaint was involved. This is one of two cases from the same source (WAES# 0805USA04694). Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317039-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-May-2008	22-May-2008	2	16-Jun-2008	14-Jul-2008	--	WAES0805USA06184	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Herpes zoster

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 20-MAY-2008 was vaccinated with the first dose of GARDASIL (lot not reported). On 22-mAY-2008, 48 hours post vaccination the patient went to the E.R. experiencing shingles rash on her neck. The patient was given unspecified pain medication and discharged from the E.R. The patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317040-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		16-Jun-2008	14-Jul-2008	PA	WAES0805USA06198	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Sensation of heaviness

Symptom Text: Initial and follow up information has been received from a nurse and an office worker concerning "almost all" patients (number of patients unspecified) who were vaccinated with GARDASIL (lot# not reported). The patients have been complaining of "heaviness" in the entire arm and "extreme pain" at the injection site after vaccination. It was reported that the pain occurs with all three doses. Patient outcomes were not reported. Patients reportedly sought unspecified medical attention by contacting the office. Subsequently, the patient recovered from "heaviness" in the entire arm and "extreme pain" at the injection site (not further specified). Attempts are being made to obtain additional information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 317041-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	--	WAES0805USA06215	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has been received from a Hair Dresser concerning an approximately 14 or 15 year old female customer who was "recently" vaccinated with GARDASIL. The Hair dresser reported that she tried to dye the patient's hair blond, she noticed the color bubbled and got hot and started turning blond very quickly and she had to wash it off immediately. At the time of the report the patient's outcome was unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317042-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	29-May-2008	29-May-2008	0	16-Jun-2008	14-Jul-2008	--	WAES0805USA06219	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Incorrect route of drug administration, Injection site erythema, Injection site pain, Injection site swelling, Paraesthesia

Symptom Text: Information has been received from a licensed practical nurse concerning a 21 year old female with penicillin allergy who on 29-MAY-2008 was vaccinated with a first dose of 0.5 ml GARDASIL via a subcutaneous route. There were no concomitant medications. On 29-MAY-2008, after receiving her first dose she felt lightheaded, the injection site became red and swollen, pain radiated down to her pinky and she felt "tingles" on the left side of her face. She sought unspecified medical attention from the nurse. At the time of the report the patient was recovering. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **317043-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-May-2008	16-May-2008	1	16-Jun-2008	14-Jul-2008	FL	WAES0805USA06280	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a nurse concerning a 16 year old female who on 15-MAY-2008 was vaccinated intramuscularly with her first dose of GARDASIL (lot# 660387/19687U). There was no concomitant medication. On 16-MAY-2008 the patient developed widespread hives. The patient's mother sought medical attention on 27-MAY-2008 and the doctor recommended BENADRYL. The patient's outcome was not reported. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317044-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	--	WAES0805USA06378	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a female (age unknown) who sometime in 2007 was vaccinated intramuscularly with a first dose of GARDASIL (Lot # unknown). There was no concomitant medication. The physician reported that the patient on unknown dates experienced burning sensation after all three doses. Subsequently, on unknown dates the patient recovered. Unspecified medical attention was sought. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317045-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
32.0	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	IL	WAES0806USA00014	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 32 year old female who in 2007 was vaccinated on unspecified dates with all three doses of GARDASIL (lot#'s not reported). There was no concomitant medication. On 19-MAY-2008 the patient had a pap test which showed she was at high risk for HPV. Prior to this her PAP tests were negative. The patient's high risk for HPV persisted and the patient sought medical attention by calling the office on an unspecified date. Additional information has been requested.

Other Meds: None

Lab Data: Pap test, 05/19/08 - high risk for HPV

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **317046-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	WI	WAES0806USA00019	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a physician concerning a female patient who in November 2007, was vaccinated with a first dose of GARDASIL (lot # not provided). Concomitant therapy included other unspecified vaccines administered on the same day. Post vaccination, the patient experienced hair loss. Subsequently, the patient recovered from the hair loss. The patient sought medical attention at the office. The patient refused to get the second dose. No product quality complaint was involved. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317047-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
51.0	M	28-May-2008	28-May-2008	0	16-Jun-2008	14-Jul-2008	--	WAES0806USA00035	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injection site pain

Symptom Text: Information has been received from a 51 year old male consumer with a history of drug reaction to CEFZIL, who on 28-MAY-2008 was vaccinated with his first dose of GARDASIL (Lot #, site and route not reported). The patient received his first dose of the vaccine "as prescribed by his physician because he was told by his girlfriend that she has 1 strain of HPV that can cause cervical cancer". On 28-MAY-2008, "right after receiving the first dose" he experienced "sore in the injection site". The patient sought unspecified medical attention. On an unspecified date, the patient recovered from "sore in the injection site after receiving first dose". No additional information was provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: 317048-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	27-May-2008	27-May-2008	0	16-Jun-2008	14-Jul-2008	AL	WAES0806USA00036	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: Information has been received from a physician concerning a 17 or 18 year old female who on 27-MAY-2008 was vaccinated with her third dose of GARDASIL (Lot #, site and route not reported). On 27-MAY-2008 the patient fainted after the injection and sustained a "bump on the head". She recovered immediately and was given crackers and coke. The dates, lot #s, route and sites of administration of the first two doses of GARDASIL were not known. The patient sought unspecified medical attention in the office. No additional information was available. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 317049-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	30-May-2008	30-May-2008	0	16-Jun-2008	14-Jul-2008	NJ	WAES0806USA00037	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a medical assistant concerning a 25 year old female with a seizure disorder and a history of depression, anxiety and migraines who on 30-MAY-2008 was vaccinated intramuscularly in the left deltoid with her first dose of GARDASIL (Lot # 660389/1968U). Concomitant therapy included LAMICTAL, DEPAKOTE and TOPAMAX. On 30-MAY-2008, 30 seconds after receiving the vaccination, the patient fainted on the table. The patient was monitored and received unspecified treatment in the office. It was reported that the patient was recovering from the fainting. No additional information was available. Additional information has been requested.

Other Meds: DEPAKOTE; LAMICTAL; TOPAMAX

Lab Data: None

History: Depression; Anxiety; Migraine

Prex Illness: Convulsion disorder

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317050-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-May-2008	21-May-2008	0	16-Jun-2008	14-Jul-2008	--	WAES0806USA00042	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Nausea

Symptom Text: Information has been received from a physician concerning a 16 year old female, with no relevant medical history and no known drug allergies, who on 21-MAY-2008 was vaccinated intramuscularly with her first dose of GARDASIL (Lot #, site and route not reported). There was no concomitant medication. On 21-MAY-2008, "about five minutes after vaccination with her first dose", the patient developed nausea, dizziness, and became sweaty and "clammy". The patient had unspecified medical attention in the office. The patient was observed for 20 minutes and the symptoms resolved. No other information was available. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 317051-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	25-Mar-2008	25-Mar-2008	0	16-Jun-2008	14-Jul-2008	PA	WAES0806USA00051	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hot flush, Pain in extremity, Palpitations, Paraesthesia, Pharyngolaryngeal pain, Rhinorrhoea

Symptom Text: Information has been received from a physician concerning an 11 year old female with asthma who on 25-MAR-2008 was vaccinated via intramuscular route in her right arm with the first 0.5 mL dose of GARDASIL (lot# 659964/1978U). Concomitant medication included an unspecified asthma medication. On 25-MAR-2008, a few hours after the dose, the patient experienced pain and tingling of the right arm and right leg as well as "hot flashes". On 26-MAR-2008, the next day, the pain and tingling and hot flashes resolved. The physician reported that on 12-MAY-2008 the patient was seen in the office and had complaints of sore throat, nasal discharge and heart palpitations. The physician ordered a complete blood count, metabolic panel, thyroid stimulating hormone, echocardiogram, electrocardiogram, and Holter monitor. The blood work and electrocardiogram were normal but results of the echocardiogram and Holter monitor were pending. On 14-MAY-2008 the patient was seen in the physician's office due to a transient episode of "heart beating fast" and dizziness while she was at school earlier that day. Vital signs were normal at the time of the examination. The physician reported that on 27-MAY-2008, the patient was seen in the office for her second dose of GARDASIL. Her exam was normal. The physician noted that the second dose of GARDASIL was deferred until final test results became available. Additional information has been requested. This is a consolidation of two reports concerning the same patient.

Other Meds: [Therapy unspecified]

Lab Data: Electrocardiogram, 05/12/08, normal; Echocardiography, 05/12/08, pending results; Holter monitoring, 05/12/08, pending results; Complete blood cell, 05/12/08, normal; Vital sign, 05/14/08, normal; Full blood chemistry, 05/12/08, normal; Ser

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **317052-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	--	WAES0806USA00053	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling, Malaise, Nausea, Pyrexia, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a 22 year old female with sulfonamide allergy to an unspecified pertussis vaccine and a history of kidney stone and other kidney problems who in January 2008, was vaccinated with the first dose of GARDASIL (lot#, dose and route not reported). Concomitant therapy included YAZ and ZOLOFT. In January 2008, after first dose of GARDASIL the patient reported that the injection site was very swollen and painful for approximately 4 weeks. She noted that after the second dose of GARDASIL (lot #, date, dose and route not reported) the injection site became swollen and painful. The patient also noted that 5-6 hours after vaccination she developed a fever, began vomiting, and proceeded to feel nauseous and sick for approximately 3 weeks. At the time of the report, the patient reported that she no longer felt sick; however the injection site was still swollen and painful. Unspecified medical attention was sought. No further information was available. Additional information is not expected.

Other Meds: YAZ

Lab Data: None

History: Kidney stone; Renal disorder

Prex Illness: Sulfonamide allergy; Allergy to vaccine

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317053-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	07-May-2008		16-May-2008	01-Jul-2008	IL	WAES0806USA00073	01-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site induration, Injection site pain, Injection site swelling, No reaction on previous exposure to drug

Symptom Text: Information has been received from a nurse concerning a 26 year old female who on an unspecified date was vaccinated with first dose of GARDASIL vaccine (yeast) and had no reaction. On an unspecified date the patient was vaccinated with a second dose of GARDASIL vaccine (yeast). On approximately 07-MAY-2008, "about 3 weeks ago" the patient experienced a swollen, painful and hard injection site. The patient sought medical attention at the physician's office. At the time of report, the patient was not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317054-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		16-Jun-2008	15-Jul-2008	NJ	WAES0806USA00084	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Human papilloma virus test positive

Symptom Text: Information has been received from a nurse concerning a 20 year old female patient with no medical history or known drug reactions who was vaccinated (date unknown) with a first dose of GARDASIL (lot # not provided). There was no concomitant medication. The patient was reported as HPV positive (PAP smear found cell abnormality). The patient contacted the physician for unknown medical attention. The patient has not recovered. There was no product quality complaint involved. Additional information has been requested.

Other Meds: None

Lab Data: Cervical smear, cell abnormality

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **317055-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-May-2008	28-May-2008	12	16-Jun-2008	15-Jul-2008	MD	WAES0806USA00089	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Herpes virus infection, Lymphadenopathy, Pyrexia

Symptom Text: Information has been received from a physician concerning a 13 year old female, with no relevant medical history and no known drug allergies, who on 16-MAY-2008 ("two weeks ago") was vaccinated with her first dose of GARDASIL (Lot #, site and route not reported). There was no concomitant medication. On 28-MAY-2008 the patient experienced multiple herpetic lesions, inguinal adenopathy and fever. The patient sought unspecified medical attention by seeing the physician. As of the time of third report, patient's multiple herpetic lesions and inguinal adenopathy and fever persisted. No further information was provided. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **317056-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	21-Apr-2008	21-Apr-2008	0	16-Jun-2008	14-Jul-2008	--	WAES0806USA00098	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Malaise

Symptom Text: Information has been received from a 23 year old female with genital warts and a history of papilloma viral infection who on 21-FEB-2008 was vaccinated with the first dose of GARDASIL (Lot # not provided). On 21-APR-2008 the patient reported she went to see her physician because she was "sick" (NOS) and was prescribed unspecified antibiotics. She reported that she mentioned to her physician that she was due for her second dose of GARDASIL and was then given her second dose of GARDASIL (Lot # not provided) that same day. On an unspecified date the patient returned to the clinic because she was concerned that she had received her second dose of GARDASIL when she was "sick and on antibiotics". She was seen by a different physician who she reported stated that "she should not have taken the second dose of the vaccine because she was sick and her immune system was low at that time". Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Papilloma viral infection

Prex Illness: Genital wart

Prex Vax Illns:

Vaers Id: 317057-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	27-Dec-2007	01-Jan-2008	5	16-Jun-2008	15-Jul-2008	--	WAES0806USA00259	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Addisons disease, Blood pressure decreased, Dyspnoea, Heart rate increased, Hypoxia, Orthostatic hypotension, Oxygen saturation decreased, Pain, Respiratory rate increased, Tachycardia, Vomiting

Symptom Text: Information has been received from a nurse concerning a 19 year old female who on unspecified date was vaccinated with dose 1 and dose 2 of GARDASIL (Lot #'s not provided). Subsequently, on an unspecified date the patient was diagnosed with Addison's disease. Additional information has been requested. 07/14/2008 MR received for DOS 5/08-12/2008 with D/C DX: Addison's Disease, postural hypotension and hypoxia. Pt presented to ER with 1 wk hx of episodes of shortness of breath with tachycardia, most recently accompanied by emesis (last 3 days) and sometimes pain. BP did drop and HR&RR up with orthostatics. With ambulation O2 sat dropped to 85%. Treated with Cortisone. To f/u as outpt. 9/25/2008 MR received from PCP including various hospital diagnostics. Seen in F/U for above hospital visit./

Other Meds: Unknown

Lab Data: Labs and Diagnsotics: CT scan of adrenal glans WNL. CXR WNL. EKG in sinus tach. at 103. PFTs WNL. Chemistry significant for Na+ 131, K+ 5.5. ACTH >1250. Prolactin 45.3. Cortisol total 4.5. Adrenal autoantibody titre>1:8. Aldosterone <3.0

History: Unknown. PMH: ADD. Anxiety.

Prex Illness:

Prex Vax Illns:

Vaers Id: **317058-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	KY	WAES0806USA00495	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Palpitations

Symptom Text: Information has been received from a physician concerning a female who was vaccinated on an unspecified date with a dose of GARDASIL (lot# not reported). Subsequently, 12 or more hours after the vaccination, the patient experienced palpitations. The patient also had a cold at the time but had not taken any medication. She also had a low grade fever attributed to the cold. The patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness: Cold

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317059-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-May-2008	06-May-2008	1	16-Jun-2008	15-Jul-2008	NV	WAES0806USA00975	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a registered nurse concerning a 17 year old white female with penicillin allergy and postpartum disorder at the time of vaccination who on 05-MAY-2008 was vaccinated with GARDASIL (lot# 659182/1757U) IM in the right deltoid at 4 PM. On 06-MAY-2008 at 11 AM the patient experienced hives. The physician recommended the patient to take BENADRYL and to call if not better. At the time of reporting it was unknown if the patient had recovered. The physician discontinued GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data:

History: Penicillin allergy

Prex Illness: Postpartum disorder

Prex Vax Illns:

Vaers Id: **317060-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	MD	WAES0806USA00986	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Herpes zoster

Symptom Text: Information has been received from a physician concerning an approximately 20 year old female (twin sister), who in approximately March 2008 (date reported as "within the last two months) was vaccinated with GARDASIL (lot# unspecified). It was reported that on unspecified date after receiving GARDASIL the patient and her twin sister developed Shingles. It was also reported that "they do not live together". Unspecified medical attention was sought. At the time of this report, the outcome was unknown. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317061-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	AL	WAES0805USA00988	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered nurse concerning a female (age not reported) who on an unspecified date was vaccinated with the first dose of GARDASIL (lot not reported). After receiving the first dose the patient experienced a rash on her abdomen and her arm. The patient took some BENADRYL and got prednisone (manufacturer unknown). The patient came back to the physician's office because she wanted to get the second shot of GARDASIL (lot not reported). About a week after the shot the patient broke out in to even more extensive rash and had to get prednisone again. The nurse reported she will not administer the third dose of GARDASIL. The patient's status was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317062-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	14-Apr-2008	21-Apr-2008	7	16-Jun-2008	14-Jul-2008	--	WAES0805USA01005	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a nurse concerning a 21 year old female with asthma who on 14-JAN-2008 was vaccinated IM in the upper left arm with the first 0.5 mL dose of GARDASIL (lot 660391/0063X). On 14-APR-2008 the patient was vaccinated IM in the upper left arm with the second 0.5 mL dose of GARDASIL (lot 660391/0063X). Concomitant therapy included APRI and albuterol. After the second dose the patient went mountain bike riding. On 21-APR-2008 the patient complained of pain in the upper left arm and shoulder. No numbness, no tingling, no fever, vital signs were stable. No treatment except for over the counter ibuprofen. Doctor's office suggested to patient follow up with orthopedic doctor. The patient has not recovered. Additional information has been requested.

Other Meds: albuterol, APRI

Lab Data: vital sign, stable

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **317063-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		16-Jun-2008	15-Jul-2008	FL	WAES0805USA01039	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Information has been received from a physician concerning a 15 year old female who was inadvertently vaccinated with an unspecified dose of GARDASIL (lot number unspecified) in the hip. Subsequently the patient experienced numbness on her leg. The patient sought unspecified medical treatment. The patient's numbness in leg persisted. The patient was re-evaluated after 2 days. Her symptoms did not improve. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 317064-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Jun-2008	16-Jun-2008	0	23-Jun-2008	27-Jun-2008	PA		27-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Syncope- this pt actually passed out about 3 minutes after receiving the injection. We had to use an ammonia inhalant to help her come to.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317065-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	14-Jul-2008	--	WAES0805USA01058	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Information has been received from a health professional concerning a female teenager who in April 2008 (reported as a "month ago") was vaccinated intramuscularly with a first dose of GARDASIL (Lot # not reported). Within 24-48 hours of vaccination, the patient experienced nausea, dizziness and feeling faint for a day. Therapy with GARDASIL was discontinued, as her mother refused to allow her to receive the second and third doses. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317066-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	06-Jun-2008	06-Jun-2008	0	23-Jun-2008	30-Jun-2008	PA		30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pallor, Syncope

Symptom Text: Syncope - this patient got dizzy about 5 minutes after receiving the injection. She told us and we sat her down - she then became very pale and nauseous along with the dizziness.

Other Meds: Ortho Tricyclen

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 317067-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	11-Mar-2008	11-Mar-2008	0	16-Jun-2008	14-Jul-2008	CA	WAES0805USA01062	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Chills, Dizziness, Dyspnoea, Fatigue, Headache, Heart rate increased, Musculoskeletal stiffness

Symptom Text: Information has been received from a nurse practitioner concerning a 13 year old female with no known drug reaction/allergies and a history of slow heart rate and an adjustment problems since moving to another country, who on 11-MAR-2008 was vaccinated intramuscularly with a first dose of GARDASIL (Lot # 659657/1487U). On the same day the patient was vaccinated with VAQTA and MENACTRA. After receiving the first dose of GARDASIL, on 11-MAR-2008, the patient experienced intermittent episodes of dizziness. Two days later, on 13-MAR-2008, the patient experienced dizziness, shortness of breath and increased heart rate which lasted a couple minutes. The next day, on 14-MAR-2008, the patient experienced fatigue, headache and tightness at the back of the neck. On 18-MAR-2008 the patient experienced shortness of breath, chills, dizziness. Later that same day she had 2 short episodes of dizziness and tightness in chest. Subsequently, "about two weeks ago", on approximately 21-APR-2008, the patient recovered. The patient was seen in the doctor's office for unspecified medical attention. No product quality complaint was involved. Additional information has been requested.

Other Meds:

Lab Data: None

History: Heart rate low; Adjustment disorder

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317068-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	12-Jun-2008	12-Jun-2008	0	23-Jun-2008	30-Jun-2008	NC	NC08079	30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB233AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Depressed level of consciousness, Dizziness, Heart rate decreased, Oxygen saturation, Pallor

Symptom Text: After receiving injections, patient complained of stomach ache and feeling lightheaded, sat on floor at check out counter, then color changed, paler and became less responsive, carried to exam room. Layed down, legs lifted, 02 99%, pulse 60, B/P 120/68 at 4pm. Rev 10 mins, O2 100%, pulse 74 lay, sat up 80, stand 85. With patient say felt better, sent home.

Other Meds: N/A

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **317069-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jun-2008	15-Jul-2008	FL	WAES0806USA01580	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Gluteous maxima	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site

Symptom Text: Information has been received from a physician concerning an unspecified number of female patients who were administered vaccinations with GARDASIL (Lot# not reported) in the buttocks. The patients outcomes are unknown. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317113-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	06-Aug-2007	06-Aug-2007	0	24-Jun-2008	24-Jun-2008	NC	WAES0709USA03322	25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0388U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received from a registered nurse for the Pregnancy Registry for GARDASIL concerning an 18 year old female who on 06-AUG-2007 was vaccinated intramuscularly in the deltoid with the first dose of GARDASIL (lot # 657622/0388U). It was reported that at the time of vaccination the patient was not pregnant. It was reported that the patient's last menstrual period was on 01-AUG-2007 and not on 01-AUG-2006 as it was previously reported. Four weeks after vaccination the patient was involved in a motor vehicle accident. After the motor vehicle accident the patient found out that she was pregnant. The pregnancy was confirmed (method unknown). At the time of the report it was unknown how far along the patient was in her pregnancy. On 12-JUN-2008 a telephone call was made to the doctor's office to obtain pregnancy outcome information and a message was left. On 13-JUN-2008 the nurse called back and reported that the patient "had a miscarriage early on in her pregnancy." She had no further information. Upon internal review patient having a miscarriage in her early pregnancy was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Motor vehicle accident

Prex Illness:

Prex Vax Illns:

Vaers Id: 317114-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	31-May-2007	27-Aug-2007	88	24-Jun-2008	24-Jun-2008	VA	WAES0710USA03548	25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received through the Merck pregnancy registry from a health professional concerning a female consumer with a history of being hearing impaired, abnormal pap smears, positive for high-risk HPV and an elective termination of previous pregnancy (7 weeks from LMP) who on 30-APR-2007 was vaccinated with the first dose of GARDASIL. The patient received the second dose of GARDASIL on 31-May-2007 and the third dose of GARDASIL on 20-Sep-2007. Subsequently, it was learned that the patient was probably pregnant at the time she received the third dose. The pregnancy was confirmed by a pregnancy test (LMP=27-Aug-2007). The patient sought unspecified medical attention. The patient did not have any adverse side effects. The outcome was unknown. The patient has transferred to another OB/GYN. On 17-JUN-2008 a follow up telephone call was made to the doctor's office for pregnancy outcome of the patient. The nurse reported that the patient had a scheduled primary Cesarean Section for anticipated size greater a than dates at 38+6 weeks estimated gestational age. She mentioned that patient had a healthy and normal female baby, weighing 8 lbs, 15 Oz. Both mother and baby were doing "fine". Upon internal review patient having Cesarean Section for anticipated size greater than 38+6 weeks was determined to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: beta-human chorionic - positive

History: Hearing impaired; Papilloma viral infection; Papanicolaou smear abnormal; Termination of pregnancy - elective

Prex Illness:

Prex Vax Illns:

Vaers Id: 317115-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	28-Sep-2007	Unknown		24-Jun-2008	24-Jun-2008	MI	WAES0712USA01399	25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Urinary tract infection

Symptom Text: Information has been received from a 25 year old female health professional with no drug reactions/ allergies and a history of 2 pregnancies (1 live birth and one elective abortion) who on 20-JUL-2007 was vaccinated with her first dose of GARDASIL, 0.5mL injection. There was no concomitant medication. On 28-SEP-2007 the patient received her second dose of GARDASIL, 0.5ml injection. On 08-OCT-2007 the patient found out that she was 8 to 9 weeks pregnant after getting the first and second doses of GARDASIL. On 27-NOV-2007 an ultrasound was performed with a normal result, "uncertain EDD", estimated to be 31-MAy-2008. Estimated conception date was 24-Aug-2007. The patient sought medical attention. Follow-up information reported that the patient had 2 previous pregnancies. One of those ended in a full term delivery, the other in a miscarriage 8 weeks from LMP. Follow-up information was received. The father of the baby was a cousin with congenital heart problems. On an unspecified date the patient had a urinary tract infection and was given MACROBID. On 27-NOV-2007 and 17-DEC-2007 the patient had a maternal serum alpha-fetoprotein test performed and the results were negative. The reason for the test was the baby's half-brother has downs syndrome. On 28-MAY-2008 a 9 pound 5 ounce baby boy was born. The length was 20 inches and 39 and 4/7 weeks from LMP. The baby's head circumference was 14 inches. The baby was large for the dates and in respiratory distress secondary to pulmonary edema and right pneumothorax. Upon internal review respiratory distress, pulmonary oedema and pneumothorax was considered to be an other medical event. Additional information has been requested.

Other Meds: MACROBID 100 mg

Lab Data: ultrasound, 11/27/07, normal, uncertain EDD; serum alpha-fetoprotein, 11/27/07, negative; serum alpha-fetoprotein, 12/17/07, negative

History: Pregnancy; Live birth; Termination of pregnancy-elective

Prex Illness:

Prex Vax Illns:

Vaers Id: 317116-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Aug-2007	21-Aug-2007	0	24-Jun-2008	24-Jun-2008	--	WAES0801USA01405	25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Congenital anomaly, Drug exposure during pregnancy, Live birth, Sinusitis

Symptom Text: Information has been received from the Merck Pregnancy Registry from a physician concerning a 15 year old white female with penicillin allergy and no reported medical history who on 21-AUG-2007 was vaccinated with her first dose of GARDASIL (Lot #6578621/0387U) and was pregnant (noted as her first pregnancy). ECD is 12-MAY-2007 and patient's LMP was 06-AUG-2007. Concomitant therapy included azithromycin (manufacturer unspecified). Lab tests included a prenatal screen (no results reported). On 04-SEP-2007 the patient experienced sinusitis. From October 2007 to May 2008 the patient took prenatal vitamins daily. On 18-OCT-2007 an ultrasound was performed to assess fetal development and was normal. Follow up information reported that on 30-APR-2008 the patient vaginally delivered a full term, live born, normal and healthy female who weighed 7 pounds 6 ounces, 19 3/4 in length apgar score 9/9 and a head circumference of 13 3/4. It was reported that the infant had a small congenital anomaly. According to the nurse, the physician's notes also indicated "bilateral hands with rudimentary 6th digit." The nurse stated that it was also noted that there is a positive family history of similar digits. There were no other anomalies and no complications for mother or baby. Additional information has been requested.

Other Meds: azithromycin 250 mg

Lab Data: ultrasound 10/18/07 - assess fetal development: Normal

History:

Prex Illness: Pregnancy NOS (LMP = 8/6/2007); Penicillin allergy

Prex Vax Illns:

Vaers Id: 317117-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Feb-2008	02-Apr-2008	61	24-Jun-2008	24-Jun-2008	NJ	WAES0805USA01035	25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received from the Merck Pregnancy Registry for GARDASIL and a nurse practitioner concerning an 18 year old female with a history of gonorrhoea and vaginitis who on 01-FEB-2008 was vaccinated with a first dose of GARDASIL (Lot number 658556/1060U). Concomitant therapy included LOESTRIN 24 FE and FLAGYL. On 28-APR-2008 the patient was vaccinated with a second dose of GARDASIL (Lot number 660387/1967U) and at same visit was found to be pregnant after a positive urine pregnancy test (LMP=02-Apr-2008). At the same visit the patient also had a regular pap test. It was reported that the patient was vaccinated in right leg. No problems reported. On 31-MAY-2008 the patient terminated the pregnancy. Upon internal review, terminated pregnancy was considered to be an other important medical event. Additional information has been requested.

Other Meds: LOESTRIN 24 FE; FLAGYL

Lab Data: urine beta-human 04/28/08 posit; Pap test 04/28/08

History: Gonorrhoea; Vaginitis

Prex Illness:

Prex Vax Illns:

Vaers Id: 317118-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
38.0	F	30-May-2008	30-May-2008	0	24-Jun-2008	25-Jun-2008	FR	WAES0806KOR00003	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0937U		Left leg	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cellulitis, Chills, Feeling hot, Inappropriate schedule of drug administration, Incorrect route of drug administration, Oedema peripheral, Pain in extremity, Pyrexia, Tenderness

Symptom Text: Information has been received from a health professional via company representative concerning a 38 year old female with old tuberculosis (diagnosed in April 2008) who on 30-MAY-2008 at 14:00 was vaccinated with a dose of GARDASIL (Lot no. 658486/0937U, expiry date: 02-APR-2010), subcutaneous injection in her left arm (intentional use of unlabelled indication of GARDASIL and inappropriate use of GARDASIL vaccination). Concomitant therapy included MYAMBUTOL, isoniazide, pyridoxine and rifampin for her tuberculosis. In the afternoon on 30-MAY-2008 the patient experienced fever, chills. On 31-MAY-2008 the patient experienced swelling in the right arm, pain in the right arm, heating sensation in the right arm and tenderness in the right arm (size 7*10 cm). The patient took PONTAL. At 21:00 on 01-JUN-2008 the patient was hospitalized via emergency room because of fever (over 40 celsius degree). The laboratory test results were noted as follows: WBC 11,630/mm^3, platelet 197,000/mm^3, hemoglobin 13 g/dl, C-reactive protein 13.7. The patient was diagnosed with cellulitis and then was treated with UBACILLIN 750 mg, injection, q.i.d from 01-JUN-2008 to 07-JUN-2008. Thereafter the patient recovered from her fever on 04-JUN-2008. The laboratory test results were as follows: WBC 4,570/mm^3 and C-reactive protein 2.73. Subsequently, the patient recovered from the symptoms of cellulitis {fever, chills, swelling in the right arm, pain in the right arm, heating sensation in the right arm and tenderness in the right arm and was discharged on 07-JUN-2008. The reporter said that there was no issue on the vaccine storage in the hospital. No adverse experience was reported so far in patients other than this patient who were vaccinated with same batch number. Causality with GARDASIL was not reported. The reporter asked the company further investigation of these events. The subsidiary asked the company further investigation of these events. The subsidiary PV Contact asked the QA check to the subsidiary MMD, and received the response th

Other Meds: ethambutol hydrochloride Apr08 - Cont; isoniazide Apr08 Apr - Cont; pyridoxine Apr08 - Cont; rifampin 01Apr08 - Cont

Lab Data: WBC count, 01Jun08, 11630 /mm^3; body temp, 01Jun08, over 40 celsius degree; hemoglobin, 01Jun08, 13 g/dl; platelet count, 01Jun08, 197000 /mm^3; serum C-reactive protein, 01Jun08, 13.7; WBC count, 04Jun08, 4670 /mm^3; serum C-reactive prot

History:

Prex Illness: Old tuberculosis

Prex Vax Illns:

Vaers Id: **317119-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Apr-2008	01-Apr-2008	0	24-Jun-2008	25-Jun-2008	NY	WAES0806USA03354	25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Emotional distress, Haemorrhage

Symptom Text: Information has been received from the mother of a consumer and a health professional for the pregnancy registry for GARDASIL, concerning a 17 year old female with pertinent medical history reported as unremarkable, who on an unspecified date in April 2008, was vaccinated with the first dose of GARDASIL, IM in the arm. There was no concomitant medication. On 22-MAY-2008 the patient received the second dose of GARDASIL. Subsequently, she became pregnant. The patient sought unspecified medical attention and had blood work. No results were provided. On 29-MAY-2008, the patient had a fetal ultrasound which revealed that the fetal pole was not identified and there was "no gestational sac." The patient's last menstrual period or weeks of gestation were not reported. The patient had a miscarriage on 11-JUN-2008. At the time of the report, the daughter was still having clots and bleeding due to the miscarriage, and was emotionally distressed. No other information was provided. Upon internal review it was determined that miscarriage was an other important medical events. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory, bloodwork- no results reported; ultrasound, 05/29/2008, fetal pole not identified; "no gestational sac"

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 317120-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-May-2007	01-Jun-2007	31	24-Jun-2008	25-Jun-2008	TX	WAES0806USA03438	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Amenorrhoea, Conversion disorder, Convulsion, Epilepsy, Somnolence, Syncope, Vaccine positive rechallenge, Weight decreased

Symptom Text: Information has been received from a physician concerning an 18 year old female with a history of Apgar score low and congenital hearing loss who in May 2007, was vaccinated with a first dose of GARDASIL 0.5 mL IM. Concomitant therapy included LOESTRIN. In June 2007, the patient experienced a grand mal seizure. The patient received her second dose of GARDASIL in July 2007. In July 2007 and August 2007 the patient experienced a seizure again and was hospitalized. The patient was seen by a neurologist. The neurologist prescribed the patient KLONOPIN. Subsequently the patient experienced 15 pound weight loss and amenorrhea. The patient was then seen by a psychiatrist who stated that he believed the seizures were due to physiological and prescribed additional medications (therapy unspecified). At the time of reporting the patient was recovering. No additional information was available. The reporter considered the events of grand mal seizure, seizure, weight loss and amenorrhea to be other medical events. Additional information has been requested. 7/9/08-records received-evaluation 1/4/08-fainting spells and seizures-Impression:conversion disorder with mixed presentation with symptoms of motor and sensory deficits as well as psychogenic seizures. Experiencing extreme psychological stress unable to deal with, derives secondary gain from the symptoms and gain attention. 7/10/08-records received for DOS 8/13/07- 8/17/07-Assessment:spells, these do not seem to be seizure with maintined consciousness during the spells. Consider psychosomatic etiology. Onset of syncope 2 years ago, circumstances of syncope burning sensation followed by altered sensorium, recalls the entire envents which last 10-12 minutes). Increasing in frequency, college entrance examination. Developed stuttering speech pattern, crying spells and jerking spell while in waiting room. 8/31/07-Condition improved. 7/10/08-records received for DOS 8/9-8/12/07-DC DX: epilepsy. Prolonged complex seizures. Somnolent due to phenobarital.

Other Meds: LOESTRIN

Lab Data: 7/10/08-records received-MRI-chronic white matter disease likely from birth. EEG normal.

History: Apgar score low; Hearing loss 7/10/08-records received-Onset of syncope 2 years ago,

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317121-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Dec-2007	01-May-2008	152	24-Jun-2008	25-Jun-2008	FR	WAES0806USA03495	25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myelitis, No reaction on previous exposure to drug

Symptom Text: Information has been received from a physician and a consumer regarding his adult daughter (age not reported) who was well tolerated with the first vaccination with GARDASIL, in December 2007, was vaccinated with a second dose of GARDASIL (injection site, route of administration, Lot# unspecified). In May 2008, the patient was diagnosed with myelitis. The patient's physician did not see a causal relationship to therapy with GARDASIL. Myelitis was considered to be an other important medical event. Other business partner numbers include E2008-05431 (0). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317122-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		24-Jun-2008	25-Jun-2008	--	WAES0806USA03777	25-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paralysis

Symptom Text: Information has been received from a health professional "that heard of" a patient (age unknown), who, on an unspecified date, was vaccinated with a dose of GARDASIL. Subsequently, the patient experienced temporary paralysis of her legs. At the time of the report, the outcome of the patient was unknown. No product quality complaint was involved. Upon internal review temporary paralysis of her legs was considered to be an other important medical event. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317147-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		24-Jun-2008	27-Jun-2008	CT		30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2622AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Hyperhidrosis, Pallor, Somnolence, Syncope

Symptom Text: Syncopal episode with prolonged (approx 45 minute). Sleepy state afterwards. c/o headache. arrousable but then would close eyes and not interact, pale, diaphoretic positive postural vital sign changes.

Other Meds: Concerta 54 mg QD; (none taken day of onset)

Lab Data: glucose 102; UA negative. previous EKG nl

History: ADD

Prex Illness: None

Prex Vax Illns:

Vaers Id: **317148-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Feb-2007	Unknown		24-Jun-2008	30-Jun-2008	IN		30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2228AA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	AHAVB163AB		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Dizziness, Tremor

Symptom Text: (1) hair loss June 08', (2) eye lashes falling out Nov 07', (3) dizzy/shaking/light headedness Nov 07'

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317159-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Jun-2008	13-Jun-2008	2	24-Jun-2008	27-Jun-2008	CA		27-Jun-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1287U	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2537AA	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2826AA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1502U	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cellulitis, Injection site erythema, Injection site warmth, Rash

Symptom Text: 6/13/2008 clinic visit with complaint of rash on both arms. Physicians notes: right arm with 12cm. x 8cm. erythema with warmth on right humerus. Two puncture marks were vaccines were given were in upper part of erythema. Diagnosis: cellulitis. MD ordered: trimethoprim - sulfamethoxazole 160-800mg 1 tab 2x 1 day x10 days.

Other Meds: None

Lab Data: None ordered

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317171-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Jun-2008	19-Jun-2008	0	24-Jun-2008	27-Jun-2008	PA		27-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Joint injury, Syncope

Symptom Text: Patient had received her 1st GARDASIL injection. While receiving return visit instructions, patient fainted, hitting her head L elbow & L knee. Attended by staff & MD. Vital signs WNL, examined by MD & given po fluids prior to discharge home.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317172-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Jun-2008	17-Jun-2008	0	24-Jun-2008	27-Jun-2008	MI		27-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling of body temperature change, Headache, No reaction on previous exposure to drug, Vomiting

Symptom Text: Received GARDASIL #3-within 30 minutes has headache, vomiting x1, and hot/cold flashes. No prior reaction to vaccine.

Other Meds: TB test done June 9th at different location per pt.

Lab Data:

History: none

Prex Illness: on menstrual cycle

Prex Vax Illns:

Vaers Id: 317236-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	19-Mar-2008	20-Mar-2008	1	24-Jun-2008	02-Jul-2008	NY		03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Listless, Pyrexia

Symptom Text: PATEINT REPORTED TO MD AT F/U APPT 6/08 THAT SHE HAD EXPERIENCED ADVERSE REACTION AFTER BOTH GARDASIL INJECTIONS IN MARCH,2008 AND MAY 2008. REACTION INCLUDED FATIGUE,FEVER, LISTLISSNESS LESS THAN 24 HOURS AFTER RECEIVING INJECTIONS LASTING ABOUT 4- 5 DAYS. PATIENT FOLLOWED UP WITH PRIMARY CARE PHYSICIAN RATHER THAN THROUGH HER GYN PHYSICIAN AND DID NOT MAKE OFFICE AWARE THAT SHE HAD HAD AN ADVERSE REACTION AFTER IST VACCINE

Other Meds: ORAL CONTRACEPTIVES

Lab Data: DONE THROUGH PCP OFFICE NOT AVAILABLE

History:

Prex Illness: NONE KNOWN

Prex Vax Illns: PT REPORTS SAME REACTION TO 2ND GARDASIL 5/14/08~HPV (Gardasil)~2~24~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317247-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Jun-2008	17-Jun-2008	1	24-Jun-2008	02-Jul-2008	--		03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oedema mouth, Rash pruritic, Swollen tongue

Symptom Text: Within 24 hours of vaccine administration, patient developed an itchy rash, tongue and soft palate swelling. This reaction resulted in two additional doctor visits requiring and injection of steroids, and a prescription of a steroid dose pack.

Other Meds: None

Lab Data:

History: Allergic to Sulfa, Codiene, and Omnicef

Prex Illness: None

Prex Vax Illns:

Vaers Id: **317263-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Jun-2008	08-Jun-2008	4	24-Jun-2008	01-Jul-2008	NM		01-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0960F	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: (L) supraclavicular lymphadenopathy - chest x-ray, blood work, referral to oncology.

Other Meds:

Lab Data: CBC, LDH, Uric acid wnl, Chest x-ray with calcified granulomata

History: Exercise induced asthma

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: **317268-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Jan-2008	14-Feb-2008	22	24-Jun-2008	01-Jul-2008	MA		02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise, Pain in extremity, Skin exfoliation, Urticaria

Symptom Text: Hives all over body, x 5days, scaling feet and hands, pain feet with walking, c/w severe sickness; treated Prednisone P8. Benadryl. hives still continue /on/off

Other Meds: ORTHO TRI-CYCLEN

Lab Data: None

History:

Prex Illness: No

Prex Vax Illns:

Vaers Id: **317337-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Sep-2007	10-Sep-2007	0	25-Jun-2008	26-Jun-2008	OH	WAES0710USA03564	26-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Labour complication, Live birth

Symptom Text: Information has been received from a consumer for the pregnancy registry for GARDASIL, concerning her 15 year old daughter with a history of ear problems who on 10-SEP-2007 was vaccinated with her first dose of GARDASIL and is pregnant. Her last menstrual period was reported as 22-AUG-2007 and her estimated delivery date was 28-MAY-2008. The patient sought unspecified medical attention. Follow-up information has been obtained from a registered nurse who reported that the patient delivered a full term 9 pound 21 inch long, normal, healthy, female via primary cesarean section on 22-MAY-2008. There were no reported complications or congenital anomalies. Upon internal review it was determined that the labour complication that required a cesarean section was an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Ear disorder

Prex Illness:

Prex Vax Illns:

Vaers Id: 317338-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
45.0	F	25-Mar-2008	25-Mar-2008	0	25-Jun-2008	26-Jun-2008	FR	WAES0806USA03240	26-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Breast swelling, Bronchospasm, Condition aggravated, Dysphonia, Dyspnoea, Fluid retention, Inappropriate schedule of drug administration, Injection site pain, Injection site swelling, Laryngeal oedema, Laryngospasm, Myocardial ischaemia, Off label use, Pyrexia, Sinusitis, Stridor, Thyroiditis, Tracheal oedema

Symptom Text: Information has been received from a patient, concerning a 45 year old female patient who was a HCP herself (dermatologist), with no allergies and no relevant medical history and at the time of vaccination she had herpes infection. On 25-MAR-2008, the patient was vaccinated with GARDASIL, (primary No 2 in series, batch number, route and site of administration not reported). As the woman was probably older than 26, it was probably off label use. Severe injection site pain and slight injection site swelling developed (the day of vaccination), she could not lie upon the spot. The pain lasted 2 weeks. 1 day after vaccination she developed high fever, she was almost hallucinating. After a few days, when she felt slightly better, her temperature was 39.6 C. Since 1 day after vaccination, she seemed to develop bronchospasm: shortness of breath and hoarseness developed, which increased in the days after that. She visited the GP after 3 days because she suspected upper respiratory tract infection, pneumonia or bronchitis. The GP said that her lungs were clean, but he prescribed Atrovent. She visited a lung specialist, who diagnosed that she did not have Asthma, but he did prescribe symbicort and nasal spray. She received antibiotics as well after telephonic consultation with the GP. A few weeks after vaccination she developed sinusitis, which caused aggravation of the shortness of breath and hoarseness. She received a second time antibiotics, and dexamethazon for 10 days and a second nasal spray. She left on April 24, developed shortness of breath during the night, for which she was taken to the ER on April 25. Her trachea was almost completely closed. Diagnosis: stridor, tracheal oedema. An ECG showed cardiac ischaemia. She received Solumedrol 125 milligram, epinephrine and Benadryl. She was monitor guarded in hospital for 5 days. On 30-APR-2008 she developed again laryngeal oedema and laryngeal spasms. The ENT specialist diagnosed oedema of the vocal cords as well, which explains her hoarseness. Sh

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Herpes virus infection

Prex Vax Illns:

Vaers Id: 317339-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-Jun-2007	02-Oct-2007	96	25-Jun-2008	26-Jun-2008	FR	WAES0806USA03241	26-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acarodermatitis, Arthralgia, Chondropathy, Condition aggravated, Dermatitis atopic, Dermatitis contact, Fatigue, Herpes zoster ophthalmic, Hyperhidrosis, Malaise, Nausea, Peripheral vascular disorder, Pruritus, Rash, Sensation of foreign body, Sleep disorder

Symptom Text: Information has been received from an agency, concerning a 14 year old female patient who was vaccinated with a second dose of GARDASIL (Batch #NF27880, Lot #1518F) intramuscular into left upper arm on 25-SEP-2007. The patient already felt unwell and experienced peripheral circulatory disorder 1 week after first vaccination with GARDASIL on 28-JUN-2007. History of knee bruise after an accident on 28-FEB-2007. On 12-JUL-2007 MRI of the knee showed normal results. On 03-SEP-2007 patellar chondropathy was diagnosed. 7 to 10 days p.v. the patient felt unwell and experienced exanthema, increased sweating and nausea. 6 weeks p.v. the patient developed a "worsening" of the left knee, Morbus Sudeck was suspected. On 08-DEC-2007 the patient developed ophthalmic herpes zoster. The patient was hospitalised on an unspecified date. Serology, several MRI, ECG, EEG and neurological examination were carried out (no results reported). The patient recovered from feeling unwell, exanthema, increased sweating and nausea after "weeks", from herpes zoster ophthalmic after 14 days. At the time of reporting to HA (18-MAR-2008) complaints in the area of the left knee were ongoing. Follow-up on 10-JUN-2008. HA provided us with several hospital reports and reports on findings. The patient had an accident on 28-FEB-2008 and achieved a knee bruise. MRI on 12-JUL-2007 showed normal results. On 03-SEP-2007 chondropathy of the knee was diagnosed. From 27-OCT-2008 till 30-OCT-2008 she was hospitalized because of scabies. At that time atopic eczema was present, too. Exact onset and duration of symptoms was not reported. On 16-NOV-2007 she presented again to a dermatologist. Atopic eczema was ongoing, additionally contact dermatitis was diagnosed. The patient was hospitalised from 10-DEC-2007 till 18-DEC-2007 because of Herpes zoster ophthalmic and allergic/atopic exanthema. The patient reported about nausea, sleep disorder, increased sweating and tiredness since about 8 weeks (exact onset not reported). She complained abou

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 12Jul07, showed normal results; chest X-ray, 12Dec07, showed normal result; magnetic resonance imaging, 12Dec07, showed normal result; electroencephalography, 13Dec07, showed normal results; hematology, 12Dec07,

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317340-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jan-2008	01-Jan-2008	0	25-Jun-2008	26-Jun-2008	FR	WAES0806USA03270	26-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hypokinesia, Immediate post-injection reaction, Injection site anaesthesia, Injection site pain, Pain in extremity

Symptom Text: Information has been received from a clinic pediatrician concerning a 14 year old female patient who was vaccinated with a second dose of GARDASIL (Batch # not reported) I.M. into the upper arm in January 2008 (exact vaccination date not reported). The patient developed numbness and pain of the arm (vaccination site) immediately p.v. The adverse events lasted for 2 to 3 days. Five months after this vaccination the patient developed suddenly pain in the extremities; she was unable to move her legs properly. The patient was hospitalized due to the adverse events on 05-JUN-2008. No pathological findings have been found. MRI (spinal + head), ENG and EMG were without pathological findings. The outcome of the events was not reported. Other business partner numbers included: E2008-05345. Additional information has been requested.

Other Meds: None

Lab Data: magnetic resonance imaging, 05Jun08, without pathological findings; electromyography, 05Jun08, without pathological findings; electronystagmography, 05Jun08, without pathological findings

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 317341-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	03-Jun-2008	04-Jun-2008	1	25-Jun-2008	26-Jun-2008	--	WAES0806USA03341	26-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Anorexia, Blindness, Dizziness, Fatigue, Headache, Migraine, Nausea

Symptom Text: Information has been received from a consumer concerning his 22 year old female friend with no pertinent medical history, drug reactions or allergies, who on 03-JUN-2008 was vaccinated with the first dose of GARDASIL, 0.5 ml, IM. There was no concomitant medication. It was reported that "the night after the vaccination," (04-JUN-2008), his friend developed "dizziness", nausea, headaches, migraine headaches, fatigue, 30 second periods of vision loss and loss of appetite. She had visited different hospitals in the area and had been admitted" a few times." The hospitalizations were for unknown periods of stay. The patient had unspecified bloodwork, magnetic resonance imaging (MRI), electroencephalography (EEG), electrocardiogram (EKG), magnetic resonance angiography (MRA) and "basically anything you can test for." There were no specifics in reference to the testing provided, and no results were reported. The patient is reportedly recovering. The patient will not be continuing the series. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory, bloodwork unspecified; magnetic resonance, no results reported; electroencephalography, no results reported; electrocardiogram, no results reported; vascular imaging, no results reported; diagnostic laboratory, basica

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **317370-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	10-Jun-2008	11-Jun-2008	1	25-Jun-2008	02-Jul-2008	GA		03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2635AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1968U	0	Gluteous maxima	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial pain, Musculoskeletal stiffness, Pain in jaw, Swelling face

Symptom Text: MENACTRA vaccine as well as GARDASIL vaccine given 6/10/2008. Pt described waking the next AM with c/o facial (cheek) swelling and pain in face and jaw - face felt stiff. Treated with Medrol Dose Pak. Symptoms resolved by 6/12/2008.

Other Meds: Byette

Lab Data:

History: NKDA; Hyperinsulinism

Prex Illness: None

Prex Vax Illns:

Vaers Id: **317374-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Jun-2008	18-Jun-2008	0	25-Jun-2008	02-Jul-2008	LA		03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1898U	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0063X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abscess, Erythema, Oedema peripheral, Skin infection, Tenderness

Symptom Text: Right deltoid erythema, tender swollen - not specific firm abscess or subQ infection noted

Other Meds: none

Lab Data: none

History: Osgood-Schlatter

Prex Illness:

Prex Vax Illns:

Vaers Id: **317389-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Jun-2008	25-Jun-2008	0	25-Jun-2008	03-Jul-2008	OH		03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	MERCK & CO. INC.	0379U	2	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1267U	1	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1781U	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy, Musculoskeletal stiffness, Pallor, Unresponsive to stimuli

Symptom Text: After injection of Hep B and varicella in the left arm and then Gardasil in the right arm, patient became very pale and she lay back on the exam table and was nonresponsive. Her eyes rolled back and her legs and arms stiffened. Eyes remained open throughout the episode and she "came to" within 1 minute. She continued to be pale for about 5 minutes but was oriented to person and place immediately upon "coming to". She sat up after about 10 minutes, color slowly came back to her lips.

Other Meds:

Lab Data: none

History: allergic to zithromax

Prex Illness: Said she was having stomach cramps from menses

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317405-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	19-Jun-2008	25-Jun-2008	6	25-Jun-2008	03-Jul-2008	GA		07-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0802U	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	183AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling cold, Injection site pain, Myalgia

Symptom Text: Client called with c/o of muscle aching and being "cold" yesterday 6-24-08. Denies fever and states has just minimal soreness at injection site. States aching started on 60-24-08 at injection site of HPV vaccine and spread to entire body and lasted only one day 6-24-08.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 317424-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Jun-2008	12-Jun-2008	0	25-Jun-2008	02-Jul-2008	ID	ID08027	03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dizziness, Flushing, Headache, Muscle spasms, Nausea, Pyrexia, Tremor

Symptom Text: Client received #3 HPV on 6-12-08 at 3:15 PM, no problems. At 9:30 PM - client started shaking x 45 minutes - then developed headache -face flushed then fever 99 took to ER. Doctor gave her Tylenol. 4 AM - at home awoke with 102 - muscle cramps - stomach ache, dizziness, nausea.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317425-1** **Related reports:** 317425-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Apr-2008	11-Jun-2008	55	25-Jun-2008	03-Jul-2008	OH		03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Confusional state, Dizziness, Dyspnoea, Fall, Headache, Loss of consciousness

Symptom Text: 6-11-08 woke up and was dizzy, weak, had breathing problems and "passed out". Told by mother to go to bed - woke up with severe headache and was confused. Fell "numerous" times. Mtr. took her to Emergency Dept. - given IV to aid severe headache. Follow-up - blood work, EEG and "lung tests".

Other Meds:

Lab Data:

History:

Prex Illness: None known.

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317425-2** **Related reports:** 317425-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.3	F	17-Apr-2008	11-Jun-2008	55	09-Dec-2008	18-Dec-2008	OH		18-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Dizziness, Dyspnoea, Fatigue, Headache, Malaise, Syncope

Symptom Text: Seizure-like activity. Dizziness. Syncope and collapse. Malaise and fatigue. Severe headaches. Abd. pain. Breathing issues.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 317428-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Jun-2008	24-Jun-2008	1	25-Jun-2008	03-Jul-2008	MI		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	U2428AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	0067X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Crying, Dizziness, Dyspnoea, Hyperventilation, Hypoaesthesia, Movement disorder, Panic attack, Paraesthesia, Vaccination complication

Symptom Text: TC from Grandmother; client awoke at midnight 6-24-08 (24 hours later) with numbness in all 4 extremities, dizziness and dyspnea. Took her to ER, she was treated for "panic attack" with Benadryl and muscle relaxer. Continues with tingling and cant make fist with her hands. 7/4/08 Reviewed hospital medical records of 6/25/2008. FINAL DX: vaccine reaction & panic crisis. Records reveal patient experienced SOB, crying, numbness/tingling, panic feeling, anxious, hyperventilating. No abnormal physical exam findings. Tx w/meds, improved & d/c to home.

Other Meds: Vitamin B

Lab Data: Blood drawn

History: Denies

Prex Illness: Denies

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317431-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-May-2008	08-May-2008	0	25-Jun-2008	03-Jul-2008	CA		03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Nausea

Symptom Text: HA, dizziness, nausea - 1-2 hours after vaccine ER visit.

Other Meds: None

Lab Data: Pulse Ox 99%

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 317539-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Oct-2007	17-Oct-2007	0	26-Jun-2008	27-Jun-2008	MD	WAES0711USA00896	27-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Foetal movements decreased, Hypertension, Pyrexia

Symptom Text: Initial and follow up information has been received from a registered nurse through the Pregnancy Registry for GARDASIL concerning a 14 year old female with a history of tinea versicolour and allergic rhinitis who on 17-OCT-2007 was vaccinated with her first dose of GARDASIL IM (lot# 657872/0515U) and was pregnant. Concomitant therapy included CLARITIN as needed for nasal symptoms. The patient sought unspecified medical attention in the office on 01-NOV-2007. On 02-NOV-2007 the patient had a positive urine pregnancy test (LMP reported as end of June 2007). The patient will be followed by her pediatrician. On 02-JAN-2008 the patient had an ultrasound which showed a single live intra-uterine pregnancy of 26 weeks. It was suggested she have another ultrasound for fetal anatomy. On 11-JAN-2008 the patient had a follow up ultrasound which showed normal progression of pregnancy. On 08-APR-2008, the patient had a fever of 102.5 and hypertension. It was also reported that the patient received prenatal care late. On 08-APR-2008 (39 weeks from LMP) the patient delivered a female infant weighing 6lbs. 8oz. There was "decreased fetal movement" detected and a caesarean section was performed. The child was sent to the NICU after delivery, the nurse suggested that it might have been precautionary, given the mother's health problems before delivery. The child being sent to the NICU after delivery and and decreased fetal movement were considered to be an other important medical event. Additional information has been requested.

Other Meds: CLARITIN

Lab Data: ultrasound, 01/02/08, single live, intra-uterine pregnancy of 26wks; ultrasound, 01/11/08, follow up - normal progression of pregnancy; urine beta-human, 11/02/07, positive

History: Tinea versicolour

Prex Illness: Pregnancy NOS (LMP = 6/30/2007); Rhinitis allergic

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317540-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Feb-2008	10-Mar-2008	34	26-Jun-2008	27-Jun-2008	FR	WAES0805USA02686	27-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a general practitioner through the Pregnancy Registry for GARDASIL concerning a 17 year old female who on 05-FEB-2008 was vaccinated with her second dose of GARDASIL (Lot#, site and route not reported). The patient was vaccinated 1 month and a half before her pregnancy. Her last menstrual period was on 10-MAR-2008. At the time of the reporting, there was no adverse effect. Follow up information has been received from a general practitioner who reported that on an unspecified date the patient underwent an induced abortion, performed for personal reasons. Upon internal review, the case was upgraded because induced abortion was considered to be an other important medical event. Other business partner numbers include E2008-04014. No further information is expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 10Mar08)

Prex Vax Illns:

Vaers Id: **317542-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Apr-2008	01-Apr-2008	0	26-Jun-2008	27-Jun-2008	--	WAES0806USA03155	27-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea

Symptom Text: Information has been received from a physician concerning an 18 year old female who in approximately April 2008, was vaccinated IM with a first dose of GARDASIL. Subsequently, the patient experienced breathing difficulties and was taken to the emergency room where she stayed for 12 hours. The specifics were unknown. At the time of the report, the outcome of the patient was unknown. Upon internal review the breathing difficulty was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 317543-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	21-Apr-2008	12-May-2008	21	26-Jun-2008	27-Jun-2008	--	WAES0806USA03819	27-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Coma

Symptom Text: Information has been received from a physician concerning a 21 year old female who on 21-APR-2008 was vaccinated intramuscularly with 0.5 ml first dose of GARDASIL. "Approximately 3 weeks later", on approximately 12-MAY-2008 the patient lapsed into a coma and was hospitalized. Magnetic resonance imaging and "several diagnostic tests" were performed but no results provided. At the time of report, the patient was still hospitalized in a coma. GARDASIL was discontinued. Lapsed into a coma was considered to be disabling, immediately life-threatening and an important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 317580-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	20-Jun-2008	23-Jun-2008	3	26-Jun-2008	02-Jul-2008	OH		02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus

Symptom Text: Pt had first GARDASIL injection on 6/20/08 and developed itching and redness of both lower legs - "below the knee" today. No rash or "Bumps" - No shortness of breath etc.

Other Meds: Multivitamin, Ortho Tri Cyclen, Lexapro

Lab Data: None

History: Allergic to Ceclor

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317582-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	10-Jun-2008	10-Jun-2008	0	26-Jun-2008	02-Jul-2008	MD		02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2774AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope approx 10-15 seconds after TDAP and GARDASIL #1. Response after 10 sec. Discharged after 1/2 hour in good condition.

Other Meds:

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **317620-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jun-2008	16-Jun-2008	0	26-Jun-2008	03-Jul-2008	OH		03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB359AA	1	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1258U	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1267U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Expired drug administered

Symptom Text: HepB vaccine administered had expired previous day

Other Meds: NONE

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **317630-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-May-2008	21-May-2008	0	26-Jun-2008	03-Jul-2008	AL		03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: pt fainted approximately 3-4 minutes past receiving vaccination. No treatment required.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 317633-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	F	18-Jun-2008	18-Jun-2008	0	26-Jun-2008	03-Jul-2008	AZ		07-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1758U	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2418AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B020AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Familial risk factor, Heart rate decreased, Hyperhidrosis, Loss of consciousness, Muscle rigidity, No reaction on previous exposure to drug, Pallor, Respiratory rate decreased, Urinary incontinence

Symptom Text: Child was given vaccine at approximately 1400 hrs. About a minute later she started becoming pale. She had a seizure-like episode with muscle rigidity and loss of bladder control. She did not appear to lose consciousness completely and was able to answer questions immediately after the episode. We laid her down and applied cool towels to her face. We gave her cool water to drink. She became diaphoretic. Her breathing and pulse remained slow and regular. She became well enough to sit up in a chair about 15 minutes after the episode, and I accompanied her to the car about 5 minutes later. According to patient, the only thing she has eaten all day was a piece of bread. She had never had a similar reaction to immunization, but her mother reported that many of her family members had either lost consciousness or become faint after immunization. She also reported that patient has had low blood pressure in the past. I called to check on her an hour later. She had eaten and was acting normally.

Other Meds: NONE KNOWN

Lab Data:

History: NONE REPORTED

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **317637-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-Jun-2008	21-Jun-2008	0	26-Jun-2008	03-Jul-2008	AZ		03-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1487U	1	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2569AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B016BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy

Symptom Text: Child received MCV4, Tdap without noticeable change in mental status. Upon administration of Human Papilloma Vaccine, patient's eyes rolled up and she began to slump from chair. She was caught and placed supine by paramedics. Per (paramedic administrators), "As soon as she was supine, she opened her eyes and began conversing with us". There was no alteration of her mental status from that point on. Patient was monitiored for another 15 minutes and was then allowed to leave. She was alert and oriented appropriately; color was good; gait was steady; speech was clear. Subsequent attempts to follow-up with patient's family revealed a non-working phone number.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **317643-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Jul-2007	28-Aug-2007	49	26-Jun-2008	27-Jun-2008	NC		13-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	0	Right arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blood glucose increased, Diabetes mellitus, Fatigue, Hyperglycaemia, Hyperphagia, Nocturia, Polyuria, Thirst, Weight decreased

Symptom Text: Became very tired, lost weight, then when we checked her Blood sugar was 428. 8/12/08-records received for DOS 8/31-9/1/07-DX:New onset diabetes. Began losing weight at end of school year from 182 to 115. Over the summer increasing thirst, polyphagia, polyuria with nocturia and increased fatigue. Began monitoring with insulin coverage as an outpatient but became hyperglycemic with sugars 401-500.

Other Meds:

Lab Data: Yes-done at hospital 8/12/08-records received-Diagnosed by PCP on 8/28/07 with glucose 404, potassium low at 3.3, anion gap increased 17, hemoglobin H1C increased >14, urine protein and ketones along with esterase and yeast .

History: mild asthma 8/12/08-records received-PMH:exercise induced asthma.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **317646-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Jun-2008	24-Jun-2008	0	26-Jun-2008	03-Jul-2008	AZ		03-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB268AA	0	Left arm	Unknown	
HPV4	MERCK & CO. INC.	0067X	0	Right arm	Unknown	
MNQ	SANOFI PASTEUR	U2573AA	0	Left arm	Unknown	
VARCEL	MERCK & CO. INC.	1892U	1	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, Oedema peripheral, Pain, Pruritus, Skin warm

Symptom Text: Patient stated today that 1 hour after receiving vaccination immediately left upper arm and below left deltoid to right above left elbow is swollen; became hot to touch; painful like itch (no aching). Felt nauseated 45 minutes after vaccination. Subsided now, but swelling and warmth left upper arm still present.

Other Meds: No

Lab Data: N/A

History: NKA; no birth defects; no medical conditions; states "is healthy".

Prex Illness: No

Prex Vax Illns:

Vaers Id: **317695-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
42.0	F	12-Apr-2008	14-Apr-2008	2	27-Jun-2008	30-Jun-2008	FR	WAES0806MYS00011	30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Abdominal pain, Death, Haemorrhage, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a health professional concerning a 42 year old female who on 12 Apr 2008 was vaccinated with GARDASIL. Prior to the vaccination, the patient was reported looking weak and lost weight. On 14 Apr 2008, the patient returned to the clinic and complained of abdominal pain and bleeding. The patient was treated with painkillers for abdominal pain and advised to return if pain persists. The patient never came back. The second dose was due on 12 Jun 2008 but the patient did not turn up. On 14 Jun 2008, the clinic was informed that the patient had died. The cause of death was unknown. The reporter felt that abdominal pain, bleeding and death were not related to therapy with GARDASIL. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317704-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		27-Jun-2008	30-Jun-2008	FL	WAES0806USA08125	09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a dose of GARDASIL and a dose of either Hep A vaccine (MSD) or HAVRIX at the same time as GARDASIL. The physician reported that this was not the only office to have this happen. The outcome was unknown. No additional Adverse Event (AE) information was reported. Upon internal review seizure was determined to be an other important medical event. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317705-1** **Related reports:** 317705-2; 317705-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	18-Mar-2008	25-Mar-2008	7	27-Jun-2008	30-Jun-2008	TX	WAES0806USA07599	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Hypoaesthesia, Myelitis transverse, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 24 year old female who was vaccinated with a second dose of GARDASIL. In March 2008, the patient experienced generalized numbness and weakness in her body after the vaccination. The patient's condition was described as a transverse myelitis. Laboratory studies performed included "blood work" (result not reported) and magnetic resonance imaging of the brain, neck and spinal cord. Spinal cord lesions were found on the spinal cord magnetic resonance imaging. The patient sought medical attention by the physician. At the time of the report the patient had not recovered. Upon internal review the transverse myelitis was considered to be an important medical event. Additional information has been requested. 7/18/08-records received-6/18-7/14/08 presented with recent onset of arm and leg numbness, electrical shock like sensation with neck flexion. Impression:recent onset of transverse myelitis one week after receiving Gardasil vaccine.

Other Meds: Unknown

Lab Data: magnetic resonance - brain, neck and spine; lesions found on spinal cord MRI; diagnostic laboratory - blood work (result not reported) 7/18/08-records received-CSF IgG index elevated, positive oligoclonal bands. CT and MRI of brain normal.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 317706-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	Unknown	Unknown		27-Jun-2008	30-Jun-2008	FR	WAES0806USA03222	30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Uterine cervix ulcer

Symptom Text: Information has been received from a physician concerning a 27 year old female housewife, who, on an unspecified date, was vaccinated with a dose of GARDASIL. Subsequently, the patient developed a cervical ulcer. The patient sought unspecified medical attention. At the time of the report, the patient had not recovered. The reporter considered the cervical ulcer to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317707-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	23-May-2008	26-May-2008	3	27-Jun-2008	30-Jun-2008	FR	WAES0806CZE00002	30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blister, Hypersensitivity, Rash pruritic

Symptom Text: Information has been received from a physician concerning a 21 year old female who on 23-MAY-2008 was vaccinated with GARDASIL. On 26-MAY-2008 the patient experienced skin allergy (itching rash, blisters) and was hospitalized from 28-May-2008 to 2-Jun-2008 on emergency department. Subsequently, the patient recovered from skin allergy. The reporter felt that skin allergy was related to therapy with GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317708-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Sep-2007	07-Sep-2007	0	27-Jun-2008	30-Jun-2008	CA	WAES0711USA00216	30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amniotic fluid volume decreased, Caesarean section, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received through the Merck pregnancy registry from a nurse practitioner concerning a 16 year old female who on 07-SEP-2007 was vaccinated with her first dose of GARDASIL IM. On 17-OCT-2007 a positive urine pregnancy test determined patient was pregnant (LMP = 14-AUG-2007). The patient also had prenatal blood work performed. The patient sought medical attention with an exam in the office. The patient's outcome is unknown. Follow-up indicated that the patient had a scheduled caesarean section at term, secondary to a decreased amniotic fluid index. It was reported that the patient "opted" for a caesarean section. The patient delivered a healthy infant with no anomalies and there were no complications. Upon internal review the decreased amniotic fluid index - resulting in a C-section was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory; urine beta-human 10/17/07 - positive

History:

Prex Illness: Pregnancy NOS (LMP = 8/14/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 317709-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Jul-2007	04-Aug-2007	11	27-Jun-2008	30-Jun-2008	NM	WAES0710USA06526	30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0960F	1	Unknown	Intramuscular	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Hyperbilirubinaemia neonatal

Symptom Text: Initial and follow-up information has been received through the Merck pregnancy registry through a physician concerning a 17 year old female with a reoccurrence of sinusitis headaches who on 24-MAY-2007 was vaccinated intramuscularly with her first dose of GARDASIL (Lot # 654535/0960F). On 24-MAY-2007, the patient was also vaccinated with MENACTRA. On 24-JUL-2007, the patient was vaccinated intramuscularly with her second dose of GARDASIL (Lot # 654535/0960F). On 22-OCT-2007, the patient had a urine pregnancy test which was positive and on an unspecified date the patient had an ultrasound. The date of the patient's last menstrual period was 28-JUL-2007 (also reported as 04-AUG-2007). The patient sought unspecified medical attention in the office. The estimated date of delivery is 03-MAY-2008. Follow-up information was received from the physician via telephone on 20-JUN-2008. The patient delivered a healthy and normal, full-term male, "with no physical anomalies". The baby did develop transient hyper-bilirubinemia after birth and was transferred to another hospital where the baby was successfully treated and discharged after 3 days. The physician reported "he's absolutely fine". Upon internal review transient hyper-bilirubinemia required hospitalization for the baby. Additional information is not expected.

Other Meds:

Lab Data: ultrasound; urine beta-human, 10/22/07, positive

History:

Prex Illness: Pregnancy NOS (LMP = 7/28/2007); Sinusitis

Prex Vax Illns:

Vaers Id: **317710-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Apr-2007	28-Jul-2007	99	27-Jun-2008	30-Jun-2008	MN	WAES0710USA03178	30-Jun-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arrested labour, Caesarean section, Drug exposure during pregnancy, Inappropriate schedule of drug administration

Symptom Text: Initial and follow up has been received from a health professional for the Pregnancy Registry for GARDASIL concerning a female 18 years old patient with epilepsy, carpal tunnel syndrome, drug hypersensitivity to phenobarbital and a smoker, with a history of no prior pregnancies who on 01-OCT-2007 was vaccinated with her third dose of GARDASIL IM and was subsequently determined to be pregnant. The patient received her first dose of GARDASIL IM on 30-JAN-2007 and her second dose of GARDASIL IM on 20-APR-2007. Concomitant therapy included TEGRETOL, vitamin D (unspecified), folic acid (unspecified) and calcium (unspecified). The patient's estimated LMP was 28-JUL-2007 with an estimated conception date of 07-SEP-2007. The patient's estimated due date is 02-JUN-2008. On 17-OCT-2007 and 18-JAN-2008 the patient had ultrasounds which were normal for screening and to establish a due date. The patient also had a serum alpha-fetoprotein test which was normal. The patient sought medical attention by contacting the office. Follow up information received from a physician reported that on 12-JUN-2008, the patient developed arrest of active labor and required a cesarean section. She delivered a healthy, normal, 7 pound 15 ounce boy with APGAR scores of 9 and 9. There were no congenital anomalies. It was reported that the patient smoked throughout her pregnancy. The patients outcome was not reported. Upon internal review it was determined that the arrest of active labour requiring a cesarean section was an other important medical event. No additional information is expected.

Other Meds: calcium (unspecified); TEGRETOL, 600 mg; folic acid, mg; vitamin D (unspecified), 50000 units

Lab Data: ultrasound, 10/17/07 - normal screening and establish due date; ultrasound, 01/18/08 - normal screening and establish due date; serum alpha-fetoprotein, normal - normal screening

History: Carpal tunnel syndrome

Prex Illness: Pregnancy NOS (LMP = 7/28/2007); Epilepsy; Drug hypersensitivity; Smoker

Prex Vax Illns:

Vaers Id: 317719-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	20-Jun-2008	20-Jun-2008	0	27-Jun-2008	02-Jul-2008	NH		03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Musculoskeletal pain, Vaccine positive rechallenge

Symptom Text: Pain in R shoulder started 3 hours after injection. Low back pain at same time with worsening pain over past 4 days. Similar milder sx occurred after 1st injection 2 mo. prior.

Other Meds: KARIVA

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317722-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	05-Jun-2008	Unknown		27-Jun-2008	02-Jul-2008	NV		03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	SMALL	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash erythematous, Rash pruritic

Symptom Text: Bumps, reactions on stomach, back, neck, chest, breast, arms, underarms. Itchy, red, noticeable.

Other Meds: ORTHOTRICYCLINE

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 317725-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Aug-2007	21-Aug-2007	0	27-Jun-2008	02-Jul-2008	TX		14-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0680U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anorexia, Ataxia, Balance disorder, Cerebellar ataxia, Cerebellar syndrome, Chest pain, Clonus, Condition aggravated, Dysarthria, Extensor plantar response, Facial palsy, Gait disturbance, Hyperreflexia, Nervous system disorder, Pallor, Tremor, Weight decreased

Symptom Text: Progressive ataxia since prior to 3/07 in pt with remote hx Langerhans histiocytosis; during this time, starting 8/21/07, received GARDASIL series with significant worsening of ataxia. 9/30/2008 Office notes received from PCP. Gardasil series given 8/21/07, 10/22/07 and 3/5/08 with no reported problems initially. WCC 6/20/08 with worsening ataxia. Has gait disturbance, slowed and slurred speech. PE (+) for above as well as R facial droop, pallor, reflexes 4+ with 3 beat clonus, Babinski (+). DX: Cerebellar Ataxia, unclear etiology. Neurology referral. Seen by heme/onc consult for tx for histiocytosis 8/8/08. Worsening of balance and tremor with tx. Chest pain resolved with reposition of PICC. Pt anorexic with wt loss. Neuro exam (+) for mild tremor, ataxia and imbalance with gait, slurred speech. Impression: CNS involvement with acute Langerhans cell histiocytosis causing ataxia and dysmetria Labs and Diagnostics: MRI brain (+) for atrophic corpus collosum, cortical gray matter abnormalities of the frontal lobe, and T2 signal abnormalities of the cerebellum. 10/13/08 Neuro consult received dated 6/24/2008 with DX: Progressive Cerebellar Ataxia. Hx of Histiocytosis X. Anemia, presumed iron deficient. Abnormal MRI. Pt presented with worsening gait difficulties, falling, difficulty using arms and progressive dysarthria. Neuro exam (+) for minimal coarse nystagmus, eye tracking difficulty, brisk reflexes, dysdiadochokinesis, dysmetria, tremor, and profound ataxia. Pt emotional and tearful-?encephalopathy/frontal release syndrome. Referred to Heme/Onc.

Other Meds:

Lab Data: in progress. Labs and Diagnostics: EEG WNL. Bone survey (-) for metastatic disease. Reticulocyte count high at 3.5. Hct, Hgb, MCV, MCH and MCHC all low. RDW high at 21.5. LP WNL.

History: progressive ataxia. PMH: Dysfunctional Uterine Bleeding, Iron Deficiency Anemia, Scoliosis s/p repair, Langerhans Histiocytosis. Normal neuro exams 7/22/05-7/14/06 except pallor r/t DUB. Smoker

Prex Illness: iron deficiency anemia

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317750-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	25-Jun-2008	25-Jun-2008	0	27-Jun-2008	07-Jul-2008	DE		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness, Dyskinesia, Dyspnoea, Hyperhidrosis, Hypoventilation, Loss of consciousness, Pallor, Urticaria

Symptom Text: Within 5 minutes of receiving HPV vaccine, patient c/o dizziness and passed out. Was aroused in seconds, jumped up violently and thrashed about then passed out a second time. Trouble breathing, blood pressure dropped from 110/76 to 90/62 and broke out in hives over all of torso. Very pale, sweaty and very shallow breathing. 911 was then contacted. Just prior to their arrival (about 7 minutes) pt aroused and was able to sit up at take in a dose of liquid Benadryl. She was stable at time of departure on ambulance, but hives were worsening.

Other Meds: Depo Provera

Lab Data:

History: Penicillan, ceclor, bactrim, percocet, codeine

Prex Illness: none

Prex Vax Illns:

Vaers Id: **317757-1 (D)** **Related reports:** 317757-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Jun-2008	15-Jun-2008	2	27-Jun-2008	30-Jun-2008	IN		10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1447U	0	Left arm	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Arrhythmia, Cardiomegaly, Cardiomyopathy, Cyanosis, Death, Left ventricular hypertrophy, Muscle rigidity, Obesity, Pulmonary oedema, Splenomegaly, Unresponsive to stimuli

Symptom Text: Death -coroner says enlarged heart & enlarge spleen 7/4/08 Reviewed PCP medical records of 1999-6/2008 which included vax record. In 8/2007, c/o of tiredness & loss of appetite. Monospot (-). On day of vax, patient was well, weight noted as 237, otherwise no complaints. 7/8/08 Autopsy report states COD as arrhythmia due to cardiomyopathy.States anatomic findings of obesity, pulmonary edema, mild & left ventricular hypertrophy w/myocardial nuclear enlargement. Patient had been found non-responsive by family. EMS found patient cyanotic w/rigor & no further resuscitation was performed. Family reported patient had been well earlier in the evening. Albuterol inhaler was found at scene but no suspicious features at scene.

Other Meds: none

Lab Data: toxicology and other test came back negative expect trace amount of nicotine (father heavy smoker)

History: overweight PMH: recurrent colds/sore throat, neg strep.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **317757-2 (D)** **Related reports:** 317757-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Jun-2008	13-Jun-2008	0	24-Sep-2008	25-Sep-2008	--		30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: DIED, LIFE THREATENING, SERIOUS

MedDRA PT Death

Symptom Text: Death

Other Meds:

Lab Data:

History: No history of problems or preexisting conditions, female, non smoker, active teenage girl, played sport - softball

Prex Illness:

Prex Vax Illns:

Vaers Id: **317764-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	27-Jun-2008	27-Jun-2008	0	28-Jun-2008	04-Jul-2008	NY		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MMR	UNKNOWN MANUFACTURER	NULL		Right arm	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	NULL		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Diffuse urticaria 3 hours after receiving Gardasil, Tdap, MMR today. Presents to ED for care

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 317774-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	26-Jun-2008	28-Jun-2008	2	30-Jun-2008	04-Jul-2008	CA		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anorexia, Body temperature increased, Chills, Crying, Delirium, Feeling abnormal, Headache, Increased upper airway secretion, Malaise, Nightmare, Pain, Pharyngeal oedema, Pharyngolaryngeal pain, Poor quality sleep, Rhinorrhoea, Tremor

Symptom Text: I had my first (and only so far) injection on Thursday June 26 at 2:45pm. I was overly emotional on Friday evening starting about 7:00pm, which included lots of crying. On Saturday I woke up after getting plenty of rest but did not feel great. I thought I might still be feeling "down" from being upset from the night before. I had no appetite but made myself eat something anyway. I did not leave the house all day and just rested on the couch. By 3pm I had chills so bad that I decided to go to bed and get under my electric blanket. My teeth were chattering loudly and I was shaking out of control. I could not warm up. My head hurt SO much. A few hours later I had my temperature taken and it was 102.6. It lasted many, many hours without breaking. If it had been 103 or higher I would have gone to the ER. My syptoms included nightmares, tossing and turning in my sleep, being delerious to the point of thinking there were other people (whom I did not know) in the room when there were not, horrible headache, crying, phlemn, runny nose, slightly swollen and very sore throat (still sore on Sunday night at 11:45pm), body ache in shoulders, neck, and mostly back. I used a cold, damp washcloth on my forehead as my head felt like it was burning up while my body still felt icy cold even with the electric blanket on high. I had taken 2 Alieve early in the day and 4 Advil later that night or early morning. By 12:30am the fever was still 101.4. By 9am the fever was down to 97.9. By 12:30pm the fever was down to the normal temperature. On Sunday at 11:45pm I still feel ill and phlemny in my throat but not my nose. Sorry for being so graphic. :-) Please contact me if you have any questions.

Other Meds: NuvaRing, Armour Thyroid

Lab Data:

History: None, no known allergies to ANYTHING.

Prex Illness: None.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317793-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	26-Jun-2008	26-Jun-2008	0	27-Jun-2008	03-Jul-2008	MN		03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Vaccine positive rechallenge

Symptom Text: Pt fainted about 10 min after each HPV vaccine. Has never fainted before, no fear of vaccines/injections. Has tolerated other vaccines well.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: Faint~HPV (no brand name)~1~11~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317866-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		30-Jun-2008	01-Jul-2008	FL	WAES0806USA03735	01-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a dose of GARDASIL and a dose of either VAQTA (MSD) or HAVRIX at the same time as GARDASIL. The physician reported that this was not the only office to have this happen. The outcome was unknown. No additional Adverse Event (AE) information was reported. Upon internal review seizure was determined to be an other important medical event. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 317867-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	17-Jun-2008	17-Jun-2008	0	30-Jun-2008	01-Jul-2008	FR	WAES0806USA07699	01-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0467U	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dyspnoea, Sensation of foreign body

Symptom Text: Information has been received from a physician concerning a 22 year old female with a pollen allergy, who on 17-JUN-2008 at 2pm was vaccinated with a third dose of GARDASIL (Lot# 0467U; Batch# NG14300). The site, and route of administration were not reported. Ninety minutes later the patient developed a globus feeling in the pharynx and had difficulty breathing. The patient was hospitalized and treated with antihistamines (not specified). The patient recovered and was discharged from the hospital on 18-JUN-2008. It was reported that the first and second doses of the vaccination were well tolerated. Other business partner numbers included: E2008-05637. Additional information is not expected. The case is closed.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pollen allergy; No reaction on previous exposure to vaccine

Prex Vax Illns:

Vaers Id: **317868-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		30-Jun-2008	01-Jul-2008	--	WAES0806USA07657	30-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Blood pressure decreased, Coma

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL. Subsequently, two weeks after vaccination the patient went into a coma and her blood pressure was "dropping a lot." The patient was reported to be a cousin of a patient of the reporting physician and is not a patient of the reporting physician. Information regarding the patient's health care provider was not provided. The patient sought unspecified medical attention. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Coma and blood pressure dropped were considered to be disabling. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317869-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	23-May-2008	30-May-2008	7	30-Jun-2008	01-Jul-2008	FR	WAES0806USA08199	01-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Type 1 diabetes mellitus

Symptom Text: Information has been received from a hospital physician concerning an adult female medical student with no reported history who on unspecified dates was vaccinated with a first and second dose of GARDASIL. On 23-MAY-2008, the patient was vaccinated with a third dose of GARDASIL (lot # not reported). On approximately 30-MAY-2008, 1 week post vaccination, the patient was diagnosed with diabetes type I. The reporting physician felt that the type I diabetes mellitus was an other important medical event. Other business partner numbers included: E2008-05651. Additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317870-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	18-Dec-2007	22-Mar-2008	95	30-Jun-2008	01-Jul-2008	FR	WAES0806USA08422	01-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Back pain, Cardiac disorder, Fatigue, Headache, Hyperhidrosis, Listless, Nausea, Sensory disturbance, Syncope

Symptom Text: Information has been received from a patient's mother who reported that her 17 year old female daughter was vaccinated with her first dose of GARDASIL (Lot # not reported) on 18-DEC-2007. The patient had a first reported syncope in a discotheque on 22-MAR-2008 and was admitted to an intensive care unit. Heart problems (unspecified) were diagnosed. The second dose of GARDASIL (Lot # not reported) was given on 03-APR-2008. Since vaccination (date not specified) the patient complained of persisting intense headache, nausea, listlessness, chronic tiredness, undefinable back pain and sweaty hands. The patient had a syncope at the beginning of June 2008. Sensory disturbance was diagnosed by a neurologist on 16-JUN-2008. Radiological examinations and MRI were without abnormal findings. The patient has not yet recovered at the time of reporting. Other business partner numbers included: E2008-05791. No further information is available.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, ??Jun08, without abnormal findings; Diagnostic radiology, ??Jun08, without abnormal findings.

History:

Prex Illness: Cardiac disorder

Prex Vax Illns:

Vaers Id: 317871-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Mar-2008	12-Apr-2008	25	30-Jun-2008	01-Jul-2008	FR	WAES0806USA08511	01-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Demyelination, Eye disorder, Fatigue, Hypoacusis, Multiple sclerosis, Paraesthesia, Sensorimotor disorder

Symptom Text: Information has been received from a general practitioner concerning a 16 year old female who on 18-MAR-2008 was vaccinated with GARDASIL (batch number, route and site, not reported). It was reported by a general practitioner to a company sales representative that a 16 year-old female patient received a dose of GARDASIL, on an unspecified date. 3 weeks post-vaccination the patient consulted neurologist for suspicion of multiple sclerosis. Additional information received on 22-JUN-2008: A 16-year-old female patient with neither relevant medical history nor familiar medical history reported received the first dose of GARDASIL (batch number, route and site, not reported) on 18-MAR-2008. Route of administration and site of injection were not reported. Around the 12 to 19-APR-2008 i.e. approximately 3 weeks after vaccination the patient experienced sensorimonitor disorder, with paraesthesia of lower limbs, hypoacusis, important fatigue and ocular troubles. On 23-Apr-2008 a neurologist requested cerebrospinal MRI performed on 2-MAY-2008 and which revealed an area of hypersignals evocating the presence of an active demyelination at brain level. There was spatial dissemination with some positive lesions at gadolinium fluid proteins at 0.28 g/L, glycorrhachia at 3.24 mm/L. Electrophoresis was on-going. Diagnosis was multiple sclerosis. The patient recovered from the symptoms above mentioned. Multiple sclerosis was considered to be an other important medical event. Other business partner numbers include E2008-05797. No further information is available.

Other Meds: None

Lab Data: cerebrospinal MRI performed on 2-MAY-2008: area of hypersignals=presence of an active demyelination at brain level spatial dissemination with some positive lesions at gadolinium and some negative lesions at gadolinium as well

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **317882-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Jun-2008	Unknown		30-Jun-2008	04-Jul-2008	GA		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	0	Right leg	Intramuscular	
	MNQ	SANOFI PASTEUR	U2632AA	0	Left leg	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB208AA	0	Right leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect dose administered

Symptom Text: Administered adult Hepatitis A vaccine to an 18 year old instead of a Pediatric Hepatitis A vaccine.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 317884-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Jun-2008	18-Jun-2008	0	30-Jun-2008	07-Jul-2008	ME		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	19684	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Pain in extremity

Symptom Text: Three hours after receiving GARDASIL #1 hands became swollen and painful x 12 hours.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **317887-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	03-Apr-2008	Unknown		30-Jun-2008	07-Jul-2008	NJ		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pregnancy test urine positive

Symptom Text: Pt. received GARDASIL injection #1 on 4/3/08. Due to insurance reasons pt. is no longer a part of our practice. Pt had a UPT done at a center on 6/3/08 which was (+) and is under the care of a practice for her maternity care.

Other Meds: YAZ birth control

Lab Data: Pt had (-) UPT prior to surgery

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317890-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Jun-2008	23-Jun-2008	0	30-Jun-2008	07-Jul-2008	IL		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Blood pressure decreased, Cold sweat, Convulsion, Fall, Gaze palsy, Heart rate decreased, Immediate post-injection reaction, Pallor, Syncope

Symptom Text: Pt. had immediate fainting spell. Recovered for 2 minutes then had seizure like movements for 10 seconds. Eyes rolled back into head, cold & clammy skin - ashen color, decreased BP & decreased P. Once recovered had no memory of fainting or falling from chair.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **317922-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Jun-2008	25-Jun-2008	0	30-Jun-2008	04-Jul-2008	CO		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	1	Left arm	Intramuscular	
	DTAP	UNKNOWN MANUFACTURER	UNKNOWN		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Cough, Fatigue, Headache, Myalgia, Pharyngolaryngeal pain, Pyrexia, Vaccination complication

Symptom Text: About 1 hour after receiving her vaccines she became ill with fever, fatigue, muscle & joint aches & severe headache. Her fever increased over the next few days & she then also developed a sore throat & cough. She was seen in an urgent care center & required IV fluids. Tests were run but they are all negative or still pending. She is being treated with Tylenol & Advil for fever & discomfort & with cough medication. She was also reexamined by a doctor today (day 6 of her reaction) who confirmed a probable reaction to being vaccinated.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns: none~ ()~NULL~~In Patient|none~ ()~NULL~~In Sibling1

Vaers Id: 317924-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Aug-2007	04-Sep-2007	6	30-Jun-2008	01-Jul-2008	MA		08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2378BA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0927U	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Agitation, Anxiety, Cognitive disorder, Delusion, Depression, Disturbance in attention, Hallucination, Hallucination, auditory, Paranoia, Psychotic disorder, Thinking abnormal

Symptom Text: Increasing depression, agitation, anxiety, paranoia, disordered thinking, attention difficulties cognitive deficits beginning shortly after first HPV shot. After second HPV shot began hearing voices with morbid thoughts/paranoid delusions. Within weeks of third shot, was hospitalized for psychosis. Current diagnosis is psychotic NOS; currently being treated with risperdal 2 mg. Hallucinations are gone but cognitive deficits linger. First vaccination was first week september, 2007; second vaccination was nov 6, 2008; third vaccination was mar 6, 2008. Hospitalization was april 25, 2008. 07/08/2008 MR received from psychiatric hospital for DOS 4/25-5/06/2008 with DX: Psychotic Disorder NOS. Pt transfered from medical hospital with psychotic symptoms including paranoid ideation, ideas of reference, delusions, auditory hallucinations and disorganized thought processes. She had had worsening sx of of worry, anxiety and intusive thoughs over the past 2 weeks to 1 month. Improved on Risperdal and d/c to day program.

Other Meds: None

Lab Data: blood tests, MRI, EEG, EKG all normal. Labs and Diagnostics: EEG WNL. All labs unremarkable.

History: seasonal allergies. PMH: RSV. Lyme Disease. Thyroglossal duct cyst surgery. NKDA

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317936-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	27-Jun-2008	27-Jun-2008	0	30-Jun-2008	07-Jul-2008	KS		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Client called at 9AM on 6/30/07 reporting that she had received a GARDASIL injection on 6/27/08 and developed a rash within 30 minutes of receiving it. The rash has spread to other areas on body.

Other Meds: None

Lab Data: Client had rash on right arm and chest "from jewelry" as documented on assessment form prior to vaccination.

History: "Pre-diabetes"; Erythromycin; Latex allergies.

Prex Illness: None

Prex Vax Illns:

Vaers Id: 317938-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	19-May-2008	20-May-2008	1	30-Jun-2008	09-Jul-2008	FL		09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Fatigue, Joint swelling, Malaise, Upper respiratory tract infection

Symptom Text: After second injection of GARDASIL, experienced fatigue, malaise, joint swelling and pain (joint symptoms continued to worsen for next 6 weeks) the next day. She had severe upper respiratory infection 2 weeks following vaccine.

Other Meds: Topamax, Lexapro, Wellbutrin, Reclipsin, Zyrtec,

Lab Data: RA - factor negative

History: NSAIDS, Penicillin, hay fever.

Prex Illness: Dysautonomia

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317942-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.4	F	27-Jun-2008	27-Jun-2008	0	30-Jun-2008	07-Jul-2008	MA		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U21616AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope vasovagal

Symptom Text: Pt had vasovagal episode after receiving vaccines.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **317969-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-May-2007	15-May-2007	0	01-Jul-2008	02-Jul-2008	LA	WAES0705USA03169	02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a through Merck pregnancy registry and a Certified Medical Assistant (C.M.A.) concerning a 16 year old female patient with a history of bacterial vaginosis who on 15-MAY-2007 was vaccinated with a dose of GARDASIL. On 16-MAY-2007 the patient discovered that she was pregnant. The outcome was not recovered. On 11-JUN-2008, a follow up telephone call was made to get the pregnancy outcome for the patient and a message was left at the patient's doctor's office. On 20-JUN-2008 the health care provider returned the call and reported that the patient was delivered by primary cesarean section at term, and had a normal and healthy female baby. The baby weighed 7 lbs 10 oz, after spontaneous onset of labor. No further information was available. Upon internal review patient having "spontaneous onset of labor" which required cesarean section considered to be an other medical event. Additional information is not available.

Other Meds: Unknown

Lab Data: Unknown

History: Vaginosis bacterial

Prex Illness:

Prex Vax Illns:

Vaers Id: **317970-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	08-Feb-2008	Unknown		01-Jul-2008	02-Jul-2008	FR	WAES0805USA05561	02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0352U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Body height below normal, Transaminases increased, Underweight

Symptom Text: Information has been received from a physician concerning a 15 year old female who was vaccinated with a third dose of GARDASIL (lot#0352U, batch#NG00320) IM into the upper arm on 08-FEB-2008. In an unspecified time after the vaccination a blood sample which was taken because the girl seemed to be too small and lightweight for her age showed elevated transaminases. It was intended to admit the patient to the hospital. At the time of reporting the symptoms were ongoing. Other business numbers included E2008-04048. Follow-up information has been received which reported that the case has to be upgraded because the patient was hospitalized (date of hospitalization not reported). The symptoms are still ongoing at the time of reporting. Additional information is expected.

Other Meds: Unknown

Lab Data: plasma gamma-glutamyl transferase, 13Feb08, 156 U/L; serum C-reactive protein, 13Feb08, normal; plasma aspartate aminotransferase test, 13Feb08, 135 U/L; plasma alanine aminotransferase test, 13Feb08, 225 U/L; plasma gamma-glutamyl transfer

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317971-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Jan-2008	15-Feb-2008	29	01-Jul-2008	02-Jul-2008	FR	WAES0806USA07790	02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0276U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Haematoma, Idiopathic thrombocytopenic purpura, Thrombocytopenia

Symptom Text: Information has been received from a gynecologist concerning a 17 year old female patient who on 17-JAN-2008 was vaccinated with a 3rd dose of GARDASIL (Batch NF58550 Lot No. 076U) I.M. into the upper arm. The patient developed hematoma mid of Feb-2008. Blood count showed thrombocytes = 3000. Werlhof's disease (immunothrombocytopenia) was diagnosed. The adverse event was treated with Cortisone. Other business partner numbers included E200-05563. No further information is available.

Other Meds: Unknown

Lab Data: Platelet count, 3000

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **317972-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		01-Jul-2008	02-Jul-2008	FR	WAES0806USA07792	02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dermatomyositis

Symptom Text: Information has been received from a general practitioner concerning an adult female who in 2007 was vaccinated with a dose of GARDASIL, (lot no., injection site and route not reported). Subsequently, on an unknown date, the patient developed dermatomyositis. Outcome was not reported. Dermatomyositis was considered to be other important medical event. Other business partner numbers included: E2008-05564. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317973-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	22-Feb-2008	01-May-2008	69	01-Jul-2008	02-Jul-2008	FR	WAES0806USA07867	02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blood pressure increased, Chest pain, Dyspnoea, Facial palsy, Myocardial infarction, Oedema peripheral, Vaccine positive rechallenge, White blood cell disorder

Symptom Text: Information has been received from a consumer concerning a female patient whose date of birth and age were not reported received the second dose of GARDASIL (Batch # not reported) in May 2008. Route of administration and site of injection were not reported. The patient had medical history of hospitalization for heart attack with increased blood pressure, thoracic pain, facial palsy, swelling hands, permanent breathlessness and modification of leukocytes after the first dose of GARDASIL (Batch # not reported) on 22-FEB-2008. 1 day after vaccination with the second dose of GARDASIL she experienced the same symptoms i.e. heart attack with increased blood pressure at 17.6 mmHg, thoracic pain, left facial palsy, swelling hands, breathlessness and modification of leukocytes. She was hospitalized three times in the following course. Outcome was not reported. The case is closed.

Other Meds: Unknown

Lab Data:

History: Heart attack; blood pressure increased; chest pain; facial palsy; hand swelling; breathlessness; leukocytes abnormal (NOS); hospitalisation

Prex Illness:

Prex Vax Illns:

Vaers Id: 317974-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Jan-2008	28-May-2008	133	01-Jul-2008	02-Jul-2008	PA	WAES0806USA08184	02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a physician concerning a 17 year old female with penicillin allergy who on 16-JAN-2008 was vaccinated with the first dose of GARDASIL. The physician reported that the patient's last menstrual period was on 02-MAR-2008. On 28-MAY-2008, the patient experienced a miscarriage. On 23-Jun-2008 she would receive the second dose of GARDASIL. At the time of the report, the patient had recovered. The patient sought medical attention at the physician's office. Upon internal review, miscarriage was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 3/2/2008); Penicillin allergy

Prex Vax Illns:

Vaers Id: 317975-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	09-Aug-2007	18-Aug-2007	9	01-Jul-2008	02-Jul-2008	FR	WAES0806USA08201	02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0278U	0	Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Asthenia, Dyspnoea, Haemoptysis, Incorrect route of drug administration, Migraine, Nausea, Vaccine positive rechallenge, Weight decreased

Symptom Text: Information has been received from an agency concerning a 15 year old female who was vaccinated with GARDASIL (lot No. 0278U, batch# NF56940) (injection site not reported) s.c. on 09-Aug-2007. The patient developed haemoptoe, dyspnea, generalized weakness generalized, weight loss, migraine-like headache, abdominal pain and nausea on 18-AUG-2007. Despite these adverse events the patient was vaccinated with a 2nd dose of GARDASIL, (lot # 0278U, batch# NF56940) on 2-NOV-07 (administration route and site not reported). No adverse effects were reported after P2. The patient was vaccinated with a 3rd dose of GARDASIL (lot# 0278U, batch# NF56940) on 21-Feb-08 (administration route and site not reported). The adverse events worsened after this vaccination. The patient was hospitalized due to a suspected appendicitis (exact date of hospitalization not reported) several times. Laboratory tests (unspecified) and endoscopy were without abnormal findings. The abdominal complaints were resolving but the patient was not fully recovered at the time of reporting. Other business partner number included E2008-05085. No further information is available.

Other Meds: None

Lab Data: endoscopy, without abnormal findings

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 317976-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jan-2008	29-Feb-2008	59	01-Jul-2008	02-Jul-2008	FR	WAES0806USA08203	02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diplopia, Eye burns, Eye pruritus, Sinusitis, Vision blurred, Visual disturbance, Visual field defect

Symptom Text: Information has been received from an Health Authority concerning a 17 year old female with a history of migraine, who was vaccinated with the third dose of GARDASIL (lot # not provided), in January 2008. It was reported that the patient was hospitalized from 17-APR-2008 to 18-APR-2008. By hospital report it was reported that the patient developed visual disturbance, diplopia, visual field defect, eye itching, eye burning and blurred vision "6 to 9 weeks ago" (onset date not specified). Examinations by an outpatient ophthalmologist, neurologist and an ear, nose and throat (ENT) specialist were without pathological findings). A Magnetic Resonance Imaging (MRI) in the outpatient department showed sinusitis on 29-FEB-2008. The sinusitis was treated with penicillin for 12 days. The examinations as cerebrospinal fluid puncture, sleep electroencephalography (EEG), visual evoked potential (VEP) which were performed in hospital showed no pathologies. The ophthalmological examination showed abnormal visus (+0.6 left eye and +0.6 right eye). There was no indication of optic neuritis. It was intended to refer the patient to the psychologist. At the time of reporting the symptoms were ongoing. Concomitant therapy included hormonal contraceptives for systemic use. Other business partner numbers included: E2008-05653 and PEI2008007916. No further information is available.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Magnetic resonance imaging, 29Feb08, sinusitis; Electroencephalography, 17?Apr08, showed no pathologies; Visual evoked potential, 17?Apr08, showed no pathologies; Ophthalmological exam, +0.6, left and right eye. No indication of optic neur

History:

Prex Illness: Migraine

Prex Vax Illns:

Vaers Id: **317977-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Jun-2008	23-Jun-2008	0	01-Jul-2008	02-Jul-2008	IL	WAES0806USA08204	02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Petit mal epilepsy, Somnolence, Syncope, Syncope vasovagal

Symptom Text: Information has been received from a nurse practitioner concerning a 14 year old female who on 23-JUN-2008 was vaccinated with the first dose of GARDASIL (LOT# 660553/0070X). The nurse reported that the patient began to collapse off the table after receiving her first dose of GARDASIL. The nurse reported that she managed to catch the patient and move her from the table down to a chair in the room where the patient then experienced a petite mal seizure that lasted for about 5 minutes. The nurse also reported that within 3 to 5 seconds after the patient received the vaccination she passed out. The patient "came to" and was helped to a chair. The patient then had a petit mal seizure that lasted from 3 to 5 seconds. The nurse stated that the patient had a vasovagal reaction with a petit mal seizure. When the patient "woke up", it was reported that she was groggy. The nurse stated that the patient remained in the office for a while until she was stable enough to go home. The nurse spoke to the patient's mother via telephone conversation later that day, and the patient's mother reported that the patient was resting and was eating. The patient was reported to be "ok" with no long-term effects from the petit mal seizure. The nurse did not know if the patient was scheduled to receive the second dose of GARDASIL. Upon internal review, petite mal seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317979-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Apr-2008	21-Apr-2008	0	01-Jul-2008	02-Jul-2008	FR	WAES0806USA08417	02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0275U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Glomerulonephritis minimal lesion, Nephrotic syndrome, Wrong technique in drug usage process

Symptom Text: Information has been received from a physician concerning a 14 year old with no relevant medical history reported, who on 21-APR-2008 was vaccinated with the third dose of GARDASIL (Lot # 0275U, Batch NF54050) via intramuscular route in her buttock. Approximately 2 months after vaccination the patient experienced a lipoid nephrosis with a nephrotic syndrome. She was prescribed 1 mg/kg/day of corticosteroids not otherwise specified. Renal puncture biopsy was not scheduled up today. The reporter considered this case medically significant and potentially serious. At the time of the reporting the patient had not recovered. Lipoid nephrosis was considered to be an other important medical event. Other business partner numbers included: E2008-05670. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 317980-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Nov-2007	08-Jun-2008	206	01-Jul-2008	02-Jul-2008	FR	WAES0806USA08419	02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1049U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Fall, Headache, Vomiting

Symptom Text: Information has been received from a paediatrician concerning a 13 year old female, who on 15-NOV-2007 was vaccinated with a first dose of GARDASIL (lot # 1536F and batch # NG01520), no adverse events occurred. On 06-JUN-2008, the patient was vaccinated with a second dose of GARDASIL (lot# 1049U and batch # NG46500) into the deltoid muscle. The patient developed vomiting on 08-JUN-2008, dizziness on 09-JUN-2008, headache and tendency to fall on 10-JUN-2008. The patient was hospitalized due to the adverse events on 12-JUN-2008. EEG showed pathologies, MRI and CT were without pathological findings. The neuron-paediatrician assumed a first episode of multiple sclerosis, but there were not yet any diagnostic results to confirm the suspicion. The patient was discharged from hospital on 15-JUN-2008. The patient has not yet recovered at the day of reporting, but she was improving significantly, in particular the dizziness and headache. Other business partner numbers included: E2008-05688. Additional information has been requested.

Other Meds: Unknown

Lab Data: electroencephalography, showed pathologies; magnetic resonance imaging, without pathological findings; computed axial tomography, without pathological findings

History: Unknown

Prex Illness:

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **317981-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Mar-2008	04-Jun-2008	79	01-Jul-2008	02-Jul-2008	FR	WAES0806USA08420	02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Disorientation, Gait disturbance, Nervous system disorder, Personality change, Sensorimotor disorder, Somnolence

Symptom Text: Information has been received from a paediatrician concerning a 14 year old female patient with a history of pollen allergy who was vaccinated with the first dose of GARDASIL on 17-MAR-2008 (IM, upper arm). It was well tolerated). On 13-MAY-2008, the patient was vaccinated with the second dose of GARDASIL, lot # not provided, IM into the upper arm. On 04-JUN-2008, the patient developed neurological and sensorimotor disorders including disorientation, gait instability, personality change and somnolence. She was hospitalized and received lorazepam 0.7 mg. There were no inflammatory signs and EEG was normal. She recovered after 2 days. On 17-JUN-2008, the patient experienced a similar episode. The final outcome was unknown. Other business partner numbers included: E2008-05763. No further information is available.

Other Meds:

Lab Data: Electroencephalography, normal; Blood drug screen, 0.7 mg lorazepam; Urine drug screen, 0.7 mg lorazepam.

History:

Prex Illness: Pollen allergy

Prex Vax Illns:

Vaers Id: **317982-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Apr-2008	15-May-2008	16	01-Jul-2008	02-Jul-2008	FR	WAES0806USA08513	02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1208U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Malaise, Muscle spasms

Symptom Text: Information has been received from a pediatrician on 23-JUN-2008, concerning a 14 year old female patient in good health at the time of vaccination; no current treatment reported, who on 29-APR-2008, received the first dose of GARDASIL (lot # 1208U and batch # NH13360). Route and site of administration were not reported. On approximately 15-MAY-2008, 15 days after vaccination, the patient developed progressive asthenia, subsequently associated with episodes of spasmophilia-type hysteriform malaise. Aetiological investigations did not reveal anything; serology and hormone test, complete blood count were normal. The patient was hospitalized on an unspecified date. The outcome was not reported. Relevant Test/Laboratory Data: serology and hormone test, complete blood count normal. Other business partner number included: E2008-05877. Additional information has been requested.

Other Meds: Unknown

Lab Data: clinical serology test, normal; complete blood cell count, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317983-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		01-Jul-2008	02-Jul-2008	FR	WAES0806USA08516	02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Alanine aminotransferase increased, Aspartate aminotransferase increased, Jaundice, Leukopenia, Pyrexia, Thrombocytopenia

Symptom Text: Information has been received from a physician concerning a 15 year old female with a history of drug allergy not otherwise specified who received the first dose of GARDASIL (batch number not reported) in April-2008 via intramuscular route in her deltoid. She has no concomitant treatment. 1 month after vaccination the patient experienced increased SGOT and SGPT with leucopenia and thrombocytopenia. Clinically the patient also had a febrile jaundice. All medical investigations performed were negative: HIV, cytomegalovirus and hepatitis serologies were negative. The patient was hospitalized a few days in order to perform a work-up. The patient had spontaneously reported on an unspecified date. Other business partner included E2008-05871. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory test, HIV, cytomegalovirus and hepatitis serologies were negative

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **317984-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	08-Apr-2008	Unknown		01-Jul-2008	02-Jul-2008	PA	WAES0806USA08321	02-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Breast cancer

Symptom Text: Information has been received from a register nurse (R.N.) concerning a 25 year old female who on 08-APR-2008 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot # 659182/1757U). The patient was diagnosed with breast cancer after receiving GARDASIL. At the time of this report, the outcome was unknown. No other information is available at this time. No product quality complaint was involved. Upon internal review, breast cancer was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **317991-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Jun-2008	30-Jun-2008	0	01-Jul-2008	09-Jul-2008	MD		05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Nausea, Pain, Pyrexia

Symptom Text: 3rd dose of GARDASIL administered on 6/30/08. Patient's mother called (4/1/08) states patient experienced 100 temperature body aches, shortness of breath and nausea after they arrived home.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 317993-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-Jun-2008	20-Jun-2008	0	01-Jul-2008	07-Jul-2008	NC	NC08083	07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0053X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Cold sweat, Dyskinesia, Heart rate normal, Respiratory rate increased, Unresponsive to stimuli

Symptom Text: Pt given vaccine & spoke a few words & 1-2 min later closed eyes & mildly jerked a couple of times & unresponsive. Pt breathing without difficulty. Skin cool & clammy. After 10 seconds became responsive & answered nurse. Once awakened child was oriented to person & place. VS BP 92/52 HR 72 R 28. Pt rested laying down. Dr. examined child. After 30 min child alert/smiling. Skin warm & dry. No complaints BP 90/52 P 76 R 24. Oriented to person/place/time.

Other Meds: None

Lab Data: None done

History: NKA

Prex Illness: None -> at office for vaccine

Prex Vax Illns: mom states child had dizzy faint/hot feeling one hour after hepatitis A vaccine~Hep A (no brand name)~UN~0~In Patient

Vaers Id: **317995-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Jun-2008	18-Jun-2008	0	01-Jul-2008	09-Jul-2008	NJ		09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Pallor

Symptom Text: Patient became dizzy, diaphoretic, and pale, she was advised to lay on the table and was given a cold juice box to drink.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318003-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
8.0	F	21-Dec-2007	Unknown		01-Jul-2008	09-Jul-2008	WA		09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2409AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1276U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: GARDASIL #1 administered age 8

Other Meds: Topical Eczema meds

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **318004-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	26-Jun-2008	Unknown		01-Jul-2008	09-Jul-2008	MI		09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB107AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Wrong drug administered

Symptom Text: Adult dose Hep A administered.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318006-1** **Related reports:** 318006-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Jun-2003	24-Jun-2003	0	01-Jul-2008	09-Jul-2008	PA		09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2774AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0063X	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB224BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypotonia, Pallor

Symptom Text: After receiving 3rd and last vaccine, turned pale and became limp while sitting on exam table. Had her lay down and was OK with seconds although still pale. BP 118/70. Checked by doctor. Left office after 20 min and appeared fine.

Other Meds: Ortho Tricycline Lo

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318006-2** **Related reports:** 318006-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	24-Jun-2008	24-Jun-2008	0	18-Aug-2008	17-Sep-2008	PA	WAES0807USA03988	17-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2774AA	0	Unknown	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AUAVB22BA	0	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	0063X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypotonia, Pallor

Symptom Text: Information has been received from a registered nurse concerning a 20 year old female patient with no known allergies or pertinent medical history who on 24-JUN-2008 at 11:00 am was vaccinated intramuscularly in the right arm with a third and last dose of GARDASIL (Lot #660391/0063X). The patient was vaccinated at the same time in the left arm with ADACEL (Lot #C2774AA) and HAVRIX (Lot # AUAVB224BA). There was no illness at the time of vaccination. On 24-JUN-2008, after receiving the third and last vaccine, the patient pale and limp while sitting on exam table. The patient was ok within seconds after lying down, although still pale. BP 118/70, patient checked by the doctor. The patient left the office after 20 minutes and appeared fine. The patient recovered from the pale on 24-JUL-2008. No further information is available.

Other Meds:

Lab Data: blood pressure, 118/7

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **318009-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Jun-2008	21-Jun-2008	0	01-Jul-2008	09-Jul-2008	--		09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Patient received vaccine in exam room and then passed out in waiting room; we stabilized her, took a BP, and let her lie down for 10 minutes.

Other Meds: PPD

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **318012-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Apr-2008	29-Apr-2008	1	01-Jul-2008	07-Jul-2008	SC		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB264AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0387U	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2889AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Local reaction

Symptom Text: Local erythema less than 2 cm in diameter.

Other Meds:

Lab Data:

History: Nasal allergy only

Prex Illness: V 20.2, Sinusitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318048-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Jun-2008	24-Jun-2008	0	01-Jul-2008	04-Jul-2008	SD		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2613AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1448U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Gaze palsy, No reaction on previous exposure to drug, Syncope, Unresponsive to stimuli

Symptom Text: I had gotten a call from patient's Mom in the morning of 6/24/08 & she stated that she was sending patient in for her shots & that she was unable to make it as was working in the field. I did review both of the VIS with Mom & she stated patient has had no history of problems with vaccinations. She also stated that the first HPV vaccination went just fine. She stated that she would be on her cell phone if anything was needed. 2pm patient came to clinic. Had no complaints. 2:05pm I gave patient her (2nd) HPV vaccination, 2:07pm then gave the Meningitis vaccination. As I put the band aid on she stated "I think I am going to black out." & then at 2:08pm her head went back, eyes rolled & she fainted-was unresponsive for approximately 10-15 seconds. As I seen this I stated her name, then my secretary's name & as my secretary opened door, patient then sat up in chair & blinked her eyes & stated "what was that?" 2:09pm Blood Pressure 100/58 Pulse 70 Respirations 16. States she can remember everything & saying she felt like she was going to black out & then that was it. Continued to take Blood pressures & was 108/68, 112/64 & 108/68. Mom called & aware & came in.Continued to monitor patient & had her sit for 30 minutes & then she stated was feeling fine & would like to go home. They then left & went to home. Mom was called again as they made it home & she is aware of the fact if anything more or if patient has any complaints of the alert 911 or their physician & to let me know also. She stated she will call if any problems. 4:35 Call to patient & her Mom answered & stated all going just fine. Patient has eaten-she now states that patient told her she didn't have anything for lunch today & possibly that might have been a factor in the situation. Has no questions or concerns at this time. 5:30pm I seen patient out for supper with her sister & niece & she stated she felt just fine. Laughed & stated she had never had that happen before & was an experience that she hopes never happens again.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **318052-1 (S)** **Related reports:** 318052-2; 318052-3; 318052-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	24-Aug-2007	01-Sep-2007	8	01-Jul-2008	03-Jul-2008	OH		06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0930U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abasia, Asthenia, Conversion disorder, Dermatitis acneiform, Dizziness, Eating disorder, Facial palsy, Fall, Headache, Hyperaesthesia, Hyperhidrosis, Hypoaesthesia, Hyporeflexia, Local swelling, Loss of control of legs, Myalgia, Myositis, Nausea, Pain, Pain of skin, Paraesthesia, Photosensitivity reaction, Red blood cell sedimentation rate increased, Skin burning sensation, Sleep disorder, Swelling face, Syncope, Vertigo, Vomiting

Symptom Text: Aug.24, second Gardasil injection received. Sept.3, pressure in jaw and head began, followed by weakness, severe pain and loss of use of legs; nausea, dizziness, fainting, swelling and drooping of face and neck. Oct.2007, lost ability to walk, burning prickles in scalp, hands, legs. Seen by several specialists including hospital neurological teams- no diagnosis given. Seen by multiple specilists Jan. 2008 - June 2008. Unable to eat solid foods, placed on liquid diet. Finally diagnosed by D.O. as having an adverse reaction to Gardasil. Special diet and pain medication given which seem to be helping in small degrees. We were told it would be a long time recovering. 2nd report 320256. 07/23/2008 MR received for DOS 10/19-24/2007 which include 2 Rheumatology consults, neuro consult, psych consult and inpt admission. Pt presented for Rheum eval 10/19/07 with c/o 6 week hx of pain and sensitivity in her face, jaw neck and thoracic region (burning & tingling) and progressive weakness in her limbs. Unable to walk without assistance. Pt reports dizziness, vertigo, syncope and photosensitivity. Sleep is disturbed. Several falls. Has sweats. Presents in sunglasses for photophobia and in a w/c. This followed a viral and /or sinus infection 6 weeks prior. PE (+) for anceiform rash on the back, scalp, face, jaw, and neck tenderness, DTRs 1+ arms, unobtainable in legs, decreased strength in arms and legs, unable to walk. Concern for neurological illness resulted in emergent admission to hospital for further eval. DOS 10/19-24/2007 with DX: weakness. other dx: fibromyalgia, migraines, asthma and chronic pain syndrome. Neuro consult as above but able to elicit patellar reflexes. Psych eval to r/o conversion d/o. Requested further eval. 2nd Rheum consult for increased sed rate. Additional sx of touch sensitivity and lower extremity numbness. Impression: Elevated Sed rate. Myalgia and myositis NOS, Headache, Difficulty in walking. Pt had some nausea and vomiting while admitted. Treated for pain and pt was ambulati

Other Meds: Topomax 50 mg 1 per day

Lab Data: MRI, CTscan, LP, Multiple Blood tests, Sed rate checked multiple times, DNA tests, Urine analysis, EEG, EMG. Hair analysis. Labs and Diagnostics: CXR WNL. Lumbar MRI Unremarkable. Cervical MRI Unremarkable. Thoracis MRI Unremarkable. Bra

History: Fibromyalgia, chemical sensitivity, migraines. PMH: fibromyalgia, migraines, asthma, hernia surgery, abd surg.

Prex Illness: None

Prex Vax Illns: None~ ()~~0~Patient

Vaers Id: **318052-2 (S)** **Related reports:** 318052-1; 318052-3; 318052-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	26-Jun-2007	27-Jun-2007	1	30-Mar-2009	31-Mar-2009	OH		31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Demyelination, Guillain-Barre syndrome, Neuropathy peripheral

Symptom Text: Seizures - non-epileptic, began July 2007 - Dec. 2008; Diagnosed Guillain-Barre Syndrome - March 2009 (onset was three weeks after 2nd Gardasil Injection. Has peripheral neuropathy in both lower legs and feet as result. Treatment was begun 2009) Myelin Sheath Degeneration - diagnosed March 2009

Other Meds: Topomax

Lab Data: Tissue Mineral Analysis; Adrenal Stress Index - Saliva Test

History: Fibromyalgia - in remission

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318052-3** **Related reports:** 318052-1; 318052-2; 318052-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	26-Jun-2007	27-Jun-2007	1	23-Jul-2008	01-Aug-2008	OH		31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abasia, Areflexia, Asthenia, Burning sensation, Chest pain, Dermatitis acneiform, Dizziness, Facial pain, Fall, Hyperaesthesia, Hyperhidrosis, Hyporeflexia, Myalgia, Neck pain, Pain, Pain in jaw, Paraesthesia, Photosensitivity reaction, Sinusitis, Sleep disorder, Swelling, Syncope, Tenderness, Vertigo, Viral infection, Wheelchair user

Symptom Text: neuromuscular pain, global weakness, intermittant swelling. 07/23/2008 MR received for DOS 10/19/2007 which include 2 Rheumatology consults, neuro consult, psych consult. Pt presented for Rheum eval 10/19/08 with c/o 6 week hx of pain and sensitivity in her face, jaw neck and thoracic region (burning & tingling) and progressive weakness in her limbs. Unable to walk without assistance. Pt reports dizziness, vertigo, syncope and photosensitivity. Sleep is disturbed. Several falls. Has sweats. Presents in sunglasses for photophobia and in a w/c. This followed a viral and /or sinus infection 6 weeks prior. PE (+) for anceiform rash on the back, scalp, face, jaw, and neck tenderness, DTRs 1+ arms, unobtainable in legs, decreased strength in arms and legs, unable to walk. Concern for neurological illness resulted in emergent admission to hospital for further eval. DOS 10/19-24/2007 with DX: weakness. other dx: fibromyalgia, migraines, asthma and chronic pain syndrome. Neuro consult as above but able to elicit patellar reflexes. Psych eval to r/o conversion d/o. Requested further eval. 2nd Rheum consult for increased sed rate. Additional sx of touch sensitivity and lower extremity numbness. Impression: Elevated Sed rate. Myalgia and myositis NOS, Headache, Difficulty in walking. Pt had some nausea and vomiting while admitted. Treated for pain and pt was ambulating on her own by d/c. No final dx made. D/C to f/u at home.

Other Meds:

Lab Data: spinal tap, ct, mri, emg, labwork. Labs and Diagnostics: CXR WNL. Lumbar MRI Unremarkable. Cervical MRI Unremarkable. Thoracis MRI Unremarkable. Brain MRI reported as WNL.CBC WNL. UA WNL. Sed rate 36 and 47. CRP 2.0. Chem unremarklable.

History: PMH: fibromyalgia, migraines, asthma, hernia surgery, abd surg.

Prex Illness:

Prex Vax Illns:

Vaers Id: **318052-4 (S)** **Related reports:** 318052-1; 318052-2; 318052-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	26-Jun-2007	29-Jun-2007	3	26-Mar-2009	27-Mar-2009	OH	WAES0903USA03234	31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Bedridden, Convulsion, Demyelination, Dyspnoea, Gait disturbance, Gastrointestinal disorder, Guillain-Barre syndrome, Hypophagia, Irritability, Joint swelling, Migraine, Neuropathy peripheral, Pain in extremity, Rash, Swelling face, Vaccine positive rechallenge, Weight decreased, Wheelchair user

Symptom Text: Information has been received from a consumer concerning her daughter a 22 year old patient with asthma who on 26-JUN-2007 was vaccinated with 0.5 ml of the first dose of GARDASIL (Lot not reported). Concomitant therapy included TOPAMAX. On approximately 29-JUN-2007 the patient experienced seizures and leg pain that would come and go. She also experienced problems breathing. After receiving her second dose of GARDASIL (Lot not reported) on 24-AUG-2007, all of her symptoms progressed extremely. She was very irritable and could hardly walk. She could crawl but she was mainly bed ridden and needed to use crutches or a wheel chair to get to her physician's office. She was experienced problems breathing and had "super migraines" that never went away and were there 24/7. She also had gastrointestinal problems and can hardly eat or digest well. She had lost a lot of weight. She also had a rash that went across her shoulders. The doctor found there was aluminum toxicity in her urine and hair. She had swelling in her face, jaw and wrists. The patient was diagnosed with GUILLAIN-BARRE syndrome, myelin sheath degeneration and peripheral neuropathy. Patient was hospitalized twice: 19-OCT-2007 to 24-OCT-2007 and on 14-DEC-2008 to 15-DEC-2008. She also visited an ER for a few hours but she was not admitted. Patient only received two doses of GARDASIL and the series was not completed. The consumer reported a multiple labs done to the patient. At the time of reporting 18-MAR-2009 the patient had not recovered from symptoms. Additional information has been requested.

Other Meds: Topamax

Lab Data: Diagnostic laboratory, ?/?/07, Aluminum toxicity in hair; Urine Al, ?/?/07, Aluminum toxicity

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **318058-1 (S)** **Related reports:** 318058-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Mar-2008	12-May-2008	48	01-Jul-2008	03-Jul-2008	RI		10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Left arm	Intramuscular	HPV4

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Aura, Blood product transfusion, Dyspnoea, Encephalopathy, Fatigue, Headache, Memory impairment, Nausea, Pallor, Palpitations, Personality change, Tachycardia, Weight increased

Symptom Text: Patient is on our inpatient service, currently on hospital day 13, admitted with 7 week history of limbic encephalopathy of unknown etiology. Symptoms inlcude 7 week history of episodes of palpitations and an olfactory aura, often followed by headache. Clinically, she demonstrates severe impairment in ability to form new long-term memories. 8/21/08-records received for DOS 6/19-7/2/08-DC DX: Limbic encephalopathy of unknown etiology. Presented with tachycardia and or pallor in setting of memory dysfunction. C/O episodes of fatigue, tachycardia associated with intermittent and occasional shortness of breath, pallor and dazed expression, nausea. Memory changes. On 5/12 presented to ED and diagnosed with questionable supraventricular tachycardia. Seen by neurologist for headaches. Personality changes increased laughter and hyperphasia and weight gain. Treated with IVIG.

Other Meds: none at time of vaccination

Lab Data: EEG shows subclinical seizures, MRI shows symmetric abnormal T2 bright signal within the head, body, and tail of the hippocampus bilaterally, worse on the right side. CSF IgG synthesis rate is increased. 8/21/08-records received-CSF 94 wh

History: allergy to amoxicillin (reaction not known); no birth defects or medical conditions

Prex Illness: none

Prex Vax Illns:

Vaers Id: **318058-2 (S)** **Related reports:** 318058-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Jan-2008	25-Mar-2008	57	02-Sep-2008	08-Sep-2008	RI		12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Amnesia, Blood product transfusion, Dizziness, Encephalopathy, Headache, Myalgia, Nausea, Pallor, Palpitations, Personality change, Tachycardia, Weight increased

Symptom Text: Diagnosed w/ Limbic Encephalopathy; headaches, palpitations, dizziness, nausea, memory loss, muscle ache 8/21/08-records received for DOS 6/19-7/2/08-DC DX: Limbic encephalopathy of unknown etiology. Presented with tachycardia and or pallor in setting of memory dysfunction. C/O episodes of fatigue, tachycardia associated with intermittent and occasional shortness of breath, pallor and dazed expression, nausea. Memory changes. On 5/12 presented to ED and diagnosed with questionable supraventricular tachycardia. Holter monitor normal. Seen by neurologist for headaches. MRI abnormal with increased hippocampal uptake and limbic encephalopathy involving grey matter more than white matter. Personality changes increased laughter and hyperphasia and weight gain. Treated with IVIG.

Other Meds: None

Lab Data: Tests administered: (WASI) Wechsler Abbreviated Scale of Intelligence/ Wechsler Intelligence scale for children fourth edition (WDC-IV; coding and symbol search) children's memory scale (CMS) 8/21/08-records received-CSF 94 white blood cel

History: Allergic to Amoxicillin

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318061-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		01-Jul-2008	04-Jul-2008	TN		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dry mouth, Dyspnoea, Fatigue, Feeling hot, Injection site pain, Pallor, Pyrexia, Tachycardia, Upper respiratory tract congestion, Vertigo, Vision blurred

Symptom Text: SHORTNESS OF BREATH, TACHYCARDIA, FEELING HOT, PALENESS, WEAKNESS, PAIN AT INJECTION SITE, BLURRED VISION, VERTIGO, DRY MOUTH (APPROXIMATELY 15 MINUTES AFTER INJECTION)TIREDNESS, CONGESTION, AND LOW FEVER (LASTING ABOUT 2 DAYS)

Other Meds: PAXIL 30 MG

Lab Data:

History: ALLERGY TO PENICILLIN

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **318062-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	23-Jun-2008	23-Jun-2008	0	01-Jul-2008	04-Jul-2008	WA		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Deafness, Dizziness, Dyspnoea, Heart rate decreased, Visual acuity reduced transiently

Symptom Text: -Extreme shortness of breath, difficulty breathing. -Extreme lightheadedness, weakness, and dizziness. -Loss of vision and hearing. -Low pulse rate: 54 after reaction compared to 75 during normal exam.

Other Meds: NECON 10/11

Lab Data: n/a

History: Oxycodone, Hydrocodone

Prex Illness: none.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318064-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jul-2008	01-Jul-2008	0	01-Jul-2008	04-Jul-2008	MI		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Heart rate decreased, Pallor

Symptom Text: Client stated she had not yet eaten today, given cookies while waiting for immunizations. Client became light-headed within one minute after receiving immunization. Assisted to supine position in chair (gravity chair). Given juice to sip. 11:01 am Pulse 60, skin slightly clammy, slightly pale. Given juice to sip. 11:04 am BP 110/66 11:07 am BP 112/64, pulse 60. States feels better, skin no longer clammy, color improving, continues in reclining position. 11:10 am Pulse 64. Finished juice. Given a sucker. Assisted to sitting position in gravity chair. Tolerated well. 11:12 am BP 110/56, pulse 72. States feels good. Color continues to improve, skin warm and dry. 11:14 am Ambulated to lobby with assistance, tolerated well, no c/o of light-headedness or other problem. Mom instructed to wait in lobby for 10 minutes and okay to leave if patient was feeling well in 10 minutes. 5:37 pm P/C to client's residence, spoke with Mom: states patient did not have any more problems since she left the HD and she is feeling fine now. Instructed to call PCP/HCHD prn.

Other Meds: unknown

Lab Data:

History: none

Prex Illness: no

Prex Vax Illns:

Vaers Id: **318067-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	30-Jun-2008	30-Jun-2008	0	01-Jul-2008	04-Jul-2008	NY		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB268DA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0063X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness

Symptom Text: loc >2 MIN, SIEZURE LIKE ACTIVITY < 1 MIN, PT. SENT TO ER VIA EMS AFTER MD EVAL.

Other Meds: NONE

Lab Data:

History: HEQADACHES (W /OC)

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **318078-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Jun-2008	30-Jun-2008	0	01-Jul-2008	07-Jul-2008	NY		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2623AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0067X		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bradycardia, Dizziness, Hyperhidrosis, Hypotension, Pallor

Symptom Text: 2-3 minutes after receiving inj Menactra, patient became diaphoretic pale, bradycardic, dizzy, hypotensive requiring prolonged assistance of approximately 45 minutes or so. 911 was called - transferred to ER.

Other Meds:

Lab Data: Labs were drawn by S/P epinephrine, IV Benadryl and IV Solumedrol, O2 mask 96

History: Patient on Zoloft and Straterra

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318079-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Jun-2008	24-Jun-2008	0	01-Jul-2008	07-Jul-2008	KY		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	625587A	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	14864	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: 2 episodes of syncope while at doctors office after receiving GARDASIL and MENACTRA vaccine. Was fine prior to getting vaccinated.

Other Meds: None

Lab Data: CT head results negative.

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318082-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	30-Jun-2008	30-Jun-2008	0	01-Jul-2008	07-Jul-2008	CA		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye swelling, Headache, Nausea, Swelling face, Vomiting

Symptom Text: 3 hours after vaccine - states felt swelling around eyes, "hard to keep eyes open". Following AM awoke with nausea and vomiting (x3) and facial swelling. Also complained of headache. Treatment at urgent care - given IV hydration, BENADRYL and ZOFRAN with relief of symptoms.

Other Meds: None

Lab Data: None performed.

History: Migraines

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318085-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	10-Jun-2008	Unknown		01-Jul-2008	09-Jul-2008	MI		09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	GLAXOSMITHKLINE BIOLOGICALS	AC14B054AA	4	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	19684	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2562AA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB233AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Wrong drug administered

Symptom Text: Tdap indicated due to age, DTaP ordered and given. Discussed with RN BSN at Health Center per CDC no ill effects, still counts as valid immunization. Instructed to complete VAERS Report.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318095-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		02-Jul-2008	03-Jul-2008	FR	WAES0806AUS00126	03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Paralysis

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning a 26 year old female who was vaccinated with GARDASIL. Subsequently, 1 day after vaccination, the patient experienced back pain and paralysis. At the time of reporting on 28-NOV-2007 the patient had recovered from back pain and paralysis. The agency considered that paralysis and back pain were related to therapy with GARDASIL. The original reporting source was not provided. Subsequently the patient's experienced was reported in an article. Upon internal medical review paralysis was considered an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318096-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jun-2008	04-Jun-2008	3	02-Jul-2008	03-Jul-2008	FR	WAES0806CZE00002	03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blister, Hypersensitivity, Rash

Symptom Text: Information has been received from a physician concerning a young female who was vaccinated with GARDASIL in June 2008. 3 days later the patient experienced strong skin allergy (rash, blisters) and was hospitalized on emergency department. The reporter felt that allergy was related to therapy with GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318097-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Feb-2007	28-Feb-2007	0	02-Jul-2008	03-Jul-2008	PA	WAES0703USA01334	03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received through the Merck pregnancy registry for GARDASIL, from a medical assistant concerning a 16 year old pregnant female who on 28-FEB-2007 was vaccinated with a dose of GARDASIL. Follow-up information has been received from a medical assistant and a cardiologist who reported that the patient delivered, vaginally, a healthy, normal, female, weighing 8 pounds, 3 ounces, at term. The pediatrician heard a "slight heart murmur" and the baby was sent to a cardiologist for an evaluation. On 27-MAY-2008 the patient was evaluated by a cardiologist. It was reported that a heart murmur was noted some time after birth. The patient had no cardiac symptoms and had normal growth and development. There was a history of hypertension in the family but not hyperlipidemia or premature coronary artery disease. On physical examination the baby's length was 66 centimeters and her weight was 7.5 kilograms, both of which were of the 50th percentile for age. Her resting heart rate was 135, respiratory rate was 32, and blood pressure was 94/54 in the right arm, 95/44 in the left arm, 105/60 in the left leg and 88/46 in the right leg. There was no pallor, cyanosis, or clubbing. Her chest was clear. There was no hepatosplenomegaly. Brachial and femoral pulses were adequate. There was no brachia-femoral delay. First and second heart sounds were normal. There were no clicks, thrills, rubs, or bruits noted. There was a grade 3, harsh systolic ejection murmur at the left sternal border. Diastole was clear. Her electrocardiogram demonstrated right ventricular hypertrophy. An echocardiogram was performed and demonstrated a mildly dilated and hypertrophied right ventricle with good systolic function. There was a dysplastic pulmonary valve with moderate pulmonic stenosis. The clinical impression was moderate pulmonic stenosis. The patient will be re-evaluated in one year with an electrocardiogram and echocardiogram and most likely will need to have the valve ballooned when she is about 2 or 3 years of age. In the interim,

Other Meds: Unknown

Lab Data: blood pressure, 05/27/08, 94/54 - baby right arm; blood pressure, 05/27/08, 95/44 - baby left arm; blood pressure, 05/27/08, 105/6 - baby left leg; blood pressure, 05/27/08, 88/46 - baby right leg; echocardiography, 05/27/08 - baby dysplast

History:

Prex Illness: Pregnancy NOS (LMP = 1/1/2007)

Prex Vax Illns:

Vaers Id: **318098-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Sep-2007	15-Sep-2007	14	02-Jul-2008	03-Jul-2008	FR	WAES0806AUS00122	03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Haemolytic anaemia, Transfusion

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing and Public Case Detail form concerning an 18 year old female who on 01-SEP-2007 was vaccinated with GARDASIL. On 15-SEP-2007, 14 days after vaccination, the patient experienced haemolytic anaemia reported as severe acute haemolytic anaemia, questionable cold amplitude IGG, paroxysmal cold and haemoglobuinurea. The agency also reported no evidence of viral or autoimmune of lymphoproliferaton origin. Subsequently, the patient was hospitalised and transfused with 4 units and received high dose of steroids penicillin over 10 weeks. On 26-OCT-2007, the patient haemoglobin was normal . RBC penicillin antibody testing was negative. Subsequently, on 26-OCT-2007, the patient had recovered from haemolytic anemia. The agency considered that haemolytic anaemia was related to therapy with GARDASIL. The original reporting source was not provided. Subsequently the patient's experienced was reported in an article. Additional information is not expected.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 15Sep07, haemolytic anaemia; red blood cell scan, ??Oct07, RBC Penicillin antibody testing: negative; urinalysis, ??Oct07, haemoglobinurea; hemoglobin, 26Oct07, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318099-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	19-Nov-2007	19-Nov-2007	0	02-Jul-2008	03-Jul-2008	FR	WAES0806AUS00129	03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Choking sensation, Oedema peripheral, Pruritus, Rash generalised, Rash pruritic, Throat irritation

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing and a Public Case Detail form concerning a 21 year old female with sleep disorder who on 19-NOV-2007 was vaccinated with GARDASIL. Other suspect therapy included AMOXIL and STILNOX. On 19-NOV-2007, after vaccination, the patient experienced rash (also reported as a red confluent itchy rash all over her body), oedema peripheral (also reported as swollen hands and feet), choking sensation and throat irritation and was hospitalised. The agency considered that rash, oedema peripheral, choking sensation and throat irritation were possibly related to therapy with GARDASIL, amoxicillin and zolpidem tartrate. The original reporting source was not provided. Subsequently the patient's experienced was reported in an article, 25-JAN-2008. Additional information is not expected.

Other Meds: amoxicillin

Lab Data: Unknown

History:

Prex Illness: Sleep disorder

Prex Vax Illns:

Vaers Id: **318100-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Jun-2007	04-Sep-2007	82	02-Jul-2008	03-Jul-2008	FR	WAES0806AUS00133	03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Agitation, Ataxia, Confusional state, Encephalitis, Endotracheal intubation, Intensive care, Leukoencephalomyelitis

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing and Public Case Detail Form concerning a 16 year old female who on 14-MAY-2007 and 14-JUN-2007 was vaccinated with the first and second dose of GARDASIL. On 04-SEP-2007, 113 days after the first vaccination and 82 days after the second vaccination, the patient experienced encephalitis, agitation, ataxia and confusional state, also reported as acute disseminated encephalomyelitis. The patient presented to the hospital on 08-SEP-2007 with agitation, confusion and ataxia. The patient was treated in the intensive care unit, intubated and ventilated and was given methylprednisolone. At the time of reporting on 20-NOV-2007, the patient's encephalitis, agitation, ataxia and confusional state persisted. The agency considered that encephalitis, agitation, ataxia and confusional state were possibly related to therapy with GARDASIL. The original reporting source was not provided. Subsequently the patient's experience was reported in an article. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 318101-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Jun-2008	Unknown		02-Jul-2008	03-Jul-2008	VA	WAES0806USA08119	03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Unknown	Unknown	
	UNK	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Grand mal convulsion, Lethargy, Loss of consciousness, Postictal state, Syncope, Tremor

Symptom Text: Information has been received from a physician concerning a 14 year old female patient who on 23-JUN-2008 was vaccinated with 0.5ml the first dose of GARDASIL (lot # 659180/17580). In June 2008, the patient experienced seizure like symptoms such as shaking and then fainted after receiving her first dose of GARDASIL as well as a few other injections. Other vaccines that the patient received at the time of visit were unknown. The patient recovered a few minutes after fainting. The patient sought medical attention. The physician reported on 23-JUN-2008 the patient received the first dose of GARDASIL (Lot Number 1758U; expiration date June 2010). Within two to three seconds, the patient's whole body started shaking for five seconds. The patient then passed out for five seconds and was then lethargic. The patient experienced a tonic-clonic seizure. The patient was postictal for twenty minutes. The patient lay down for fifteen minutes and then sat up for another twenty minutes. The patient got up fine and then left the office. No labs or diagnostic tests were performed. No treatment was given. Upon internal review, tonic-clonic seizures were determined to be an other important medical event. This is one of several reports from the same source. Additional information has been requested.

Other Meds:

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318102-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	Unknown	16-Mar-2008		02-Jul-2008	03-Jul-2008	VA	WAES0806USA08371	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Antinuclear antibody, Arthralgia, Joint swelling, Pallor, Systemic lupus erythematosus, Vasospasm

Symptom Text: Information has been received from a registered nurse concerning a 10 year old female patient with no allergies and family history of lupus who was vaccinated with two doses of GARDASIL. The patient developed lupus after vaccination. The vaccinations were administered at another location and no information was available on administration dates. The onset of the systemic lupus was unclear. The patient was performed unspecified blood and laboratory tests. The patient was first seen at the office on 16-MAY-2008. The patient's lupus persisted. Upon internal review, lupus was determined to be an other important medical event. Additional information has been requested. 7/14/2008 MR received from Rheumatology consult for initial and f/u visits 5/16/2008 and 5/29/2008. DX: Raynauds. Probably Lupus with limited manifestations of disease at this time. Pt presented for eval of a 2 mon hx of cold induced vasospasm in the hands in conjunction with a high ANA. Pt had cold induced pallor to the level of the PIP joint. Occasional arthralgias w/o joint swelling.

Other Meds: Unknown

Lab Data: Unknown. Labs and Diagnsotics: ANA (+) at 1: 640 speckled. Alpha 1 Globulin 0.38. Anti smith antibody (+). ESR in the 40's. UA (+) for moderate leukocytes, 5-9 WBCs, 2+ bacteria, 5-9 epis

History: Unknown PMH: none. Fam hx lupus.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318103-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Feb-2008	01-Feb-2008	0	02-Jul-2008	03-Jul-2008	--	WAES0806USA08730	03-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Benign intracranial hypertension, Brain neoplasm, Headache, Vision blurred

Symptom Text: Information has been received from a physician concerning a 12 year old female who in February 2008, was vaccinated with a dose of GARDASIL (lot number, injection site and route not reported). On the same day, the patient experienced headache and after several days she started with blurred vision, and was seen by an ophthalmologist that diagnosed Pseudo tumor Cerebri. The Pseudo tumor Cerebri was confirmed by an MRI of brain. Upon internal review, brain neoplasm was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance - confirm Pseudo tumor Cerebri

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318109-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	03-Apr-2008	03-Apr-2008	0	02-Jul-2008	09-Jul-2008	KY		09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2543AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1487U	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC42B020AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Dizziness, Inappropriate schedule of drug administration, Pyrexia

Symptom Text: 04/03/08 child received three vaccines. Ran high fever 103 degree temp. C/O dizziness and stayed in bed all day post vaccinations.

Other Meds: None

Lab Data: None

History: NKA, no illnesses

Prex Illness: None

Prex Vax Illns: ~Tdap (Boostrix)~1~10~In Patient

Vaers Id: 318111-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Jun-2008	25-Jun-2008	0	02-Jul-2008	09-Jul-2008	CA		09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye rolling, Fall, Syncope

Symptom Text: Patient stood up appox. 2 mins after injection, fainted, fell to the floor, and eyes rolled into the back of her head; this lasted 7-10 seconds, pt sat up - we monitored blood pressure for 1 hour.

Other Meds: TRENTINOIN 0.1% cream

Lab Data: glucose level: 96 normal & blood pressure every 10 mins

History: 1 acne, 2 allergic rhinitis

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318114-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jul-2008	01-Jul-2008	0	02-Jul-2008	09-Jul-2008	NC		09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Grand mal convulsion, Immediate post-injection reaction, Urinary incontinence

Symptom Text: Within one minute of GARDASIL injection, patient became dizzy, followed by clonic/tonic seizure of 30-40 seconds duration. Also lost bladder control. Afterwards, was A + O, resp. + BP normal, not post-ictal.

Other Meds: None

Lab Data: An EEG has been scheduled 7/9/08.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 318152-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	02-Jul-2008	02-Jul-2008	0	02-Jul-2008	05-Jul-2008	MT		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: PT GIVEN VACCINE, WAITED IN ROOM 10 MINUTES, PT FELT FINE, WENT TO LEAVE AND FAINTED, ASSISTED HER TO CHAIR WHERE SHE PROCEEDED TO FAINT AGAIN. ASSISTED PT TO TABLE TO LIE FLAT.VITAL SIGNS MONITORED. PT MONITORED EVERY 5 MINUTES. SLOWLY BEGAN TO RAISE HEAD OF BED AS PT TOLERATED. AMBULATED PT BEFORE ALLOWING HER TO BE DISCHARGED. TOTAL TIME FROM REACTION TO DISCHARGE 1.5 HOURS.

Other Meds: ORTHO TRI CYCLEN LO

Lab Data:

History: SULFA ALLERGY; MEDICAL CONDITIONS- IBS, DYSMENORRHEA

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318155-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	25-Jun-2008	27-Jun-2008	2	02-Jul-2008	05-Jul-2008	GA		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2559AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1776U	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0053X	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2766AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cellulitis, Familial risk factor

Symptom Text: Cellulitis developed on child's upper right arm (just like her brothers with same varivax vaccine on same day). Required abx tx and resolved.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318168-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Jun-2008	12-Jun-2008	2	02-Jul-2008	09-Jul-2008	NY		09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2616AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1889U	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral

Symptom Text: Swelling to R deltoid 6 cm area.

Other Meds: PPD, Aventis, C2812AA, LA, no previous doses

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318191-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Jun-2008	Unknown		03-Jul-2008	10-Jul-2008	CA		10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1585U	0	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1758U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Syncope

Symptom Text: Patient was given HPV #2 (LA) IM at approx. 11:00am. VARIVAX was given at approx. 11:10 am on (RA) SobQ. After VARIVAX was given pt. felt dizzy and faint. Patient then fainted and began to convulse for approx. 2-3 seconds. Pt. awake approx. 5 seconds later EPINEPHRINE was administered approx. 11:16 am 1 ml was given on (Rt) sub Q. at approx. 11:20 paramedic arrived. 11:35 am BENADRYL 1ml/50mg was administered. Taken to ER for observation

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318196-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Jul-2008	02-Jul-2008	1	03-Jul-2008	10-Jul-2008	PA		05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus generalised, Rash, Rash pruritic, Skin warm, Urticaria

Symptom Text: Patient states she developed hives 12 hours after GARDASIL vaccine administration. She describes red, warm, welt-like, pruritic lesions and generalized itchiness on arms, legs bilateral and abdomen and back. They resolved after use of over the counter Benadryl but pruritis remained. Denied shortness of breath, wheezing, oral swelling, dizziness, syncopy. She was advised to continue Benadryl (plus over the counter Claritin/Zyrtec) until symptoms completely resolved by our nurse 7/2/08 and myself 7/3/08.

Other Meds: Springtec 28 generic; oral contraceptive pills

Lab Data: None

History: Allergic rhinitis; mild asthma; migraine; h/a; general anxiety disorder; high risk HPV pap 8/07

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318199-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Jun-2008	24-Jun-2008	0	03-Jul-2008	10-Jul-2008	NH		10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2771AA	4	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Dyskinesia, Fall, Gaze palsy, Pallor

Symptom Text: Pt was given the Tdap vaccine and then the GARDASIL and as soon as she had the GARDASIL vaccine she fell back into the chair. Her eyes rolled back, had some jerking moments only a few seconds. No seizure activity. Was alert in a few minutes and able to speak. Skin was pale BP 106/70, BS-98. Had not eaten breakfast. Color was better after 30 min. able to sit up and left under her own power.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318205-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Jul-2008	02-Jul-2008	1	03-Jul-2008	05-Jul-2008	MI		07-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2938AA	5	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2619AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1968U	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAAVB284DA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amnesia, Anaemia, Back pain, Dizziness, Fall, Headache, Loss of consciousness, Syncope, Tremor, Vomiting

Symptom Text: On the day after vaccinations @ 1pm in the afternoon (received her vaccines 4:30pm the day before), patient complained of backache, dizziness and headache. Parent said she bumped into her brother and all of a sudden fell to the ground. She started shaking and seemed to be "unconscious" (fainty). She also vomited @ that time. She doesn't remember falling. She was taken immediately to the local ER. All tests @ ER were normal; "just slightly anemic"

Other Meds: None

Lab Data: EKG CATscan Bloodwork UA

History: None; Was tested for possible muscle problem but none was found

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318209-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Jun-2008	19-Jun-2008	0	03-Jul-2008	05-Jul-2008	MI		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope following administration of immunization.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318210-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	19-Jun-2008	19-Jun-2008	0	03-Jul-2008	05-Jul-2008	MI		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope following administration of immunization.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **318212-1 (S)** **Related reports:** 318212-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Jun-2008	28-Jun-2008	1	03-Jul-2008	07-Jul-2008	IL		30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	05244	1	Unknown	Intramuscular	HPV4

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Body temperature increased, Cardiac arrest, Chest tube insertion, Dyspnoea, Endotracheal intubation, Gastrointestinal tube insertion, Headache, Intensive care, Mechanical ventilation, Myelitis transverse, Pain in extremity, Paralysis, Paralysis flaccid, Plasmapheresis, Pleural effusion, Pneumonia aspiration, Pneumothorax, Respiratory alkalosis, Respiratory failure, Tracheostomy

Symptom Text: 14 year old (previously health) (no recent history of URIs or trauma)- History significant for fact that she received Gardasil at clinic on 6/27/08 (2nd dose- first dose in April 2008)- On 6/28/08 patient with acute onset severe headache, left arm pain(paralysis)- leading to parents to call 911- by the time ambulance arrived patient with flaccid paralysis and asystolic event in ambulance requiring atropine IV-- currently in ICU with bilateral upper and lower extremity paralysis and respiratory failure (ventilated)-- diagnosed with : classic transverse myelitis currently of unknown etiology8/28/08-records received-presented to ED on 6/28/08 with acute onset of flaccid paralysis, sudden onset of severe headache on day of presentation followed by arm pain. Shortly thereafter lost tone in all extremities. Intubated in field and went into asystole. Placed on ventilator. Hospital course complicated by right sided pleural effusion and pneumothorax requiring placement of chest tube. DX with aspiration pneumonia. Nasogastric tube insertion. Unable to be extubated. Respiratory alkalosis. Plasmapheresis. PE on 7/7/08 no change since admission. Dyspnea. DX:transverse myelitis of unknown etiology, intubated secondary to respiratory failure with persistent sensation of air hunger. 9/10/08-DC Summary received for DOS 6/28-8/7/08- DX:Transverse myelitis. Plasmapheresis. Etiology of transverse myelitis was negative. Re-developed temperature and deep touch sensation in extremities, three weeks after event regained deep tendon reflexes and positive Babinski sign bilaterally. Neuropathic pain. Tracheostomy and mechanical ventilation. Asystole of unknown etiology. Transferred to rehabilitation facility.

Other Meds: none- no herbals, other OTC medications, no prescription medications

Lab Data: (6/28) ESR - 18, CRP <5, lactate 1.3, NH3 73 (6/30) CSF - 5wbc(2S, 83L, 15M) , 99 RBC, 103 Glu, 19 Pro - CSF for HSV, enterorvirus, westnile IgM all pending - CSF bacterial culture negative, ATIII 106, Protein C 114, Protein S 84, INR 1.2,

History: none

Prex Illness: none- no recent viral illness- no history of trauma

Prex Vax Illns:

Vaers Id: **318212-2** **Related reports:** 318212-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		23-Jul-2008	24-Jul-2008	--	WAES0807USA03046	08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cardiac arrest, Myelitis transverse

Symptom Text: Information has been received from a medical officer at CBER, concerning a 14 year old female who on an unknown date was vaccinated with the first dose of GARDASIL. Within 24 hours of the vaccination, the patient experienced immediate asystole followed by transverse myelitis. Upon internal review, immediate asystole and transverse myelitis were considered to be other important medical events. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318217-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	26-Jun-2008	27-Jun-2008	1	03-Jul-2008	05-Jul-2008	MI		07-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness, Upper respiratory tract infection

Symptom Text: Pt reported flu like symptoms and Upper respiratory symptomsafter receiving Gardasil lot#0279x exp10-23-2010

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **318224-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	08-Nov-2007	22-Nov-2007	14	04-Jul-2008	05-Jul-2008	WA		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Dizziness, Ear discomfort, Ear pain, Eustachian tube dysfunction, Fatigue, Headache, Hypoaesthesia, Joint sprain, Meniscus lesion, Middle ear effusion, Musculoskeletal stiffness, Nausea, Paraesthesia, Rhinitis allergic, Sinus headache, Tremor, Upper respiratory tract congestion

Symptom Text: Fluid and feeling of pressure in ears; shakiness/trembling; dizziness; tingling/numbness in legs; sudden sharp head pain; nausea; stiff neck. Symptoms are intermittent and unpredictable in their onset. Lasts anywhere from a day to a week. Physician refused to acknowledge that the vaccine could be a potential cause of symptoms, no treatment given. 7/21/2008 MR received from PCP from 7/10/2007 (1st HPV4) through 5/01/2008. No c/o after 1st HPV4. #2 given 11/08/07. Seen 2/28/08 with c/o recurring URI sx, neck pain, fluid in ears with occ soreness, sinus pressure, feeling tired, lightheaded, nauseous. Assessment: Eustachian tube dysfunction. allergic Rhinitis. Seen again 3/17/08 with improvement in ear plugging and congestion. HPV4 #3 given. Returned 5/01/08 with c/o L knee pain. Assessment: Sprained medial and collateral ligaments of L knee. Acute meniscal tear L knee.

Other Meds: bupropion; NuvaRing birth control; buspirone

Lab Data: Symptoms continue. Allergy tests performed and came back negative.

History: anxiety / panic disorder, depression. PMH: Anxiety, Depression, Panic Attacks

Prex Illness: common cold

Prex Vax Illns:

Vaers Id: **318232-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	30-Jun-2008	02-Jul-2008	2	03-Jul-2008	10-Jul-2008	NM		10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB268EA	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	L5LLU	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0960F	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site irritation, Injection site mass, Injection site pruritus, Injection site warmth

Symptom Text: 3-4 cm warmth, erythematous mass, burning sensation, pruritic at injection site of varicella.

Other Meds: No

Lab Data: N/A

History:

Prex Illness: No

Prex Vax Illns:

Vaers Id: **318244-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		07-Jul-2008	08-Jul-2008	FR	WAES0806USA09042	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death, Malaise, Pulmonary embolism

Symptom Text: Information has been received from a physician concerning a 20 year old female with no relevant medical history reported who was vaccinated with a first dose of GARDASIL on an unspecified date. Subsequently, exact onset not reported, the patient felt unwell. About 6 weeks post vaccination, she experienced pulmonary embolism with fatal outcome. An autopsy is scheduled. Other business partner numbers included: E2008-05832. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **318245-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Feb-2007	Unknown		07-Jul-2008	08-Jul-2008	--	WAES0703USA03656	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1425F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Stillbirth

Symptom Text: Initial and follow up information has been received from a physician's assistant for the Pregnancy Registry for GARDASIL concerning a 14 year old female with no known allergies and attention deficit/hyperactivity disorder who on 15-FEB-2007 was vaccinated with GARDASIL (Lot#655165/1425F). Concomitant therapy included CONCERTA. On 15-MAR-2007, a urine pregnancy test revealed the patient was pregnant (LMP & EDD = approximately 28-JAN-2007 & 04-Nov-2007). On 17-MAR-2007, a quantitative HCG showed 6-7 weeks gestation. The patient had no symptoms and sought unspecified medical attention. On 01-JUL-2008 the physician's assistant (PA) was informed by the patient's sister, that the patient delivered a stillborn baby "early." The PA was given very limited information and did not know the date of delivery or estimated gestational age. No further information is available.

Other Meds: CONCERTA

Lab Data: urine beta-human, 03/15/07 - positive; total serum human, 03/17/07, 6-7 week gestation

History:

Prex Illness: Pregnancy NOS (LMP = 1/28/2007); Attention deficit/hyperactivity disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318257-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		07-Jul-2008	08-Jul-2008	FR	WAES0806USA09130	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a health professional concerning a female with no relevant medical history reported who on an unspecified date, was vaccinated with her second dose of GARDASIL. On an unspecified date post vaccination, the patient experienced her first seizure. No further details were reported. The patient's seizure was considered to be an other important medical event. Other business partner numbers included E2008-06027. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318258-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	20-Jun-2008		07-Jul-2008	08-Jul-2008	FR	WAES0806USA08919	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Coma, Convulsion, Somnolence

Symptom Text: Information has been received from a physician (general practitioner and diabetologist) concerning a female who was vaccinated with GARDASIL. On 20-JUN-2008 the patient was admitted to the hospital for suspicion of seizure. On 21-JUN-2008 the patient was transiently comatose and subsequently somnolent for 1 hour. At the time of the report the outcomes of the seizure, transient coma and subsequent somnolence were unknown. The reporter assessed the causal relationship between the adverse event and the vaccination as "possible." Other business partner numbers included: E2008-05834.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 318259-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	19-Nov-2007	20-Nov-2007	1	07-Jul-2008	08-Jul-2008	FR	WAES0806AUS00123	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Diarrhoea, Drug withdrawal convulsions, Malaise, Vomiting

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing and Public Case Detail Form concerning a 20 year old female who on 19-NOV-2007 was vaccinated with GARDASIL. Other suspect therapy included LEXAPRO. Concomitant therapy included DIANE 35 ED. On 20-NOV-2007, 1 day after vaccination, the patient experienced diarrhoea, drug withdrawal convulsions, malaise and vomiting reported as diarrhoea, vomiting and was unwell and had seizures, and was hospitalised. The patient had run out of escitalopram oxalate and had not taken it for 6 days (also reported as stopped 14-OCT-2007). The agency considered that diarrhoea, drug withdrawal convulsions, malaise and vomiting were possibly related to therapy with GARDASIL or withdrawal from therapy with escitalopram oxalate, or a combination of both or an other illness. The original reporting source was not provided. Subsequently the patient's experience was reported in an article. Additional information is not expected. A copy of the published literature article is attached as further documentation of the patient's experience.

Other Meds: LEXAPRO; escitalopram oxalate

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318260-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		07-Jul-2008	08-Jul-2008	FR	WAES0806AUS00125	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cranial nerve paralysis

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning a 15 year old female who was vaccinated with GARDASIL. Subsequently, 1 day after vaccination, the patient experienced cranial nerve paralysis. At the time of reporting on 21-NOV-2007, the patient's cranial nerve paralysis persisted. The agency considered that cranial nerve paralysis was related to therapy with GARDASIL. The original reporting source was not provided. Subsequently the patient's experience was reported in an article. Upon internal medical review cranial nerve paralysis was considered an other important medical event. Additional information is not expected. A copy of the published literature article is attached as further documentation of the patient's experience.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 318261-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
33.0	F	01-Oct-2007	01-Oct-2007	0	07-Jul-2008	08-Jul-2008	FL	WAES0804USA06319	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Inappropriate schedule of drug administration, Premature labour

Symptom Text: Information has been received from a 33 year old female physician for the Merck Pregnancy Registry for GARDASIL, with hypothyroidism and no known drug allergies, who on 01-OCT-2007 was vaccinated intramuscularly into the deltoid with a first dose of GARDASIL. Concomitant medication included SYNTHROID. The patient reported that her last menstrual period was 18-SEP-2007 and she ovulated and conceived 03-OCT-2007. The patient sought unspecified medical attention with another physician. A pregnancy test was performed. On 17-JAN-2007 amniocentesis performed at 16 weeks reported that cytomegalovirus, enterovirus and Toxoplasma were not detected. She went into preterm labor at 34 weeks on 18-MAY-2008 and delivered her daughter by cesarean section at 17:02, weight 400 grams. She reported that she did not experience any other problems with her pregnancy (except an elevated Downs syndrome risk for which she had the amniocentesis). She does not think that the vaccine had anything to do with her preterm labor. Placenta pathology report indicates a third trimester placenta at 34 weeks gestation with subchorionic fibrin deposition and less than 5% of placental disc. Also noted were microcalcifications, intraparenchymal hemorrhage, no acute chorioamnionitis, and a trivascular umbilical cord. On 19-MAY-2008 the patient recovered. No product quality complaint was involved. Upon internal review preterm labor at 34 weeks delivering by cesarean section was considered to be an other important medical event. Additional information has been requested.

Other Meds: SYNTHROID, 100 microgm

Lab Data: diagnostic laboratory, elevated Down syndrome risk; amniocentesis, 01/17/08, cytomegalo virus, enterovirus and Toxoplasma were not detected; beta-human chorionic; pathology analysis, 05/18/08, see narrative

History:

Prex Illness: Pregnancy NOS (LMP = 9/18/2007); Hypothyroidism

Prex Vax Illns:

Vaers Id: **318262-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	11-Mar-2008	Unknown		07-Jul-2008	08-Jul-2008	FR	WAES0806USA06047	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Brain neoplasm, Dizziness postural

Symptom Text: Information has been received from a gynecologist concerning a 21-year-old female patient who on 11-MAR-2008 was vaccinated via intramuscular route into the right upper arm with a first dose of GARDASIL. Concomitant suspect therapy included hormonal contraceptives started shortly after vaccination. Subsequently, on an unknown date, the patient complained about dizziness on standing up. Neurological tests and examinations through an ENT (ear nose throat) specialist (not specified) showed normal findings. MRI results were pending. Symptoms were ongoing at the time of reporting. Follow up information was received which reported that the case was upgraded as an other important medical event since diagnosis of brain tumor has been established. On 08-MAY-08 a cranial MRI was carried out. it showed that a brain tumor (no other specified). No further information is available since the patient did not present at the office again. It is possible that she has moved to her parents in another city. Other business partner numbers included E2008-04228.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: magnetic resonance imaging, 08May08, Comment: cranial MRI showed a brain tumor (no otherwise specified); neurological examination, Comment: normal; magnetic resonance imaging, Comment: pending

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318263-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Sep-2007	03-Sep-2007	0	07-Jul-2008	08-Jul-2008	FR	WAES0806AUS00121	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0138U		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Headache, Muscle spasms, Neck pain, Vision blurred

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 15 year old female who on 03-SEP-2007 was vaccinated with GARDASIL (Lot No. 655742/0138U, Batch No. J0799, Expiry date 07-AUG-2009). On 03-SEP-2007 the patient experienced headache, dizziness, muscle spasms, neck pain and vision blurred and was hospitalised. It was described that 20 minutes post vaccination, the patient experienced severe headache, dizziness, neck pain/spasms, blurred vision and was seen by a general physician, an optometrist and a paediatrician. A neck x-ray and a head CT were performed. The patient was admitted to hospital for investigation. All her results were found to be negative. At the time of reporting to the agency on 26-NOV-2007, the outcome of headache, dizziness, muscle spasms, neck pain and vision blurred was unknown. The agency considered that headache, dizziness, muscle spasms, neck pain and vision blurred were possibly related to therapy with GARDASIL. The original reporting source was not provided. Subsequently the patient's experience was reported in an article. Additional information is not expected.

Other Meds: Unknown

Lab Data: Neck X-ray, 03Sep07, negative; Head computed axial tomography, 03Sep07, negative.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318264-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-May-2008	31-May-2008	1	07-Jul-2008	08-Jul-2008	FR	WAES0806USA07985	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTIPV	UNKNOWN MANUFACTURER	NULL		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mass, Myalgia, Pyrexia

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 30-MAY-2008, was vaccinated with the first dose of GARDASIL and a dose of DT-IPV in the shoulder. Batch number and routes were not reported. In the morning of 31-MAY-2008, the patient had fever between 40 and 41 degrees C and muscle soreness. The patient was directed to hospital where she was under observation at emergency room. On the evening of the same day, she left the hospital. According to the emergency department, the reaction was to GARDASIL. The patient fully recovered in two days. On 11-JUN-2008, the physician observed a "mass" on each wrist which seemed to be cyst although that it presented abnormal osseous excrescence reported as rigid, remain fixed and were painful. The events appeared a week after the vaccination. A work up was scheduled. At the time of the report, the patient was not recovered. Fever and muscle soreness have been reported following both DT-IPV and human papillomavirus vaccines. Time to onset, clinical feature and quick recovery are consistent with the role of the vaccines. No conclusion can be drawn regarding the mass on each wrist that appeared one week after vaccination as neither results of investigations nor final diagnosis are available. Another etiology can therefore not be ruled out. Other business partner numbers included: E2008-05572. The fever, muscle soreness and pain were considered to be other medically important conditions.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 318265-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-Aug-2007	22-Aug-2007	1	07-Jul-2008	08-Jul-2008	VA	WAES0806USA08590	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	0	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Anticoagulant therapy, Asthenia, Cardiac murmur, Cardiac operation, Cerebrovascular accident, Chest discomfort, Confusional state, Convulsion, Dizziness postural, Dysarthria, Embolic stroke, Endocarditis, Expressive language disorder, Extensor plantar response, Gait disturbance, Headache, Hypoaesthesia, Intracardiac thrombus, Memory impairment, Mental status changes, Mitral valve incompetence, Muscular weakness, Palpitations, Paraesthesia, Pyrexia, Strabismus, Streptococcal infection, Vision blurred, Vomiting

Symptom Text: Information has been received from a medical assistant concerning an approximately 15 year old female who in approximately 2007, "about a year ago," was vaccinated with a first dose of GARDASIL. On the same date experienced a stroke with unspecified symptoms. The patient was hospitalized for treatment of the stroke and underwent open heart surgery. The patient suffered a second stroke (date unspecified) subsequent to the open heart surgery. At the time of the report the patient was recovering. Additional information has been requested. 8/08/2008 MR received for DOS 8/22-9/12/2007 with D/C DX: Infective endocarditis 2' to Streptococcus sanguinis infection. Left sided CVA 2' to embolic stroke from mitral valve thrombus. Moderate to severe mitral valve regurgitation. Residual R upper extremity weakness 2' to L sided CVA. Pt presented to ER with c/o severe H/A as well as right-sided weakness, numbness, vomiting and mental status changes. Pt had had some subjective fever with chest discomfort and palpitations over the past 4 weeks. Pt now with confusion and unintelligable language. PE (+) for 3-4/5 muscle strength on R side. 3/6 holosystolic murmur. R sided toes not downgoing. Dizziness upon standing, poor short-term memory, slurred speech, blurry vision and intermittant R eye esotropia. Admitted with dx of bacterial endocarditis and septic ebolic stroke of the L posterior cerebral artery. Concern for seizures with normal EEG. Tx with heparin/lovenox and abx via a Broviac cath with partial resolution of neuro sx. By d/c able to ambulate, but somewhat unsteady gait r/t paresthesias on the R side. Lower extremity strength returning with some residual weakness in the upper extremities.

Other Meds: Unknown

Lab Data: Unknown. Labs and Diagnostics: CT scan of the head read as normal. MRI & MRA (+) for stroke in L PCA. Multiple Echos (+) for Mitral valve vegetation (thrombus) and mitral regurg. Blood cx (+) for gram (+) cocci initially then (-). EEG WN

History: Unknown. PMH: VSD, MVP. On oral contraceptives in the past. D/C 2 weeks prior to admission. Wisdom tooth extraction 3 months ago.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318266-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		07-Jul-2008	08-Jul-2008	PA	WAES0806USA08593	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a female who was a premature infant with a history of seizures as an infant (no current seizure history) who was vaccinated with a first dose of GARDASIL. Subsequently, the patient had a seizure the following day. The patient sought unspecified medical attention. At the time of the report the patient's outcome was recovered. Upon internal review, the seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Premature baby; Convulsion

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318267-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		07-Jul-2008	08-Jul-2008	OH	WAES0806USA08777	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a physician concerning some patients who were vaccinated with a dose of GARDASIL. After receiving GARDASIL the patients fainted or had seizures. At the time of the report, it was unknown if the patients had recovered from the events. Upon internal review, seizures were considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318268-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	28-Nov-2007	01-Jan-2008	34	07-Jul-2008	08-Jul-2008	FR	WAES0806USA08864	04-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Arrhythmia, Muscle rupture, Muscle spasms, Pain in extremity, Sleep disorder

Symptom Text: Information has been received from a pharmaceutical assistant concerning a 28 year old female with a history of cervical conization in 2004 who on 28-NOV-2007 was vaccinated with a 3rd dose of GARDASIL IM into the left upper arm. Other suspect drug included thyroid medication. Concomitant therapy included hormonal contraceptives for systemic use. In January 2008, the patient developed cardiac arrhythmia and sleep disorder. Cardiological examination was normal including prolonged electrocardiogram (ECG). Since March 2008 she additionally developed pain and cramps in the legs and anxiety. She experienced also a rupture of a muscle fiber. Further investigations are planned. The patient was vaccinated with a 1st dose and 2nd dose of GARDASIL, both lot # not reported on an unspecified date, which were well tolerated. Other business partner numbers included: E2008-05846. Additional information has been requested.

Other Meds: hormonal contraceptives (unspecified); thyroid

Lab Data: electrocardiogram, Comment: cardiological examination was normal including prolonged ECG

History: Cervical conisation

Prex Illness:

Prex Vax Illns:

Vaers Id: **318269-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	20-Aug-2007	08-Sep-2007	19	07-Jul-2008	08-Jul-2008	IA	WAES0806USA08855	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received through a Merck pregnancy registry from a 27 year old female with penicillin allergy and no pertinent medical history who on 20-AUG-2007 was vaccinated with a single dose of GARDASIL. There was no concomitant medication. She became pregnant in September 2007. A pregnancy test was performed (result not provided). Her LMP was 08-SEP-2007. Expected date of delivery was 14-JUN-2008. The patient did not have any adverse symptoms as a result of receiving GARDASIL. She did not have any additional doses of GARDASIL. On 11-JUN-2008 the patient gave birth to a baby girl. The child had been diagnosed with congenital cataracts in both eyes. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic - results pending

History:

Prex Illness: Pregnancy NOS (LMP = 9/8/2007); Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318272-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		07-Jul-2008	08-Jul-2008	FR	WAES0806USA08861	07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diplegia, Monoparesis, Paresis

Symptom Text: Initial information has been received from a physician concerning a female who was vaccinated with a second dose of GARDASIL on an unspecified date. About 10-11 days post-vaccination the patient experienced signs of paresis in legs. The patient was admitted to a neurological hospital. Other business partner numbers included E2008-05884. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318273-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	23-May-2008	30-May-2008	7	07-Jul-2008	08-Jul-2008	FR	WAES0806USA09038	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Type 1 diabetes mellitus

Symptom Text: Information has been received from a hospital physician concerning a female medical student who on 23-MAY-2008 was vaccinated with a third dose of GARDASIL. One week post vaccination she was diagnosed with type 1 diabetes mellitus. The patient had not recovered. The reporter contacted to enquire whether an increase of autoimmune diseases is known after administration of GARDASIL. Other business partner numbers included E2008-05651. Additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 318274-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Jul-2007	18-Aug-2007	33	07-Jul-2008	08-Jul-2008	MA	WAES0709USA03475	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received from the Merck pregnancy registry for GARDASIL from a physician concerning a 17 year old female who on 16-JUL-2007 was first vaccinated with 0.5 ml, GARDASIL. Concomitant therapy included albuterol which the patient used infrequently. On 17-SEP-2007, the patient presented to the office to get her second dose of GARDASIL but a urine test showed positive HCG and the client was pregnant (LMP 18-AUG-2007). The second dose of GARDASIL was not administered. Followup phone call information from a pediatrician reported that the patient had not been back to the pediatrician's office since she found out she was pregnant. However, the pediatrician was able to report that via their tracking system, it appeared that the patient was still pregnant and had an upcoming appointment. She also reported the patient had been admitted to the hospital for pre-term labor from 28-MAY-2008 to 31-MAY-2008. No outcome information was reported. Additional information has been requested.

Other Meds: Albuterol

Lab Data: urine beta-human, 09/17/07, positive HCG, client pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 8/18/2007)

Prex Vax Illns:

Vaers Id: **318275-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	19-Apr-2007	31-May-2007	42	07-Jul-2008	08-Jul-2008	NY	WAES0706USA03468	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received through the Merck pregnancy registry from a 23 year old female, with no pertinent medical history, who on 19-APR-2007 was vaccinated IM with a third dose of GARDASIL. There was no concomitant medication. Subsequently, the patient became pregnant. Date of conception was reported as 31-MAY-2007. The patient reported a beta-human chorionic gonadotropin test (unspecified) was performed. There were no adverse reactions. At the time of the report the outcome of the patient was unknown. On 29-FEB-2008 the patient gave birth to a liveborn infant via cesarean section. The indication for the cesarean section was not provided. The infant was healthy, normal, and delivered at full term. Additional information is not expected.

Other Meds: None

Lab Data: beta-human chorionic

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318276-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Nov-2007	Unknown		07-Jul-2008	08-Jul-2008	FR	WAES0807AUS00041	04-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0582U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Encephalitis viral, Multiple sclerosis, Neurological symptom

Symptom Text: Information has been received from a physician via CSL as part of a business agreement (manufacturer control # GARD 2008 07 01 001) concerning a 25 year old female who on 06-AUG-2007 was vaccinated with the first dose of GARDASIL (Lot No. 655743/0313U, Batch No. J1022, Expiry date, 08-AUG-2009). On 01-NOV-2007 the patient was vaccinated with the second dose of GARDASIL (Lot No. 657874/0582U, Batch No. J2299, Expiry date 26-FEB-2010). Subsequently the patient experienced neurological symptoms post GARDASIL. Initially the patient was diagnosed with viral encephalitis. In May/June 2008 the patient was diagnosed with multiple sclerosis by a neurologist that was confirmed by MRI. Upon internal medical review, multiple sclerosis was considered an important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance imaging May/June 2008 - diagnosed with multiple sclerosis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318277-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	05-Apr-2007	23-Aug-2007	140	07-Jul-2008	08-Jul-2008	--	WAES0803USA02153	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal injury, Anaemia, Caesarean section, Delivery, Drug exposure during pregnancy, Fall, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a consumer, a 21 year old female, through the Merck Pregnancy Registry for GARDASIL, who on 05-APR-2007 was vaccinated with a first dose of GARDASIL (Lot # unknown), and on 18-SEP-2007 she was vaccinated with a second dose of GARDASIL (Lot # unknown). On 21-OCT-2007 she found out she was pregnant after the second dose. The consumer had performed two pregnancy tests, one was done on 22-OCT-2007 and then another on 08-NOV-2007. Both tests came back positive (estimated LMP 23-AUG-2007). Unspecified medical attention was sought. The consumer reported that she is 29 weeks pregnant. Follow up information has been received from a certified nurse midwife. The patient's significant past medical history was benign. The patient had one previous pregnancy which was a full term delivery. The patient's LMP was confirmed to be 19-AUG-2007 and her estimated delivery date to be 25-MAY-2008. On 04-JAN-08 the patient was started on prenatal vitamins (unspecified) for pregnancy/nutrition. The nurse midwife indicated that the following labs/diagnostics studies were performed: on an unspecified date for Hepatitis C Antibody (tested reactive); on an unspecified date recombinant immunoblot assay (RIBA) (negative); on 04-JAN-2008 alpha-fetoprotein (AFP) (negative) and on 10-JAN-2008 an ultrasound for anatomay (WNL, confirmed dates). On 10-MAR-2008 the patient had a 24 hour urine test and liver function tests which were within normal levels. On 10-MAR-2008, the patient also had a hematocrit of 30, which was done because of anemia. The reporter noted that on 24-MAR-2008, at 31 weeks gestation, the patient fell and hit her abdomen. Labs and electronic fetal monitoring were within normal at that time. On1 5-APR-2008 the patient was started on ED Cyte F for the anemia. No product quality complaint was involved. On 23-MAY-2008, at 39 5/7 weeks from the LMP, the patient underwent primary caesarean section for multiple variable fetal heart decelerations shown on electronic fetal monitoring, and delivered a full

Other Meds: Unknown

Lab Data: Ultrasound, 01/10/08, WNL, Anatomy, confirmed dates; Fetal monitoring tests, 03/24/08, WNL; Fetal monitoring tests, 05/23?/08, Variable fetal heart decelerations; Beta-human chorionic, 10/22/07, positive, pregnant; Beta-human chorionic, 11/

History:

Prex Illness: Pregnancy NOS (LMP = 8/19/2007)

Prex Vax Illns:

Vaers Id: 318278-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Jan-2008	Unknown		07-Jul-2008	08-Jul-2008	FR	WAES0806USA08646	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0352U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diplopia, Dizziness, Hypoaesthesia, Neck pain, Vision blurred

Symptom Text: Information has been received from a general practitioner concerning a 16 year old female with history of breast surgery in March 2008, who on 28-NOV-2007 was vaccinated with the first dose of GARDASIL (Lot # 0276U; batch NF58550) which was well tolerated. On 24-JAN-2008, the patient was vaccinated with the second dose of GARDASIL (Lot # 0352U; batch NG00320). Since January 2008, the patient experienced recurrent neck pain with dizziness, numbness of the skin and double/blurred vision. In the course she presented to a chiropractor once. After "setting maneuver" symptoms improved for short time. She was hospitalized for diagnostics from 11-APR-2008 to 17-APR-2008. All examinations including ophthalmologic check up, electroencephalography (EEG), cranial magnetic resonance imaging (MRI), sonography, X-ray of cervical spine and routine laboratory test showed normal results. Treatment was carried out with analgesics (not specified), ruby light and massage and lead to slow improvement. A psychogenic cause for the complaints was assumed. At the time of the report she had not yet completely recovered. Other business partner numbers included: E2008-05737. Additional information has been requested.

Other Meds: Unknown

Lab Data: ophthalmological exam, Normal; electroencephalography, Normal; magnetic resonance imaging, Normal; ultrasound, Normal; spinal X-ray, Normal; diagnostic laboratory test, Normal

History: Breast operation

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318279-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Oct-2007	09-May-2008	221	07-Jul-2008	08-Jul-2008	FR	WAES0806USA08650	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Grand mal convulsion

Symptom Text: Information has been received from a paediatrician concerning a 14 year old female with house dust mite allergy and history of manifestation of neurodermatitis after the first hepatitis B vaccination (Manufacturer not reported) on 10-SEP-2002, who was vaccinated with the first dose of GARDASIL in October 2007 (lot # not reported) and the second dose of GARDASIL (lot # not reported) in December 2007. Both doses were well tolerated. The patient was vaccinated with the third dose of GARDASIL (Lot # 1201U; batch NG29050) IM into the left upper arm on 05-MAY-2008. On 09-MAY-2008, the patient experienced two grand mal convulsions. The patient was hospitalized. Diagnosis of grand mal epilepsy was established. Electroencephalogram (EEG) was pathological. Cerebrospinal fluid (CSF) and cranial magnetic resonance imaging (MRI) were normal. Continuous medication with antiepileptics (valproate sodium) was started. No further convulsions under therapy. File closed. Other business partner numbers included: E2008-05759. No further information is available.

Other Meds:

Lab Data: electroencephalography, pathological; spinal tap, normal; magnetic resonance imaging, normal

History: Neurodermatitis

Prex Illness: House dust mite allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318280-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		07-Jul-2008	08-Jul-2008	IL	WAES0806USA08944	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from an office manager in a physicians office concerning a female (age unreported) who on an unspecified date, was vaccinated with a dose of GARDASIL, no lot number reported. It was reported that within 5 minutes of being vaccinated with GARDASIL, the patient fainted and then also experienced convulsions. Unspecified medical attention was sought. At the time of this report the outcome was unknown. Upon internal review convulsions were considered an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318281-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-May-2008	14-Jun-2008	24	07-Jul-2008	08-Jul-2008	FR	WAES0806USA09125	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypothyroidism, Local swelling

Symptom Text: Initial information has been received from a general practitioner concerning a 14 year old female with a history of spasmophilia who on 21-MAY-2008 was vaccinated with a first dose of GARDASIL. On 14-JUN-2008, i.e. 24 days after vaccination, the patient experienced an increased volume of her neck. At clinical examination the physician found an important inflammatory thyroid and biological work-up confirmed a hypothyroidism with important increase of antiperoxidase antibodies. As to an endocrinologist hypothyroidism was already there before and link with vaccination was excluded. An unspecified treatment was prescribed to the patient. At the time of reporting the outcome was not specified. Hypothyroidism was considered to be an other important medical event. Other business company numbers included E2008-06048. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, important increase of antiperoxidase antibodies.

History: Spasmophilia

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318282-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Jun-2008	23-Jun-2008	0	07-Jul-2008	08-Jul-2008	FR	WAES0806USA09128	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a pediatrician concerning a 15 year old female who on 23-JUN-2008 was vaccinated with a first dose of GARDASIL (lot # 1427U, batch # NH15200) IM into the deltoid muscle (site not reported). Immediately post-vaccination the patient experienced syncope and a questionable tonic myoclonus. The patient was hospitalized on 23-Jun-08. EEG was normal. The patient was discharged on 25-Jun-08. Other business partner numbers included E2008-05859. Additional information has been requested.

Other Meds: Unknown

Lab Data: electroencephalography, Comment: normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318283-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Apr-2008	23-Apr-2008	0	07-Jul-2008	08-Jul-2008	NE	WAES0807USA00072	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Uterine dilation and curettage

Symptom Text: Information has been received from a licensed practical nurse through the Merck Pregnancy Registry concerning an 18 year old female who on 23-APR-2008 was vaccinated with a first dose of GARDASIL, 0.5mL intramuscularly (lot# 0152X). There was no concomitant medication. The patient became pregnant after receiving the first dose of GARDASIL. The patient's last menstrual period was 11-APR-2008. On 28-MAY-2008 the patient had labs and diagnostic studies including HCG and progesterone levels and ultrasound. On 01-JUN-2008 the patient was hospitalized for a dilatation and curettage (D&C) because she miscarried. The reason for the miscarriage was unknown, but believed to be spontaneous. She was discharged the same day. The patient's estimated due date was 16-JAN-2009. On 16-JUN-2008, the patient received a second dose of GARDASIL (lot# 0250X). No further detail was provided. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound, 05/28/08, Results not reported; serum alpha-human, 05/28/08, result not reported; serum progesterone test, 05/28/08, Results not reported

History:

Prex Illness: Pregnancy NOS (LMP = 4/11/2008)

Prex Vax Illns:

Vaers Id: **318284-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	23-Jun-2008		07-Jul-2008	08-Jul-2008	CA	WAES0807USA00082	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse mid-wife concerning a 20 year old female who on unspecified dates was vaccinated with a first and second dose of GARDASIL (lot number, injection site and route not reported). The patient fainted and had a "seizure like" reaction after vaccinations. On an unspecified date, the patient was vaccinated with a third dose of GARDASIL (lot number, injection site and route not reported). On approximately 23-JUN-2008, also reported as "last week", the patient fainted and had a "seizure like" reaction. It was unknown whether the patient sought medical attention. The patient had recovered from all the events. Upon internal review "seizure like" reaction was determined to be an other important medical event. This is one of two reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318288-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	19-Mar-2007	Unknown		07-Jul-2008	08-Jul-2008	TX	WAES0806USA08989	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a medical assistant, and a physician (through the patient's mother) concerning a 22 year old female patient with hyperglycaemia who on 19-MAR-2007 was vaccinated intramuscularly with a first dose of 0.5mL GARDASIL (lot # not reported). On 14-MAY-2007 the patient was vaccinated with a second dose of GARDASIL (lot#657621/0387U); and on 11-SEP-2007 the patient was vaccinated with a third dose of GARDASIL (lot# 657868/0523U). Concomitant therapy included ibuprofen, PHENERGAN and "NARCO" (therapy unspecified). The patient's mother and the medical assistant reported that the patient experienced three seizures since receiving the GARDASIL, (timing for each seizure not specified). The mother also reported that the patient was scheduled to see a neurosurgeon. The medical assistant reported that on unspecified date, the patient recovered. Additional information has been requested.

Other Meds: (therapy unspecified); ibuprofen; PHENEGRAN (PROMETHAZINE

Lab Data: Unknown

History:

Prex Illness: Hyperglycaemia

Prex Vax Illns:

Vaers Id: 318289-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	06-May-2008	Unknown		07-Jul-2008	08-Jul-2008	TX	WAES0806USA08616	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Impaired work ability, Injected limb mobility decreased, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 21 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL. On 06-MAY-2008 the patient was vaccinated IM into the deltoid with a second 0.5ml dose of GARDASIL. The patient developed unspecified arm pain at an unspecified time after the injection and inability to raise the arm above the shoulder level which caused her disability from her work. The patient sought treatment with a chiropractor. At the time of the report the patient was not recovered. The physician considered the unspecified arm pain and inability to raise the arm above the shoulder level to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318290-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	03-Apr-2007	Unknown		07-Jul-2008	08-Jul-2008	FL	WAES0707USA01047	08-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arrested labour, Caesarean section, Drug exposure during pregnancy, Live birth

Symptom Text: Initial and follow up information has been received from the Merck pregnancy registry for GARDASIL via a medical assistant (also reported as a nurse) concerning a 24 year old female who on 03-APR-2007 was vaccinated with the first dose of GARDASIL. On 05-Jun-2007 the patient was vaccinated with the second dose of GARDASIL. Concomitant therapy included prenatal vitamins (unspecified). The patient was 9 weeks and one day pregnant. Unknown medical attention was sought. The patient delivered by primary cesarean section secondary to arrest of active labor at 8cm. She delivered a healthy and normal infant at 40 weeks estimated gestational age, weighing 9 lbs. 7 oz. Upon internal review primary cesarean secondary to arrest of active labor at 8 cm was considered to be an other important medical event. Additional information has been requested.

Other Meds: Vitamins (unspecified)

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318302-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	14-Apr-2008	14-Jun-2008	61	07-Jul-2008	10-Jul-2008	NJ		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	1	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Ataxia, Hypoaesthesia, Muscular weakness, Paraesthesia, Stress

Symptom Text: May 2008, my daughter started to experience bilateral leg weakness, bilateral arm weakness. She required care as of 6/14/08 and was hospitalized by her neurologist on 6/30/08 for a complete neuro work-up. She had numbness and tingling in all 4 extremities. Still hospitalized. 8/25/08-records received for DOS 6/30-7/4/08-DC DX: Ataxia. Seen in ED 6/16/08-C/O paresthesia started 1 week ago includes tingling. In ED on 6/18/08 with C/O numbness to arms and legs. In ED on 6/27/08 with C/O paresthesia and numbness to entire body Presented with 2 week history of weakness in upper extremities and motor weakness. Medical history is consistent with anxiety and stress. PE: bilateral upper extremity motor weakness 3/5. Transferrred to rehabilitation facility.

Other Meds: BCP

Lab Data: MRI-head, neck, thorax; Spinal tap, CT scan of brain; labs, U/A- 8/25/08-records received-Hematology profile within normal limits. Cerebrospinal fluid minimal amount of increased protein 49 and culture negative. Serology negative. Hepatiti

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **318304-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Jun-2008	26-Jun-2008	0	07-Jul-2008	14-Jul-2008	MI		14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal behaviour, Aggression, Anger, Confusional state

Symptom Text: After HPV #3 reported acute behavior change, angry, confrontational, confused, trying to leave house. Had resolved by the time she reached ER.

Other Meds:

Lab Data:

History: ADHD, anxiety

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318306-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Jun-2008	27-Jun-2008	0	07-Jul-2008	14-Jul-2008	WA		14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2560AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0928U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Loss of consciousness

Symptom Text: Patient was given MENACTRA & GARDASIL in the L upper arm. Within 10 seconds she passed out for about 5 seconds. She complained of dizziness & headache when she woke up.

Other Meds: None

Lab Data: BP 120/68, HR 91, O2 sat 100% on RA

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 318309-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	06-Jun-2007	11-Jun-2007	5	07-Jul-2008	14-Jul-2008	MD		14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anorexia, Anxiety, Fatigue, Syncope

Symptom Text: Fainted after receiving shot. Over the next two months, experienced fatigue, loss of appetite, anxiety. With doctor's agreement, opted not to get the remaining two shots in the series.

Other Meds: ASACOL, purinethol, ORTHO TRI CYCLEN, NORITATE

Lab Data: Neurologist confirmed normal fainting episode; no indication of seizure disorder.

History: Crohn's disease, mitral valve prolapse, rosacea

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318314-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Jun-2008	25-Jun-2008	0	07-Jul-2008	14-Jul-2008	AZ		06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB268AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1758U	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2562AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2771AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus

Symptom Text: Pink-red erythema L deltoid - itching - MCD. Pink-red erythema L deltoid - itching - Hep A. Cold compresses & MOTRIN.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns: ~Vaccine not specified (no brand name)~1~11~In Sibling

Vaers Id: **318316-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Apr-2008	Unknown		07-Jul-2008	14-Jul-2008	MI		14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Patient received vaccine (HPV) 2nd dose during pregnancy. Reported to Merck 6/17/08.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318324-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Jul-2008	01-Jul-2008	0	07-Jul-2008	15-Jul-2008	IL		15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB280AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1967U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breath holding, Gaze palsy, Musculoskeletal stiffness, Pallor, Syncope vasovagal, Unresponsive to stimuli

Symptom Text: Patient pale with apparent vasovagel event. (Patient unresponsive, stiff, hands positioned up toward chest, fixed eyes, held breath approximately 30-40 secs.). Patient then was conscious, communicative and pallor improved within 1-2 minutes. Patient symptom free and rechecked 15-20 minutes later, released home with mom.

Other Meds: None

Lab Data: None

History: N/A

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318327-1** **Related reports:** 318327-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	17-Jun-2008	17-Jun-2008	0	07-Jul-2008	15-Jul-2008	--		19-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depression, Drug administered at inappropriate site, Hypoaesthesia, Injected limb mobility decreased, Injection site erythema, Injection site swelling, Libido decreased, Mood altered, Muscular weakness, Nausea, Pain in extremity, Paraesthesia, Stress, Trichotillomania, Vomiting

Symptom Text: Pt experienced right arm pain, she received her second GARDASIL injection on June 17, 2008. Pain continues to get worse, can't move arm to much. Pain originates in deltoid and travels down her arm. She has numbness and tingling in hands. A lot of swelling and redness at the injection site. Weakness is present in entire arm. She is also having nausea and vomiting, beginning 5 days ago. 24 year old female with adverse reaction to IM GARDASIL injection. Exam is unremarkable. Will treat her symptoms aggressively and have her follow-up in 1-2 days as needed. PHENERGAN 25 MG OR TABS, LORTAB 7.5 7.5-500 MG OR TABS, ZYRTEC 10 MG OR TABS, given to pt. 7/21/08-records received for DOS 6/17/08-received gardasil vaccine. 6/23/08 C/O pain right arm can't move arm much, travels down arm with numbness and tingling. Weakness in entire arm. Nausea and vomiting. Impressions:adverse reaction to vaccine. 7/1/08-received depo provera. 7/11/08-depression, decreased libido, angry, mood outbursts, pulling own hair, stress due to premature baby and recent marriage.

Other Meds:

Lab Data:

History: 7/21/08-records received- PMH:cocaine and ecstacy use.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318327-2** **Related reports:** 318327-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	17-Jun-2008	18-Jun-2008	1	07-Jul-2008	09-Jul-2008	UT		14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	5	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse drug reaction, Anger, Hypoaesthesia, Injected limb mobility decreased, Injection site erythema, Injection site swelling, Mood swings, Nausea, Pain in extremity, Paraesthesia, Self esteem decreased, Stress, Trichotillomania, Vomiting

Symptom Text: Patient experienced right arm pain, after receiving her second gardasil injection on 06/17/2008. Pain continues to get owrse, can't move arm easily. Pain originates in deltoid and travels down her arm. She has numbness and tingling in hands. Swelling and redness at injection site. Also having nausea and vomiting which began 5 days ago. Date seen 07/05/2008. 7/21/08-records received for DOS 6/23/08-presented with right arm pain, can not move arm much. Numbness and tingling weakness in entire arm. Nausea and vomiting. Assessment:adverse reaction to Gardasil. office visit 7/1/08-received Depo-provera injection. Office visit 7/11/08-C/O feels angry, mood outbursts, does not like self worried baby does not like her. Pulling own hair. Stress, premature baby, new married.

Other Meds: medroxyprogesterone

Lab Data:

History: Morphine, tramadol 7/21/08-PMH:sober for 6 years-cocaine in past/snorted and extasy.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318375-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Nov-2007	16-Dec-2007	19	07-Jul-2008	09-Jul-2008	NV		09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Menorrhagia, Menstruation irregular, Migraine, Muscle atrophy, Spine malformation

Symptom Text: heavy bleeding- menstrual(7-11 days ////// more often migraines (double the occurances//relpax/////////degenerated muscles on the left side of her spine - recently diagnosed by her chiropracter and claims her spine has shifted as result causing her to be 14cm unevenly carrying her weight requesting to see her mandatory for at least a year causing extereme back pain - abnormal periods of which havent been able to steady without stopping them alltogether with birth controls //depo- & ortho

Other Meds: albutertol//// relpax

Lab Data: ct- scan/////x-rays///er visits ///doc visits/// chiropratic care

History: asthma- migranes

Prex Illness: none- was check uo / flu appt/ international trip upcoming

Prex Vax Illns:

Vaers Id: **318378-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	U	07-Jul-2008	07-Jul-2008	0	07-Jul-2008	09-Jul-2008	MD		09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Pallor

Symptom Text: Light headedness, diaphoresis, and pale skin color after HPV vaccination. These symptoms resolved within 5 minutes after patient was assisted to a seated position and a cool compress applied to her forehead.

Other Meds: Loratadine 10mg PO EVERY DAY

Lab Data:

History: Penicillins and SULFA drugs

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318381-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Oct-2007	11-Dec-2007	52	07-Jul-2008	10-Jul-2008	LA		14-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	12654	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2812AA	2	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	424562A	2	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Diarrhoea, Gastroenteritis, Muscle spasms, Myoclonus, Nausea, Vomiting

Symptom Text: stomach spasms, which have been diagnosed as abdominal myoclonus. has led to spasms in back, legs, face. Is on klonzapen daily, cymbalta. was on other medications but have since been taken off them. had to sit out semester of college. 8/14/08-records received for DOS 12/14-12/16/07-DC DX: Gastroenteritis now improved. Developed nausea, vomiting, diarrhea and abdominal crampy pains, presented to ED.

Other Meds:

Lab Data: numerous blood tests, ct scans, mri's, colonoscopy, endoscopy, spinal tap, eeg, ekg, 8/14/08-records received-CBC, complete metabolic profile, anylase, lipase, ultrasound of gallbladder all normal. CT scan of abdomen negative.

History: allergic to codeine

Prex Illness: upper respritory infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318384-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Aug-2007	06-Sep-2007	16	07-Jul-2008	09-Jul-2008	IL		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0802U	1	Gluteous maxima	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Back pain, Chills, Fatigue, Nausea, Ovarian cyst, Pyrexia, Urinary tract infection

Symptom Text: After first dosage, within 24 hours developed severe admoninal pain, fever, fatigue. We thought she had the flu. Improved. After second dose, again adominal pain, fever, nauseau, fatigue. Treated in ER for possible kidney infectin. Extreme pain continued and peditrician ordered a CT Scan performed revealing the development of two ovarian cysts. She missed 7 weeks of school after the second dose. Pain medication was provided while we waited for the cysts to dissolve on their own. 7/16/08-records received for DOS 9/6/07-presented to ED with C.O left lumbar pain, chills and fever. DX: UTI.

Other Meds:

Lab Data: Blood work. CT Scan. Ultrasounds 7/16/08-records received-CT abdomen and pelvis bilateral large cysts seen in ovaries and free fluid in cul-de-sac which could be a ruptured cyst. Urine culture blood culture no growth.

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318386-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Jun-2008	28-Jun-2008	2	07-Jul-2008	09-Jul-2008	TN		07-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024RA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2574AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0067X	2	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB268EA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eyelid ptosis, Facial palsy, Paraesthesia, Urticaria

Symptom Text: Urticaria 2 days post vaccine. Left facial palsy 9 days post vaccine. 8/4/08-records received-office visit 7/5/08-C/O hives started 2 days after injection coming and going for 1 week. Left eye lid drrops since 6/29/08-partial facial nerve palsy. 7/7/08-left side of face droops and tingles. no further visits.

Other Meds: Ortho Novum

Lab Data:

History: Ovarian Cyst

Prex Illness:

Prex Vax Illns:

Vaers Id: **318399-1 (S)** **Related reports:** 318399-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Jul-2007	10-Aug-2007	28	07-Jul-2008	10-Jul-2008	NY		14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688F	0	Left arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anaemia, Arthralgia, Autoimmune disorder, Fasciitis, Inflammation, Joint range of motion decreased, Musculoskeletal pain, Myositis, Oedema peripheral, Pain in extremity

Symptom Text: autoimmune myositis, fasciitis, anemia, chronic autoimmune disease. Patient developed symptoms in ipsilateral arm about 3 weeks postvaccination, progressed to severe inflammatory autoimmune disease that has lasted for 1 year and is ongoing. 07/09/2008 Office notes received from Rheumatologist from 9/7/2007 to 4/03/2008 with DX: Myositis/Fasciitis L arm. Pt developed L shoulder pain and decreased ROM in 8/2007 which has persisted. Pt then developed forearm pain and swelling, elbow pain and pain upon extending fingers and wrist. PE (+) for TMJ pain and inability to fully open mandible, tenderness of the anterior humeral head, upper inner aspect of the arm below the humeral head, and the lateral aspect of the L forearm. Pain upon dorsiflexion of L wrist. Swelling noted on L forearm. Started on Pred. Much improved by 10/11/07 with Pred taper scheduled. Increased pain with decreased pred. Dose increased and Methotrexate started. Episode of inflammation L leg (ankle and shin pain) 4/2008.

Other Meds: none

Lab Data: EST 80; CRP 50; Hgb 8.3. Muscle biopsy showed myofasciitis. Bone marrow bx, CT chest/abd/pelvis negative. Multiple serologies for other autoimmune entities negative. Labs and Diagnostics: Hgb 8.7. Hct 27.2. Platelets 499K. ESR 64. AN

History: none. PMH: TMJ. NKDA.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **318399-2 (S)** **Related reports:** 318399-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Jul-2007	10-Aug-2007	28	14-Aug-2008	15-Aug-2008	--	WAES0807USA05069	15-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688F	0	Left arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anaemia, Arthralgia, Autoimmune disorder, Dyskinesia, Fasciitis, Inflammation, Musculoskeletal pain, Myositis, Oedema peripheral, Pain in extremity, Temporomandibular joint syndrome, Tenderness

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 17 year old female with no medical history, no known drug allergies and no previous illness was vaccinated intramuscularly into the left arm with a first dose of GARDASIL (Lot # 653735/0688F) on 13-JUL-2007. There was no concomitant therapy. The patient experienced autoimmune myositis, fasciitis, anemia, chronic autoimmune disease. Patient developed symptoms in ipsilateral arm about 3 weeks post vaccination, progressed to severe inflammatory autoimmune disease that has lasted for 1 year and is ongoing. On 09-JUL-2008 office notes received from the Rheumatologist from 07-SEP-2007 to 03-APR-2008 with diagnosis: Myositis/Fasciitis left arm. Patient developed left shoulder pain and decreased range of motion ROM in August 2007 which has persisted. Patient then developed forearm pain and swelling, elbow pain and pain upon extending fingers and wrist. Physical examination (+) for temporomandibular joint pain and inability to fully open mandible, tenderness of the anterior humeral head, upper inner aspect of the arm below the humeral head, and the lateral aspect of the left forearm. Pain upon dorsiflexion of left wrist. Swelling noted on left forearm. Started on prednisolone. Much improved by 11-OCT-2007 with prednisolone taper scheduled. Increased pain with decreased prednisolone. Dose increased and methotrexate started. Episode of inflammation left leg (ankle and shin pain) April 2008. The listing indicated that the events required an ER visit and one or more of the events was considered to be disabling and to be immediately life-threatening. This was originally reported by a physician. The VAERS ID # 318399. A standard lot check investigation was performed. All in-process quality checks for the lot in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met

Other Meds: None

Lab Data: muscular biopsy - myofasciitis; computed axial - myofasciitis; computed axial - chest/abdomen/pelvis: Negative; bone marrow biopsy - negative; diagnostic laboratory, 80 - ESt: 80; hemoglobin, 8.7; platelet count, 499 K; erythrocyte, 64; hem

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318401-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Jul-2008	01-Jul-2008	0	07-Jul-2008	09-Jul-2008	MO		10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	UNKNOWN MANUFACTURER	UNKNOWN	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Right arm	Unknown	
	TD	UNKNOWN MANUFACTURER	UNKNOWN	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Cold sweat, Syncope

Symptom Text: Daughter received Gardisil vaccine along with other vaccines. No adverse reaction to needle puncture. Nurse commented patient was very relaxed. But, patient fainted approximately 5 minutes after receving vaccines. Blood pressure dropped and skin was clammy. Treatment was nurse practioner checked patient. Fainting was not identified on doctor handout sheet of possible side effects.

Other Meds: none

Lab Data: None

History: none

Prex Illness: none

Prex Vax Illns: none~Tetanus Diphtheria (no brand name)~5~0~In Patient

Vaers Id: **318402-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
35.0	F	Unknown	Unknown		08-Jul-2008	10-Jul-2008	CA		11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Back pain, Discomfort, Inappropriate schedule of drug administration, Muscle spasms, Vaccine positive rechallenge

Symptom Text: I am 35 yrs old I received my first dose of gardasil in Jan 08 afterwards i had terrible back muscle spasms, I didnt think much of it but this has happened in dose 2 and 3. I got my 3rd dose last week and my muscle spasms in my back are so bad i have had to use muscle relaxers and bengay etc. I have a hard time doing my daily activities, terrible pain and discomfort.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318418-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	23-Jun-2008	23-Jun-2008	0	07-Jul-2008	15-Jul-2008	TX		15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Within 20 minutes of GARDASIL client fainted.

Other Meds:

Lab Data: none

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **318434-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Dec-2007	Unknown		08-Jul-2008	17-Jul-2008	CA		17-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0011UU	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Computerised tomogram normal, Facial palsy, Hypoaesthesia facial, Vaccine positive rechallenge

Symptom Text: Within 24 hours of receiving vaccine experienced unilateral facial numbness, resolved within 1 wk. Experienced same type of event with both HPV #1 + HPV #2. Saw neurologist for consultation, CT scan negative, facial palsy resolved on its own. No specific neuro. Follow up recommended.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318438-1** **Related reports:** 318438-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Jun-2008	27-Jun-2008	0	08-Jul-2008	17-Jul-2008	CT		17-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Depressed mood, Dizziness, Nausea, Pharyngeal oedema

Symptom Text: Several hours after receiving HPV #1, pt + nausea, lightheaded, dizzy, depressed, throat swelling.

Other Meds:

Lab Data: Allergic reaction

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318438-2** **Related reports:** 318438-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Jun-2008	27-Jun-2008	0	18-Aug-2008	17-Sep-2008	CT	WAES0807USA04348	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Depression, Throat tightness

Symptom Text: Information has been received from a consumer concerning her daughter, a 15 year old female with a history of syncope vasovagal and no allergies who on 27-JUN-2008 was vaccinated with the first dose of GARDASIL (lot # not reported) injection in left arm. Concomitant therapy included CLARITIN. On 27-JUN-2008 the patient experienced throat closed up and sudden severe depression on the day she received vaccine. The patient was taken to the emergency room but was not admitted to the hospital. Her throat still did not feel fully recovered and she still occasionally has bouts of sadness. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Claritin

Lab Data: None

History: Syncope vasovagal

Prex Illness:

Prex Vax Illns:

Vaers Id: **318478-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	07-Jul-2008	07-Jul-2008	0	08-Jul-2008	09-Jul-2008	--		09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2899AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye rolling, Malaise, Musculoskeletal stiffness, Respiratory rate increased, Tremor

Symptom Text: After leaving office, mom reports that pt said she wasn't feeling well, then had several minutes of eyes rolling back, arms stretched out and stiff, with shaking. No jerking, no tongue biting or incontinence. Afterwards, was looking forward again, breathing hard, acting appropriately, with no postictal state. Had not eaten or drank that day. Mom called me (the pediatrician) the following day to let me know.

Other Meds:

Lab Data:

History:

Prex Illness: Had not eaten or drank that day.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318480-1** **Related reports:** 318480-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	07-Jul-2008	07-Jul-2008	0	08-Jul-2008	10-Jul-2008	NY		10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash erythematous, Rash generalised, Rash pruritic, Urticaria

Symptom Text: disseminated welts, erythematous, puritic. Started on lower back then spread to arms, legs and traveling to face . Started 1 hour after injection and still spreading 24 hours later.Advised Benadryl po at onset of rash. Pt states very little relief and advised to report to local ER for management and eval.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **318480-2** **Related reports:** 318480-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	07-Jul-2008	07-Jul-2008	0	18-Aug-2008	16-Sep-2008	NY	WAES0806USA01596	23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Accidental exposure, Medical device complication, Rash erythematous, Rash pruritic, Urticaria

Symptom Text: Information has been received from physician concerning a patient who on approximately 26-MAY-2007 was accidentally exposed to 0.5 ml of GARDASIL (lot# 0151X). The physician reported that a while administering the GARDASIL the prefilled syringe safety device deactivated and syringe leaked onto patient's arm. Conflicting follow-up information was received from a nurse who reported that the patient" was never administered with the prefilled syringe". No adverse event reported. At the time of this report the patient's outcome was unknown. Follow up information was received which reported that the patient was a 25 year old female with no pre-existing allergies, birth defects or medical conditions who on 07-JUL-2008 at 6 pm was vaccinated with a first dose of GARDASIL in her arm. There was no illness at time of vaccination. On 07-JUL-2008 the patient experienced disseminated welts, erythematous and pruritic which started on lower back then spread to arm, leg with traveling to face started 1 hour after the vaccination (7 pm) and was still spreading 24 hours later. The patient was advised BENADRYL at the onset of rash. The patient stated that it was very little relief and was advised to report to local emergency room for management and evaluation. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 318481-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Aug-2007	25-Aug-2007	11	08-Jul-2008	10-Jul-2008	SC		17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	1	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal distension, Abdominal pain, Abdominal pain upper, Abdominal tenderness, Cholecystectomy, Constipation, Decreased appetite, Dehydration, Diarrhoea, Dyspepsia, Early satiety, Fatigue, Gallbladder disorder, Gallbladder operation, Gastritis, Gastrointestinal disorder, Gastrointestinal motility disorder, Hypokalaemia, Impaired gastric emptying, Nausea, Stress, Vaccine positive rechallenge, Vomiting, Weight decreased

Symptom Text: Patient experienced severe gastrointestinal symptoms after Gardasil injections. Injections 6/12/07 and 8/14/2007 followed by emergency room visits 8/25/07 and 11/1/07, third injection 12/20/07 followed by emergency room visit and extended hospitalization 2/08. Severe abdominal pain and vomiting occured each time which would not stop without emergency medical and drug intervention. Multiple diagnostic and lab tests indicated possibility of gall bladder involvement. Gall bladder was removed 12/5/07. The final Gardasil injection was after gall bladder surgery and another gastrointestinal episode with emergency treatment and a 5 day hospitalization occured after this. Patient had no history of gall bladder or gastrointestinal symptoms before beginning series of Gardasil injections. No underlying cause has been clearly established for these conditions, symptoms or multiple episodes by either primary physician, surgeon, gynecologists or gastroenterologist. Tests indicated slow gall bladder emptying, slow gastric emptying and slight gastritis concurrent with these multiple episodes, but patient had no symptoms indicating slow stomach or gallbladder functioning prior to beginning Gardasil. All other tests and screens were negative for anything unusual. Patient has had no recurrence of the symptoms since 2/08, but she is on continuing drug treatment for the gastrointestinal issues. We are reporting this to assist in identifying any trends related to similar gastrointestinal symptoms, since these conditions are not typical for a 15/16 year old female and the timing of the three injections and the repeated recurrence of these unusual and previously nonexistent symptoms seems a bit more than coincidental. 7/23/08 MR received for several OVs beginning in 11/2007 through 3/2008. Seen 11/7/2007 with c/o 3 episodes of nausea, vomiting and abdominal pain. One episode required IV fluids for dehydration. Pt reports early satiety, weight loss, decreased appetite, fatigue, stress, indigestion, constipation, abdominal bloatin

Other Meds: Loestrin

Lab Data: Abdominal ultrasound, HIDA scan, endoscopy, gastric emptying study, CAT scan, other laboratory tests. Labs and Diagnostics: K+ 3.1. Urinalysis with 2+ ketones. Gastric emptying study (+) for abnormal gastric emptying. Labs and Diagnosti

History: None. PMH: Anxiety

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318482-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-Jul-2008	08-Jul-2008	0	08-Jul-2008	10-Jul-2008	SC		10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Right arm	Intramuscular	
	MEN	SANOFI PASTEUR	U2606AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024CA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0511X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site rash

Symptom Text: After administering the Varicella Vaccine child's left arm the injection site area became red and had raised bumps around injection site.

Other Meds: None

Lab Data: Patient given 25mg of Benadryl as ordered by Dr. Ballance.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 318483-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-May-2007	24-Jun-2007	53	08-Jul-2008	10-Jul-2008	NH		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Abdominal rigidity, Abdominal tenderness, Anxiety, Asthenia, Autonomic nervous system imbalance, Back pain, Cheilitis, Chest pain, Crying, Delusional perception, Dizziness, Dysuria, Feeling abnormal, Feeling hot, Hot flush, Hyperhidrosis, Loss of consciousness, Myalgia, Nausea, Pain, Petit mal epilepsy, Presyncope, Pyrexia, Syncope, Tenderness, Unresponsive to stimuli, Vaccine positive rechallenge, Visual disturbance, Vomiting

Symptom Text: lightheadedness,dizzy,seeing spots,abd pn, nausea,and Left upper quad pain. After 2nd dose in July of 07 she experienced all of these plus severe hot flashes, sweats,severe muscle pain and weakness, collapsing and passing out as well as chest pain. She is now sick on a monthly basis and her sickness usually lasts 7-8 days. She also becomes delusional at times and spacey. 7/14/2008 MR received from PCP from 5/2/2007 through 7/3/2008. HPV #1 5/2/07. Seen 6/15/07 with c/o several week hx of abdominal pain, nausea and fever. PE WNL. Assessment: Abdominal pain, nausea of ? etiology. Referred to ER PRN. F/U ER visit 6/24/07. PE (+) for abd tenderness, worse in LUQ and epigastric area. (+) guarding. Assess: Abd pain NYD ? constipation. 7/30/07 2nd HPV. ER visit for abdominal pain 1/24/08 with Assess: Abdominal pain, possibly due to medication intolerance, benign exam. Hx sinusitis. Anxiety componant. Seen 2/28/08 where pt became hot, started crying, c/o body aches, felt like passing out. BS 89. Seen 3/2/2008 w/ c/o constant back pain which radiates to the chest, feeling dizzy. PE (+) for abd tenderness and tenderness over L chest wall, costochondral joint. DX: Abd pain LUQ. ? Splenomegaly. Chest wall pain. dizziness. Refered to endocrinology clinic. Seen for unusual spells with features of power, diaphoresis, visual disturbance, abdominal pain, and vomiting. Witnessed absence spell where pt became pale and unresponsive. BS 87. Pulse 80. No clear dx. ? conversion rxn. Seen 6/9/08 with R sided abd pain and feeling faint. PE (+) for abd tenderness, perleche. Assessment syncope. 6/30/08 seen w/ c/o dysuria, recuurent back pain with vasomotor symptoms. Paraspinus muscle spasms noted L2-4. 7/3/08 pain and vomiting persist. .

Other Meds: albuterol

Lab Data: Several different lab studies, ultra sounds, x-rays, ct scans and an appointment with the endocrinologist which didn't do us any good. She was a prefectly healthy kid until she received this vaccine. Labs and Diagnostics: Abd US 2/18/08 W

History: PMH: GERD

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318484-1 (S)** **Related reports:** 318484-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	05-Dec-2007	19-Dec-2007	14	08-Jul-2008	10-Jul-2008	SD		10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	1	Right arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Arthropathy, Renal disorder, Systemic lupus erythematosus

Symptom Text: Patient development joint symptoms first, near Christmas 2007 Then after several months (March 2008)developed a serious kidney problems and was diagnosed with Lupus erythematous. She is currently undergoing intermittent chemo treatment with a Pediatric Rheumatologist in Omaha, Nebr. Date of vaccination was her second HPV(Gardasil) Her first was 8/14/2007 at same clinic, location and same manufacturer of vaccine. (This may have been reported previously from a relative in the family who is a pharmacist.)

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **318484-2 (S)** **Related reports:** 318484-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	05-Dec-2007	19-Dec-2007	14	08-Aug-2008	11-Aug-2008	--	WAES0807USA05073	11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	1	Right arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Arthropathy, Chemotherapy, Renal disorder, Systemic lupus erythematosus

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under an act. On 14-AUG-2007 as 12 year old female was vaccinated with her first dose of GARDASIL. On 05-DEC-2007 she was vaccinated with her second dose of GARDASIL (lot # 658556/1060U) IM into the right arm. Near Christmas 2007 patient developed joint symptoms first. Then after several months (March 2008) she developed a serious kidney problems and was diagnosed with lupus erythematosus. She was undergoing intermittent chemo treatment with a Pediatric Rheumatologist. It was reported that the patient's Pediatric Rheumatologist. It was reported that the patient's experience was considered to be immediately life-threatening. The VAERS ID # is 318484. A standard lot check investigation was performed. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the center and was released. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318486-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	28-May-2008	03-Jun-2008	6	08-Jul-2008	17-Jul-2008	MA		20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Balance disorder, Disturbance in attention, Dizziness, Dizziness postural, Fatigue, Headache, Impaired driving ability, Impaired work ability, Muscular weakness, Nausea, Nuclear magnetic resonance imaging normal, Presyncope, Sensation of heaviness, Vertigo

Symptom Text: Kristen recieved her 3rd series of Gardisil May 27 @ her MD office, approx felt dizzy for 2 week duration aftr (she felt that she had to hold on to the walls when she walked). On friday she made an appt with her Md to be checked. She was given an appt for June 10th. She was having a hard tiime focusing andwas unable to work because just sitting at her desk made her feel like she was going to faint... She saw her Pcpand after eval felt she should see a ENTspecialist. Allher blood work was normal but kristen was unable to drive or sit up because of the feeling she was going to pass out. Unable to get an appt promptly with and ENT specialist. We Wemt to MEEI in boston for an eval. She was cleared by ENT. Kristen proceed to feel worse and the stared c/o of arm heaviness that proceeded toleg heavisness. In discussion with her NOP kATHY tHERIEN SHE SUGGEST TO SEE A NEUROLOGIST. Agin extreme difficult getting appt with specialist. MRI was ored secondary to dizziness, nausea arm and leg weakness. MRI negative. Relieved but still no answer Why a 21 year old active girl is physically debilitated unable to drive or work etc. lab work normal .. After concern and discussion that symptoms are not improving . NP decied to tx for lyme disease. no improve however now sever joint discomfort Very scary to see a 21 yr old girl unable to get out of bed . np fevers etc 8/15/08-records received for DOS 6/17/08-C/O dizzy, nausea, headache, feels off balance, intermittent episodes of dizziness followed by nausea. Dizziness occurs primarily when standing. Fatigued, some weakness in arms on and off. Returned from foreign travel one month ago. Impression: vertigo and nausea.

Other Meds:

Lab Data: neg Lab work done at beverly hospital. Lyme neg, cmv etc ep call north shore pedi for vaccine man and numberstein barr neg 8/15/08-records received-Chemistry and CBC normal. EBV negative. Borrelia negative.

History: Hx of mono and Whooping cough 2 yrs prior 8/15/08-records received-PMH: asthma. infectious mononucleosis.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318488-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Jul-2008	03-Jul-2008	0	08-Jul-2008	10-Jul-2008	HI		10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	09304	1	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	B268EA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Blood pressure decreased, Dizziness

Symptom Text: Patient was seen for general physical exam. She felt dizzy and weak approximately 3-5 minutes after the vaccines were administered (Havrix and Gardasil). She was placed in the exam room on the bed with the head of bed elevated 30 degrees. Initial Blood Pressure at time of office visit was 110/80; 5 min after vaccine administration was 70/50; 20 min after vaccine administration was 100/80. No medications were given. She was sent home after indicating that she felt better (about 15 min after the last BP reading).

Other Meds:

Lab Data: Hypotension (see above)

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **318489-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jul-2008	02-Jul-2008	0	08-Jul-2008	10-Jul-2008	MD		10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0445X	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Hyperhidrosis, Injection site pain, Joint stiffness, Loss of consciousness

Symptom Text: My daughter felt significant pain at the innoculation site. After a couple of minutes she became dizzy and passed out. Her eyes were open and her arms were tense and bent at the elbows while she was unconscienous. This lasted for about a minute. Afterward, she was perspired and felt weak. We were kept in the doctor's office for about one hour and 15 minutes afterwards.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: None~ ()~NULL~~In Patient|None~ ()~NULL~~In Sibling1|None~ ()~NULL~~In Sibling2

Vaers Id: **318491-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		08-Jul-2008	09-Jul-2008	--	WAES0806USA08737	09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: DIED, LIFE THREATENING, SERIOUS

MedDRA PT Death, Hypersensitivity

Symptom Text: Information has been received from a physician who was told by a patient's mother that a female patient with a sulfa allergy who on an unspecified date was vaccinated with a first dose of GARDASIL (lot number, injection site and route not reported), which was well tolerated. On an unspecified date, the patient was vaccinated with a second dose of GARDASIL (lot number, injection site and route not reported). Subsequently the patient died. The cause of death was reported as allergic reaction to GARDASIL. The physician stated that the patient who died was not her patient and she knew no further details. Follow-up information was received from the physician who reported that a other of one of her patients had said to her, that she "thought" she read this report on the internet. The physician asked the patient's mother to find out where she read the report. The patient's mother could not find the report and did not know where to locate the source information. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **318492-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Sep-2007	11-Dec-2007	84	08-Jul-2008	09-Jul-2008	FR	WAES0806USA08659	09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Deafness transitory, Dizziness, Headache, No reaction on previous exposure to drug, Tinnitus

Symptom Text: Information has been received from a health authority concerning a 14 year old female who was vaccinated with a first dose of GARDASIL (lot # not reported) on 18-SEP-2007. No adverse effects occurred. The patient was vaccinated with a second dose of GARDASIL (lot # not reported) on 27-NOV-2007. Two weeks post vaccination she developed headache and dizziness for 4 weeks. On 18-MAR-2008, the patient was vaccinated with the third dose of GARDASIL (lot # not reported). Two weeks post vaccination, the patient developed deafness for 1 day with subsequent tinnitus of the left ear for 3 weeks. The patient's cholesterol was 212 mg/dL (date not reported). The patient was recovered at the time of reporting. It was reported that the deafness, tinnitus, headache and dizziness were other medically important events. Case closed. Other business partner numbers included: E2008-05825 and PEI2008008353. No further information is available.

Other Meds: Unknown

Lab Data: Serum cholesterol, 212 mg/dL

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318493-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-May-2008	18-May-2008	0	08-Jul-2008	09-Jul-2008	FR	WAES0806USA08660	09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Abscess limb, Incisional drainage

Symptom Text: Information has been received from a health authority (case n. 86495) concerning an 11 year old female patient with no previous medical history reported who on 18-MAY-2008 was vaccinated with the first dose of GARDASIL (Batch n. unspecified). On the same day she presented with abscess to the deltoid region of the right arm. She was treated with incision and drainage. At the time of report, the patient's condition had improved. The outcome is not reported. The case is closed. The event was reported to be life threatening. Other business partner numbers included: E2008-05909, IT250/08 and 86495. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318494-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Jan-2008	17-Jun-2008	168	08-Jul-2008	09-Jul-2008	FR	WAES0806USA09126	09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from a general practitioner (this case was poorly documented) concerning a 19 year old female who in January 2008, was vaccinated with a second dose of GARDASIL via intramuscular route in her deltoid. On 17-JUN-2008 the first symptoms of multiple sclerosis appeared. Previous unspecified vaccinations were well tolerated. Multiple sclerosis was considered to be an other important medical event. Other business partner numbers included E2008-05898. Additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: 318495-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Mar-2008	06-May-2008	63	08-Jul-2008	09-Jul-2008	FR	WAES0806USA09127	09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0510U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Ataxia, Dizziness, No reaction on previous exposure to drug

Symptom Text: Information has been received from a Health Authority (HA reference # PEI2008009014) concerning a 12 year old female whose first dose on 04-MAR-2008 of GARDASIL (Lot # 0510U, batch # NG20180) via intramuscular route in her left upper arm and was well tolerated. On 05-MAY-2008 she was vaccinated with the third dose of GARDASIL (Lot # 0513U, batch # NG34780) via intramuscular route in her left upper arm. On 06-MAY-2008 the patient experienced ataxic gait and dizziness. The patient was hospitalized from 08-MAY-2008 to 11-MAY-2008 and from 29-MAY-2008 to 16-JUN-2008. Guillain-Barre syndrome was ruled out. The patient had not yet recovered at the time of report to Health Authority. Other business partner numbers included E2008-05905. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318496-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		08-Jul-2008	09-Jul-2008	FR	WAES0807PHL00001	07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Monoparesis

Symptom Text: Information has been received from a physician concerning an patient who in 2008 was vaccinated with GARDASIL. In 2008 the patient experienced paralysis of the hand after injection. Upon internal medical review, paralysis of the hand after injection was considered as an other medical event. No further information is available because the reporting physician does not want to divulge the name of the physician who had the actual experience with one of his patients.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318497-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	30-Jun-2008	30-Jun-2008	0	08-Jul-2008	09-Jul-2008	MA	WAES0807USA00053	09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope, Tonic clonic movements

Symptom Text: Information has been received from a registered nurse concerning a female who on 30-JUN-2008 was vaccinated with the first dose of GARDASIL 0.5 ml IM. On 30-JUN-2008 the patient experienced faint and tonic clonic for 10 seconds. The patient regained consciousness and was observed in the office for 30 minutes. The patient was given juice and her blood pressure and pulse were monitored. The patient was discharged home. The patient recovered from faint and tonic clonic on that same day. The patient sought medical attention in office. Upon internal review, tonic clonic was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318498-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		08-Jul-2008	09-Jul-2008	FR	WAES0807USA00368	09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Nervous system disorder

Symptom Text: Information was received from a hospital neuro-paediatrician concerning an adolescent female patient (age not reported), who was vaccinated with a dose of GARDASIL (number in series, lot number, injection site and route not reported) on an unspecified date. Subsequently (latency not reported) the patient developed headache and "neurologic disorder" and was hospitalized on an unspecified date. Cranial MRI, lumbar puncture/CSF (cerebrospinal fluid) and SSEP (somatosensory evoked potential) were all normal. No cause for the symptoms could be found. At the time of report the patient had not yet recovered. Other business partner numbers included: E2008-05940.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, normal, Cranial MRI was normal; spinal tap, normal, Lumbar puncture/CSF (Cerebrospinal fluid) was normal; somatosensory evoked potential, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 318499-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-May-2008	Unknown		08-Jul-2008	09-Jul-2008	FR	WAES0807USA00520	09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Anogenital warts, Drug exposure during pregnancy, Haemorrhage

Symptom Text: Information has been received from a gynaecologist concerning a 17 year old female who started a spontaneous pregnancy (estimated conception date: 25-MAY-2008) 6 days before receiving the third dose, on 31-MAY-2008, of GARDASIL (Lot#, batch # and route of administration not reported). She had received the first and second doses in December 2007 and February 2008. The patient was concomitantly treated with ALDARA for vulvar condylomae she probably had since February 2008 and were noticed in May 2008. The patient had stopped contraception. ON 10-MAY-2008, she experienced miscarriage followed by bleeding lasting 5 to 6 days. It was also reported that the patient had unprotected sexual intercourse on 25-MAY-2008. She was seen by her gynaecologist on 25-JUN-2008 due to her positive pregnancy test on 17-JUN-2008. She was then approximately one month pregnant (WAES # 0806USA08890). No adverse reaction was reported. Upon internal review, miscarriage was determined to be an other important medical event. Further information is expected. Other business partner numbers included: E2008-05982. Additional information has been requested.

Other Meds: ALDARA

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318500-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		08-Jul-2008	09-Jul-2008	OH	WAES0807USA00562	09-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Cyanosis, Listless, Pallor, Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL. After receiving GARDASIL the patient fainted and had a severe seizure. The patient was listless and had a dusky color after the seizure. The physician observed the patient for 1/2 hour and then sent her home accompanied by her mother. The patient was then sent to a neurologist. At the time of the report, it was unknown if the patients had recovered from faintness, listless and dusky color. Upon internal review, seizure was considered to be an other important medical event. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318521-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	08-Jul-2008	08-Jul-2008	0	08-Jul-2008	17-Jul-2008	MI		17-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2621AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Local reaction, Pruritus, Urticaria

Symptom Text: Pruritus of R forearm - hives like local reaction.

Other Meds: albuterol

Lab Data:

History: asthma, allergic rhinitis

Prex Illness: serous otitis media

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318524-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Jun-2008	Unknown		08-Jul-2008	17-Jul-2008	FL		17-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Pain in extremity

Symptom Text: Seen in office. 1 wk later 2nd HPV c/o, pain R arm and R side chest pain. Pain with deep insp & cough.

Other Meds: MOTRIN

Lab Data: CXR, -; pulse ox, 99% RA; R humerus X-ray, -; R shoulder X-ray, -

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318525-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Jul-2008	04-Jul-2008	1	08-Jul-2008	17-Jul-2008	CA		17-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0072	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	GSKAC52602	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0538	1	Left arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U2553AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Within 24 hours of I2s administered on 7/3/08, pt c/o pain in elbows when fully extended & fully flexed. No local reaction, no fever; L arm improving moreso than R arm; will try ADVIL & if symptoms persist parent instructed to call back; no family members ill; pt. does not c/o arthralgias in other joints.

Other Meds: DDaVP 1 spray q.o. noc

Lab Data:

History: Nocturnal enuresis; amenorrhea

Prex Illness:

Prex Vax Illns:

Vaers Id: **318537-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		09-Jul-2008	10-Jul-2008	FR	WAES0807USA00673	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blindness, No reaction on previous exposure to drug

Symptom Text: Information has been received from a nurse, (It was reported, "This is a hear say case:") concerning a female patient (age not reported) who was vaccinated with a first dose of GARDASIL (Lot #, route and site of administration not reported) on an unknown date. No adverse effect occurred. The patient was vaccinated with the second dose of GARDASIL (Lot #, route and site of administration not reported) on an unspecified date. On an unknown date the patient experienced blindness (not otherwise specified). She was hospitalized on an unspecified date. The outcome was not reported. Other business partner numbers included: E2008-05954. No further information is available. Case closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318538-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jul-2008	01-Jul-2008	0	09-Jul-2008	10-Jul-2008	--	WAES0807USA00615	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Grand mal convulsion, Immediate post-injection reaction, Urinary incontinence, Visual disturbance

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female with no known pertinent medical history or drug reactions/allergies who on 01-JUL-2008 was vaccinated with a first dose of GARDASIL (lot# 659657/1487U) 0.5 ml IM in her left deltoid. There was no concomitant medication. The patient reported seeing "black spot before her eyes" immediately after the vaccination. The patient was laid down and had a tonic-clonic seizure which lasted 30-40 seconds. The patient did have a loss of bladder control. After the event the patient was observed in the office and discharged home with her mother. The patient was recovered on 01-JUL-2008. An Electroencephalography was scheduled to be completed the following week. Upon internal review the tonic-clonic seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **318539-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		09-Jul-2008	10-Jul-2008	FR	WAES0807AUS00054	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Myalgia, Pancytopenia, Pyrexia, Retroperitoneal lymphadenopathy, Splenomegaly

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and Case Line Listing concerning a female who was vaccinated with GARDASIL. Subsequently, 3 weeks after vaccination the patient experienced pancytopenia, splenomegaly, retroperitoneal lymphadenopathy and pyrexia and was hospitalised. It was described that the patient experienced pancytopenia with fever, splenomegaly, retroperitoneal lymphadenopathy and myalgia. At the time of reporting to the agency on 19-DEC-2007, the patient had recovered from pancytopenia, splenomegaly, retroperitoneal lymphadenopathy and pyrexia. The agency considered that pancytopenia, splenomegaly, retroperitoneal lymphadenopathy and pyrexia were probably related to therapy with GARDASIL. The original reporting source was not provided. Subsequently the patient's experience was reported in an article. Additional information is not expected. A copy of the published literature article is attached for further documentation of the patient's experience.

Other Meds: Unknown

Lab Data: abdominal computed axial tomography, retroperitoneal lymphadenopathy on CT abdomen

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318540-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Oct-2007	15-Oct-2007	14	09-Jul-2008	10-Jul-2008	FR	WAES0807AUS00053	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Confusional state, Convulsion, Headache, Malaise

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 15 year old female who in October 2007 was vaccinated with the third dose of GARDASIL. On 15-OCT-2007 the patient experienced convulsion, confusional state, headache and malaise and was hospitalised. It was described that the patient was fitting and experienced headache, was unwell, vague but was conscious throughout. At the time of reporting to the agency on 14-DEC-2007, the patient had recovered from convulsion, confusional state, headache and malaise. The agency considered that convulsion, confusional state, headache and malaise were possibly related to therapy with GARDASIL. The original reporting source was not provided. Subsequently the patient's experience was reported in an article. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318541-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		09-Jul-2008	10-Jul-2008	FR	WAES0807AUS00052	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Nausea

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning 21 year old female who was vaccinated with GARDASIL. Subsequently, after vaccination the patient experienced convulsion, dizziness and nausea. At the time of reporting to the agency on 03-DEC-2007, the patient had recovered from convulsion, dizziness and nausea. The agency considered that convulsion, dizziness and nausea were related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review, convulsion was considered an other important medical event. Subsequently the patient's experience was reported in an foreign article, 25-JAN-2008, page 6. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 318542-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	Unknown	Unknown		09-Jul-2008	10-Jul-2008	FR	WAES0807AUS00051	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Inappropriate schedule of drug administration, Syncope

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning a 27 year old female who was vaccinated with GARDASIL. Concomitant therapy included analgesic or anesthetic (unspecified), LEXAPRO and ZELDOX. Subsequently, after vaccination the patient experienced convulsion and syncope. At the time of reporting to the agency on 06-DEC-2007, the patient had recovered from convulsion and syncope. The agency considered that convulsion and syncope were related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review, convulsion was considered an other important medical event. Subsequently the patient's experience was reported in an article. Additional information is not expected.

Other Meds: analgesic or anesthetic (unspecified), Unk - Unk; escitalopram oxalate, Unk - Unk; ziprasidone hydrochloride, Unk - Unk

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318543-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		09-Jul-2008	10-Jul-2008	GA	WAES0807USA00422	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blindness transient

Symptom Text: Information has been received from an office manager at physician's office concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (Lot number not provided). No concomitant medications were reported. The office manager reported that the physician had a patient who reported to him that she developed temporary blindness after receiving GARDASIL. The onset date was unknown. The patient was not vaccinated by this physician's office. The patient did go to the ER for treatment. The patient's sight did return. There was no product complaint. Upon internal review the temporary blindness was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318544-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	23-Aug-2007	23-Aug-2007	0	09-Jul-2008	10-Jul-2008	NY	WAES0709USA00992	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received from a 23 year old female consumer through the Merck Pregnancy registry and an other health professional who on approximately 23-JUN-2007 was vaccinated with 0.5 ml of a first dose GARDASIL. There was no concomitant medication. On 23-AUG-2007 the patient was vaccinated with second dose of GARDASIL. On 06-SEP-2007 the patient reported that she was pregnant. The patient's last menstrual period was 02-AUG-2007. The estimated delivery date was 08-MAY-2007. Unspecified medical attention was sought. A urine test was performed (results not reported). On 26-JUN-2008, it was reported that the patient had a pregnancy loss at 20 weeks estimated gestational age (EGA) and was then seen for a postpartum visit in January after her 20 week loss. At the time of this report, the patient's outcome was unknown. Upon internal review, spontaneous abortion was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: urinalysis - results not reported

History:

Prex Illness: Pregnancy NOS (LMP = 8/2/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318545-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	04-Apr-2007	14-Apr-2007	10	09-Jul-2008	10-Jul-2008	--	WAES0706USA04891	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0244U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Foetal macrosomia, Hypertension, Premature rupture of membranes

Symptom Text: Initial and follow up information has been received, via the Merck pregnancy registry, from a registered nurse, concerning a 26 year old female patient with chronic hypertension, who on 24-JAN-2007 was vaccinated with the first dose of GARDASIL (Lot # not provided), and on 04-APR-2007 was vaccinated with the second dose of GARDASIL (Lot #656051/0244U). Concomitant therapy included ALDOMET and prenatal vitamins (manufacturer unspecified). The patient later found out she was pregnant, with the date of the LMP on 14-APR-2007, and an estimated date of delivery on 19-JAN-2008. The nurse confirmed that the pregnancy was normal to date. On an unspecified date, the patient delivered at 39 weeks a healthy and normal male. The patient had spontaneous rupture of membranes and ultimately had a cesarean section. The patient's cesarean section was secondary to fetal macrosomia and chronic hypertension. The baby weighed 10lbs 1.6oz. There were no complications for the baby and mother postoperatively. The baby was discharged home along with the patient. Upon internal review, fetal macrosomia and chronic hypertension were considered other important medical events. Additional information is not expected.

Other Meds: ALDOMET (METHYLDOPA); vitamins (unspecified)

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 4/14/2007); Hypertension

Prex Vax Illns:

Vaers Id: **318546-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Jan-2007	09-Mar-2007	37	09-Jul-2008	10-Jul-2008	NY	WAES0702USA01776	10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1426F		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received from a physician and a Merck Pregnancy Registry concerning an 18 year old female with a history of asthma who on 31-JAN-2007 was vaccinated intramuscularly with a 0.5 mL dose of GARDASIL, (Lot # 655205/1426F). Concomitant therapy included albuterol. The patient's last menstrual period was on 01-JAN-2007. Subsequently the patient had a positive pregnancy test on 07-FEB-2007. The patient sought unspecified medical attention. The patient had a qualitative human chorionic gonadotropin (HCG) test. No problems reported. On 09-MAR-2007, the patient had an elective termination of the pregnancy. She was approximately 9 weeks estimated gestational age (EGA). According to the physician, the patient didn't have an elective abortion because of the vaccine. This was an unplanned pregnancy and the patient wanted to go on to college, this was the primary reason. The fact that she had the vaccine maybe contributed a little bit after that. At the time of this report, the patient's outcome was unknown. Upon internal review, elective abortion was considered an other important medical event. Additional information is not expected.

Other Meds: albuterol

Lab Data: diagnostic laboratory, Qualitative HCG; beta-human chorionic, 02/07/07, (+), positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/1/2007); Asthma

Prex Vax Illns:

Vaers Id: **318557-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Jul-2008	07-Jul-2008	0	09-Jul-2008	21-Jul-2008	MD		21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB222AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Clonus, Convulsion, Syncope

Symptom Text: Syncopal episode immediately following injection with a few seconds of convulsive seizure-like clonic movements. No postictal Sx after event. Vital signs stable.

Other Meds:

Lab Data:

History: Asthma

Prex Illness:

Prex Vax Illns:

Vaers Id: **318558-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jul-2008	06-Jul-2008	5	09-Jul-2008	21-Jul-2008	AZ		21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site oedema, Injection site pain, Local swelling, Lymphoedema

Symptom Text: Localize redness, edema, pain at injection site; Lymphedema of neck area.

Other Meds: Depo Provera

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **318560-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Jul-2007	18-Jul-2007	1	09-Jul-2008	21-Jul-2008	FL		05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0245U	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Weight increased

Symptom Text: Parents concerned that child has had an abnormal weight gain since receiving GARDASIL vaccine - BMI - BMI 2 months before 1st GARDASIL was 2 cm. BMI - tests - 1 year after 2nd GARDASIL is 3 cm. Child's nomstrad cholealyagy very regular - child had diarrhea for 3 months after 2nd GARDASIL - mother to give Benadryl.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **318569-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	11-Jun-2008	Unknown		09-Jul-2008	21-Jul-2008	NC		21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: GARDASIL vaccine administered 3 days prior to due menses. Patient with (+) pregnancy test on 6/24/08. Injection given on 6/11/08. LMP 5/13/08 - 3rd injection of series.

Other Meds: FLAGYL; IGM; VOLTAREN-50mgs

Lab Data: Pelvic U/S and Viable screen on 7/2/08. Single Viable IUP at 7 weeks 2 days.

History: PCN allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **318573-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Nov-2007	25-Mar-2008	134	09-Jul-2008	10-Jul-2008	NC		11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Loop electrosurgical excision procedure, Smear cervix abnormal, Surgery

Symptom Text: My Daughter started having pap smears when she was 16 and things were fine until she started getting the shots. After the second dose she had a abnormal pap. Her dr further investigated and ended up burning cells off cervix. The next pap came back CIN 11 Moderate Dysplasia. She ended up having a LEEP done in March 08. She will go back to the dr in August, 08 to have another pap. This is a result of this vaccine. My daughter was fine until these shots and now she may later on have to have further surgery.

Other Meds: birth control

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318574-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Apr-2008	24-Apr-2008	1	09-Jul-2008	10-Jul-2008	GA		11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2417AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0524U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Asthenia, Dizziness, Mucous membrane disorder, Nasal congestion, Pyrexia, Tachycardia

Symptom Text: Fever started after getting vaccine, pt went to ER w/ fever 103.5, dizziness weakness, nasal congestion, abdominal pain, dry mucous membranes, tachycardia, moderate distress

Other Meds: none

Lab Data: CBC: WBC 8.7, Neut %81.6, lymph 8.0, hgb 12.2, hct 37.3, plt 179, na 132, k 3.7, cl 98, co2 26.2, gluc 110, bun 12, creat 0.8, UA: trace protein, Specific gravity 1.015, ph 6.0 ketones 3+, urobili 4.0, trace blood, wbc occ, epithelial cell

History: n/a

Prex Illness: none

Prex Vax Illns: n/a~ ()~NULL~~In Patient

Vaers Id: 318575-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Aug-2007	01-Mar-2008	191	09-Jul-2008	10-Jul-2008	OH		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	UNKNOWN MANUFACTURER	UNKNOWN		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0928U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Back pain, Contusion, Ecchymosis, Hypoaesthesia, Monoplegia, Muscular weakness, Paraesthesia

Symptom Text: We requested the vaccine for our daughter before she entered college. After the vaccine(on 8/23/07) she started to have leg tingling, which we thought was from a softball injury.She came home on spring break and was hospitalized from 3/02/08 to3/10/08 with leg paralysis that still cannot be explained. After massive doses of steroids and every test known to man (which came back normal) she regained the use of her legs 8 days later. We dont know if this will happen again or what caused it, but thought it should be reported due to others having the same thing happen. I have another daughter that is 10 that i was going to get the vaccine for, but want to make sure its safe before I do.if you have more questions, contact me because there was alot more than listed here that happened. 7/10/08-records received for DOS 3/2-3/10/08-DC DX: Chronic low back pain. Lower extremity weakness of unclear etiology. Prior to admission developed worsening of lower back pain with weakness in lower extremities and numbness for 2 weeks. C/O pins and needles sensation. States no feeling in legs and unable to move them or walk. PE: lower extremity strength 10/5 bilaterally.Chronic ingoing and outgoing problems for many years. C/O ecchymosis and easy bruising. All blood tests normal. Evaluated for possible adjustment disorder with anxiety over the conversion disorder. 8/28/08-office notes include neurology visit 12/17/07-impression:symptoms suggesting sacroiliac joint pain on right side, sensory changes and slight weakness and positive findings on straight leg raise suggest mild right L5 radiculopathy.

Other Meds:

Lab Data: CBC,Xrays,CT scan,spinal tap...all came back normal.She has slight scoliosis and a slight disc problem that They said was not the cause of her problem. 7/10/08-records received- MRI brain normal. MRI cervical spine diffuse disk bulge at

History: 7/10/08-records received-History of back injury from playing softball. PMH: epidural injections. Slipped disk at L5. Chronic back pain.

Prex Illness: none. was just getting vaccines for college

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318576-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
41.0	M	01-Dec-2007	Unknown		09-Jul-2008	10-Jul-2008	GA		11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: None at this time. However, I do not plan on getting the third injection which was due in August 2008. Date of first vaccination is estimated.

Other Meds:

Lab Data: N/A

History: high cholesterol

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: **318577-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-May-2006	04-Apr-2008	704	09-Jul-2008	10-Jul-2008	NC		10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection, Smear cervix abnormal

Symptom Text: I did not have adverse symptoms. However, I had never had an abnormal pap smear until receiving the vaccine. My pap smear prior to the vaccine was normal. I just received the results from my first pap smear after taking the vaccine and the HPV virus is now present. I spoke with two other friends of mine regarding the matter and they stated the same thing happened in there cases.

Other Meds: Yasmin

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **318580-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	15-Apr-2008	16-Apr-2008	1	09-Jul-2008	10-Jul-2008	WI		10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	1	Gluteous maxima	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Gait disturbance, Headache, Hypoaesthesia, Hypoaesthesia facial, Hypoaesthesia oral, Incorrect route of drug administration, Injection site pain, Migraine, Myalgia, Nausea, Pyrexia, Vaccine positive rechallenge, Vision blurred

Symptom Text: After the 1st shot I was dizzy, nasueous, developed a fever. The next day a bad headache followed and the muscle that received the shot (butt) hurt terribly for the next week and a half. The 2nd shot I received I had the same symptoms only this time I ended up being hospitalized for a "migraine". I had numbness in my face, arms and hands, my entire mouth went numb and I had severely blurred vision and couldn't walk straight. I've never had this before in my life and it seems to follow each shot. It definitely escalated with the 2nd shot and I've become wary of having the 3rd done because of this.

Other Meds:

Lab Data: Had CT scan of my head done and blood work.

History:

Prex Illness:

Prex Vax Illns: illness/severe headache~HPV (Gardasil)~1~23~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318583-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	11-Jun-2008	12-Jun-2008	1	09-Jul-2008	10-Jul-2008	GA		11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Musculoskeletal pain, Musculoskeletal stiffness, Myalgia, Neck pain

Symptom Text: I received my shot in my left arm on the afternoon of the 11th of June. In the days following, I began to have sore muscles in my left triceps and biceps and left neck/shoulder. The arm pain continued for no more then a day, but the morning of the 17th I woke up, got out of bed, and my neck kinked. The stiff neck was so severe that I could barely move it and it was incredibly painful the entire day. I was forced to look down the entire day because lifting my head up was too painful. I treated it with advil and vicodin and heat packs. The pain went on for days (continuing to lessen) until the 23rd when I could no long feel any lingering neck pain. I had never had a stiff neck last that long previously.

Other Meds: Nuvaring

Lab Data:

History: Non-serum Rheumatoid Arthritis

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318585-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-May-2008	17-May-2008	1	09-Jul-2008	10-Jul-2008	MA		11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site mass, Injection site pain, Myalgia

Symptom Text: My daughter rec'd the first HPV shot 03/16/08 and complained of soreness at injection site which subsided within a couple of days. She went for 2nd dose on 05/16/08 and her arm has not been the same since. She complains of muscle soreness and has a small bump at injection site to this day July 9, 2008. She sometimes has difficulty lifting her arm up. I brought her to her MD and nurse practitioner told her to exercise the arm and said this is a normal to feel pain afterwards. I feel this is from the HPV vaccine and consider it to be a consequence of that shot. I will NOT allow her to get the 3rd dose. It was recommended by the NP that she should probably get this third and final shot in her leg, because of the problem she had with her arm. I fear that if the same thing happens she will have problems walking if this shot was to be given in her leg, just as she had problems moving and lifting her arm. I feel this is directly related to the HPV vaccine because she never had a problem with her arm/ muscle before.

Other Meds: LO-ovrel

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318588-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	20-Dec-2007	02-Jan-2008	13	09-Jul-2008	10-Jul-2008	PA		10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Alopecia effluvium, Anxiety, Burning sensation, Pain of skin, Stress

Symptom Text: About 1 week after receiving the first shot, I noticed my hair started to fall out. I went to the dermatologist who said I had telogen effluvium (temporary hair loss). They said it occurs when something "shocks" the bodies system. I have also seen an endocrinologist to rule out all illnesses/diseases (all tests came back negative). I have seen so many doctors and everyone tells me something different. I saw another dermatologist who said the hair loss can last from 6 months to 2 years. I am now suffering from anxiety and stress because of this and nothing seems to be working. My scalp is sore all the time and sometimes burns. It is extremely uncomfortable. The dermatologist can't see anything (meaning it is some underlying symptom).

Other Meds:

Lab Data:

History: NA

Prex Illness: NA

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318590-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	19-Jul-2007	15-Jun-2008	332	09-Jul-2008	10-Jul-2008	MD		11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bone pain, Oedema peripheral, Pain in extremity

Symptom Text: Patient developed painful swelling of left foot in 6/08. At one point, pain had traveled up her leg to her back/spine and neck. She continues to have painful swelling of the foot. There was no injury reported. Bloodwork and xrays have not yielded a diagnosis. She is on pain medication only with minimal improvement. She has been referred to a rheumatologist.

Other Meds: Augmentin x 14d 7/19/07, Albuterol, Flonase, Allegra, now on Naprosyn and Zantac also since onset of sx

Lab Data:

History: Exercise-induced asthma, eczema, allergic rhinitis, overweight

Prex Illness: sinusitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318591-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Apr-2008	21-Apr-2008	6	09-Jul-2008	10-Jul-2008	OR		11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Fall

Symptom Text: Patient had a ground level fall, she landed on the right side of her head, this occurred while she was "warming up" to run track. EMS called. Bystanders suggest there might have been some seizure-type activity.

Other Meds:

Lab Data: CMP, EKG, EEG

History:

Prex Illness: Sore throat

Prex Vax Illns:

Vaers Id: **318593-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	10-May-2008	10-May-2008	0	09-Jul-2008	10-Jul-2008	IL		10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness, Injection site erythema, Injection site pain, Pyrexia

Symptom Text: Injections were extremely painful. Second injection caused flu like symptons associated with fever. Site at injections were extremely painful, sore and red for several days. Guardisil was the injections given.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns: previous report John~DTaP+IPV+HepB+Hib (no brand name)~1~0~In Sibling1|previous report John~Pneumo (no brand name)~0~0~In Siblin

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318594-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Oct-2007	30-Oct-2007	8	09-Jul-2008	21-Jul-2008	IA		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	1	Left leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Arthralgia, Blood test normal, Chest pain, Disturbance in attention, Dyspnoea, Fatigue, Headache, Hyperaesthesia, Lymphadenopathy, Malaise, Mononucleosis heterophile test negative, Pain, Pneumonia, Sinusitis, Streptococcal identification test positive

Symptom Text: On July 25, 2007 patient went into the Pediatrician's office for a School Physical. The nurse practitioner recommended the Gardasil vaccine. After discussing with her the possible side effects and the fact that patient, has many allergies and I was concerned about possible reactions to the vaccine. The nurse assured us that the vaccine that should not give her a problem. I agreed to the vaccine. The second shot was given to patient on or about October 22, 2007. Within a week of getting, the second vaccine patient started complaining of generally not feeling well. Patient began feeling very tired and generally "achy" all over. She started missing school. Through the entire month of November, patient missed school occasionally due to fatigue and overall achiness. This progressed and became worse. By the end of December, patient had started missing entire weeks of school. She had headaches, joint pain, ached all over, fatigue, difficulty breathing on occasion. Because patient was so ill that when it was time to receive the 3rd shot of Gardasil, we chose to wait even though the doctors reassured us that it would be alright. The symptoms appeared to be consistent with Mono, so in early January we took her to the doctor. He ran Mono tests, Strep tests and blood tests. The strep test was positive, the mono test was negative and the blood tests showed no problems. The doctor prescribed on Antibiotics for the strep. Through the entire Month of January, she was ill, and went through several rounds of antibiotics. Her glands were swollen, her body was in pain, her stomach and chest hurt, legs and joints hurt (at times you could not even touch her, she would cry in pain). There were days that she just could not get out of bed, severe fatigue. By February, patient had developed pneumonia and was so ill that the doctor contemplated putting her in the hospital. The only reason he did not hospitalize her was that due to her allergies to antibiotics he indicated that he really did not have anything

Other Meds: None

Lab Data:

History: Food Allergies; Environmental Allergies; Eposodic Asthma; Antibiotic Allergies

Prex Illness: none

Prex Vax Illns: Rash; Fever~Influenza (no brand name)~1~7~In Patient

Vaers Id: 318596-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	22-Oct-2007	05-Nov-2007	14	09-Jul-2008	21-Jul-2008	IA		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	1	Left leg	Intramuscular	DTP

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Arthralgia, Disturbance in attention, Dizziness, Drug hypersensitivity, Eating disorder, Fatigue, Headache, Pain, Paraesthesia, Sinusitis, Weight decreased

Symptom Text: Patient was 11 on July 25, 2007 when she went into the Pediatrician's office for a School Physical. Patient received the first vaccine during the visit and received the second shot on or about October 22, 2007. Patient began struggling with fatigue and general achiness about 2 weeks after the vaccine. This progressed and became worse. She had issues with fatigue and overall body pain, joint pain, headaches and stomachaches. Patient was able to work through it part of the time but still missed a lot of school. At the end of February, Patient had severe headaches, dizziness, stomach pain, and fatigue. Patient had virtually stopped eating. She had lost 10 pounds in a matter of a month. The diagnosis was "sinus infection." The doctor prescribed an antibiotic. Patient had an adverse reaction to the antibiotic and had to be prescribed a different one. She was on Antibiotics for several weeks without any improvement. In addition to the above noted symptoms reported to the doctors, patient reported difficulty concentrating and severe leg pain and tingling down to her ankles. We have enlisted the help of a Integrated Manual Therapist to get the toxins out of her body. She has been in treatment since mid April and has been improving. She is still having occasional severe headaches, stomach pain and fatigue. Patient has begun eating again but has not gained any weight back (she has lost a total of 20 pounds).

Other Meds: None

Lab Data:

History: Environmental Allergies; eposodic asthma

Prex Illness: None

Prex Vax Illns: Rash, Fever~Influenza (no brand name)~1~7~In Sibling

Vaers Id: 318598-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-Jul-2008	08-Jul-2008	0	09-Jul-2008	10-Jul-2008	MI		07-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1346U		Left arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U2558AA		Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0387U		Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2844AA		Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Concussion, Dizziness, Fall, Gaze palsy, Head injury, Headache, Loss of consciousness, Neck pain, Pain of skin, Somnolence, Subarachnoid haemorrhage, Subdural haematoma, Syncope, Unresponsive to stimuli

Symptom Text: Client had sat in imms room for approximately ten minutes after receiving the vaccinations prior to going to waiting room. Client was waiting for mother to take care of business with clerk for a few more minutes and she went unconscious. Her head hit the floor very hard on the back of her head. Per mother her eyes rolled back and client was non responsive. A rather large hematoma occurred approximately 5 cm by 2 cm and raised approximately .5 cm. Our physician on site assessed client and gave instructions to mother and told mother that Client has a level 1 or 2 concussion. Ice was applied to hematoma and mother was told if confusion or lethargy was to occur she should take client to the hospital. Later that afternoon mother felt client was having trouble staying awake and kept dozing off. Client was taken to ER (09/08/2008) and sent to another facility for observation over night. Hospital discharged client 09/09/2008 with a diagnosis of a small intracranial bleed per clients mother. 7/11/08 Reviewed ER medical records of 7/8/2007. FINAL DX: intracranial hemorrhage of subdural hematoma & subarachnoid hemorrhage Records reveal patient experienced syncope at MD office w/lightheadedness, fall, LOC x 30-45 secs w/head & neck pain when awakened. Exam revealed tenderness at base of skull. Transferred to higher level of care. 8/5/08 Reviewed hospital medical records of 7/8-7/9/2008. FINAL DX: SAH & small SDH s/p fall Records reveal patient continued to experience HA s/p fall. Kept overnight for observation. Did well w/minimal scalp tenderness next AM & D/C to home w/PCP f/u.

Other Meds:

Lab Data: LABS: CT scan revealed ICH of SDH & SAH. Reviewed by neurosurgery & concurred w/prior assessment.

History: PMH: imperforate anus & TE fistula in infancy both repaired. Daily enema.

Prex Illness:

Prex Vax Illns:

Vaers Id: 318603-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-May-2007	21-Sep-2007	128	09-Jul-2008	10-Jul-2008	CA		13-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0210U	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Consciousness fluctuating, Constipation, Convulsion, Monoplegia, Muscle twitching, Muscular weakness, Pain in extremity, Radiculitis brachial

Symptom Text: In September 2007 patient had her very first seizure. Then on February 14 2008 she had a second seizure. On March 8 2008 she began to have some weakness in her right arm. I took her to the emergency room the next day when she was no longer able to move her arm. It was paralized, from her shoulder to her finger tips.After admitting her to the hospital, her arm became extremely painful.She was on morphine for 3 weeks. The pain went away but her arm is still paralized, with some slight improvem7/21/08-records received for DOS 3/08-3/23/08-DC DX:right brachial neuritis or plexitis. Right arm weakness and pain. Seizure disorders. Constipation. Previously healthy until September 2007, presented in September with altered level of consciousness. Asymptomatic until February 14, presented with altered consciousness.Two days prior to admission felt twitching in right arm, progressed to pain with noted weakness. Work-up negative for stroke. No seizure activity while in hospital.

Other Meds: none

Lab Data: In the hospital they did 2 MRI's a CT scan an EKG, numerous blood tests, and an EMG. Everything came back normal except the EMG showed that the F2 waves were a little abnormal.A neurologist redid the EMG about 2 months later and found that

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **318608-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	10-Mar-2008	10-Mar-2008	0	09-Jul-2008	10-Jul-2008	--		11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Fatigue, Feeling cold, Groin pain, Hyperhidrosis, Injected limb mobility decreased, Injection site pain, Insomnia, Loss of consciousness, Oedema peripheral, Pain, Pain in extremity, Pallor, Paraesthesia, Presyncope, Pruritus, Pyrexia, Rash erythematous, Tinnitus

Symptom Text: I presented to the doctor with the flu on Monday March 10 2008. The doctor said that it did not matter for the injection. The nurse was called and I was given the first injection. That night all through the night my arm became swollen and sore, I had intense pain in my lower back, groin and shooting pains down my legs. I had tingling in my feet and arms. The next day I nearly fainted when I sat up and every time I moved I had chronic dizziness coupled with ringing in my ears and black outs. Later that evening a red rash started to appear on my arm. I couldn't move my arm without extreme pain. I felt paralysed. A rash appeared on my lower back it looked like a heat rash. I had high fevers and intense pain lots of sweat and then I would feel very cold as if my spine was frozen. The back rash dissappeared but the arm rash increased in size. I went back to the doctor who said the rash would go down - the doctor did not administer anything. The rash did not go down. By the Thursday the rash had increased in size, my upper arm was swollen and itchy, I could not move my arm, I was pale, dizzy, feverish and I had pains in my back and legs. I had insomnia. I consulted a homeopath (as I no longer trusted the doctor) who administered china and apis and other herbs. It wasn't until I started taking these that the rash went down and the fever broke. During the month after the injection I suffered terrible insomnia and dizziness and pain at the injection site. During the two months after the injection I had inexplicable fatigue. Now, (5 months on) I experience a dull throb at the injection site, pain down my arm to my fingers with tingling. I am still experiencing intense fatigue and I believe my immune system is very poor.

Other Meds: Diane 35 ED

Lab Data:

History: Endometriosis. I am allergic to thinks that sting (bees, wasps, ants)

Prex Illness: Early onset of cold/flu

Prex Vax Illns:

Vaers Id: **318610-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	08-Jul-2008	08-Jul-2008	0	10-Jul-2008	10-Jul-2008	FL		10-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	
	MEN	UNKNOWN MANUFACTURER	NULL		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inflammation, Injection site erythema, Injection site pain, Injection site swelling, Local reaction, Myalgia, Pain, Pain in extremity

Symptom Text: Pt received highly recommended vaccinations of Meningococcal AND HPV into right deltoid. The first 12 hours very sore with localized redness and some swelling; ice compress and ibuprofen choice of treatment. 48 hours post injection the site is very painful, red, swollen. A new isolated area below primary site is now becoming inflamed with shooting pain radiating to right ring finger. Also discomfort to right pectoralis. No s/s of dyspnea,pallor,or parasthesia; Benadryl 25mg by mouth administered along with thin topical benadryl cream.

Other Meds: none

Lab Data:

History: asthma

Prex Illness: none

Prex Vax Illns:

Vaers Id: 318613-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Jul-2008	08-Jul-2008	0	09-Jul-2008	21-Jul-2008	MN		21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope-few sec. Laid on floor. Nl mental status.

Other Meds: ZOLOFT, ALLEGRA D

Lab Data:

History: Anxiety, seasonal allergies

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318614-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	30-Jun-2008	01-Jul-2008	1	09-Jul-2008	21-Jul-2008	CO		21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2409AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1060U	0	Right arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB284CA	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1793U	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bone pain, Dizziness, Fall, Feeling abnormal, Head injury, Headache, Loss of consciousness, Neck pain

Symptom Text: Woke up this AM with headache and neck pain radiating down to thoracic spine. Approximately 1/2 hr pt fell and due to dizziness/passed out and hit (Lt) side of head above eye. Pt states she doesn't "feel right".

Other Meds: None

Lab Data: EKG; WBC and Chem 8; Head CT

History: PCN; Suprax

Prex Illness: N/A

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318616-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		09-Jul-2008	21-Jul-2008	PA		21-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB234BA	0	Left arm	Unknown	
TDAP	SANOFI PASTEUR	C2492BA	0	Left arm	Unknown	
VARCEL	MERCK & CO. INC.	1512U	1	Left arm	Unknown	
HPV4	MERCK & CO. INC.	1262U	0	Left arm	Unknown	
MNQ	SANOFI PASTEUR	C2331AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dysmenorrhoea, Nausea, Vomiting

Symptom Text: Soon (1-2 minutes) after last vaccine given, pt had a strong menstrual cramps (which she was having prior to visit) and became nauseous. She vomited x2 and felt weak. She recovered in 20-30 minutes and went home.

Other Meds: OCP

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318619-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		09-Jul-2008	21-Jul-2008	IL		21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: "Patient" fainted right after I gave GARDASIL injection. She was only out for a few seconds.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318621-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-Jul-2008	09-Jul-2008	0	09-Jul-2008	21-Jul-2008	IA	IA08009	21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2938AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1968U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Cl given HPV & Tdap vaccine & fainted in hallway 5-10 minutes later. Mother eased her to floor & no apparent injury.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **318622-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	09-Jul-2008	09-Jul-2008	0	09-Jul-2008	21-Jul-2008	IA	IA08008	21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1662U	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Syncope

Symptom Text: Client fainted after administration of vaccines. Approximately 5 minutes after given was standing up and fell to floor. No apparent injury.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318630-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	10-May-2008	10-May-2008	0	10-Jul-2008	11-Jul-2008	FR	WAES0807PHL00006	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a physician concerning his 21 year old female niece who on 10-MAY-2008 was vaccinated with her first dose of GARDASIL. Patient had no history of allergies and had no concomitant medications at the time of the vaccination. On 11:00 am of 10-MAY-2008, immediately after the vaccination was completely given, the patient experienced seizure and fainting which lasted for approximately 30 seconds. The reporting physician mentioned that the patient did not have breakfast yet when she received the vaccination. Subsequently, the patient recovered from seizure and fainting. The physician mentioned that after the event, the patient was monitored for other similar episodes. At the time of reporting, patient did not have any similar experience yet. The reporter felt that seizures and fainting were related to therapy with GARDASIL. Upon internal medical review, seizure is considered as an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318631-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jan-2008	01-May-2008	121	10-Jul-2008	11-Jul-2008	FR	WAES0807USA00975	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Blood product transfusion, Facial paresis, Paraesthesia

Symptom Text: Information has been received from a medical student concerning a female patient who in January 2008 was vaccinated IM into the deltoid muscle with a 3rd dose of GARDASIL. The patient developed unilateral facial paresis for the first time in May 2008, additionally she developed paraesthesia and loss of energy. The events resolved under treatment with immunoglobulins (unspecified) in May 2008. The adverse events reoccurred end of June 2008 and were ongoing at the time of the reporting. The patient was hospitalized on an unspecified date and the following care was in the outpatient department. On an unspecified date, the patient was vaccinated with 1st and 2nd dose of GARDASIL. No adverse effect occurred. Other business partner numbers included E2008-06126.

Other Meds: Unknown

Lab Data: Unknown

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: 318632-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	20-Jun-2008		10-Jul-2008	11-Jul-2008	FR	WAES0807USA00977	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Coma, Somnolence

Symptom Text: Information has been received from a general practitioner and diabetologist concerning a 17 year old female who on an unspecified date was vaccinated with GARDASIL (batch# not reported). On 20-JUN-2008 the patient was transiently comatose and subsequently somnolent for 1 hour. On 20-JUN-2008, she was admitted to a university hospital for suspicion of seizure. The reporter assessed the causal relationship between the adverse events and GARDASIL to be "possible." Outcome was not reported. Other business partner numbers included: E2008-05834. No further information was available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 318636-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Nov-2007	03-Sep-2007	-67	10-Jul-2008	11-Jul-2008	TX	WAES0802USA04515	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Live birth, Urinary tract infection

Symptom Text: Information has been received from a nurse, for the Pregnancy Registry for GARDASIL, concerning a 16 year old female who on 31-MAY-2007 was vaccinated with her first dose of GARDASIL (route and lot# not provided). On 31-JUL-2007 the patient was vaccinated with her second dose of GARDASIL (route and lot# not provided). On 09-NOV-2007 the patient was vaccinated with her third dose of GARDASIL (route and lot# not provided). Subsequently, it was reported that the patient had a sonogram (date unspecified) and was pregnant (Gestation 6.5 months, LMP 03-SEP-2007). Follow up information received stated that on 18-FEB-2008 that patient was diagnosed with a bacterial urine infection and was treated with MACROBID 1 tablet, PO, BID for 7 days. The outcome of the bacterial UTI was not reported. On 09-MAY-2008 at 38 6/7 weeks gestation the patient gave birth to a male infant 6 pounds 7.7 oz., 19.3 inches, the babies Apgar score was reported as 1. It was reported that the baby was born with an unspecified infection which was treated with unspecified antibiotics. It was reported that the baby "had a hard time breathing and stayed in the hospital for 1 week". Additional information regarding the prolonged hospitalization of the baby was not provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound

History:

Prex Illness: Pregnancy NOS (LMP = 9/3/2007)

Prex Vax Illns:

Vaers Id: 318637-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	28-Mar-2008	28-Mar-2008	0	10-Jul-2008	11-Jul-2008	TN	WAES0804USA06374	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blighted ovum, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received for the Pregnancy Registry for GARDASIL from a 25 year old female consumer who on 28-MAR-2008 was vaccinated with her third dose of GARDASIL (lot# not reported). Concomitant therapy included prenatal vitamins (unspecified) once daily. On 06-APR-2008 the patient found out she was 4 weeks pregnant. The patient had a positive home pregnancy test. Subsequently the patient experienced no adverse events and sought unspecified medical attention. The patient's estimated conception date was approximately 19-MAR-2008, her last menstrual period was 06-MAR-2008 and her estimated delivery date was 10-DEC-2008. On 05-MAY-2008 an ultrasound was performed for viability, the results showed no defectable fetal parts or cardiac activity within the sac. On 20-MAY-2008 an ultrasound was performed and showed no fetal pole or yolk sac, which suggested a blighted ovum. The patient did not provide any information on the first and second dose. At the time of the report, the outcome of the patient was unknown. Upon internal review the blighted ovum was considered to be an other important medical event. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 05/05/08, reason-viability no defectable fetal parts or cardiac activity within sac; ultrasound, 05/20/08, no fetal pole or yolk sac seen; suggested blighted ovum; beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 3/6/2008)

Prex Vax Illns:

Vaers Id: **318638-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-May-2008	21-May-2008	0	10-Jul-2008	11-Jul-2008	--	WAES0805USA05817	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received from a physician and a nurse practitioner concerning a 17 year old female no past medical history reported, and no previous pregnancies, who on 21-MAY-2008 (also reported as April 2008) was vaccinated with a 0.5 mL dose of GARDASIL and then discovered that she was pregnant. No concomitant medications were reported. No adverse effects reported. The patient sought unspecified medical attention in the office. The patient was referred to an obstetrician for obstetrical care. The patient's last menstrual period was 01-APR-2008 and estimated date delivery is 07-JAN-2009. A urine pregnancy test in the office on 17-MAY-2008 was negative and on 21-MAY-2008 the urine pregnancy test was positive. On 03-JUN-2008 ultrasound results showed that the patient was 8 weeks and 5 days pregnant. On 19-JUN-2008 the patient had a spontaneous abortion at nine weeks. Pathology and chromosomal testing was pending. Spontaneous abortion was considered to be an other important medical event. No further information is available.

Other Meds: None

Lab Data: ultrasound, 06/03/08 - 8 + 5 weeks; urine beta-human, 05/21/08 - positive; urine beta-human, 05/17/08 - negative

History:

Prex Illness: Pregnancy NOS (LMP = 4/1/2008)

Prex Vax Illns:

Vaers Id: **318639-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	Unknown	Unknown		10-Jul-2008	11-Jul-2008	FR	WAES0807AUS00048	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion, Inappropriate schedule of drug administration, Loss of consciousness

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning a 27 year old female who was vaccinated with GARDASIL. Subsequently, after vaccination the patient experienced Grand mal convulsion and loss consciousness. At the time of reporting to the agency on 24-DEC-2007, the patient had recovered from Grand mal convulsion and loss of consciousness. The agency considered the Grand mal convulsion and loss of consciousness were related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review, Grand mal convulsion was considered an other important medical event. Subsequently the patient's experience was reported in an article. Additional information is not expected. A copy of the published article is attached as further documentation of the patient's experience.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 318640-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	14-Dec-2007	14-Dec-2007	0	10-Jul-2008	11-Jul-2008	FR	WAES0807AUS00055	11-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0734U		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Fatigue, Feeling abnormal, Impaired work ability, Injection site erythema, Injection site pain, Malaise, Somnolence

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and Case Line Listing concerning a 24 year old female who on 14-DEC-2007 was vaccinated with GARDASIL (Lot No. 658214/0734U, Batch No. J2926, Expiry date 13-MAR-2010). On 14-DEC-2007, one hour after vaccination, the patient experienced malaise, fatigue, feeling abnormal, injection site pain and somnolence. It was described that the patient's symptoms of feeling unwell, tired and sleepy were persistent for 6 days at the time of reporting to the agency on 21-DEC-2007. The patient was not able to work. Not specific but soreness and tenderness at site of immunisation. There were nil findings on exam. The patient was apyrexial and normotensive. The patient's PR was 80 (units not specified). Slightly tender aspect around immunisation site with some redness and not hot. The agency considered that malaise, fatigue, feeling abnormal, injection site pain, and somnolence were possibly related to therapy with GARDASIL. Malaise, fatigue, feeling abnormal, injection site pain and somnolence were considered to be disabling. The original reporting source was not provided. Subsequently the patient's experience was reported in an article. Additional information is not expected. A copy of the published article is attached as further documentation of the patient's experience.

Other Meds: Unknown

Lab Data: total heartbeat count, 80, PR

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318641-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	31-Jul-2007	15-Aug-2007	15	10-Jul-2008	11-Jul-2008	FL	WAES0807USA00819	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0263U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Gaze palsy, Postictal state, Staring, Tremor

Symptom Text: Information has been received from a physician concerning a 16 year old female with no pertinent medical history or history of drug allergies or reactions who on 31-JUL-2007 was vaccinated intramuscularly with the first dose of GARDASIL (lot no. 655849/0263U). There was no concomitant medication. On 15-AUG-2007 and 01-SEP-2007, the patient experienced a seizure. On 01-SEP-2007 the patient was taken to the emergency room. The patient was also taken to see a neurologist where she was diagnosed as having generalized seizures. An electroencephalography was performed (results not reported). At the time of this report, the outcome was unknown. Generalized seizures were considered to be other important medical events. Additional information has been requested. 10/16/2008 ER record received for 9/1/07 with DX: Seizure-new onset. Pt was sitting at home when pt began staring up and shaking with eyes rolled back in the head. Witnessed by family. Post-ictal upon arrival. D/C for outpt f/u

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **318652-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-Jul-2008	08-Jul-2008	0	10-Jul-2008	21-Jul-2008	VA		22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0012X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Gaze palsy

Symptom Text: Shortly after receiving the shot she had seizure like motion extension of legs eyes rolled back, mild guttural noises. No loss of bowel/urine.

Other Meds:

Lab Data: none

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **318658-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	23-Jun-2008	Unknown		10-Jul-2008	21-Jul-2008	MD		22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0243U	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Muscular weakness, Paraesthesia

Symptom Text: Feel tingling after 2nd shot, both legs weak, fell to ground. One time event. Reported to nurse practitioner 7/9/08, AM. Felt like she was going to faint. Did not lose consciousness.

Other Meds:

Lab Data:

History: Smoker

Prex Illness: None reported

Prex Vax Illns:

Vaers Id: 318666-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	13-Jun-2008	13-Jun-2008	0	10-Jul-2008	21-Jul-2008	IL		21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Chest discomfort, Chest pain, Crying, Depressed level of consciousness, Dizziness, Dyspnoea, Fatigue, Flushing, Hot flush, Hyperhidrosis, Hypoaesthesia, Wheezing

Symptom Text: Within 1-2 minute(s) of injection, patient experienced weakness, wheezing, (L) arm went numb, felt like a brick was on her chest & had trouble breating-chest pain, hot flash & sweats, facial flushing, dizzy, slow to respond, began crying (Experienced lasted about 1 minute) Next day, patient was still weak & tired.

Other Meds: YAZ Birth Control Pill

Lab Data:

History: Allergy: Polyhistamine

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318667-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Jun-2008	28-Jun-2008	0	10-Jul-2008	21-Jul-2008	TX		21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	2	Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Continual pain at admin. site.

Other Meds:

Lab Data:

History:

Prex Illness: N/a

Prex Vax Illns:

Vaers Id: **318668-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	10-Jul-2008	10-Jul-2008	0	10-Jul-2008	21-Jul-2008	ID		21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	?	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site mass, Nausea, Somnolence, Syncope

Symptom Text: Fainted, nausea and sleepy immediately following injection. Golf ball size lump at injection site.

Other Meds: NO

Lab Data:

History: NO

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318669-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	09-Jul-2008	09-Jul-2008	0	10-Jul-2008	21-Jul-2008	MN		21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X IMED	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Nausea

Symptom Text: NAUSEA, SORE ARM AT SITE.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 318675-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		10-Jul-2008	21-Jul-2008	--		21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	12674	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Skin warm

Symptom Text: after receiving the second dose of gardasil the patient experienced fatigue which lasted one day, she also reports the right deltoid which received the gardasil vaccine became "hot".

Other Meds: N/A

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns: AS ABOVE~ ()~NULL~~In Patient

Vaers Id: **318676-1 (S)** **Related reports:** 318676-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Jul-2007	16-May-2007	-54	10-Jul-2008	15-Jul-2008	MI		30-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Bronchitis, Dizziness, Hypoglycaemia, Hypotension, Loss of consciousness, Migraine, Nausea, Syncope vasovagal, Ventricular tachycardia

Symptom Text: Seven days after vaccine was given patient experienced sudden unconsciousness, severe abdominal pain on the right side. Patient was also found to have low blood pressure and severe hypoglycemia. Symptoms were treated in ambulance with IV fluids. Hospital and subsequent doctor visits diagnosed patient with ventricular tachycardia relating to the event. 7/11/08-records received- First Gardasil vaccination 7/9/07- 7/11/08-records received-5/21/07-C/O passing out from low blood sugar. Syncopal episode with nausea. DX:Dizziness and giddiness. Holter monitor 6/4/07-mild supraventricular tachycardia. Presented to ED with sore throat and fever. Acute exudative tonsillitis. First Gardasil vaccination 7/9/07 7/28/08-records received for DOS 5/16/07-presented to ED with C/O near syncope and abdominal pain times 3 days, diarrhea. Lightheadedness and pain when standing. Nausea times 3 days. Recent bronchitis. Migraine Headaches. Impression: syncope vasovagal, hypoglycemia, abdominal pain intestinal colic.

Other Meds: none

Lab Data: 7/28/08-records received-US of abdomen normal, chloride elevated 108, Hemoglobin low 11.0, glucose urine 1000, nitrite positive, glucose 40.

History: none 7/11/08-records received-5/21/07-C/O passing out from low blood sugar. Syncopal episode with nausea. DX:Dizziness and giddiness. Holitor monitor 6/4/07-mild supraventricular tachycardia. Presented to ED with sore throat and fever. Acute exudative tonsillitis.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **318676-2 (S)** **Related reports:** 318676-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Jul-2007	16-May-2007	-54	11-Sep-2008	12-Sep-2008	--	WAES0808USA04466	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Blood glucose decreased, Bronchitis, Condition aggravated, Diarrhoea, Dizziness, Hypoglycaemia, Hypotension, Loss of consciousness, Migraine, Nausea, Pain, Pharyngolaryngeal pain, Pyrexia, Supraventricular tachycardia, Syncope vasovagal, Tonsillitis, Ventricular tachycardia

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 16 year old female with mild supraventricular tachycardia and a medical history of dizziness and giddiness, decreased blood sugar, syncope, tonsillitis and nausea, who on 09-JUL-2007, was vaccinated with the first dose of GARDASIL (Lot # 657737/0522U), intramuscularly, into the right arm. On 21-MAY-2007, the patient was complained of passing out from low blood sugar. She also experienced a syncopal episode with nausea. The patient was diagnosed with dizziness and giddiness. On 04-APR-2007, the patient was presented to the emergency dispatch with sore throat and fever. The patient was diagnosed with exudative tonsillitis. A Holter monitor was used to diagnose supraventricular tachycardia. On 16-JUL-2007, the patient experienced sudden unconsciousness and severe abdominal pain on the right side and nausea for 3 days. The patient was also found to have low blood pressure and severe hypoglycemia. The symptoms were treated in ambulance with IV fluids. The patient went into the hospital and had a subsequent doctor visit, and was diagnosed with ventricular tachycardia relating to the event. The patient also experienced diarrhea, lightheadedness, pain when standing, recent bronchitis, migraine headaches, impression syncope vasovagal, hypoglycemia, and abdominal pain intestinal colic. On an unknown date, a urine test and a blood work were performed. The results of the urine test were hemoglobine low 110, glucose urine 1000, nitrite positive. The results of the blood work were glucose 40 and chloride elevated 108. An other test was performed which the result was a normal abdomen. The listing indicated that one or more of the events was considered to be immediately life-threatening. The original reporting source was not provided. The VAERS ID# is 318676. A standard lot check investigation was performed. All in-process quality checks for the lot number in question were satisfactory. In additi

Other Meds: Unknown

Lab Data: Holter monitoring, 06/04/07 - mild supraventricular tachycardia; abdominal ultrasound - normal; urine glucose (quant), 1000; serum chloride - chloride elevated 108; hemoglobin, 11.0 - hemoglobin low; blood glucose, 40; urinalysis - nitrite

History: Syncope; Blood sugar decreased; Dizziness; Giddiness; Nausea; Tonsillitis

Prex Illness: Supraventricular tachycardia

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318680-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	31-Jul-2007	22-Nov-2007	114	10-Jul-2008	18-Jul-2008	VA		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	09306	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Anaemia, Arthralgia, Colitis ulcerative, Diarrhoea, Diarrhoea haemorrhagic, Hypoalbuminaemia, Influenza, Nausea, Weight decreased

Symptom Text: Symptoms of and diagnosed with ulcerative colitis in November 2007 requiring 2 hospitalizations for exacerbation since 11/2007 7/14/08-records received-office visit 7/31/07-C/O tired. 11/28/81-DX ulcerative colitis. Loose stools and abdominal spasms. Tired weak. 12/24/07-GI consults-history of ulcerative colitis in remission. Presented with abdominal pain, diarrhea, anemia and hypoalbuminemia. Weight loss, joint pains. 2/18/08-Continues in remission. Flu symptoms 10 days ago. Intermittent shoulder, ankle and wrist pain. 5/30/08-Sick visit, off steroids. Three days prior increasing stooling and minor bleeding and severe cramps. 7/21/08-records received for DOS 5/31-6/4/08-DC DX: ulcerative colitis flare. Presented with 2 weeks of abdominal cramping and 3 days of diarrhea tht had become bloody. Nausea.

Other Meds: Albuterol Inhaler for PRN use

Lab Data: Bloodwork, colonoscopy 7/21/08-records received-Sed rate increased 37, amylase increased 102 and lipase 470, WBC 15.1 and CRP 3.55. Abdominal series 11/22/07-no acute abdominal findings. Abdominal series:11/5/07-large amount of retained st

History: Reactive Airway Disease 7/21/08-records received-PMH:ulcerative colitis diagnosed 11/2007.

Prex Illness: None

Prex Vax Illns:

Vaers Id: 318684-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	26-Jun-2008	06-Jul-2008	10	10-Jul-2008	21-Jul-2008	DE		21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Palpitations

Symptom Text: PATIENT RECIEVED THE SHOT ON 7/26/08 AND ON 7/6/08 SHE STATES SHE HAD A FEW MINUTES OF DIZZINESS AND PALPATATIONS. THEN NOW HAVE BEEN COMING AND GOING SINCE THEN BUT NOT AS SEVERE. EXAM WAS COMPLETELY NORMAL AND NO TREATMENT WAS INITIATED. I DO NOT FEEL IT IS SECONDARY TO THE IMMUNIZATION BUT PATIENT DOES

Other Meds: SINGULAR, ASTELIN, ORTHO TRICYCLIN

Lab Data: NONE

History: ALLERGIC RHINITIS, ANXIETY, ANEMIA

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318685-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		10-Jul-2008	21-Jul-2008	CA		21-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	NULL	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	NULL		Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site swelling

Symptom Text: Swelling over injection site on left arm, about 2cmx 2cm in size, erythematous and itching.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318686-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Jul-2008	02-Jul-2008	1	10-Jul-2008	21-Jul-2008	CA		21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Dizziness, Nausea

Symptom Text: Day after injection had dizziness, nausea and diarrhea. Symptoms intensified and were the worst 2 days after receiving injection. Symptoms did not resolve until 8 days later. Not treatment was given for symptoms.

Other Meds:

Lab Data:

History: Healthy without pre-existing health problems.

Prex Illness: Healthy.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318693-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	26-Sep-2007	Unknown		10-Jul-2008	21-Jul-2008	PA		21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1208F	2	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amnesia, Anorexia, Back pain, Blindness, Chills, Fatigue, Headache, Nausea, Pallor, Pollakiuria, Pyrexia, Vision blurred

Symptom Text: Pale skin, Daily headaches, blurred to no vision, fatigue, loss of appetite, severe back pain, nausea, fever, chills, increased urination, loss of memory.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **318696-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	07-Jul-2008	Unknown		10-Jul-2008	21-Jul-2008	IL		22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Tonic clonic movements, Unresponsive to stimuli

Symptom Text: Pt passed out immediately after getting GARDASIL. She was unresponsive for <1 minute. She did have tonic clonic movements for 15-20 seconds. Pt was fasting with glucose 64.

Other Meds:

Lab Data: glu, 64; potassium, 3.0

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318717-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	07-Jun-2007	08-Jul-2007	31	11-Jul-2008	14-Jul-2008	KS	WAES0710USA00601	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0212U		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Prolonged labour

Symptom Text: Initial and follow up information has been received from a physicians assistant through the Merck pregnancy registry concerning herself, a 26 year old female with no known allergies and no pertinent medical history who on 07-JUN-2007 was vaccinated with GARDASIL (Lot # 0212U) and discovered she was pregnant on 28-JUL-2007 (LMP 08-JUL-2007). Concomitant therapy included a prenatal vitamin. The patient sought medical attention (office visit). No labs or diagnostic studies were performed. On 02-OCT-2007, the patient reported she was twelve weeks pregnant, felt fine and had no adverse symptoms. On 05-DEC-2007 the patient underwent a routine ultrasound indicated for the pregnancy and the result was negative. The patient reported that on 10-APR-2008 she underwent a cesarean section due to delayed cervical dilation during labor. She delivered a normal male infant weighing: 6lbs 13ozs; length: 19". The patient reported that both mother and baby were doing fine. Upon internal review, the patient's cesarean section due to delayed cervical dilation was considered to be an other important medical event. Additional information is not expected.

Other Meds: Vitamins (unspecified)

Lab Data: ultrasound, 12/05/07, Neg.

History:

Prex Illness: Pregnancy NOS (LMP = 7/8/2007)

Prex Vax Illns:

Vaers Id: 318719-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	18-Oct-2007	14-Nov-2007	27	11-Jul-2008	14-Jul-2008	FR	WAES0807AUS00057	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0491U		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Antiphospholipid syndrome, Contraception, Deep vein thrombosis

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing and a Public Case Detail Form concerning a 20 year old female who on 18-OCT-2007 was vaccinated with GARDASIL (Batch # J2138, Lot # 657870/0491U). Concomitant therapy included hormonal contraceptives (unspecified). On 14-NOV-2007, 27 days after vaccination, the patient experienced deep vein thrombosis, also reported as deep vein thrombosis, a large iliofemoral DVT, and antiphospholipid syndrome and was hospitalized. The patient's CT scan showed an acute thrombus expanding the left external and left common iliac veins to the upper end of the common iliac vein. There were no other abnormalities with the pelvis. The patient had high titre anticardiolipin IgG with the titre being more than 64. She also had evidence of anti-beta 2 lycoprotein 1 at a level of 137gU (<20). The patient's antinuclear antibodies were negative and double stranded DNA was low. The patient was treated with CLEXANE and warfarin. At the time of reporting on 04-JAN-2007, the patient's deep vein thrombosis and antiphospholipid syndrome persisted. The agency considered that deep vein thrombosis and antiphospholipid syndrome were possibly related to therapy with GARDASIL. The original reporting source was not provided. Subsequently the patient's experience was reported in an article. Additional information is not expected. This is an amended report. The lot # 657870/0491U has been added to the narrative. A copy of the published article is attached as further documentation of the patient's experience.

Other Meds: hormonal contraceptives (unspecified), Unk - Unk

Lab Data: computed axial tomography, CT scan acute thrombus expanding the left external and left common iliac veins; serum ANA, Antinuclear antibodies were negative and double stranded DNA was low; serum beta(2)-glycoprotein 1 IgG Ab, 137 gU; serum c

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318723-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		11-Jul-2008	14-Jul-2008	FR	WAES0807AUS00066	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Gait disturbance, Malaise

Symptom Text: Information has been received in a newspaper article, 06-JUL-2008, received from a mother of a 16 year old female who in 2007 ("last year") was vaccinated with the first dose of GARDASIL. In 2007 the patient felt sick after her first dose of GARDASIL. It was also reported that the patient could hardly walk after the third dose of GARDASIL. The patient's mother took her to three hospitals in a bid to find out what was wrong with her but she could not confirm whether the cause of her daughter's illness was definitely the GARDASIL as it had emerged at the same time. Upon internal medical review, "could hardly walk after the third" was considered to be disabling. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318725-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		11-Jul-2008	14-Jul-2008	FR	WAES0807AUS00068	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Activities of daily living impaired, Anorexia, Asthenia, Influenza like illness, Malaise, Weight decreased

Symptom Text: Information has been received in a newspaper article, 06-JUL-2008, and also on the news (Sunday - 06-JUL-2008) received concerning a 16 year old female who was vaccinated with GARDASIL. Subsequently the patient felt a bit off after the first two doses of GARDASIL but did not think anything of it. The patient reported that she missed the fourth term of school in 2007 after becoming so ill that she was unable to get out of bed. The patient's mother reported that after her daughter received her third dose of GARDASIL she started getting flu-like symptoms and it went downhill. The patient lost her appetite, dropping 5 kg and 8 kg and got so weak that she couldn't walk unaided. Upon internal medical review, "dropping 5 kg and 8 kg and got so weak that she couldn't walk unaided" was considered to be disabling. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 318727-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	23-May-2008	03-Jun-2008	11	11-Jul-2008	14-Jul-2008	FR	WAES0807USA00921	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1146U		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypoaesthesia, Malaise, Muscular weakness, Pelvic pain, Syncope vasovagal

Symptom Text: Information has been received from a health professional concerning a 19 year old female with a history of appendicectomy, hypothyroidism and bone surgery who on 23-MAY-2008, was vaccinated with a dose of GARDASIL (lot # 1146U, batch # NG00400) IM. 11 days later on 03-JUN-2008 she experienced a vagal malaise at school with important pain in pelvis and developed numbness of lower extremities and weakness of lower extremities. Mobile accident unit was called. Electrolytogram and complete blood count was normal. Diagnosis was vagal malaise. She was not hospitalized but came out of hospital in a wheelchair and still had weakness and loss of sensitivity of lower limbs. On 06-JUN-2008 she went to hospital due to persisting symptom to perform complementary work-up. Neurological examination: loss of sensitivity of lower limbs, there was tendon reflex, muscular tonus was resolving. A problem of functional origin was privileged, she was not hospitalized. Medical consultation on 18-JUN-2008: muscular tonus was normal, she was walking normally without any limp, there was tendon reflex, loss of sensitivity of both lower limbs but recovery of bilateral sensitivity with socks. Thyroid work-up was normal. Medullar RMI was scheduled. She had recovered from weakness of lower extremities. She had not recovered from numbness of lower extremities. Other business partner numbers included: E2008-06319. Additional information has been requested.

Other Meds: Unknown

Lab Data: neurological examination, 06Jun08, Comment: loss of sensitivity of lower limbs; neurological examination 06Jun08, Comment: there was tendon reflex; neurological examination, 06Jun08, Comment: muscular tonus was resolving; diagnostic laborat

History: Appendicectomy; Hypothyroidism; Bone operation

Prex Illness:

Prex Vax Illns:

Vaers Id: 318728-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Sep-2007	10-Dec-2007	91	11-Jul-2008	14-Jul-2008	FR	WAES0807USA00973	14-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diarrhoea, Dizziness, Epilepsy, Loss of consciousness, Night sweats, Syncope vasovagal, Weight decreased

Symptom Text: Information has been received from a gynecologist concerning a 16 year old female with migraine headaches and without family history of epilepsy who on 10-SEP-2007 was vaccinated IM with a first dose of GARDASIL in the upper arm. Concomitant therapy included hormonal contraceptives (unspecified) (manufacturer unknown) for systemic use. On 10-DEC-2007 the patient suddenly developed unconsciousness for several hours in the morning. Additionally, she experienced persisting dizziness and diarrhea for several weeks as well as night sweats and loss of weight. In the time following the events the unconsciousness reoccurred. The patient was hospitalized from 21-JAN-2008 to 23-JAN-2008, 27-JAN-2008 to 28-JAN-2008, 28-FEB-2008 to 04-MAR-2008 and from 01-APR-2008 to 04-APR-2008. On 09-JAN-2008 the patient had and ear, nose and throat examination which showed normal results. The patient had abdominal and thyroid sonography and cranial magnetic resonance imaging which showed normal results. An ophthalmologic examination was normal as well as visual evoked potentials. On 22-JAN-2008, electroencephalogram (EEG) showed intermittent focal disorder right parietal, but no typical epileptic activity was detected. On 28-FEB-2008 the patient had a "prolonged electrocardiograph" which showed normal results. A prolonged-Video-EEG was normal. In a control on 29-FEB-2008 and on 25-MAR-2008 no focal disorder was detected. Differential diagnosis were epilepsy and syncope. The neurological department of the university favoured vasovagal syncopes, but a final diagnosis could not be established. At the time of the report, the outcomes of the syncope vasovagal, epilepsy, unconsciousness, dizziness, diarrhea, night sweats and loss of weight were unknown. Other business partner numbers included: E2008-06028. Additional information is not expected. This case is closed.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: electroencephalography, 22Jan08, intermittent focal disorder right pariental; no typical epileptic activity; electrocardiogram, 26Feb08, "prolonged ECG" normal result; abdominal ultrasound, normal results; electroencephalography, Prolonged

History:

Prex Illness: Migraine

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318742-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Apr-2008	Unknown		11-Jul-2008	20-Aug-2008	LA		20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2549AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2863AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash pustular

Symptom Text: 7-1-08 mother called called to report that within 3-4 days of 4-17-08 + 6-17-08, daughter broke out with pustules on her legs, arms, and abdomen. She was brought to PMD on both occasions. He ordered antibiotics and could not give a dx. Pustules resolved within 1-2 wks. Mother seems to think it may be related to HPV vaccine.

Other Meds: None

Lab Data: None

History: eczema as a child

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318746-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	28-Jun-2008	30-Jun-2008	2	11-Jul-2008	20-Aug-2008	TX		20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2638AA	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1758U	1	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2565AA	1	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1512U	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Mass, Oedema peripheral, Rash papular

Symptom Text: Redness swollen and bumps/lumps on both arms beginning 2 days ago.

Other Meds:

Lab Data:

History:

Prex Illness: Reaction medication

Prex Vax Illns:

Vaers Id: **318759-1** **Related reports:** 318759-2; 318759-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	M	08-Mar-2007	08-Mar-2007	0	11-Jul-2008	21-Jul-2008	NC		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427F	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Areflexia, Arthralgia, Death of companion, Depression, Diarrhoea, Dizziness, Fatigue, Frequent bowel movements, Hyperaesthesia, Hypoaesthesia, Hyporeflexia, Injection site erythema, Joint swelling, Mood altered, Muscle spasms, Muscular weakness, Neck pain, Neurological symptom, Night sweats, Pain, Purulent discharge, Rash papular, Skin exfoliation, Skin lesion, Tenderness, Tremor

Symptom Text: I recieved the guardisil vaccine three shot series. I was also administered one hepatitis A vaccine shot and the heptatis B series at the same time. Since the administration of the guardisil vaccine. I have had an increase in pain levels throughout the body. I have total body aches that are extremely sensitive to touch and hot water. I have trouble closing my hands and weakness in the left and right arms. I have also had severe calf muscle cramping that came on with sudden onset. I also had episodes of depression and directly after the shots were given I had severe stomach cramping and diarrhea. The bowel movements were extreme and very painful my family had to lift me off the toilet. I had dizziness and redness at the injection site. My genital area began chafing and a layer skin peeled off the scrotum and penis. This happened rapidly after the second shot in the series. I continue to have weakness and arthritic type pain my whole body aches since the vaccine. I've had pain in the neck area with no MRI findings. My moods immediately changed after the guardisil series. The loss of a friend seemed to make it worse. I felt fatigued and my pain started increasing. I was prescribed a medication for the painful diarrhea. I've had numerous neurological problems and uncontrollable leg and hand shaking since administration of the vaccine. I have night sweats with an unknown cause. 8/18/2008 MR received from PCP dated 11/7/2006 to 6/30/2008. Pt received HPV4 #1 on 3/8/07 and #2 on 4/30/07. Seen multiple times for multiple sx (see PMH). Seen 7/5/07 for numbness in feet and L leg weakness and knee pain. On PE absent knee reflexes and ankles 1+. Assessment: bilateral knee pain, probably patellofemoral syndrome. Seen 8/7/07 for new skin lesion- a light brown papule on dorsum of L hand-appears benign. Seen 9/7/07 for increasing back pain, shaking, spasms and numbness of legs attributed to PMH of DDD. 3rd HPV4 given. Seen 10/4/07 for new papule on R flank, swollen, tender and draining pus, possible furuncle. Tx with abx. Se

Other Meds: duragesic. ambien pulmicort rhinocort niaspan topomax

Lab Data: All blood tests for arthritis SED rate ect have come back normal. I have a lower back problem buldegeing disk but all of these other symptoms were onset after the vaccines were administered. My depression symptoms are gone but I still have

History: lower back pain buldgeing disk. High cholesterol, allergies seasonal. PMH: Tonsillitis, persistant sore throat of uncertain cause, genital ulcer-uncertain cause, allergic rhinitis, degenerative disc disease, irritable bowel syndrome, hyperlipidemia, asthma, anxiety depression, sinusitis, insomnia, day and night sweats, hot flashes,chronic lower back pain due to DDD and MVA, MRSA.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **318759-2** **Related reports:** 318759-1; 318759-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	M	Unknown	Unknown		18-Aug-2008	30-Sep-2008	--	WAES0807USA02473	30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Diarrhoea, Loss of consciousness, Nervous system disorder, Vaccine positive rechallenge, Wrong technique in drug usage process

Symptom Text: Information has been received from a 27 year old male with an allergy to prednisone who about a year ago in 2007 received the complete series of GARDASIL vaccine. Lot # and dates when it was received are not available. Concomitant therapy included hepatitis A virus vaccine (unspecified) and hepatitis B virus vaccine (unspecified) when patient received his first dose of GARDASIL vaccine. Per patient, he passed out every time he received a dose of GARDASIL vaccine and he experienced three times after receiving each dose of GARDASIL. Patient also reported that he had diarrhea, bad neurological problems and arthritic type of pain about a week after receiving the third dose GARDASIL vaccine. Patient noted that he went to the emergency room numerous times last year because of the arthritic pain but he was not admitted to the hospital. It was reported the patient had an MRI done (date and results not provided). No further information provided. The patient's passed out and diarrhea and bad neurological problems and arthritis type of pain persisted. The patient sought medical attention from a neurologist. No further information is available.

Other Meds:

Lab Data:

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **318759-3** **Related reports:** 318759-1; 318759-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	M	14-Mar-2007	14-Mar-2007	0	15-Jul-2008	23-Jul-2008	NC		29-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	MERCK & CO. INC.	NA123	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	NA123	2	Left arm	Intramuscular	
HEP	MERCK & CO. INC.	NA123	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Arthralgia, Depression, Diarrhoea, Dizziness, Fall, Frustration, Gait disturbance, Head injury, Hypoaesthesia, Loss of consciousness, Mental disorder, Muscle spasms, Muscular weakness, Nausea, Tendonitis

Symptom Text: I was administered the guardasil vaccine and the hepatitis A and B vaccine. Since being given the vaccine I got sick the night after haveing the vaccine. I was sick with severe diharea I felt light headed and everything went black my mother came into the bathroom and I had passed out and hit my head on the toilet seat. I first started haveing weakness in my legs. I fell down the steps several times. I informed my docotor but he never reall paid much attention. It seemed he was preocupied. Shortly after that I started haveing numbness in my feet and legs my calf muscled spasm and cramp so bad I limp. This happens on a weekly basis. I started experiencing upper body pain it felt like something arthritic. All day long it felt like a constant severe dull ache. I kept telling my doctor about my pain. He finally sent me to a rhumatologist who did not find anything in my blood to suggest an arthritic condition. after this time there were some deaths and the increased pain and deaths seemed to escalate my feelings. My doctor started saying I was depressed and telling people I was depressed. I didn't feel depressed I felt anxiety from being in severe pain with little relief. I felt frustrated I wasn't being listened too. I hurt really bad and still do. I found out I have tendonitis in my left arm my doctor missed. I belive this was either caused by quinilone antibiotics. My pain has steadily increased since the vaccines. I felt nauseated on a daily basis and my doctor started prescribing me antidepressants without telling me what they were for. He took it to the extreme in trying to get me diagnosed with a mental condition. All the new pain I was feeling was onset after the vaccines. I do have a buldgeing disk in my back that has gone untreated after a failed surgery and the symptoms were ignored until I recently got into a knowledgeable speacialist who started getting things treated. I still have leg pain and arthritic type pain. My docotor seemed to ignore all the new symptoms and tried to blame everything on depressio

Other Meds: kadian ambien

Lab Data: I've had all sorts of blood work and arthritis that would cause this kind of pain has been ruled out. I can guess at the dates of the vaccines the doctor hopefully will feel it's proper to give me the requested data and I can provide the ex

History: degenerative disk disease and asthma

Prex Illness: bad back dik at L5-S1

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318761-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	07-Mar-2008	07-Mar-2008	0	11-Jul-2008	21-Jul-2008	NC		21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	758U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Influenza like illness, Nausea, Pain, Pyrexia, Vaccine positive rechallenge

Symptom Text: On 12-14-07 pt received 1st HPV dose and parent noted flu like s/s. On 3-7-08 pt recevied 2nd HPV dose and parent noted fever 101, nausea, body aches, dizziness, and h/a lasting for two days.

Other Meds: 12-17-07 no meds. On 3/07/08 o/v she was taking vits.

Lab Data:

History: childhood kidney condition

Prex Illness: no

Prex Vax Illns:

Vaers Id: 318763-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Mar-2008	30-Apr-2008	58	11-Jul-2008	21-Jul-2008	SC		17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	0	Right arm	Intramuscular	
	TTOX	UNKNOWN MANUFACTURER	UNKNOWN TO ME	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amblyopia, Body mass index increased, Granuloma, Keratosis pilaris, Livedo reticularis, Retinal haemorrhage, Retinal oedema, Uveitis, Visual disturbance, Vitreous disorder, Vitreous floaters

Symptom Text: HPV #1 administered on 3/3/08 along w/ Td vaccine. Pt diagnosed with intermediate uveitis both eyes 4/30/08. 10/10/07 Reviewed opthamology records of 4/30-5/28/08. FINAL DX: amblyopia, peripheral fibrovitreous with empty vitrous left eye, peripheral uveitis, granuloma Records reveal patient experienced vitreous fibrosis, longstanding floaters of both eyes, seeing 'ghosting around images' x 1 year. 10/3/08 Reviewed PCP medical records of 3/3/08. FINAL DX: none provided Record reveals patient experienced usual state of good health on day of vaccination. BMI 90% although very active. No record provided for Td, only HPV. No other records available at this time. 10/17/08 Reviewed additional medical records of 5/1-9/17/2008. FINAL DX: bilateral peripheral uveitis, vitreoretinal disease, bilateral pars planitis, possible familial exudative vitreoretinopathy, keratosis pilaris, mottling of skin over legs.

Other Meds: none

Lab Data: Extensive eye exam including fluorescent pictures taken of eyes LABS: fluorescein angiography c/o retinal edema w/hemorrhaging

History: None PMH: myopia, right exotropia, floaters bilaterally. Family hx of ADD, RA, CAD, MI, congenital cataracts

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318764-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Jun-2008	18-Jun-2008	1	11-Jul-2008	21-Jul-2008	PA		21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1891U	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Gaze palsy, Somnolence

Symptom Text: PARENT STATES THAT PT HAD A SEIZURE LAST LESS THAN 1 MINUTE. MOM WAS NOT PRESENT AT THE TIME OF SEIZRE GRANDMOTHER WAS. PT'S EYES ROLLED INTO BACK OF HEAD AND SNORTED THEN BECAME GROGGY IMMEDIATELY FOLLOWING THESE EVENTS ACCORDING TO MOM.

Other Meds:

Lab Data: NONE

History: SEASONAL ALLERGIES, FAINTING SPELLS

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318777-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	02-Mar-2007	09-Mar-2007	7	11-Jul-2008	15-Jul-2008	CA		17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0186U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Alopecia, Anxiety, Arthralgia, Blepharitis, Bruxism, Cervix disorder, Chills, Confusional state, Depression, Dry eye, Dysaesthesia, Dysuria, Eye pruritus, Fatigue, Feeling abnormal, Fibromyalgia, Flank pain, Hepatomegaly, Impaired work ability, Insomnia, Joint stiffness, Musculoskeletal stiffness, Myalgia, Nausea, Neck pain, Pain, Pain in extremity, Pain in jaw, Pollakiuria, Pruritus, Pyelonephritis, Rash erythematous, Renal disorder, Renal pain, Splenomegaly, Urinary tract infection, Vision blurred

Symptom Text: A few days following my final Gardasil vaccination that received on March, 2, 2007, I had excruciating pain my arm near my elbow. I had to quit my job on March 29 because the pain was too unbearable to continue office tasks like typing. By then, the pain had spread to my neck, and shoulders. On April 3, 2007, I went to see an orthopedist specializing in the arm and hand. He put me on short-term disability and prescribed physical therapy. I went twice a week for approximately 2 months, but the pain kept getting worse. By August, the throbbing, burning pain in my neck was unbearable. On August 24, I saw a neurologist who diagnosed the problem as fibromyalgia. He prescribed Lyrica and Ultram, but neither drug worked, so I discontinued them. In September of 2007, my general doctor ordered blood tests which all returned normal. I had an MRI done of my neck as well, and it returned normal. The MRI did show, however, that abnormal growths had started to form on my thyroid. By October, I felt anxious, depressed, fatigued, and in extreme pain throughout my upper body. By November, my skin became very dry and my hair started falling out. I tried physical therapy one more time, twice a week for three weeks, but again it didn't work. In December of 2007, I was sleeping roughly 11 hours a night. My dentist prescribed me a night guard, because my neck and jaw pain had caused me to begin grinding my teeth. In January of 2008, all of my symptoms continued. By this time my entire body ached. On January 21, I went to an ophthalmologist, because my eyes had become so dry and itchy. He diagnosed the problem as blepharitis, similar to the dry skin I had developed. Because my vision had become blurry, for the first time in my life I was prescribed glasses. On February 15, 2008, I saw a rheumatologist who conducted extensive blood tests and an MRI of the brain. I had become very confused and foggy headed. However these tests came back normal. He prescribed Doxepin, in order to help me gain better sleep. On June 16, 2008 I was rushed t

Other Meds: Ortho-Cyclen

Lab Data: I have extensive bloodwork, MRI (neck and brain), CT scan (kidneys and abdomen), ultrasounds (thyroid, heart, kidneys, bladder), x-rays (neck, shoulders, arms hands) available for submission. LABS: PPD (+) 9/07 (extensive foreign travel)

History: None PMH: anxiety & fatigue x several years, depression, EBV infection in past. Fibromyalgia. contraception.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318781-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Jul-2008	09-Jul-2008	7	12-Jul-2008	22-Jul-2008	MA		22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling

Symptom Text: The patient developed severe pain in her right arm where the second Garadsil vaccine was placed. I saw her 1 week after the vaccine was administered, and the site of the vaccine was swollen and the pt had excruciating pain.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318786-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Jul-2008	07-Jul-2008	4	13-Jul-2008	22-Jul-2008	FL		08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Back pain, Bedridden, Dysmenorrhoea, Injection site discomfort, Injection site pain, Menstruation irregular, Neck pain, Pain in extremity

Symptom Text: 7/13/08 Re: 13yr healthy, 5'5" 106lb active, phsically fit, golfs, swims. Gardasil administered Thur, July 3. Extreme pain at injection site and significant pain & discomfort for several days following. Pain was at injection site, elbow up, upper arm, shoulder neck & upper back. My daughter began menstruating May. Her period May was light and June was normal. This month however began July 11, the week leading up to menstruating she suffered incredible cramping. With the onset of her period, she became bedridden and suffered horribly. Call to triage nurse gave all helpful tips but I went through them with my daughter with very little relief. ie. Midol, we had reduced pain with Pamprin but still the level of pain was dibilitating and kept her in bed 2 days, rolling around in pain. Pamprin has 500mg per pill. She took 2 every 4 hours just to keep the level bareable. Even with this level of pain medicine she was not able to resume normal activity. This level of medicine is too much for a 13 yr old! other suggestions laying flat rather than crunched in fetal position that she had been, warm pad, deep breath to work through pain, TV to take mind off agony, massage, comfort foods - tried them with little relief. The women on my side of family have no history of cramps or the severe reaction to normal healthy menstrual cycle as well as the females on my husband's side of family. Menstrual flow is normal, nothing excessive to indicate another reason for such severe pain. I feel the Gardasil vaccination is responsible for this unusual extreme pain. She was too ill to drive to dr office but I will be calling them again Monday morning 7/14/08.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 318796-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Jun-2008	30-Jun-2008	0	11-Jul-2008	20-Aug-2008	PA		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2632AA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Influenza like illness, Injection site swelling, Oedema peripheral, Pain, Pyrexia

Symptom Text: Received GARDASIL in right deltoid & MENACTRA in left deltoid on 06/30/08, Monday. Monday afternoon started with Flu-like symptoms. Fever & chills, swelling right arm, body aches. No redness at injection site but swelling.

Other Meds: ZYRETEC 10 mg daily; SINGULAIR 10 mg; (DIFFERIN CREAM)

Lab Data:

History: RAD- Allergies

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318813-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-May-2008	21-May-2008	0	14-Jul-2008	15-Jul-2008	FR	WAES0807CAN00019	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Ear discomfort, Headache, Hypoacusis, Immediate post-injection reaction, Syncope vasovagal

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 21-MAY-2008 was vaccinated with GARDASIL (lot # not available) for HPV prophylaxis. On 21-MAY-2008, 5 minutes post injection the patient experienced decreased hearing, headaches, unusual sensation in ears and vasovagal but unusual (also described as lightheaded and felt faint) which lasted about 15 minutes. On 21-MAY-2008 the patient recovered from decreased hearing, headaches, unusual sensation in ears and vasovagal but unusual. The physician reported that the patient has never had a reaction to shots, needles, surgery, or pain before. Upon internal review, decreased hearing was considered to be an Other Important Medical Event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 318814-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Dec-2007	Unknown		14-Jul-2008	15-Jul-2008	FR	WAES0807USA00976	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0352U	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dyspnoea, No reaction on previous exposure to drug, Sensation of foreign body

Symptom Text: Information has been received from a health agency concerning a 16 year old female who on 20-DEC-2007 was vaccinated with a third dose of GARDASIL (lot # 0352U, batch # NG00320). In December 2007, the patient experienced dyspnoea of unknown origin and a globus feeling of the throat. She was hospitalized on an unspecified date. Electrocardiogram, electroencephalography, pulmonary function test, arterial blood oxygen saturation test and ears, nose, and throat examination showed all normal results. The adverse events were ongoing at the time of reporting. The patient was vaccinated with a first dose of GARDASIL (lot # 655671/1024U, batch # NE51780) on 28-JUN-2007 and a second dose of GARDASIL (lot # 1473F, batch # NF46730) on 23-AUG-2007. No adverse effects occurred. It was pointed out by the reporter that patient informed herself in the internet about HPV vaccination and possible side effects and only than reported the events to the physician. Other business partner numbers included E2008-06194. No further information is available.

Other Meds: Unknown

Lab Data: electrocardiogram, normal results; electroencephalography, normal result; pulmonary function test, normal result; ears, nose, and throat examination, normal result; arterial blood O2 saturation

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: **318815-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Dec-2007	27-Dec-2007	0	14-Jul-2008	15-Jul-2008	FR	WAES0807USA01404	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1518F	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Ear, nose and throat examination normal, Headache, Inappropriate schedule of drug administration, Neurological examination normal, Sleep disorder, Vaccine positive rechallenge

Symptom Text: Information has been received from a gynaecologist concerning a 15 year old female who on 27-DEC-2007 was vaccinated intramuscularly in left upper arm with a first dose of GARDASIL (Batch#NF23330/lot#1518f). The night post vaccination, the patient developed dizziness, headache and sleep disorder. Examinations by a neurologist and an ENT specialist showed normal results. Despite ongoing symptoms, on 30-APR-2008, the patient was vaccinated with a second dose of GARDASIL (Batch#NH06410/lot#1068U). The symptom were persisting but not worsening (no change). The case was assessed as serious (to be an other important medical event) because of long term duration of the adverse events. Other business partner numbers included: E2008-06153. No further information was available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 318816-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Jul-2008	03-Jul-2008	0	14-Jul-2008	15-Jul-2008	FR	WAES0807USA01401	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0465U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Depressed level of consciousness, Hyperpyrexia, Hypotonia, Injection site pain, Pallor, Presyncope

Symptom Text: Information has been received from a health authority concerning a 12 year old female, with no medical history reported, who on 03-JUL-2008 was at 10:30 was vaccinated intramuscularly with the third dose of GARDASIL (Lot # 0465U/batch # NG17850). On 03-JUL-2008 the patient's mother reported that about 11:30 on the same day, the patient presented with sharp pain at the injection site, followed by lypothimia and pallor for which she was admitted to the hospital. On the same day, after 4 hours the patient presented with hyperpyrexia, decreased sensorium and hypotonia. At the time of this report, the patient's outcome was unknown. Other business partner numbers include: E200806324, 86957 and IT27508. Additional information is not expected. This case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 318817-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Sep-2007	24-Sep-2007	0	14-Jul-2008	15-Jul-2008	MT	WAES0801USA03495	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0960F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Caesarean section, Depression, Drug exposure during pregnancy, Genital haemorrhage, Nausea, Pelvic pain

Symptom Text: Initial and follow-up information has been received from a registered nurse for the Pregnancy Registry for GARDASIL concerning a 16 year old female with asthma who on 24-SEP-2007 was vaccinated IM with a 0.5 ml first dose of GARDASIL (lot #654535/0960F). On approximately 12-NOV-2007, the patient developed depression and was placed on tapering dose of PROZAC. On 05-DEC-2007, the patient was vaccinated IM with a 0.5 ml second dose of GARDASIL (lot #654535/0960F). Subsequently the patient became pregnant. Unspecified medical attention was sought. Last menstrual period was approximately 25-AUG-2007 and estimated date of delivery was 31-MAY-2007. On approximately 10-DEC-2007, the patient developed nausea and was placed on therapy with PHENERGAN. On 03-JAN-2008, the patient had vaginal spotting. Abdominal ultrasound was within normal limits. On 14-JAN-2008, the patient pelvic pain. An gallbladder ultrasound on 14-JAN-2008 (also reported as 15-JAN-2008) was within normal limits. On an unspecified date, the patient developed abdominal pain. The patient had an ultrasound on 31-MAR-2008 (results not reported). On 23-MAY-2008, the patient had a cesarean section due to cephalopelvic disproportion. The patient gave birth to a normal male infant (weight 6 pounds, 11 ounces) that was given for adoption. Upon internal review, cephalo-pelvic disproportion leading to a cesarean section was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, 01/14/2008 - WNL; ultrasound, 01/15/08 - results not reported; ultrasound, 01/03/08 - WNL; ultrasound, 03/31/08 - results not reported

History:

Prex Illness: Pregnancy NOS (LMP = 8/25/2007); Asthma

Prex Vax Illns:

Vaers Id: 318818-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	19-Jun-2008	20-Jun-2008	1	14-Jul-2008	15-Jul-2008	--	WAES0807USA00493	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Convulsion, Dermatitis, Drug hypersensitivity, Dyskinesia, Excoriation, Fall, Foaming at mouth, Headache, Loss of consciousness, Muscle spasms, Mydriasis, Staring, Urinary tract infection, Urticaria, Wheezing

Symptom Text: Information has been received from a nurse concerning her previously healthy, menstruating 13 year old daughter with a sibling with seizure disorder who on 19-JUN-2008 was vaccinated with a first dose of GARDASIL. Concomitant suspect vaccination on 19-JUN-2008 included a second dose of VARIVAX. Other suspect therapy included BENADRYL (dose, duration and indication not reported) and BACTRIM given on 23-JUN-2008 and 24-JUN-2008 of the treatment of urinary tract infection (dose not reported). On 20-JUN-2008 the patient experienced severe headache and right arm swelling. On 22-JUN-2008 at 9:30 AM, the patient experienced a seizure for one hour, fell and experienced a "huge abrasion under the chin." The patient began to seizure again at 3:00 PM and was admitted to the intensive care unit. The reporter stated that the seizures started with a headache and then the patient had a blank stare. She had severe right hand spasms and moved her head back and forth. She had involuntary muscle movements with rhythmic movements, mostly of the upper extremity, and jerky, spastic contractions in the lower extremities with plantar flexion of the right foot and a jerky knee. She had dilated pupils and "foaming at the mouth." Sometimes she had wheezing. Sometimes was responsive and sometimes not. Seizure duration was reported as long as 45 minutes and "for hours." On approximately 22-JUN-2008 diagnostic work-up included an electroencephalogram (EEG) which was negative and a magnetic resonance imaging (MRI) and computerized axial tomography (CT) which were normal. "Blood work" and urinalysis were normal. On approximately 23-JUN-2008 the patient had a urinary tract infection that was treated with BACTRIM on 23-JUN-2008 and 24-JUN-2008. The patient was diagnosed with pseudoseizure. On 24-JUN-2008 the patient experienced a 10 minute seizure and was discharged. she was hospitalized for 2.5 days. On approximately 29-JUN-2008, the patient experienced hives and dermatitis which may have been due to an allergy to BACTRIM and was hospitalized. T

Other Meds: Unknown

Lab Data: electroencephalography, 06/22?/08 negative; magnetic resonance, 06/22?/08 normal; computed axial, 06/22?/08, normal; diagnostic laboratory, normal - "blood work"; urinalysis, normal

History:

Prex Illness: Familial risk factor

Prex Vax Illns:

Vaers Id: **318820-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Aug-2007	27-Aug-2007	7	14-Jul-2008	15-Jul-2008	FR	WAES0807USA00919	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cystitis, Incorrect route of drug administration, Pyelonephritis, Vaccine positive rechallenge

Symptom Text: Information has been received from local health authorities (reference number RN20080171) concerning an 18 year old female with type I diabetes mellitus who on 20-AUG-2007 was vaccinated with a first dose of GARDASIL subcutaneously. She should have received the vaccine intramuscularly. On 27-AUG-2007 the patient developed pyelonephritis requiring hospitalization. On an unspecified date the patient recovered. After the second dose of GARDASIL on an unspecified date there was reappearance of urinary symptoms, urine test strips was positive. After the third dose of GARDASIL on an unspecified date there was a recurrence of cystitis. Other business partner number included E2008-06315. No further information is available.

Other Meds: Unknown

Lab Data: urinalysis, positive

History:

Prex Illness: Diabetes mellitus insulin-dependent

Prex Vax Illns:

Vaers Id: **318821-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		14-Jul-2008	15-Jul-2008	--	WAES0807USA01113	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Quadriplegia

Symptom Text: Information has been received from a physician who heard from a friend, concerning a 17 year old female who was vaccinated with GARDASIL (lot # not reported). The patient, who had apparently been healthy, became quadriplegic within a month. No further information was available. Upon internal review, the patient's quadriplegia was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318822-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		14-Jul-2008	15-Jul-2008	IL	WAES0807USA01381	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Reaction to previous exposure to any vaccine

Symptom Text: Initial and follow-up information has been received from a certified medical assistant and an other health professional through a Merck pregnancy registry concerning a 16 year old female with depression and a history of "female problems" (unspecified), miscarriage (prior to first GARDASIL(and early spontaneous abortion (WAES #0702USA00083) who on 23-JAN-2007 was vaccinated intramuscularly with a 0.5 mL first dose of GARDASIL. On an unspecified date in 2007, the patient received the second dose of GARDASIL. Concomitant therapy included PAXIL. Subsequently on an unspecified date in 2007, the patient had another miscarriage (date not reported). The reporter stated that she did not think the events were related to GARDASIL. After internal review, spontaneous abortion was considered to be an other important medical event. It was also reported that this patient was vaccinated with the first dose of GARDASIL and experienced adverse events (WAES #0702USA00083). Additional information is not expected.

Other Meds: PAXIL

Lab Data:

History: Reproductive tract disorder; Miscarriage

Prex Illness: Pregnancy NOS (LMP = Unknown); Depression

Prex Vax Illns:

Vaers Id: **318823-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jul-2008	01-Jul-2008	0	14-Jul-2008	15-Jul-2008	FR	WAES0807USA01400	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NH16170	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cold sweat, Convulsion, Immediate post-injection reaction, No reaction on previous exposure to drug, Peripheral vascular disorder, Somnolence, Tonic clonic movements

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 28-APR-2008 was vaccinated with a first dose of GARDASIL (lot # not reported) which was well tolerated (no adverse effect occurred). On 01-JUL-2008, the patient was vaccinated with a second dose of GARDASIL (batch # NH16170) IM into the upper arm. On 01-JUL-2008, immediately post vaccination, the patient developed peripheral circulatory disorder followed by a cerebral seizure with tonic-clonic movements, which lasted for approximately 30 to 60 seconds. Afterwards she was somnolent and cold-sweaty. Her blood pressure was low (no value reported). She was treated with oxygen and an unspecified infusion and was admitted to the hospital via an emergency ambulance. Subsequently, the patient recovered. Other business partner numbers included: E2008-06241. No further information is available.

Other Meds: Unknown

Lab Data: blood pressure measurement, 01Jul08, low

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318824-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	07-Apr-2008	07-Apr-2008	0	14-Jul-2008	15-Jul-2008	FR	WAES0807USA01402	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Inappropriate schedule of drug administration, Injection site inflammation, Local reaction, Off label use, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a Health Authority via a health professional concerning a 27 year old female who on 07-APR-2008 was vaccinated with a first dose of GARDASIL IM in her arm. On 07-APR-2008, the patient experienced local inflammation at site of injection, fever and fatigue. On 17-APR-2008, the patient fully recovered. On 07-APR-2008, the patient was vaccinated with a second dose of GARDASIL IM in her buttock. On 11-JUN-2008, the patient experienced inflammation at site of injection (5 cm around the site of injection), fatigue, and fever. On 18-JUN-2008, the patient recovered. This is a case of misuse with serious adverse events: Off label use (patient of 27 years old) who experienced adverse events. The reporter felt that the events were serious (Other Important Medical Events). Other business partner numbers included: E2008-06265. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318828-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	20-Mar-2008	20-Mar-2008	0	14-Jul-2008	21-Jul-2008	--		21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Syncope, Visual acuity reduced

Symptom Text: Dizziness, faintness, blackened vision immediately after second vaccination.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318832-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Jun-2008	24-Jun-2008	0	14-Jul-2008	22-Jul-2008	WV		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Myalgia

Symptom Text: Fatigue and muscular pain.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318834-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	26-Jun-2008	03-Jul-2008	7	14-Jul-2008	22-Jul-2008	NM		22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Rash, Rash papular

Symptom Text: 7/7/08: Pt reports sudden onset of rash across abdominal area. 1 cm papulo squamous lesions, red, four total scattered on abdomen.

Other Meds: PROZAC 20mg one PO QD

Lab Data: None performed

History: NKDA

Prex Illness: upset stomach

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318835-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-Dec-2007	14-Dec-2007	7	14-Jul-2008	22-Jul-2008	NY		22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1428F	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Nausea, Pain in extremity

Symptom Text: Pt states after receiving GARDASIL, has had pains to feet. Persistent nausea. Abdominal pains.

Other Meds:

Lab Data: CBC/SMA12/Abd sono/physical exam

History: migraine

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318836-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	08-Jul-2008	08-Jul-2008	0	14-Jul-2008	22-Jul-2008	FL		22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2656AA	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024CA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0072X		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Fall, Heart rate decreased, Loss of consciousness, Oxygen saturation normal

Symptom Text: Pt given GARDASIL per protocol & when patient went to stand-up; she passed out - she fell into fiance's arms (no injury). Pt. was lied back onto table - had HR in 40s; B/P 76/48; awoke immediately - alert & oriented. Rested x20-30 min B/P increased 90/70 HR 80 O2 98%.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318838-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	26-Apr-2008	26-Apr-2008	0	14-Jul-2008	22-Jul-2008	MD		22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea, Arthralgia, Fatigue, Menorrhagia, Photophobia

Symptom Text: Excess fatigue. Heavy periods after absence of period. Joint pain. Sensitivity to light (continued 3 mos).

Other Meds: LEXAPRO-20mg

Lab Data: pelvic ultrasound, blood tests

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **318839-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-May-2008	09-May-2008	0	14-Jul-2008	22-Jul-2008	CA		22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Musculoskeletal stiffness, Paraesthesia

Symptom Text: Felt dizzy & weak 5 minutes after receiving the shot; fingers felt tingly, then stiff; I sat down & felt better after ~20 minutes. Occurred at the doctor's office.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318840-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	30-Jun-2008	01-Jul-2008	1	14-Jul-2008	22-Jul-2008	MD		22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2638AA	0	Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	C2953BA		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Prolonged H/A for 3 days. H/A did resolve by day #4.

Other Meds: None

Lab Data: None

History: Obesity

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318847-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	08-Jul-2008	10-Jul-2008	2	14-Jul-2008	22-Jul-2008	AZ		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Pruritus

Symptom Text: Both hands swollen and itchy and knee started 7/10/08. Patient has history of severe; Reaction to onions - she was treated for allergic reaction one week prior

Other Meds: DayQuil; Albuterol inhaler; Zithromax started 7-8-08

Lab Data:

History:

Prex Illness: Sinusitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318851-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	15-May-2008	16-May-2008	1	14-Jul-2008	22-Jul-2008	DE		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Pt rec'd GARDASIL (initial injection) by nurse on 5/15/08 -> Pt called office following day approx 3 pm reported she developed rash on chest, arm, neck - 4 hrs after injections denied any other potential contact. Pt has some eczema (works around chemicals at beauty salon).

Other Meds:

Lab Data:

History: Severe eczema

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318852-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Jul-2008	02-Jul-2008	1	14-Jul-2008	22-Jul-2008	LA		23-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1446U	1	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB284CA		Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2566AA	1	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2774AA	1	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1577U	2	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Pruritus, Pyrexia, Swelling

Symptom Text: Severe reaction, swelling, fever, itching. Treated at medical center. Doctor treated with cortisone and Benadryl and cold pack.

Other Meds:

Lab Data: No lab drawn

History: NKDA

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318853-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Jun-2008	23-Jun-2008	0	14-Jul-2008	22-Jul-2008	VA		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope, Syncope vasovagal

Symptom Text: Vasovagal reaction, near syncopal episode

Other Meds:

Lab Data:

History: seasonal allergies

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318854-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	29-Jan-2008	21-Feb-2008	23	14-Jul-2008	23-Jul-2008	NY		05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Cold sweat, Disturbance in attention, Dizziness, Feeling abnormal, Feeling hot, Gait disturbance, Muscular weakness, Skin warm, Vertigo

Symptom Text: I was supposed to be abroad for the semester. Mid February, on 2/21, I went to class in the morning and got the feeling of being light-headed, spacey and weak. Before the episode started, my hands felt really hot and clammy. After class, I went back to my senoras house to rest, but it did not get better. CC-CS decided to take me to the clinic to see what was wrong. The doctor there wasn't sure and decided to do a blood test, which turned out normal. Around noon, I called home. About a week before this, I was sitting at dinner and got the similar feeling. I felt really out of it, light-headed feeling in both my head and my knees, spacey. I did not have the clammy feeling in my hands, however. I didn't think anything of it and just went to bed. I felt fine the next morning. The next day after calling my mom (Thursday), my dad flew out because I had not gotten any better. We tried walking, but every time I was out, I got the symptoms and had to sit or go back to the hotel. On Saturday, I had the episodes so bad that I felt like I couldn't stand on my own, so my dad decided to take me to the ER. The doctor there diagnosed me as possibly having vertigo. At the hospital, they checked my heart and took blood and everything was normal. To cure vertigo, the doctor gave me medicine. The medication didn't work however. After nine days with my dad, I was no better, so we decided on 2/28 that it was best for me to come home to pursue further testing and to see doctors. So far I have seen: Neurologist, my primary doctor, ENT, ENT, Endocrinologist. When I get the episodes, the feelings that I experience are: The episodes always start with feelings in my hands (clammy and hot). Feeling of light-headedness in head and similar feeling in my knees. Feeling spacey and out of it. Weak and feeling faint/feeling like I am going to collapse. When the episode is severe, I find that I have to try extra hard to focus to try to let it pass. The episodes can happen anywhere, at any time. Typically, they don't start

Other Meds:

Lab Data: I have undergone extensive testing, which includes: Blood work, EEG, VNG, balance and vestibular studies, EMG, tilt table, spinal tap, wore a Holter monitor for 24 hours, and a MRI of the brain. All of the tests have been negative.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **318878-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Jun-2008	09-Jul-2008	12	14-Jul-2008	23-Jul-2008	AZ		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Gingival pain, Periodontitis, Purulent discharge, Stomatitis

Symptom Text: 12 days after immunization, onset of painful gum lesions with purulent exudate, still present at OV 7/14/08. Treated with penicillin and Periogard for acute periodontitis. No previous history of similar symptoms, good dental hygiene.

Other Meds: DepoProvera

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318880-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	M	14-Mar-2007	14-Mar-2007	0	15-Jul-2008	23-Jul-2008	NC		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	MERCK & CO. INC.	NA123	2	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	NA123	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	NA123	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Arthralgia, Depression, Diarrhoea, Dizziness, Fall, Frustration, Gait disturbance, Head injury, Hypoaesthesia, Loss of consciousness, Mental disorder, Muscle spasms, Muscular weakness, Nausea, Tendonitis

Symptom Text: I was administered the guardasil vaccine and the hepatitis A and B vaccine. Since being given the vaccine I got sick the night after haveing the vaccine. I was sick with severe diharea I felt light headed and everything went black my mother came into the bathroom and I had passed out and hit my head on the toilet seat. I first started haveing weakness in my legs. I fell down the steps several times. I informed my docotor but he never reall paid much attention. It seemed he was preocupied. Shortly after that I started haveing numbness in my feet and legs my calf muscled spasm and cramp so bad I limp. This happens on a weekly basis. I started experiencing upper body pain it felt like something arthritic. All day long it felt like a constant severe dull ache. I kept telling my doctor about my pain. He finally sent me to a rhumatologist who did not find anything in my blood to suggest an arthritic condition. after this time there were some deaths and the increased pain and deaths seemed to escalate my feelings. My doctor started saying I was depressed and telling people I was depressed. I didn't feel depressed I felt anxiety from being in severe pain with little relief. I felt frustrated I wasn't being listened too. I hurt really bad and still do. I found out I have tendonitis in my left arm my doctor missed. I belive this was either caused by quinilone antibiotics. My pain has steadily increased since the vaccines. I felt nauseated on a daily basis and my doctor started prescribing me antidepressants without telling me what they were for. He took it to the extreme in trying to get me diagnosed with a mental condition. All the new pain I was feeling was onset after the vaccines. I do have a buldgeing disk in my back that has gone untreated after a failed surgery and the symptoms were ignored until I recently got into a knowledgeable speacialist who started getting things treated. I still have leg pain and arthritic type pain. My docotor seemed to ignore all the new symptoms and tried to blame everything on depressio

Other Meds: kadian ambien

Lab Data: I've had all sorts of blood work and arthritis that would cause this kind of pain has been ruled out. I can guess at the dates of the vaccines the doctor hopefully will feel it's proper to give me the requested data and I can provide the ex

History: degenerative disk disease and asthma

Prex Illness: bad back dik at L5-S1

Prex Vax Illns:

Vaers Id: **318888-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		14-Jul-2008	15-Jul-2008	--	WAES0807USA01942	15-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Systemic lupus erythematosus

Symptom Text: Information has been received from a gynecologist concerning a female patient (age not reported) with lupus erythematosus who was vaccinated on an unknown date with the first dose of GARDASIL (lot #, route, and injection site not reported). The outcome was not reported. On an unknown date, the patient was vaccinated with the second dose of GARDASIL (lot #, route, and injection site not reported). After vaccination, the patient's lupus erythematosus aggravated. The outcome was not reported. Upon internal review, the case was considered as medically significant. Other business partner numbers include E2008-06022. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History:

Prex Illness: Lupus erythematosus

Prex Vax Illns:

Vaers Id: 318890-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	10-May-2007	17-Sep-2007	130	14-Jul-2008	21-Jul-2008	PA		17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0305U	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U1967AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0263U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Hypoaesthesia, Nystagmus, Paraesthesia

Symptom Text: Patient had unusual persistence of weakness. Both legs, below knees, numbness, tingling sensations. Underwent extensive tests at hospital- all neg. 9/12/08-records received for DOS 9/20-9/21/07-DC DX: Peripheral neuropathy. Presented to ED with C/O bilateral lower extremity weakness/numbness began 2 days prior. Tingling began next day.PE: decreased sensation, strength 4/4 times four. End point nystagmus L>R. Follow-up with neurology clinic.

Other Meds:

Lab Data: Blood: ANA positive 1:80, All negative CBC, CRP negative, CSF - pcr for several minutes negative, CSF studies negative, MRI negative. 9/12/08-records received-Calcium increased 10.5 CSF protein 29. ANA positive.Cultures negative. Brain MRI

History: mitral valve prolapse, chest pain borderline Qtc 10/06 9/12/08-records received-Allergy to Augmentin causes hives.

Prex Illness: None

Prex Vax Illns: Unconsolable~DTP (no brand name)~UN~2~In Sibling

Vaers Id: **318894-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	13-Jun-2008	14-Jun-2008	1	14-Jul-2008	22-Jul-2008	GA		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus generalised, Rash

Symptom Text: 6/17/08 Pt c/o rash- Saturday 6/14/08 am. with itching to chest and over body for about 2 days "annoying" rash, then disappeared. Denies any shortness of breath, no fever or tongue swelling. Took a BENADRYL tablet x 1 dose and nothing else.

Other Meds: FLAGYL oral tablets started on 6/14

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 318900-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-Jul-2007	09-Jul-2007	2	11-Jul-2008	28-Aug-2008	MD	WAES0801USA00535	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pregnancy

Symptom Text: Initial and follow up information has been received through a physician and a nurse for the Pregnancy Registry for GARDASIL regarding a 17 year old female, with attention deficit/hyperactivity disorder, and no known previous pregnancies, who on 21-MAY-2007 was vaccinated with her first dose of GARDASIL (Lot # 657621/0387U; route and site not reported). On 09-JUL-2007, the patient was vaccinated with her second dose of GARDASIL (Lot # 658490/0802U; route and site not reported). On 22-OCT-2007, the patient was vaccinated with influenza virus vaccine (unspecified). On 26-NOV-2007, the patient was vaccinated with her third dose of GARDASIL (Lot # 659437/1266U; route and site not reported). Concomitant therapy included FOCALIN and FOCALIN XR. On 31-DEC-2007, the patient was diagnosed with scabies and treated with ATARAX and ELIMITE cream. On 03-JAN-2008, the patient had an ultrasound due to an enlarged abdomen. The results of the ultrasound showed that the patient was pregnant (33.7 weeks gestational age). The patient's LMP was reported as November 2007. On 23-JAN-2008, the patient gave birth to a normal baby girl (5 lbs, 13 oz and 18 in). There were no congenital anomalies. There were no complications during labor and delivery. It was reported that the patient had no prenatal care. No additional information was provided. No additional information is available.

Other Meds: FOCALIN, 5 mg; FOCALIN XR, 25 mg; Influenza Virus Vaccine

Lab Data: Ultrasound, 01/03/08, 33.7 weeks gestational age

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Prophylaxis; Attention deficit/hyperactivity disorder

Prex Vax Illns:

Vaers Id: **318902-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Aug-2007	23-Aug-2007	0	11-Jul-2008	28-Aug-2008	WI	WAES0710USA04908	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a Merck Pregnancy Registry for GARDASIL from a registered nurse concerning an 18 year old female, with no drug reactions or allergies, with a history of anaemia, who on 23-AUG-2007 was vaccinated, intramuscularly, with the first 0.5 mL dose of GARDASIL. Concomitant therapy included prenatal vitamins (unspecified). The patient was subsequently determined to be pregnant, and had an exam in the office. The patient had an abdominal ultrasound. Her last menstrual period was 24-JUN-2007 and estimated delivery date was 30-MAR-2008. No problems were reported. No further details were available. Follow up phone call information was received from a nurse who reported that the patient delivered a normal, healthy baby in March 2008. The baby was checked by a pediatrician and everything was fine. No anomalies were found. No additional information is expected.

Other Meds: Vitamins (unspecified)

Lab Data: Abdominal ultrasound

History: Anaemia

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318903-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Mar-2007	14-Jul-2007	108	11-Jul-2008	28-Aug-2008	--	WAES0710USA03340	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter for the Pregnancy Registry for GARDASIL who on 28-MAR-2007 was vaccinated with her first dose of GARDASIL (lot# not reported). On 30-JUL-2007 the patient was vaccinated with her second dose of GARDASIL (lot# not reported) and was pregnant. On 08-AUG-2007 the patient was vaccinated with her third dose of GARDASIL (lot# not reported). The date of conception was 22-JUL-2007 (LMP approximately 14-JUL-2007). The patient sought unspecified medical attention and her outcome is unknown. Attempts were made to receive additional information, but this case has been lost to follow-up. No additional information is expected.

Other Meds: Unknown

Lab Data: Beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 7/14/2007)

Prex Vax Illns:

Vaers Id: 318904-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-Apr-2007	06-Jul-2007	70	11-Jul-2008	28-Aug-2008	WI	WAES0710USA03188	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse through the Merck Pregnancy Registry concerning an 18 year old female patient with no known medical history or drug reactions/allergies, who on 25-JAN-2007, was vaccinated intramuscularly in the left deltoid with the first 0.5 mL dose of GARDASIL (lot# 654702/0011U). On 27-APR-2007 the patient was vaccinated intramuscularly in the left deltoid with the second 0.5 mL dose of GARDASIL (lot# 657006/0188U). On 07-AUG-2007 the patient was vaccinated intramuscularly in the left deltoid with the third 0.5 mL dose of GARDASIL (lot# 658100/0525U). There was no concomitant medication. The nurse reported that after receiving three doses of GARDASIL the patient is now pregnant. The patient's last menstrual period was on 20-JUL-2007. Her estimated conception date was 04-AUG-2007 which changed her estimate delivery date to 26-APR-2008. An ultrasound done on the 10-DEC-2007 confirmed the change of her EDC. Unspecified medical attention was sought. It was also reported that the patient has not had any previous pregnancies or live births. At the time of this report, the patient's outcome was unknown. Follow up information by an other health professional confirmed that the baby was born and enrolled in a program but she could not provide any additional details at this time. There was no product quality complaint. Follow up information stated that on 28-APR-2008, the patient gave birth to a liveborn infant female weighing 8 pounds 12 ounces. Her APGAR score was reported as 8 - 9. The patient was 41 weeks from her last menstrual period. The infant's head circumference was 13 inches. The infant was reported as normal with no congenital anomalies. There were no complications or abnormalities reported during the pregnancy or labor/delivery. At the time of this report, the patient recovered. Additional information is not expected.

Other Meds: None

Lab Data: Ultrasound, 12/10/07, changed EDC

History:

Prex Illness: Pregnancy NOS (LMP = 7/20/2007)

Prex Vax Illns:

Vaers Id: 318905-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	24-Jul-2007	27-Jul-2007	3	11-Jul-2008	28-Aug-2008	CT	WAES0709USA03249	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received from the Merck pregnancy registry via a registered nurse concerning a 22 year old female smoker with a history of depression with no treatment medications, 2 previous pregnancies, 1 full term delivery at 38 weeks, 1 elective termination, and a cousin with open neural tube defect, who on 24-JUL-2007 was vaccinated IM, into the left deltoid, with a 0.5 ml first dose of GARDASIL (lot # 658822/0927U). It was reported that a pregnancy test was negative at the time of vaccination. Subsequently, the patient became pregnant. The patient's last menstrual period was 14-JUL-2007 and the estimated date of delivery was 19-APR-2008. On 13-AUG-2007 the patient was started on VITAFOL-B, once a day. On 17-SEP-2007 an ultrasound was performed for routine viability source and dating, and the results were intrauterine pregnancy and a positive fetal heart. On 10-OCT-2007 the patient showed to be positive for Coxsackie B titers. On 15-OCT-2007 the patient was vaccinated with a 0.5 mL dose of influenza virus vaccine (unspecified). On 12-NOV-2007 a Maternal Serum Alpha-Fetoprotein Screening was performed for genetic screening, and the results were within normal limits. On 15-NOV-2007 a level II ultrasound was performed for genetic screening and fetal anatomy, and the results were within normal limits. On 18-DEC-2007 a fetal echocardiography was performed and was within normal limits. On 31-JAN-2007 at 28 weeks gestation the patient received a 300 microgram dose of globulin, immune because she was Rh negative. Unspecified medical attention was sought. At the time of the report, the patient's outcome was unknown. On 12-APR-2008 the patient gave birth to a female infant at 39 weeks. The infant weighed 6 pounds 3 ounces, was 18.5 inches long, had an apgar score of 8/9, and a head circumference of 32cm. The infant was normal with no congenital anomalies, complications, or abnormalities. The patient experienced Leukocytosis, Bandemia, and positive Coxsackie B titers during p

Other Meds: Unknown

Lab Data: Ultrasound, 09/17/07, reason-routine viability source and dating result - intrauterine pregnancy with fetal heart; Ultrasound, 11/15/07, level II reason - genetic screening and fetal anatomy result - within normal limits; Echocardiography,

History: Termination of pregnancy - elective

Prex Illness: Pregnancy NOS (LMP = 7/14/2007); Smoker; Depression

Prex Vax Illns:

Vaers Id: 318906-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	13-Aug-2007	13-Aug-2007	0	11-Jul-2008	28-Aug-2008	IN	WAES0709USA00534	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received from a healthcare worker and a certified medical assistant through the Pregnancy Registry for GARDASIL regarding a 19 year old female with a history of seasonal allergies who on 04-JUN-2007 was vaccinated with her first dose of GARDASIL (Lot # 655617/1447F; site and route not reported). On 13-Aug-2007, the patient was vaccinated with her second dose of GARDASIL (Lot #, site and route not reported). On 05-Sep-2007 it was reported that the patient was pregnant. The patient sought unspecified medical attention in the office. The patient had a urine pregnancy test which was positive. "The LMP is unspecified, but the physician believes that the patient is within the first month of pregnancy." On 08-MAY-2008, the patient delivered a normal baby boy (9lbs, 5 oz and 22 1/4 inches) at 40 weeks gestation. The baby's Apgar scores were 8 and 9. The baby was healthy "other than slight jaundice treated with bili light". There were no congenital anomalies or abnormalities. There were no complications with the pregnancy, labor or delivery. Additional information is not expected.

Other Meds: None

Lab Data: Urine beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = 8/1/2007); Seasonal allergy

Prex Vax Illns:

Vaers Id: 318907-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	18-Jul-2007	18-Jul-2007	0	11-Jul-2008	28-Aug-2008	OH	WAES0708USA05316	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received from the Merck Pregnancy Registry via a licensed practical nurse concerning a 20 year old female with a history of social alcohol use in the first and second week until pregnancy confirmed who on 18-JUL-2007 was vaccinated intramuscularly with a first dose of GARDASIL. Concomitant therapy included SKELAXIN five times total for a muscle relaxant and ADVIL 200 mg (frequency not reported). Subsequently the patient was five months pregnant and did not realize it. The patient was a Gravida 1, Para 0. The patient's last menstrual period was in early February 2007 and the date of conception was on 14-FEB-2007. At 25 weeks gestation the patient visited the physician for her 1st obstetric appointment. On 23-JUL-2007 an ultrasound was performed to confirm pregnancy revealing a 25 week gestation. On 30-JUL-2007 another ultrasound was performed that revealed an intra-uterine pregnancy at 25 4/7 weeks gestation and confirmed male fetus. On 06-NOV-2007, at thirty nine and five days from the LMP the patient delivered a normal male infant. Labor and delivery were uncomplicated. The apgar scores were 9 and 9. At the time of the report the patient had recovered. Follow up information was received on 28-MAR-2008 from the physician's office. The mother called the physician's office on 07-JAN-2008 at 1:43 pm and reported that the infant was 2 months old and had a stuffy nose, sneezing and watery eyes. The infant also had a slight temperature of 100 degrees on 06-JAN-2008. On 7-JAN-2008 at 1:55 pm it was noted to observe the infant and do DIMETAPP and ADVIL/MOTRIN. Additional information is not expected.

Other Meds: ADVIL, 200mg; SKELAXIN

Lab Data: Ultrasound, 07/30/07, viable IUP at 25 4/7 weeks gestation; Ultrasound, 07/23/07, pregnancy confirmation of 25 week gestation; Apgar score, 11/06/07, 9; Body temp, 01/06?/08, 100 Fahrenheit, Infant's body temperature measurement

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Alcohol use; Muscle relaxant therapy.

Prex Vax Illns:

Vaers Id: **318908-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	06-Aug-2007	06-Aug-2007	0	11-Jul-2008	28-Aug-2008	--	WAES0708USA03678	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received for the Pregnancy Registry for GARDASIL from a nurse practitioner concerning a female (age not reported) who was vaccinated with a first dose of GARDASIL (lot# unknown) injection. Subsequently the patient received her first dose 8 days post conception. Medical attention was sought. No adverse experience was reported. The date of the last menstrual period and the estimated date of delivery is unknown. Follow-up information was received from a nurse practitioner. The female patient was 21 years old with no pertinent medical history and no drug reactions/allergies. There was no concomitant medication. The patient's date of last menstrual period was 14-JUL-2007 and on 16-JAN-2008 the patient was 26 weeks gestation. The patient had a shortened cervix (unknown if this was a condition prior to pregnancy). On 06-AUG-2007 the patient received a first dose of GARDASIL (unknown if this was the first or second dose) from her primary physician. On 20-AUG-2007 the patient had a positive pregnancy test. The nurse mentioned the pregnancy was going well. The estimated date of delivery is 19-APR-2008. The patient delivered a female baby on 21-APR-2008. Additional information is not expected.

Other Meds: None

Lab Data: Beta-human chorionic, 08/20/07, positive

History:

Prex Illness: Pregnancy NOS (LMP = 7/14/2007); Shortened cervix

Prex Vax Illns:

Vaers Id: 318912-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	02-Jul-2007	02-Jul-2007	0	11-Jul-2008	28-Aug-2008	PA	WAES0708USA00062	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received for the Pregnancy Registry for GARDASIL from a Nurse Practitioner concerning a 26 year old female with anemia and a history of cutaneous intraepitheleal neoplasia who on 02-JUL-2007 was vaccinated IM with a first dose of GARDASIL lot #658100/0525U. Concomitant therapy included hormonal contraceptives (unspecified), prenatal vitamins, PROMETRIUM, and SLOW FE. Last menstrual period was the end of JUN-2007. Estimated delivery date was 05-APR-2008. Subsequently, the patient became pregnant and it was confirmed by a home pregnancy test. She was not experiencing any known symptoms. Unspecified medical attention was sought by the patient. There were no reported complications during the pregnancy. On 15-MAR-2008, the patient delivered a normal set of twins, one male 6 pounds and 4 ounces, and one female 6 pounds 1 ounce. There were no congenital anomalies and no reported complications or abnormalities. No additional information is expected.

Other Meds: SLOW FE; Hormonal contraceptives; PROMETRIUM 100mg; Vitamins (unspecified)

Lab Data: Beta-human chorionic, positive

History: Cervical intraepithelial neoplasia II

Prex Illness: Pregnancy NOS (LMP = 6/30/2007); Anaemia

Prex Vax Illns:

Vaers Id: 318913-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Nov-2006	09-Nov-2006	0	11-Jul-2008	28-Aug-2008	PA	WAES0705USA02922	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Drug administered at inappropriate site, Drug exposure during pregnancy, Gestational diabetes

Symptom Text: Information has been received through the Merck pregnancy registry from a licensed practical nurse concerning an 18 year old female smoker with a penicillin allergy who on 09-NOV-2006 was vaccinated in the left buttocks with the first dose of GARDASIL (Lot #653735/0688F). Concomitant therapy included NUVARING, LOESTRIN 24 FE and prenatal vitamins (unspecified). On 04-JAN-2007, the patient was vaccinated in the right gluteal with the second dose of GARDASIL (Lot #655765/1425F). It was reported that the patient was pregnant, after receiving the vaccine. Her last menstrual period was reported as 13-MAR-2007 and estimated due date 18-DEC-2007. On an unspecified date in 2007, the patient had the following infections or illnesses during pregnancy gestational diabetes mellitus and anemia. On 07-MAY-2007, an ultrasound was performed results reported were 7 6/7 IUG which confirmed the pregnancy. On 20-JUL-2007, a pregnancy quad screen and ultrasound were performed results were within normal limits. On 29-SEP-2007, 1 hour glucose "HcH" was performed results were not reported. On 18-OCT-2007, an ultrasound was performed results were within normal limits. On 03-DEC-2007, an ultrasound was performed results were within normal limits. On 17-DEC-2007 (39 4/7 weeks gestation), it was reported that the patient delivered a normal healthy baby girl, weight 7lbs 8 oz and Apgar score was 8/9. No congenital anomalies, complications or abnormalities were reported. The seriousness and outcome of the GDMA and anemia were not reported. Additional information is not expected.

Other Meds: NUVARING; LOESTRIN 24 FE; Vitamins (unspecified)

Lab Data: Ultrasound, 05/07/07, 7 6/7 IUG, confirming pregnancy; Diagnostic laboratory, 07/20/07, Quad screen was within normal limits; Ultrasound, 12/03/07, within normal limits; Ultrasound, 07/20/07, within normal limits; Ultrasound, 10/18/07, with

History:

Prex Illness: Pregnancy NOS (LMP = 3/13/2007); Smoker; Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318916-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	20-Apr-2007	20-Apr-2007	0	11-Jul-2008	28-Aug-2008	IN	WAES0705USA00163	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Drug exposure during pregnancy, Pre-eclampsia

Symptom Text: Information has been received from the step-mother of a 21 year old female and through a Merck Pregnancy Registry. The 21 year old female had no pertinent medical history and no drug reactions or allergies who on approximately 16-APR-2007, "approximately 2 weeks ago" was vaccinated "in the hip area" with the first dose of GARDASIL. The lot number was not available. There was no concomitant medication. It was reported that the patient discovered that she was pregnant approximately a week and a half later on 27-APR-2007. The patient had not visited her physician regarding the pregnancy as of today. It was reported that the patient was approximately 6 weeks pregnant. In follow-up it was reported by a nurse practitioner, who was a nurse midwife concerning a 21 year old, female, patient, with the last menstrual period was 16-MAR-2007, who on 20-APR-2007 received her first dose of GARDASIL, (Lot # 657006/0188U). It was reported that the patient was pregnant with an estimated date of delivery of 21-Dec-2007. It was reported that the patient sought unspecified medical attention. Laboratory evaluation revealed a positive serum pregnancy test and the patient had a fetal ultrasound (results not reported). Follow-up information indicated that on 12-DEC-2007 the patient gave birth to an infant that weighed 7 pounds 12 ounces. The infant was healthy and normal. It was reported that the mother experienced "mild pre-eclampsia and blood pressure issues." Additional information has been requested.

Other Meds: None

Lab Data: Ultrasound, fetal; Serum beta-human, positive.

History:

Prex Illness: Pregnancy NOS (LMP = 3/16/2007)

Prex Vax Illns:

Vaers Id: 318918-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	25-Jan-2007	25-Jan-2007	0	11-Jul-2008	28-Aug-2008	--	WAES0704USA05634	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0962F		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Herpes virus infection, Streptococcal identification test positive

Symptom Text: Initial and follow up information has been received from a medical assistant via the pregnancy registry for GARDASIL, concerning a 22 year old female with allergies to amoxicillin, CECLOR and erythromycin, who on 25-JAN-2007 was vaccinated with a single, first dose of GARDASIL at another clinic (lot #654510/0962F). Concomitant therapy included an unspecified prenatal vitamin and ferrous sulfate (unspecified). Subsequently the patient became pregnant (LMP 09-JAN-2007, EDD 16-OCT-2007). On 19-MAR-2007 an ultrasound showed that the pregnancy was 10.8 weeks along, her EDD was 08-OCT-2007, and it showed the "size and dates" (not further specified). As of 25-APR-2007 the patient had not experienced any side effects. Follow up information from the MA, confirmed that on 08-OCT-2007, an 8 pound 9 ounce, 20 inch long, normal female infant (Apgar score 8.7) was born, at 39 weeks after the date of LMP. The pregnancy and delivery had been without complications. Follow-up information was received from a health professional. The baby had a head circumference of 31.5. The patient was Group B streptococcus positive. The patient had herpes in the last 3 weeks of pregnancy and was treated with acyclovir. The patient also had UNISOM for allergies and PRILOSEC for heartburn. Additional information is not expected.

Other Meds: Ferrous sulfate, 325mg; Vitamins (unspecified), dose

Lab Data: Ultrasound, 03/19/07, 10.8 weeks, EDD 08-OCT-2007, size and dates

History:

Prex Illness: Pregnancy NOS (LMP = 1/9/2007); Penicillin allergy; Drug hypersensitivity; Iron low

Prex Vax Illns:

Vaers Id: **318919-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	16-Jan-2007	Unknown		11-Jul-2008	28-Aug-2008	NY	WAES0703USA03170	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427F		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Gestational diabetes

Symptom Text: Information has been received from a physician for the Pregnancy Registry for GARDASIL concerning an approximately 23 year old female with a history of seizures who on 16-JAN-2007 was vaccinated intramuscularly with a 0.5 mL first dose of GARDASIL (lot # 655619/1427F). Concomitant therapy included YASMIN and CARBATROL. Subsequently the patient was found to be about 9 weeks pregnant at the time of the vaccination and sought unspecified medical attention. A pregnancy test was performed which was positive (not further specified). Follow-up information was received from the physician who reported that the mother developed gestational diabetes and went on to deliver a healthy, normal infant at term. No further information was available. Additional information is not expected.

Other Meds: CARBATROL; YASMIN

Lab Data: Beta-human chorionic, positive

History: Convulsion

Prex Illness:

Prex Vax Illns:

Vaers Id: **318920-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
31.0	F	Unknown	07-Jan-2007		11-Jul-2008	28-Aug-2008	IL	WAES0703USA00029	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received through the Merck pregnancy registry, from a registered nurse, concerning a 31 year old female patient who in August 2006 and October 2006 was vaccinated with the first and second doses of GARDASIL, respectively. On 07-JAN-2007 the nurse reported that the "patient has become pregnant during the 3-dose series." The nurse added that "no adverse reactions have been reported for this patient." Date of the last menstrual period was 7-JAN-2007 and the patient delivered on 07-OCT-2007 at 39 weeks estimated gestational age. She had an uncomplicated vaginal birth and a healthy female infant. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 1/7/2007)

Prex Vax Illns:

Vaers Id: **318921-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		11-Jul-2008	28-Aug-2008	MI	WAES0701USA00641	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pain, Vomiting

Symptom Text: Initial and follow-up information has been received from a physician and a nurse through a Merck Pregnancy Registry concerning a 19 year old female patient, who was vaccinated by injection with the first, 0.5 ml dose of GARDASIL. After a couple of weeks the patient developed vomiting pains and was rushed to the Emergency Room. The patient was tested and diagnosed as being pregnant. The patient sought medical attention. Follow-up information indicated that the patient vaginally delivered a healthy, normal female at 39 weeks on an unspecified date. The infant weighed 6 pounds 14 ounces. The baby experienced some jaundice as a newborn. It was reported that the mother and baby were doing well. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318937-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		11-Jul-2008	28-Aug-2008	--	WAES0806USA00549	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Thyroid disorder

Symptom Text: Information has been received from a consumer concerning her granddaughter who was vaccinated on an unspecified date with GARDASIL (lot# not reported). subsequently the patient experienced an elevated thyroid and the grandmother wanted to know if this was related to GARDASIL. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318940-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		11-Jul-2008	28-Aug-2008	GA	WAES0806USA00383	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Medication error, No adverse event

Symptom Text: Information has been received from a certified medical assistant concerning "no more than ten patients" who were vaccinated with GARDASIL (lot#, route and dose not reported), which was inadvertently stored in the freezer for 2 weeks. The medical assistant reported that no adverse event was reported. No additional information was provided. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318942-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	12-May-2008	12-May-2008	0	11-Jul-2008	28-Aug-2008	--	WAES0806USA00370	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a nurse concerning a 22 year old female who on 12-MAY-2008 was vaccinated with the first dose of GARDASIL 0.5 ml intramuscularly. The nurse stated that on 02-JUN-2008, the patient called the office stating that her arm had been painful at the injection site for the past 3 weeks. At the time of the report the patient was not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318943-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	15-Jan-2008	Unknown		11-Jul-2008	28-Aug-2008	--	WAES0806USA00355	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Flushing, Hot flush

Symptom Text: Information has been received from a registered nurse concerning a 25 year old female with allergies to penicillin and sulfa antibiotics, who on 27-NOV-2007 was vaccinated with the first dose of GARDASIL 0.5 ml intramuscularly (lot# 658560/1062U). There was no concomitant medication. The nurse reported that on 15-JAN-2008, the patient received the second dose of GARDASIL 0.5 ml intramuscularly (lot# 658560/1062U). The nurse noted that in March 2008, the patient developed red flushing on her cheeks, nose and forehead and experienced hot flashes. The patient sought unspecified medical attention. The nurse reported that the patient recovered (date unspecified). No other information was available. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy; Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **318945-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
35.0	F	01-Apr-2008	19-May-2008	48	11-Jul-2008	28-Aug-2008	CA	WAES0806USA00333	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: Information has been received from a physician concerning a 35 year old female patient with no medical history reported, who on approximately 01-APR-2008, was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL. On 19-MAY-2008, "approximately two weeks ago," the patient developed redness, swelling, pain and heat at the injection site after receiving her second dose. Unspecified medical attention was sought. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318947-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	20-Aug-2007	12-May-2008	266	11-Jul-2008	28-Aug-2008	PA	WAES0806USA00310	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a 19 year old female with a sulfonamide allergy who on 16-FEB-2007 was vaccinated IM with a first 0.5 ml dose of GARDASIL (Lot# 656049/0187U) in the right deltoid. On 20-APR-2007 she was vaccinated IM with a second 0.5 ml dose of GARDASIL (Lot #657621/0387U) in the left deltoid. On 20-AUG-2007 she was vaccinated IM with a third 0.5 ml dose of GARDASIL (Lot #658556/1060U) in the left deltoid. Concomitant therapy included ORTHO TRI-CYCLEN. The patient had a negative papanicolaou test on 20-APR-2008 and a positive test on 12-MAY-2008. The patient sought medical attention in the office. At the time of the report the patient's outcome was unknown. Additional information has been requested.

Other Meds: Ortho Tri-Cyclen

Lab Data: Pap test, 05/12/08, positive; Pap test, 04/20/08, negative.

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **318948-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Apr-2008	22-Apr-2008	0	11-Jul-2008	28-Aug-2008	NY	WAES0806USA00304	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue

Symptom Text: Information has been received from a physician concerning a 17 year old female with obesity, asthma, depression and allergy to amoxicillin who on 22-APR-2008 was vaccinated IM with a first 0.5 ml dose of GARDASIL. There was no concomitant medication. On 02-MAY-2008 the patient experienced fatigue. The patient sought medical attention in the emergency room for evaluation but was not admitted. Laboratory studies performed included erythrocyte sedimentation rate, mononucleosis serological test, complete blood count and all results were negative. At the time of the report, the patient was recovering. The physician stated she does not believe that the fatigue and the vaccination with GARDASIL are associated. Additional information has been requested.

Other Meds: None

Lab Data: Erythrocyte, negative; Complete blood cell, negative; Serum Epstein-Barr virus, negative, mononucleosis.

History:

Prex Illness: Obesity; Asthma; Depression; Penicillin allergy

Prex Vax Illns:

Vaers Id: **318949-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	08-May-2008	11-May-2008	3	11-Jul-2008	28-Aug-2008	WV	WAES0806USA00303	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oedema peripheral, Pruritus, Pyrexia, Skin papilloma

Symptom Text: Information has been received from a certified nurse midwife concerning a 20 year old female with sulfonamide allergy and no pertinent medical history who on 08-MAY-2008 was vaccinated IM with a first 0.5 ml dose of GARDASIL (Lot# 660387/1967U) in the left deltoid. Concomitant therapy included hormonal contraceptives (unspecified). On 11-MAY-2008, "3 days later" the patient developed about 16 warts in total all over the back of her hands. The patient's hands started to swell, she was very itchy and had a low grade fever. The patient sought medical attention in the emergency room but was not admitted to the hospital. The patient was seen by the dermatologist and had a biopsy (awaiting results). At the time of the report, the patient's outcome was not recovered. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: Biopsy, 05/??/08, awaiting results

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **318954-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		11-Jul-2008	28-Aug-2008	OK	WAES0805USA00111	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Medication error, No adverse event

Symptom Text: Information has been received from a licensed practical nurse concerning an 18 year old female student with no pre-existing allergies, birth defects or medical conditions, who was vaccinated with a dose of GARDASIL that was stored as low as 31F. There was no illness at the time of vaccination. No symptoms reported. There was no product quality complaint. Additional information will be provided if available. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 318955-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	16-Nov-2007	16-Nov-2007	0	11-Jul-2008	28-Aug-2008	IL	WAES0804USA05020	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1425F	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Medication error, No adverse event

Symptom Text: Information has been received from a health professional concerning a female patient who on 20-AUG-2007 was vaccinated with a first dose of GARDASIL (Lot# 655165/1425F). On 16-NOV-2007, the patient was vaccinated into the left arm with a second dose of improperly stored GARDASIL (Lot# 655165/1425F). No adverse symptoms were noted. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318956-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	09-Apr-2008	09-Apr-2008	0	11-Jul-2008	28-Aug-2008	CT	WAES0804USA04740	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Device malfunction, Underdose

Symptom Text: Information has been received from a health professional concerning a female who on 09-APR-2008 was vaccinated with a partial dose of GARDASIL (lot # 655604/0052X) due to a malfunction of the pre-filled syringe. The syringe malfunctioned before the complete dose could be administered. The patient was subsequently administered a complete dose of GARDASIL at the same office visit. No problems were reported. Patient outcome was not reported. Additional information has been requested. The SR # is 1-3040431198.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318957-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	07-Mar-2008	07-Mar-2008	0	11-Jul-2008	28-Aug-2008	ID	WAES0804USA04016	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Initial information and follow up has been received from a nurse concerning a patient who was vaccinated on an unspecified date with her first dose of GARDASIL (lot# not reported). The patient received the second dose of GARDASIL (lot# not reported) 7 months after the first dose. On 07-MAR-2008 the patient received the third dose of GARDASIL (lot# 659180/1758U) (9 1/2 months after the first dose). Concomitant therapy included MIDRIN and INDOCIN. The patient's outcome was not reported. The patient has been notified of need to repeat dose #3. Additional information has been requested.

Other Meds: Midrin; Indocin (Indomethacin sodium)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318958-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	03-Apr-2008	03-Apr-2008	0	11-Jul-2008	28-Aug-2008	CT	WAES0804USA01233	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Device leakage, Injection site irritation, Underdose

Symptom Text: Information has been received from a nurse practitioner concerning a female who on 03-APR-2008 was vaccinated with a first dose of GARDASIL (lot #655327/1287U). During administration of the vaccine, the vaccine leaked out of the syringe, ran down the patient's arm and then the patient received partial dose. The patient also experienced a burning sensation when the vaccine entered her arm. The nurse practitioner indicated that she put the needle on the syringe properly and she looked at the syringe after vaccination and didn't notice anything unusual. At the time of the report, the patient's outcome was unknown. The SR is 1-2829187985. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318959-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	20-Mar-2008	20-Mar-2008	0	11-Jul-2008	28-Aug-2008	--	WAES0803USA03493	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: Initial and follow up information has been received from a Nurse concerning a 25 year old female who on 27-JUL-2007 was vaccinated with a 1st dose of GARDASIL (lot# not reported). There was no concomitant medication. On 20-MAR-2008 the patient was vaccinated with a 2nd dose of GARDASIL (lot# not reported). The patient sought unspecified medical attention in the office. The patient did not have any symptoms. No further information is expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **318960-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-Oct-2007	04-Oct-2007	0	11-Jul-2008	28-Aug-2008	SC	WAES0801USA02105	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	188U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pregnancy induced hypertension

Symptom Text: Initial and follow up information has been received for the Merck Pregnancy Registry from a registered nurse concerning a 17 year old female with no pertinent medical history or drug reactions/allergies who on 04-OCT-2007 was vaccinated with GARDASIL (lot# 657006/0188U) 0.5 mL IM while pregnant. There was no concomitant medication. The patient was approximately 13 weeks pregnant when she received her first dose, but she did not know that she was pregnant at the time. The patient's date of last menstrual period was 11-JUL-2007. Gestation was 27 and 1/2 weeks. Medical attention was sought. The patient's estimated date of delivery was 16-APR-2008. The mother experienced pregnancy induced hypertension and was treated with NORVASC. It was reported that the patient delivered at 38 weeks gestation, a 7lb. 11 oz. healthy baby girl. On 28-MAY-2008 she was vaccinated with GARDASIL. At the time of the report the outcome of the pregnancy induced hypertension was unknown. Additional information is not expected.

Other Meds: None

Lab Data: Urine beta-human

History:

Prex Illness: Pregnancy NOS (LMP = 7/11/2007)

Prex Vax Illns:

Vaers Id: **318961-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	20-May-2008	27-May-2008	7	11-Jul-2008	28-Aug-2008	--	WAES0806USA00850	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site reaction, Rash papular, Rash pruritic

Symptom Text: Information has been received from a physician assistant concerning a 20 year old female with unspecified pertinent medical history and no drug reactions/allergies reported, and no concomitant medications who on 20-MAY-2008 was vaccinated with the first dose of GARDASIL, IM to the left arm. The patient contacted the office on 27-MAY-2008, because of a rash that covered both arms, stomach, and back. There was also a "mark" at the injection site which was the left arm. The rash started on the left arm and then spread to the stomach, back and right arm. The rash is itchy and there are little white bumps everywhere that cannot be seen unless the skin is stretched and can be detected by touch. No further information is available. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318962-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	03-Jun-2008	03-Jun-2008	0	11-Jul-2008	28-Aug-2008	IN	WAES0806USA00826	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female (age unreported) who on 03-JUN-2008 was vaccinated with a dose of GARDASIL. The patient reportedly developed syncope after receiving a dose of GARDASIL. The patient was at the physician's office when she experienced the syncope. It was reported that the patient recovered on the same day 03-JUN-2008. No further information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318963-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	03-Jun-2008	03-Jun-2008	0	11-Jul-2008	28-Aug-2008	--	WAES0806USA00814	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female who on 11-SEP-2006 was vaccinated with a first dose of GARDASIL. On 03-JUN-2008 she was vaccinated with a second dose of GARDASIL. The patient experienced pain at the injection site after injections. At the time of the report, the outcome of the injection site pain was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318964-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Apr-2008	Unknown		11-Jul-2008	28-Aug-2008	FL	WAES0806USA00806	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site swelling

Symptom Text: Information has been received from a licensed practical nurse concerning a 17 year old female patient with no medical history and an allergy to dust and animal dander, who on 30-APR-2008 was vaccinated intramuscularly in her left deltoid with the first dose of GARDASIL (Lot # 659657/1487U). Concomitant therapy included hormonal contraceptives (unspecified). Subsequently, the patient developed swelling at the injection site. The swelling then changed to a 3 centimeter knot. The patient sought unspecified medical attention by the physician. At the time of this report the patient's outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: Unknown

History:

Prex Illness: Allergy to animal dander; House dust allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318965-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	22-Oct-2007	22-Oct-2007	0	11-Jul-2008	28-Aug-2008	--	WAES0806USA00772	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Information has been received from a consumer who reported that on 18-MAY-2007 she was vaccinated with the first dose of GARDASIL (lot #, and route not reported). The consumer reported that on 22-OCT-2007 she was vaccinated with the second dose of GARDASIL (lot #, and route not reported). She noted that she did not receive the third dose of GARDASIL in January, because she had the flu. No further information was provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318966-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	05-Jun-2007	Unknown		11-Jul-2008	19-Aug-2008	TX	WAES0806USA00689	20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Information has been received from a physician concerning a 24 year old female with no specified pertinent medical history or drug allergies, who on 05-JUN-2007 was vaccinated with the first dose of GARDASIL. The second dose of GARDASIL, was given on 02-AUG-2008. The third dose of GARDASIL, IM, was given on 03-DEC-2008. Subsequently the patient developed genital warts. The patient sought unspecified medical attention and had not recovered at the time of reporting. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318967-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-Feb-2008	20-Feb-2008	0	11-Jul-2008	22-Aug-2008	PA	WAES0806USA00688	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Vaccine positive rechallenge

Symptom Text: Information has been received from a practical nurse concerning a 14 year old female with pertinent medical history and drug reactions/allergies reported as none, who on 20-FEB-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 658556/1060U). Following the first dose of GARDASIL vaccine (yeast), the patient experienced difficulty breathing. The second dose of GARDASIL vaccine (yeast), (lot # 660391/0063X), 0.5 ml, IM was given on 03-JUN-2008. The patient also experienced difficulty breathing following this vaccination. These episodes reportedly lasted for less than 5 minutes shortly after receiving each dose. The patient was seen at the physicians office and recovered on the same date of the vaccinations.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318968-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
32.0	F	05-May-2008	Unknown		11-Jul-2008	22-Aug-2008	--	WAES0806USA00686	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myalgia

Symptom Text: Information has been received from a 32 year old female consumer who on an unspecified date was vaccinated with a dose of GARDASIL vaccine (yeast). On 05-MAY-2008, the patient received her second dose of GARDASIL vaccine (yeast), 0.5 ml, IM (lot # not specified). Concomitant therapy included influenza virus vaccine (unspecified), two weeks prior to receiving GARDASIL vaccine (yeast). Subsequently the patient experienced muscle aches and pains. The patient reported that she sought unspecified medical attention and had diagnostic blood work performed. No results were reported. Therapy with GARDASIL vaccine (yeast) was discontinued. At the time of reporting the patient had not recovered. No additional information is expected.

Other Meds: influenza virus vaccine

Lab Data: diagnostic laboratory - blood work

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318969-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		11-Jul-2008	22-Aug-2008	DE	WAES0806USA00683	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Device leakage, Underdose

Symptom Text: Information has been received from a certified medical assistant concerning a patient (age and gender not reported) who was vaccinated with a dose of GARDASIL (lot #0152X) on an unspecified date. It was reported that the patient received a quarter dose of GARDASIL, the syringe leaked as the patient was being given the vaccination. This is an amended report as the service request number was received. Additional information has been requested. This is a corrected report as amended.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318970-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Apr-2008	03-Apr-2008	0	11-Jul-2008	22-Aug-2008	KY	WAES0806USA00673	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lip swelling

Symptom Text: Information has been received from a medical assistant concerning a 17 year old female with no known drug allergies and no pertinent medical history who on 03-APR-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast), 0.5 ml, IM. There were no concomitant medications. Subsequently, in the night of 09-APR-2008 the patient developed swollen lips. She sought medical attention in the office and the swelling resolved without any treatment the following night. No other details were provided. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 318971-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	18-Apr-2008	18-Apr-2008	0	11-Jul-2008	22-Aug-2008	--	WAES0806USA00654	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dysmenorrhoea, Metrorrhagia

Symptom Text: Information has been received from a registered nurse concerning a 22 year old female with sulfonamide allergy and a penicillin allergy who on 18-APR-2008 was vaccinated intramuscularly with the first dose of GARDASIL (lot # 660389/1968U). Concomitant therapy included LEVAQUIN, PREVACID (patient given prescription on 18-APR-2008) and SEASONIQUE. On 18-APR-2008, the patient experienced lightheadedness, dizziness, menstrual-like cramping and spotting. The patient also started LEVAQUIN on that day. On 19-APR-2008, the patient recovered from lightheadedness, dizziness, menstrual-like cramping and spotting. The patient did not seek medical attention. No product quality complaint was involved. Additional information has been requested.

Other Meds: SEASONIQUE; PREVACID; LEVAQUIN

Lab Data: None

History:

Prex Illness: Sulfonamide allergy; Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318972-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Mar-2008	01-Mar-2008	0	11-Jul-2008	22-Aug-2008	--	WAES0806USA00647	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Dyspnoea, Wheezing

Symptom Text: Information has been received from a physician concerning a 17 year old female with no known allergies who in the first week of March 2008, was vaccinated intramuscularly with the first dose of GARDASIL vaccine (yeast). Two hours after dose given the patient developed cough, shortness of breath and wheezing. The patient went to emergency room and was given steroids and antibiotic. The patient felt better the next morning (within 24 hours). Subsequently, the patient recovered from cough, shortness of breath and wheezing. It was reported that the patient will most likely not be getting second dose of GARDASIL vaccine (yeast) (also reported as discontinued). It was unknown if the symptoms were related to GARDASIL vaccine (yeast) or not. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318973-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Apr-2008	25-Apr-2008	7	11-Jul-2008	22-Aug-2008	TX	WAES0806USA00620	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lip swelling, No reaction on previous exposure to drug, Oedema mouth, Oedema peripheral, Pruritus, Swelling face, Urticaria

Symptom Text: Information has been received from a physician and the mother of a 15 year old female with attention deficit/hyperactivity disorder, allergies to penicillin, erythromycin, amoxicillin, azithromycin, PHENERGAN with CODEINE, SILVADENE, and PROMETHAZINE with CODEINE), who on 19-FEB-2008 was vaccinated intramuscularly with her first dose of GARDASIL (Lot # 659962/1740U; site not reported). On 18-APR-2008, the patient was vaccinated intramuscularly with her second dose of GARDASIL (Lot # 660387/1967U; site not reported). Concomitant therapy included ADDERALL TABLETS and ORTHO EVRA. It was reported that the therapy with ORTHO EVRA started "concomitantly with the vaccine" (reported as on 18-APR-2008, 20-APR-2008 and 21-APR-2008). On approximately 25-APR-2008 (also reported as 27-APR-2008 and "within one week of the vaccine") the patient developed hives all over her body. The next morning, 26-APR-2008, the patient had swelling in her hands and feet and the patient was treated with ALLEGRA and prednisone (unspecified). On 27-APR-2008, the patient developed swelling on her face, mouth and lips. On 27-APR-2008, the patient went to the emergency room for outpatient treatment and received a "steroid shot" (not further specified), BENADRYL and ZANTAC. "The itching persisted for a little while and then all symptoms resolved" (date unspecified). On approximately 27-APR-2008, the patient discontinued therapy with ORTHO EVRA. It was reported that the patient had no adverse effects or problems with the first dose of GARDASIL. The physician suspected that the reactions were related to GARDASIL OR ORTHO EVRA. Additional information has been requested.

Other Meds: ADDERALL TABLETS; ORTHO EVRA

Lab Data: Unknown

History:

Prex Illness: Attention deficit/hyperactivity disorder; Penicillin allergy; Drug hypersensitivity; Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318974-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		11-Jul-2008	22-Aug-2008	--	WAES0806USA00596	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Myalgia

Symptom Text: Information has been received from a female who was vaccinated with a dose of GARDASIL vaccine (yeast). The patient stated she has experienced fatigue and muscle pain since receiving the vaccination. At the time of the report, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318975-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Aug-2007	Unknown		11-Jul-2008	22-Aug-2008	--	WAES0806USA00593	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nasopharyngitis

Symptom Text: Information has been received from a mother concerning her 19 year old daughter with pollen allergy who in AUG-2007 was vaccinated with a first dose of GARDASIL. Concomitant therapy included allergenic extract. She never received the second dose because when she was scheduled she had a bad cold. The patient did not seek medical attention. At the time of the report, the patient recovered from the bad cold. This one of two reports from the same source. Additional information is not expected.

Other Meds: allergenic extract

Lab Data: Unknown

History:

Prex Illness: Pollen allergy

Prex Vax Illns:

Vaers Id: **318977-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Jul-2008	16-Jul-2008	FR	WAES0807USA01472	16-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crohns disease, Erythema nodosum

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL on an unspecified date. On an unspecified date the patient developed an erythema nodosum. On an unspecified date, Crohn's disease was diagnosed. At the time of reporting, the outcome was not specified. Crohn's disease was considered to be an other important medical event. Other business partner numbers included E2008-06390. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318978-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Mar-2007	17-May-2007	77	15-Jul-2008	16-Jul-2008	VA	WAES0706USA03490	16-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0187U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed practical nurse, for the Pregnancy Registry for GARDASIL concerning a 25 year old female with a history of dysplasia and loop electrosurgical excision procedure (LEEP performed in 2003) and no drug reactions and allergies who on 01-MAR-2007 was vaccinated with GARDASIL (lot number 656049/0187U) 0.5 ml IM. Concomitant therapy included NUVARING and LEXAPRO. The nurse reported that on 13-JUN-2007 the patient was vaccinated with another dose of GARDASIL (Lot number 657737/0522U) 0.5 mL IM. Medical attention was sought. On 13-JUN-2007 a beta-human chorionic gonadotropin test (unspecified) was performed and the results were positive for pregnancy. No symptoms have been reported. No further information is available. The date of the last menstrual period is 17-MAY-2007. The estimated date of delivery is 21-Feb-2008. Follow-up information was received via telephone from a licensed practical nurse. The patient had an early spontaneous miscarriage at 6+ weeks EGA. Additionally it was reported that the patient had been using the NUVARING when the patient conceived. Upon internal review spontaneous abortion was considered to be an other medical event. Additional information is not expected.

Other Meds: LEXAPRO; NUVARING

Lab Data: beta-human chorionic, 06/13/07 - positive

History: Dysplasia; Loop electrosurgical excision procedure

Prex Illness: Pregnancy NOS (LMP = 5/17/2007); Contraception

Prex Vax Illns:

Vaers Id: **318979-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-May-2008	15-May-2008	2	15-Jul-2008	16-Jul-2008	FR	WAES0807USA01191	16-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Vascular purpura

Symptom Text: Information has been received from the health authority (reference # MA20081028) concerning a 15 year old female with a history of purpura and rheumatoid in her childhood, who on 13-MAR-2008 was vaccinated with a first dose of GARDASIL (batch# not reported). On 13-MAY-2008 the patient was vaccinated with a second dose of GARDASIL (batch# not reported). On 15-MAY-2008 purpuric lesions appeared. On 20-MAY-2008, the patient complained of articular pain in the knees and ankles. On 25-MAY-2008, during a medical exam the lesions were observed on legs and ankles. No fever was experienced, neither alteration of her general health status nor adenopathy and thrombocytopenia were observed. On 04-JUN-2008, the lesions persisted. A check-up with dermatologist was scheduled. At the time of the report, the patient did not recover. The reporter considered purpura vascular and polyarthralgia to be other important medical events. Other business partner numbers included: E2008-06353 and MA20081028. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Purpura; Rheumatoid arthritis

Prex Illness:

Prex Vax Illns:

Vaers Id: **318980-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Apr-2008	28-Apr-2008	6	15-Jul-2008	16-Jul-2008	FR	WAES0807USA01407	16-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Basedows disease

Symptom Text: Information has been received from the health authority concerning a 16 year old female who on 22-APR-2008 was vaccinated with a dose of GARDASIL (batch # not reported). On 28-APR-2008, clinical diagnosis was established during consultation and the scintigraphy confirmed basedow's disease. The patient was treated with NEO-MERCAZOLE and was under observation. On 06-MAY-2008 biological values showed: T4L 38.5 (N=<18) - anti-Tg antibodies (thyroglobulin) 8987 (N=<50); T3L 19.6 (N=<3.8) - anti-TPO antibodies (thyroid peroxidises) 94 (N=<60). At the time of the report, the patient did not recover. The reporter considered basedow's disease to be an other important medical event. Other business partner numbers included: E2008-06317 and CF20080290. No further information is available.

Other Meds: Unknown

Lab Data: radionuclear scan, 28Apr08, Basedow's disease and hyperthyroidy; serum antithyroglobuin antibody, 06May08, 8987; serum antithyroid peroxidase antibody, 06May08, 94; total serum thyroxine, 06May08, 38.5; total serum triiodothyronine test, 06

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318981-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-May-2008	16-May-2008	0	15-Jul-2008	16-Jul-2008	FR	WAES0807USA01409	16-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Dysgraphia, Headache, Hypoaesthesia, Injected limb mobility decreased, Muscle spasms, Nausea, Paraesthesia, Paresis, Sensorimotor disorder, Skin warm

Symptom Text: Information has been received from health authorities concerning a 16 year old female patient with a history of appendicectomy who on 16-MAY-2008 was vaccinated with a second dose of GARDASIL (batch number not reported) in the right arm, via intramuscular route. Shortly after vaccination, occurred nausea and headache which resolved spontaneously within a few hours. Two days after occurred paresis and hypoesthesia of the right upper limb where the vaccination was performed. Following the twenty four hours sensitomotor deficiency increased with impossibility to mobilise the right arm, important hypoesthesia for warmth, pain and touch. Only a deep pressure was observed. Ten days later, deficiency started to resolve with still the inability to write. There was also paresthesia type of electric shock and muscular spasms. Electromyography was normal as MRI. On 10-JUN-2008, the patient was recovering from motor and sensitive but there was a presence of hypoesthesia especially at forearm. On 23-JUN-2008 the patient used her arm normally and did not complain anymore. The reporter considered hypoesthesia, paresthesia, muscular spasm, paresis, nausea, headache, mobility decreased and sensorimotor disorder to be disabling. Additional information was not available. Other business partners included are: E2008-06346.

Other Meds: Unknown

Lab Data: electromyography, normal; magnetic resonance imaging, normal

History: Appendicectomy

Prex Illness:

Prex Vax Illns:

Vaers Id: **318984-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	08-May-2008		11-Jul-2008	22-Aug-2008	--	WAES0806USA01291	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse for the Pregnancy Registry for GARDASIL vaccine (yeast) concerning a 22 year old female with sulfonamide allergy who on 04-DEC-2007 was vaccinated IM with the first 0.5 ml dose of GARDASIL vaccine (yeast) (Lot # not reported). On an unspecified date the patient was vaccinated with a second dose (Lot # not reported). On 05-JUN-2008, the patient was vaccinated with the third dose of GARDASIL vaccine (yeast) (Lot # not reported) then the office discovered that she was pregnant (LXP: 08-MAY-2008). The office performed a pregnancy test prior to the administration of the vaccine that demonstrated a "weak positive". Then after the vaccination a second pregnancy test was performed that displayed a positive result. No adverse effects reported. Concomitant therapy included hormonal contraceptives (unspecified). Unknown medication attention was sought in the office. The outcome was not reported. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: urine beta-human - 06/05/08 - weak, urine beta-human - 06/05/08 - posit

History: LMP = 5/8/2008, Sulfonamide allergy

Prex Illness: Pregnancy NOS

Prex Vax Illns:

Vaers Id: **318985-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		11-Jul-2008	22-Aug-2008	--	WAES0806USA01284	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myalgia

Symptom Text: Information has been received from a female consumer who was vaccinated with the first and second dose of GARDASIL. Patient reported that she experienced muscle pain after receiving the first two doses of GARDASIL and does not plan on receiving the third dose. The outcome was not reported. This case is lost to follow. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318986-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Jun-2008	05-Jun-2008	0	11-Jul-2008	22-Aug-2008	OH	WAES0806USA01213	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Syncope

Symptom Text: Information has been received from an office manager concerning a 14 year old female who on 05-JUN-2008 was vaccinated with GARDASIL (dose and lot# not reported). On 05-JUN-2008, moments after vaccination, the patient felt nauseous lightheaded and fainted. No injuries were reported. Patient was monitored and taken by wheel chair to the car. The patient sought medical attention in the doctor's office. The patient outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318987-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	05-Jun-2008	05-Jun-2008	0	11-Jul-2008	22-Aug-2008	NY	WAES0805USA01147	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Accidental exposure, Device malfunction, No adverse event

Symptom Text: Information has been received from a registered nurse who reported an ocular exposure with GARDASIL vaccine (lot# not reported) on 05-JUN-2008 caused by a syringe malfunction while administering the vaccine to the patient. This was not a GARDASIL vaccine pre-filled syringe. The nurse is not experiencing any problems with her eyes. Patient outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318988-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Dec-2007	27-Dec-2007	0	11-Jul-2008	22-Aug-2008	GA	WAES0806USA01134	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a medical assistant concerning a 15 year old female who on 27-DEC-2007 was vaccinated with GARDASIL vaccine (lot# unspecified). There was no concomitant medication. It was reported that on the same day the PAP test was performed and that the results showed a "lot-grade" abnormality. No other information was available. Additional information has been requested.

Other Meds: None

Lab Data: Pap test 12/27/07 - "low-grade" abnormality

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318989-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	24-Jul-2007	24-Jul-2007	0	11-Jul-2008	22-Aug-2008	NE	WAES0806USA01071	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event

Symptom Text: Information has been received from a a registered nurse concerning a female who on 19-Feb-2007 and 34-Jul-2007, was vaccinated intramuscularly with 0.5 mL of her first and second doses, respectively, of GARDASIL vaccine (lot#s unspecified). No adverse event reported. At the time of this report, the outcome was unknown. No additional information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318990-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Apr-2007	07-Apr-2008	366	11-Jul-2008	22-Aug-2008	CT	WAES0806USA01067	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0314U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Feeling abnormal, Somnolence

Symptom Text: Information has been received from a physician concerning a 17 year old female with asthma, hypersensitivity (NOS) and menstrual cramps who on 08-AUG-2006, 19-Oct-2006 and 07-Apr-2007, was vaccinated with first (lot# unspecified), second (lot#653938/0954F) and third (lot#657005/0314U) doses, respectively, of GARDASIL vaccine. Concomitant therapy maybe included LOESTRIN, albuterol and ANAPROX. It was reported by patient's mother that since the third dose the patient sleeps too much, is tired and is "foggy." Unspecified medical attention was sought by calling office. At the time of this report the patient had not recovered. Additional information has been requested.

Other Meds: albuterol; LEOSTRIN; ANAPROX

Lab Data: None

History:

Prex Illness: Asthma; Hypersensitivity; Menstrual cramps

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318991-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		11-Jul-2008	22-Aug-2008	WA	WAES0806USA01057	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL vaccine. The physician reported that the patient experienced pruritus and itchiness after receiving GARDASIL vaccine. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318992-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	05-Jun-2008	05-Jun-2008	0	11-Jul-2008	22-Aug-2008	--	WAES0806USA01039	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Feeling abnormal, Lethargy, Nausea

Symptom Text: Information has been received from a physician assistant concerning a 23 year old female with penicillin allergy and allergic reaction to CECLOR who on 05-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (LOT# 660387/2967U) 0.5 mL, intramuscularly in left deltoid. There was no concomitant medication. The physician assistant reported that on 05-JUN-2008, the patient experienced dizziness, lethargy, nausea and detached feeling following vaccination. The patient received the GARDASIL vaccine, walked 10 minutes through heat and then about 1 hour after vaccination experienced the dizziness, lethargy, nausea and detached feeling that lasted for 30 minutes. The patient returned to the physician assistant's office and was still experiencing some nausea 3 hours after vaccination. At the time of the report the patient was still recovering. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy; Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318994-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	02-Oct-2007	Unknown		11-Jul-2008	22-Aug-2008	NY	WAES0806USA00972	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, No reaction on previous exposure to drug, Paraesthesia

Symptom Text: Information has been received from a nurse practitioner concerning a 24 year old female with no illness at the time of vaccination, no drug allergies/reactions or pertinent medical history who on 02-OCT-2007 was vaccinated with a first dose GARDASIL vaccine in the left deltoid at 5 PM. On 10-DEC-2007, the patient had a second dose of GARDASIL vaccine (lot # 659441/1446U) in the left deltoid at 5 PM. On 10-APR-2008, the patient had a third dose of GARDASIL vaccine (lot# 659180/1758U) in the left deltoid at 9 AM. There was no concomitant medication. Subsequently, the patient reported tingling and numbness in fingers of both hands for 3 days after each administration of the vaccine. The symptoms resolved spontaneously. The patient was evaluated by her primary care physician after the second dose. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **318995-1 (S)** **Related reports:** 318995-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	08-Jul-2008	08-Jul-2008	0	15-Jul-2008	22-Jul-2008	KS		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Loss of consciousness, Presyncope, Syncope

Symptom Text: Syncope, repeat episodes over an hour, observation o/n in hospital. 7/21/08-records received for DOS 7/8-7/9/08-DC DX-Syncope episode, status post Gardasil, resolved. After receipt of vaccine, presyncopal and then passed out time 3.

Other Meds: Albuterol Inhaler PRN; Paroxetine Hcl PO 20 mg two tablets daily

Lab Data: None 7/21/08-records received-Drug screen negative.

History: Depression

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **318995-2 (S)** **Related reports:** 318995-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	08-Jul-2008	08-Jul-2008	0	18-Aug-2008	29-Sep-2008	KS	WAES0807USA02624	29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a LPN concerning a 25 year old female with penicillin allergy and no illness at time of vaccination who on 08-JUL-2008, 2:30 pm was vaccinated with the first dose of GARDASIL (Lot# 660553/0070X) via IM. On 08-JUL-2008, 2:50 pm the patient experienced syncope, repeat episodes over an hour and was in observation in hospital overnight for one day. On 09-JUL-2008, the patient recovered from syncope. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **318996-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Apr-2008	28-Apr-2008	0	11-Jul-2008	22-Aug-2008	OH	WAES0806USA00923	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, No adverse event

Symptom Text: Information has been received from a registered nurse concerning a 16 year old female with a history of atypical pap smear with high risk human papillomavirus prior to vaccination on 28-FEB-2008, who on 28-APR-2008 was vaccinated intramuscularly in the left deltoid with GARDASIL vaccine. There was no concomitant medication. The nurse reported that the patient is now pregnant and no problems were reported. The reporter also noted that the patient had an ultrasound and a blood pregnancy test. The patient's last menstrual period was 07-APR-2008 and has an estimated due date of 12-JAN-2009. The patient sought medical attention for pregnancy follow up. No other information was reported. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound-pregnant; (blood) beta-human chorionic-pregnant

History: Papanicolaou smear abnormal

Prex Illness:

Prex Vax Illns:

Vaers Id: **318998-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	04-Jun-2008	04-Jun-2008	0	11-Jul-2008	22-Aug-2008	MA	WAES0808USA00919	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: Information has been received from a licensed practical nurse concerning a patient who in January 2006, was vaccinated with the first dose of GARDASIL vaccine (lot#, dose and route not reported). On 04-JUN-2008, the patient was vaccinated with the second dose of GARDASIL vaccine (lot# dose and route not reported). No adverse events were reported. No other information was available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **318999-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	21-May-2008	21-May-2008	0	11-Jul-2008	22-Aug-2008	PA	WAES0806USA00909	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Headache, Syncope

Symptom Text: Information has been received from a physician concerning an 18 year old female with mild hypertension and a history of mildly elevated aspartate aminotransferase and increased cholesterol who on approximately 21-MAY-2008 was vaccinated intramuscularly with GARDASIL vaccine (lot # and dose not reported). Secondary suspect therapy included lisinopril (manufacturer unknown). Two weeks ago approximately 21-MAY-2008 when she received the vaccine, the patient experienced quick fainting episode. She was well for one week. The physician reported that for the past week, the patient has had a persistent frontal headache, dizziness and fatigue that seems worsening. The physician noted that the patient was not previously being treated for the hypertension and that the patient's primary care physician thought that the headache might be due to her hypertension. The patient underwent a head CT and CT angiogram, and labs including thyroid test and CBC for which the results were reported as all being normal. On 03-JUN-2008, the reporting physician started the patient on lisinopril (manufacturer unknown). The patient's headache and dizziness did not change after she was started on lisinopril (manufacturer unknown). Additional information has been requested.

Other Meds: Unknown

Lab Data: head computed axial - Normal; angiography - Normal; complete blood cell - Normal; thyroid function test - Normal

History: Aspartate aminotransferase increased; Cholesterol levels raised

Prex Illness: Hypertension

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319000-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Jun-2008	02-Jun-2008	0	11-Jul-2008	25-Aug-2008	MO	WAES0806USA00865	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Axillary pain, Hyperhidrosis, Injection site pain, Nausea, Pain, Pyrexia, Vomiting

Symptom Text: Information has been received from a physician concerning a 14 year old female who on approximately 02-JUN-2008 was vaccinated in her right deltoid with GARDASIL vaccine (yeast) (lot #, and dose not reported). Concomitant therapy included meningococcal AVYW conj vaccine (dip toxoid) (MENACTRA). The physician reported that the patient experienced excessive pain that radiated to her armpit. That night the patient was sweating, had nausea, and was vomiting. The physician noted that the patient also had a fever of 102 and shooting pain that went across her abdomen. The physician also stated that when the patient came back in the office for a check up she still had a lot of pain at the injection site. Medical attention was sought by the patient. No further information was provided. Additional information has been requested.

Other Meds: MENACTRA

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319001-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	29-Apr-2008	30-Apr-2008	1	11-Jul-2008	25-Aug-2008	--	WAES0806USA00860	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass

Symptom Text: Information has been received from a physician assistant concerning a 21 year old female patient with no drug allergies or medical history reported, who on 29-APR-2008 was vaccinated intramuscularly into the left deltoid with the first dose of GARDASIL vaccine (yeast). On approximately 30-APR-2008, within a few days of receiving her initial dose, the patient developed a pea sized lump at the injection site. At the time of this report the patient had not recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319004-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-Jul-2008	09-Jul-2008	0	15-Jul-2008	22-Jul-2008	WI		23-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2864AA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB216AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1740U	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2426AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Myalgia, Nausea, Vomiting

Symptom Text: Nausea, muscle aches, headache onset at 2200 on 10-9-08. Emesis x 2 during the night. Mom using TYLENOL for comfort.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319009-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	02-Jul-2008	03-Jul-2008	1	15-Jul-2008	23-Jul-2008	CA		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2936BA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2572AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0063X	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	0336X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Loss of consciousness, Syncope

Symptom Text: Weakness and syncope. LOC x several minutes. Symptoms resolved.

Other Meds:

Lab Data: CBC, Electrolytes - normal.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319012-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	08-Jul-2008	08-Jul-2008	0	15-Jul-2008	23-Jul-2008	MS		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1263U	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2543AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2842AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling abnormal, Immediate post-injection reaction, Urticaria

Symptom Text: Client complained of lightheadedness and feeling bad immediately after injection. Whelps noted on chest and back. BENADRYL 2 teaspoon by mouth and PRELONE 2 teaspoons by mouth.

Other Meds:

Lab Data: EKG

History:

Prex Illness: Elevated blood pressure

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319017-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	09-Jun-2008	30-Jun-2008	21	15-Jul-2008	23-Jul-2008	MO		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Headache, Urticaria

Symptom Text: Severe hives began 6/30/08. Received Gardasil #2 6/9/08. Hives several days = at office with hives, chills and headache 7/9/08 = 10 days.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **319021-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jul-2008	04-Jul-2008	3	15-Jul-2008	23-Jul-2008	WI		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bronchitis, Dyskinesia, Eye rolling, Fatigue, Loss of consciousness, Malaise, Syncope

Symptom Text: 3 days after 2nd HPV (2/28/08), she had a syncopal episode. She was also ill at time, seen in clinic and diagnosed with bronchitis. 3 days after 3rd HPV (7/1/08), she was sitting in a chair, said "I don't feel well", then mom saw her eyes roll back. She had LOC. Mom noted brief jerking of arms and legs. Within 1 minute she was alert and coherent. Felt tired rest of day. No illness. Felt was prior two days.

Other Meds:

Lab Data:

History: None known

Prex Illness: No

Prex Vax Illns: Syncope~HPV (Gardasil)~2~15~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319024-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	08-Jul-2008	08-Jul-2008	0	15-Jul-2008	23-Jul-2008	MO		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Dizzy, light headed.

Other Meds: Depakote - ER; YAZ/Florinef

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 319029-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	11-Apr-2008	19-Apr-2008	8	15-Jul-2008	23-Jul-2008	NC		18-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Areflexia, Dysstasia, Ear infection, Fall, Gait disturbance, Muscle spasms, Muscle strain, Muscular weakness

Symptom Text: Approximately one week after receiving the third dose of the HPV vaccine on April 11, 2008, patient developed cramping in both calves which became increasingly severe, resulting in difficulty walking, inability to stand on the balls of her feet, and loss of reflexes in both ankles and knees as determined by a physical therapist. Patient was seen by a neurologist several days later who found no neurological abnormalities in his exam of her and diagnosed her with "muscle strain of the backs of her legs." Patient is continuing to experience problems with her legs, some days being better than others. Every morning she wakes up with cramping of the calves, and some days she is able to "walk it off," and other days her legs hurt all the time. She is a musical theatre graduate and makes her living singing and dancing. She has been unable to dance since her calves have been affected. Approximately two weeks after the second dose of the HPB vaccine the end of December, 2007, patient experienced ankle weakness which resulted in falling frequently, and she was seen by an orthopaedic surgeon in April 2008 when her ankles did not improve. The orthopaedic surgeon recommended physical therapy for "floppy ankles." It was after the third dose of the vaccine as described in the paragraph above when she experienced problems with her calves, and which led her to see the physical therapist not only for the floppy ankles, but also for the painful calves. Because patient is not recovering, she has an appointment to see an internist who is also board certified in rheumatology. Now that we are aware of her complications following the HPV vaccine, we will, of course, report this to the internist. 8/6/08-office notes received-patient concerned that inadequate dose was administered. Second dose administered 4/11/08 followed by 3rd dose 4/29/08 lot#1967 12/15/08-records received-consultant visit 10/23/08-C/O muscle aches dating back to march 2008 after an ear infection and vaccine. Aching in claves occur after exercise and interm

Other Meds: LEXAPRO 10mg/day

Lab Data: 4/25/08, cursory exam by physical therapist, no reflexes of ankles, knees, weakness of legs, cramping of calves; 4/28/08, neurological exam by neurologist, normal except for leg cramps 12/15/08-records received-EMG demonstrated significant

History:

Prex Illness:

Prex Vax Illns: very high fever~DTP (no brand name)~UN~1~In Patient

Vaers Id: **319030-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	U	02-Jul-2008	02-Jul-2008	0	15-Jul-2008	23-Jul-2008	NY		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1975U	2	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2604AA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Pyrexia, Vomiting

Symptom Text: Fever, 102 degrees, lightheaded, vomit.

Other Meds:

Lab Data:

History: well

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319032-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	09-Jul-2008	09-Jul-2008	0	15-Jul-2008	23-Jul-2008	HI		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2767AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0092X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0250X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Tremor

Symptom Text: After last immunization given (HPV), pt body shaking approx 5-10 seconds, skin pale, lightheaded, dizzy.

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **319072-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Jul-2008	14-Jul-2008	0	15-Jul-2008	23-Jul-2008	MD		23-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2826AA	0	Left arm	Intramuscular	
IPV	SANOFI PASTEUR	A0273-2	4	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB253BA	1	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0955F	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2329AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Paraesthesia, Syncope, Unresponsive to stimuli, Vomiting

Symptom Text: PT FAINTED AFTER RECEIVING 5 VACCINES: (HPV#1; HAV#2 - RT DELTOID) AND (IPV, MENACTRA, AND TDAP - LT DELTOID). PT SAID RT ARM WAS TINGLING PRIOR TO HER PASSING OUT. PT WAS UNRESPONSIVE FOR APPROX. ONE MINUTE AND ONE EPISODE OF VOMITING AFTER REGAINING CONSCIOUSNESS.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **319080-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	23-Jun-2008	24-Jun-2008	1	15-Jul-2008	23-Jul-2008	AZ	AZ0810	25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anorexia, Dizziness, Nausea, Vaginal discharge

Symptom Text: 6/23/08 Received 1st HPV. Starting 6/24/08 client experienced dizziness, nausea after eating, loss of appetite. Pt was menstruating (1st day) when she received vaccination. At the end of cycle client experienced watery blood, and now water, yellow drainage. Referred to private medical care.

Other Meds:

Lab Data: None

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319097-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Jun-2008	27-Jun-2008	0	15-Jul-2008	23-Jul-2008	PA		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2606AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C2995AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injury, Laceration, Syncope

Symptom Text: Syncopal episode, patient hit lip on desk, splitting it open. Did arouse after about 10 seconds.

Other Meds: None

Lab Data:

History: NKA

Prex Illness: None

Prex Vax Illns:

Vaers Id: **319098-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	03-Jul-2008	04-Jul-2008	1	15-Jul-2008	23-Jul-2008	MA		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2418AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Dizziness (intermittent) for 4 days.

Other Meds:

Lab Data:

History:

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319111-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	25-Dec-2007	Unknown		11-Jul-2008	25-Aug-2008	--	WAES0806USA08555	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event

Symptom Text: Information has been received from a female consumer who on approximately 25-DEC-2007, "around Christmas 2007", was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot no., route and site of administration were not reported). The patient reported that she missed the other two doses of GARDASIL vaccine (yeast) because she could not afford it. No adverse event reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319112-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		11-Jul-2008	25-Aug-2008	CT	WAES0806USA07613	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a physician concerning a multiple patients (no demographics provided) who on unspecified dates were vaccinated with GARDASIL vaccine (yeast) (lot #s unspecified) and had stinging at the injection site. At the time of this report the outcome was unknown. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided when available. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319113-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	03-Apr-2008	03-Apr-2008	0	11-Jul-2008	25-Aug-2008	CT	WAES0806USA01768	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Accidental exposure

Symptom Text: Information has been received from a nurse practitioner who on 03-APR-2008 was administered a first dose of GARDASIL vaccine (yeast) (lot #655327/1287U) to a patient. During administration of the vaccine, the vaccine leaked out of the syringe and ran down the nurse practitioner's arm and hand. The nurse practitioner indicated that she put the needle on the syringe properly and she looked at the syringe after vaccination and didn't notice anything unusual. At the time of the report, the patient's outcome was unknown. The SR# is 1-2829187985.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319114-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	01-May-2008		11-Jul-2008	25-Aug-2008	--	WAES0806USA01377	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a female consumer with a history of papanicolaou smear abnormal who was vaccinated with three doses of GARDASIL vaccine (yeast) (lot numbers not reported). The consumer reported that "even after getting three doses of GARDASIL vaccine (yeast) vaccine last year, I still have abnormal PAP smear results". The consumer stated that "she had abnormal pap smear results before getting vaccinated with GARDASIL vaccine (yeast) last year". The consumer reported that "a recent ASCUS pap smear result just taken in MAY 2008 is abnormal too". The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Pap test - 05/??/08 - ASCUS

History: Papanicolaou smear abnormal

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319115-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		11-Jul-2008	25-Aug-2008	NC	WAES0806USA01375	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a physician concerning his daughter who was vaccinated with a dose of GARDASIL vaccine (yeast) (lot#, dose, site and route not reported). The physician reported that his daughter complained that the injection was painful. The patient's outcome was unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319116-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		11-Jul-2008	25-Aug-2008	TN	WAES0806USA01356	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Menstrual disorder

Symptom Text: Information has been received from a pharmacist concerning a female with a history of liver transplant, salsa allergy and aspirin allergy who began experiencing two menstrual periods each month after receiving two doses of GARDASIL vaccine (yeast) (lot#'s not reported). The patient sought unspecified medical attention in the physician's office. The dates of the GARDASIL vaccine (yeast) injections were not provided and the onset of adverse symptoms was not specified. No other symptoms or treatments were reported and no other information was available. The patient has not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Liver transplant, Hypersensitivity, drug hypersensitivity

Prex Illness:

Prex Vax Illns:

Vaers Id: 319117-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	06-Jun-2008	06-Jun-2008	0	11-Jul-2008	25-Aug-2008	WI	WAES0806USA01326	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Information has been received from a registered nurse concerning a female who on 16-AUG-2007 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot # not reported). On 06-JUN-2008 the patient was vaccinated with a second dose of GARDASIL vaccine (yeast) (lot # not reported). The patient sought unspecified medical attention during the office visit for the second dose. No problems were reported. Patient outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319118-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		11-Jul-2008	25-Aug-2008	--	WAES0806USA01320	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a Nurse Practitioner concerning a female who was vaccinated intramuscularly with a 0.5 mL first dose of GARDASIL vaccine (yeast) (lot # not reported). Subsequently the patient developed severe and prolonged arm pain in the same arm that the vaccine was administered. The pain lasted for a period of two weeks. the patient sought unspecified medical attention by speaking to nurse practitioner. Subsequently, on an unspecified date, the patient recovered from the severe and prolonged arm pain. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319119-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	20-May-2008	22-May-2008	2	11-Jul-2008	25-Aug-2008	CA	WAES0806USA01313	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a consumer concerning her 13 year old daughter with sickle cell anaemia who on 20-MAY-2008 was vaccinated intramuscularly with a 0.5 mL first dose of GARDASIL vaccine (lot # not reported). The consumer reported that "her daughter has been experiencing hair loss since getting her first dose of GARDASIL vaccine. The patient's hair loss persisted (reportedly began "2 or 3 days after vaccination"). There was no concomitant medication. The patient sought unspecified medical attention. The consumer reported that her daughter "will not be continuing the series." Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Sickle cell anaemia

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319120-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	02-Jan-2008	16-Jan-2008	14	11-Jul-2008	25-Aug-2008	PA	WAES0806USA01307	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lip swelling, Oedema peripheral, Rash papular, Swelling face

Symptom Text: Information has been received from a consumer concerning her 19 year old daughter who is "allergic to sulfa" and on 02-JAN-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot # not reported). On 05-MAR-2008 her daughter was vaccinated intramuscularly with a 0.5 mL second dose of GARDASIL vaccine (yeast) (lot # not reported). There was no concomitant medication. The consumer reported that "her daughter experienced swelling after getting the first shot. First her lips swelled up, then her face and then her arms. The swelling usually lasts about 10 hours". The consumer also reported that after the second vaccination, administered on 05-MAR-2008, her daughter developed "sporadic white bumps" on her arms. It was also reported that "after the first time she experienced swelling, she experienced swelling on 21-FEB-2008, 22-FEB-2008, 20-MAR-2008, 26-MAR-2008, 01-APR-2008, 08-APR-2008, 10-APR-2008, 26-APR-2008, 27-APR-2008, 26-MAY-2008, 27-MAY-2008 and 30-MAY-2008. She did not have records of every date she experienced swelling. She is presently not experiencing any swelling. She will not be completing the series. The daughter sought unspecified medical attention. The consumer reported that her daughter's swelling improved after stopping therapy.

Other Meds: None

Lab Data: None

History: Sulfonamide allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **319121-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Apr-2008	01-Apr-2008	0	11-Jul-2008	25-Aug-2008	KY	WAES0806USA01292	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter who in April 2008, was vaccinated IM with the first 0.5 mL dose of GARDASIL vaccine. There was no concomitant medication. The patient felt faint after receiving the vaccine. The patient also fainted after additional blood work was done after she received the vaccine. The patient's mother decided that she will not continue the dosing series. Unknown medical attention was sought. The patient recovered the day after the vaccination. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319266-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	10-Mar-2008	10-Mar-2008	0	11-Jul-2008	02-Sep-2008	PA	WAES0803USA01967	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	VARZOS	MERCK & CO. INC.	NULL		Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: Information has been received from a physician concerning a 13 year old female consumer who on 10-MAR-2008 was inadvertently vaccinated SQ with 0.65mL of zoster vaccine live (Oka/Merck) instead of varicella virus vaccine live (Oka/Merck) (MSD). Concomitant vaccinations included MENACTRA and GARDASIL (MSD). Subsequently, the nursing error was discovered the next day on 11-MAR-2008. Medical attention was sought in the office. At the time of the report the patient's status was unknown. There was no product quality complaint involved. Follow up information from the medical assistant indicated she inadvertently picked up the wrong bottle as both the zoster vaccine live (Oka/Merck) and the varicella virus vaccine live (Oka/Merck) (MSD) were in the same location in the freezer. The medical assistant indicated that both are labeled clearly, it was human error. Follow-up information has been received from the medical assistant concerning this 13 year old white female with rhinitis allergy who on 10-MAR-2008 was inadvertently vaccinated SQ with 0.65mL of zoster vaccine live (Oka/Merck) instead of varicella virus vaccine live (Oka/Merck) (MSD). The medical assistant indicated that the patient has not experienced an adverse event thus far. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Rhinitis allergic

Prex Vax Illns:

Vaers Id: **319284-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Jun-2008	14-Jun-2008	0	16-Jul-2008	17-Jul-2008	FR	WAES0807COL00003	17-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Headache, Injection site pain, Nausea, Oedema peripheral, Pyrexia, Somnolence

Symptom Text: On 14-JUN-2008 a female of 12 year old assisted to a vaccination day and was placed on therapy with GARDASIL, 0.5 ml, first dose. On 14-JUN-2008 the patient experienced injection site pain, fever, nausea, headache, dizziness and somnolence. Subsequently, the patient recovered from fever, nausea, headache and dizziness. At the moment of the report, the patient presented injection site pain to the touch from the elbow to the shoulder and somnolence. She assisted to the emergency room and was prescribed with acetaminophen every 6 hours (dose unknown). Patient's mother reported that the patient since the day of vaccination has been somnolent and her arm is swelled. The reporter felt that injection site pain, fever, nausea, headache and dizziness were related to therapy with GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319286-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Oct-2007	01-Nov-2007	31	16-Jul-2008	17-Jul-2008	--	WAES0807USA01170	22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Autoimmune disorder

Symptom Text: Information has been received from a physician concerning his daughter a 25 year old female who in April 2007, was vaccinated with a first dose of GARDASIL (route and administrating site not reported). In June 2007, the patient was vaccinated with a second dose of GARDASIL (route and administrating site not reported). In October 2007, the patient was vaccinated with a third dose of GARDASIL (route and administrating site not reported). In approximately November 2007, the patient experienced symptoms indicative of autoimmune disorder. Specialists were looking at her having either scleroderma or dermatomycosis. The patient's autoimmune disorder persisted and was considered to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319287-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	29-May-2008	29-May-2008	0	16-Jul-2008	17-Jul-2008	SC	WAES0807USA01553	17-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for the Pregnancy Registry for GARDASIL concerning a female with no pertinent medical history, drug reactions or allergies who on 29-MAY-2008 was vaccinated intramuscularly with a first 0.5 ml dose of GARDASIL. There was no concomitant medication. Subsequently the patient was determined to be pregnant. Her LMP was 08-MAY-2008. Expected date of delivery was 12-FEB-2009. On 09-JUL-2008 the patient was seen in office. A urine pregnancy test was positive for pregnancy and an ultrasound revealed a 6-week fetal gestation. The physician reported that the patient may have had a spontaneous abortion, a miscarriage, as per the ultrasound. Additional information has been requested.

Other Meds: None

Lab Data: Ultrasound, 07/09/08, 6 week fetal gestation, Beta-human chorionic, 07/09/08, positive.

History:

Prex Illness: Pregnancy NOS (LMP = 5/8/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319289-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jul-2008	17-Jul-2008	TX	WAES0807USA01601	17-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Paralysis

Symptom Text: Information has been received from a physician concerning a female with a history of dental procedure in which paralysis occurred who was vaccinated with GARDASIL IM. The patient developed paralysis after vaccination. The patient was considered to be disabling. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Surgical procedure

Prex Illness:

Prex Vax Illns:

Vaers Id: **319292-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Mar-2008	01-Mar-2008	0	16-Jul-2008	17-Jul-2008	CA	WAES0807USA01664	07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature baby, Premature labour

Symptom Text: Information has been received from a physician, for the pregnancy registry for GARDASIL concerning a 15 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL (route and administrating site not reported). In March 2008, the patient was vaccinated with a second dose of GARDASIL (route and administrating site not reported). The patient became pregnant during the GARDASIL series. On approximately 01-JUL-2008 the patient was attempting to get clearance from her physician for a sport physical. The physician insisted on a pregnancy test which was positive. On approximately 07-JUL-2008 the patient delivered and the infant was born at 32 weeks gestation. The infant was placed on a respirator in the Neonatal Intensive Care Unit. Additional information has been requested.

Other Meds: Unknown

Lab Data: beta-human chorionic, 07/01/08, pregnancy

History:

Prex Illness: Pregnancy NOS (LMP = 11/25/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319294-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		16-Jul-2008	17-Jul-2008	--	WAES0807USA01667	17-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Paralysis

Symptom Text: Information has been received from a physician concerning her daughter an 18 year old female who on an unspecified date was vaccinated with GARDASIL. The patient experienced temporary paralysis and was hospitalized. Subsequently, the patient recovered from temporary paralysis. The reporter felt that temporary paralysis was related to therapy with GARDASIL. Temporary paralysis was considered to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319296-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Jul-2008	09-Jul-2008	0	16-Jul-2008	17-Jul-2008	PA	WAES0807USA01668	17-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Loss of consciousness, Muscle twitching, Pallor

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 09-JUL-2008 was vaccinated with a second dose of GARDASIL (lot# 657872/0515U) (route and administrating site not reported). There was no concomitant medication. After receiving the GARDASIL the patient was going to receive a tuberculin purified protein derivative. Right before the patient was going to receive the tuberculin purified protein derivative she passed out and twitched/convulsed for about thirty seconds, when the patient came to she was very dizzy and pale/white. The physician reported that when the patient came to they gave her water and the patient stayed for 15 minutes. She got color back in her face, she was fine and left the office. The physician reported that they did not end up giving the tuberculin purified protein derivative to the patient at all. When the patient received the first dose of GARDASIL she was fine. Upon internal review the twitching/convulsing was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319298-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Oct-2007	01-Apr-2008	154	16-Jul-2008	17-Jul-2008	FR	WAES0807USA01693	07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0859F	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia, Peroneal nerve palsy, Vaccine positive rechallenge

Symptom Text: Information has been received from an internist concerning a 15 year old female who on 21-AUG-2007 was vaccinated with a first dose of GARDASIL (batch# not reported) and was well tolerated. On 30-OCT-2007 the patient received a second dose of GARDASIL (batch# NE29660, lot# 654740/0859F). About 6 months after the second vaccination, approximately April 2007 and prior to the third dose, the patient had experienced a short episode of paresthesia in the leg which had resolved. On 07-MAY-2008 the patient received a third dose (batch# NNH15190/lot# 1114U) intramuscularly into the deltoid muscle. On 23-MAY-2008 the patient developed paresthesia in the face and leg and experienced peroneal paralysis. On 26-JUN-2008, MRI was performed but the results were pending at the time of reporting. The patient had not recovered. The reporter considered paralysis peroneal, paresthesia foot, paresthesia lower limb and facial paresthesia to be other important medical events. Other business partner numbers included: E2008-06192. Additional information is not available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 26Jun08, Comment: MRT results pending

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319299-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	24-Jun-2008		16-Jul-2008	17-Jul-2008	FR	WAES0807USA01420	17-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blindness, Optic neuritis, Visual field defect

Symptom Text: Information has been received from a health professional concerning a 16 year old female with no medical record or family history of eye illness who in late May 2008 or the beginning of June 2008 (exact date not reported) was vaccinated with the second dose of GARDASIL (batch number, site and route not reported). On 24-JUN-2008 the patient suffered a sudden loss of vision in the left eye, bilateral neuritis and defective visual field in both eyes. On 30-JUN-2008, the patient was admitted into the hospital. She is currently still hospitalized and is being treated with corticoids. The patient's symptoms persisted. Other business partner number included: E2008-06263. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **319300-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	28-Jun-2007	08-May-2007	-51	16-Jul-2008	17-Jul-2008	--	WAES0709USA00022	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Foetal distress syndrome, Oligohydramnios

Symptom Text: Information has been received as part of a pregnancy registry from a nurse practitioner concerning a 19 year old female with no prior pregnancies and a history of low grade squamous intraepithelial lesion (LSIL) with a colposcopy and atypical squamous cells of undetermined significance (ASCUS) in May 2007 with her last pap smear who on 28-JUN-2007 was vaccinated with a first dose of GARDASIL (Lot# 657868/0523U). The patient was treated with FLAGYL from 14-JUN-2007 to 21-JUN-2007 for bacterial vaginosis. The nurse reported that the patient was pregnant when she received her first dose of GARDASIL. The patient's last menstrual period (LMP) was 08-MAY-2007 and her estimated date of delivery (EDD) was 12-FEB-2008. No other symptoms were noted. Follow up information has been received from a health professional from the obstetrician's office who reported that on 06-MAR-2008 at 39 weeks estimated gestational age, the patient was induced due to oligohydraminos (amniotic fluid index (AFI) not available). The patient had subsequent non-reassuring fetal heart rate (FHR) tracing which resulted in a primary cesarean section. The patient delivered a healthy and normal male weighing 3065 grams with apgar scores of 8/9. The reporter noted that the patient and the baby were fine at the postpartum visit. Upon internal review, the patient's non-reassuring fetal heart rate resulting in a cesarean section is considered to be an other important medical event. Additional information is not expected.

Other Meds: FLAGYL, 500 mg

Lab Data: beta-human chorionic, 07?/??/07, positive

History: Low grade squamous intraepithelial lesion; Colposcopy; Atypical squamous cells of undetermined significance

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319302-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-May-2007	Unknown		16-Jul-2008	17-Jul-2008	NY	WAES0708USA00911	17-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amniotic cavity infection, Caesarean section, Drug exposure during pregnancy, Live birth

Symptom Text: Information has been received from the Merck Pregnancy Registry via a physician concerning a 16 year old female who in May 2007 was vaccinated with a second dose of GARDASIL. Subsequently, the physician reported that the patient did not know she was pregnant and may have been two months pregnant at the time of the vaccination with GARDASIL. Unspecified medical attention was sought. Follow up information has been received from a nurse who reported that on 19-MAR-2008, the patient delivered a live female by cesarean section. There was a "complicating amniotic infection". The patient was seen by home nursing care after the cesarean section. The nurse could not verify if the delivery was full term, and had no further information. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **319309-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-Jul-2008	07-Jul-2008	0	16-Jul-2008	24-Jul-2008	MN		17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0181U	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2770AA	5	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Akinesia, Asthenia, Dizziness, Feeling abnormal, Generalised erythema, Lethargy, Loss of consciousness, Presyncope

Symptom Text: Pt had vaccinations administered - remained in office for 30 mins after vaccination waiting for other family members to complete their appointments. AT 1:00 am received phone call from mom that pt reported feeling funny and was passing out on her. Advised to return pt to clinic - pt was lethargic, unable to move extremities to clinic. Transferred to ER. 9/16/08-records received for DOS 7/7/08-presented to ED with C/O feeling faint, weak and unable to move, felt flushed and had brief erythema all over. DX-presyncopal episode. Prolonged weakness following number one. Transient weakness status post immunizations.

Other Meds:

Lab Data: 9/16/08-records received-ECG normal.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319310-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	08-Jul-2008	08-Jul-2008	0	16-Jul-2008	24-Jul-2008	VA		30-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Colposcopy, Dizziness, Dysarthria, Headache, Hypersensitivity, Nausea, Retching, Vertigo, Vomiting

Symptom Text: Vaccine administered approx 1347 hr - pt was monitored x 25 min without adverse reaction. On call MD received call that evening from ER in which pt presented with slurred speech and vertigo and N/V. 7/25/08-records received for DOS 7/8/08-presented to ED with C/O dizziness, five hours prior had first injection of Gardasil and colposcopy for abnormal cells. After sleeping for 3 hours she felt like words were slurring drunk like and dizzy, had dry heave, right sided headache. DX: allergic reaction to Gardasil.

Other Meds:

Lab Data: Referred to PCP 7/25/08-records received-Labs WNL. CT scan normal study.

History: Amoxicillin/Penicillin

Prex Illness: None reported/observed

Prex Vax Illns:

Vaers Id: **319358-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	10-Sep-2007	16-Sep-2007	6	16-Jul-2008	21-Jul-2008	IN		23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Altered state of consciousness, Amnesia, Blood pressure increased, Clumsiness, Confusional state, Disorientation, Dizziness, Headache, Hyperhidrosis, Loss of consciousness, Mental status changes, Nausea, Neck pain, Pallor, Sensory loss, Syncope, Syncope vasovagal

Symptom Text: One week after receiving second dose (Sept. 10, 2007)started passing out with no memory. EEG, EKG, catscan, stress test, cardio MRI. Periods of dizziness 5-6 times a day. After third dose (Dec. 31, 2007) 45 minutes periods of now knowing who she was, where she was, who parents, teachers, friends were. Everyday for almost 3 months. Psych tests done, video EEG, brain MRI. All tests negative. All symptoms disappeared May 8, 2008. 08/19/2008 ER record received for DOS 9/16/2008 with DX: Syncopal episode of unclear etiology. Neck strain. Pt was running and felt dizzy and nauseous. Pt didn't arrive at finish line and family went to find. Pt awoke being shaken by family member. Down ~10-15 minutes. C/o neck pain on awakening and mental status changes noted by family. Returned to baseline o/n and d/c home. 8/15/08 Cardiac consult received dated 9/18/07 with f/u 10/12/07 and 1/24/08. DX: syncope, peri-exertional. No heart disease. Vasovagal etiology most likely. Seen for eval of syncopal event 9/16/07. By 10/12/07 visit c/o SOB. Some improvement of dizziness on Florinef. By 1/24/08 experiencing episodes of "spacing out" with dx: altered consciousness-likely vasovagal syncope. elevated BP. No structural heart disease. 9/11/2008 Neuro consult received for OVs 1/29/08 and 3/10/08. No definitive dx but summarized as episodes of transient alterations in awareness, including dizziness, clumsiness and confusion. Syncope, seizures and psychogenic causes are in the differential. Pt experiencing episodes several times daily with occasional 2-3 day periods with none. Pt is pale and confused and cannot feel extremities during. Recent episode began with headache and sweating. not tired after. PE WNL.

Other Meds: none

Lab Data: EEG, EKG, brain and heart MRIs, psych eval. All tests back normal. Labs and Diagnostics: Echo WNL. CT scan brain and C-spine (+) maxillary and R ethmoid sinus disease, otherwise (-). CBC and Chemistry WNL. CPK 276. CKMB 2.2. HCG (-). Dr

History: none. PMH: concussion 4/2006. Foot surgery.

Prex Illness: none

Prex Vax Illns: none~ ()~~0~In Patient|none~ ()~~0~In Sibling|none~ ()~~0~In Sibling

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319368-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Jul-2008	15-Jul-2008	0	16-Jul-2008	25-Jul-2008	TN		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2966AA	0	Left leg	Intramuscular	
	HPV4	MERCK & CO. INC.	0072X	3	Right leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Syncope

Symptom Text: Received Adacel and #1 Gardasil. After receiving the immunizations patient was alert and talkative. Moved from exam table to chair. Nurse observed pt. became very pale. Had her put head down between her legs and then she fainted. used Amonia Inhalant to revive. Patient revived quickly and was examined by MD. Observed for 15 minutes more and was discharged without further incident.

Other Meds: None

Lab Data: Had Hct drawn prior to immunization

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319376-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Jul-2008	16-Jul-2008	0	16-Jul-2008	25-Jul-2008	WI		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1788U	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2543AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	17406	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2864AA	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Hypotonia, Immediate post-injection reaction, Loss of consciousness, Pallor

Symptom Text: Client experienced complete loss of consciousness with associated flaccidity/loss of muscle control within 1 minute of adminstation of Gardasil. Loss of consciousness lasted 1-2 minutes. Lowered client to the floor where she regained consciousness but maintained extreme pallor for the duration of her stay. BP upon recovery 96/64.

Other Meds: none

Lab Data: None

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319379-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Jul-2008	15-Jul-2008	1	16-Jul-2008	25-Jul-2008	TX		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	2	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1348U	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site rash, Injection site warmth

Symptom Text: Generalized rash, approximately 2 inches in diameter at location where subcutaneous injection was given in right arm. Rash slightly raised, soreness at location of rash, and rash warm to the touch. Varicella vaccine given on 7/14/08 and did not notice rash until 7/15/08 per patient.

Other Meds: Patient takes claritin occassionally for seasonal allergies.

Lab Data: none

History: none

Prex Illness: Seasonal allergies - stuffy nose, sneezing. No report of fever or any other illness at time of vaccination.

Prex Vax Illns: none~ ()~NULL~~In Patient

Vaers Id: **319382-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-May-2008	Unknown		16-Jul-2008	25-Jul-2008	KS		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal distension, Anger, Crying, Death of relative, Irritability, Menarche, Menstruation irregular, Mood swings, Stress

Symptom Text: Within first week after vaccination patient started having symptoms of increased moodiness, anger outburst, irritability, bloating, tearfullness. Started menses 5/30/08 (day of vaccination) Patient states she has continued to have these symptoms periodically over the last 2 months. She also feels her periods have become irregular since getting the shot. Menarche, however was 2/2008 and pt reported irregular cycle the month prior. Patient also has had many stressors recently, with maternal grandmother recently passing. Patient in counselling and counselor is the one who states that she has had several clients with increased anger outburst and mood swings since receiving gardasil. Currently patient states she is not having any anger or mood issues, still complains of bloating. LMP 7/9/08

Other Meds: neobenz 5.5% apply to affected areas qd

Lab Data: TSH, free T4 and comprehensive panel pending

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319384-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Jul-2008	02-Jul-2008	0	16-Jul-2008	25-Jul-2008	CA		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0245U		Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2572AA		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Malaise, Somnolence, Upper respiratory tract infection

Symptom Text: Pt describes symptoms as occurring after 3rd Gardasil injection. Also received meningococcal vaccine on same day. Symptoms include headache, dizziness, URI symptoms, goggy feeling, malaise for 7 days. Improved for 3 days then symptoms reoccurred. Vaccines administered on July 2, 2008. Outpatient clinic visit on 15 July.

Other Meds: None

Lab Data: None at this time

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **319399-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Jul-2008	15-Jul-2008	0	16-Jul-2008	24-Jul-2008	FL		24-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Disorientation, Dizziness, Hyperhidrosis, Pallor, Skin discolouration

Symptom Text: Sweating/perspiration, discoloration (pallor), dizziness, disorientation. BP 100/62 patient laid down ammonia capsule administered.

Other Meds: YAZ

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **319403-1** **Related reports:** 319403-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Jun-2008	19-Jun-2008	0	16-Jul-2008	25-Jul-2008	PA		01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	3	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Feeling of body temperature change, Headache, Hot flush, Hyperhidrosis, Inappropriate schedule of drug administration, Migraine, Muscle spasms, Muscular weakness, Pain in extremity

Symptom Text: Headaches severe, hot-cold flashes, muscle weakness, sweats, fatigue, pains in leg. Was given 4th shot by mistake. 7/31/2008 MR received for 2 OV's 6/27/08 and 7/9/08 with DX: Fatigue. Pt reports hot flashes, sweats, migraines, leg cramps and fatigue which began after receipt of 4th HPV4 vax (given in error). PE WNL. MD reports no obvious relation between vaccine and fatigue. Seen again 7/9/08 with same c/o. MD reports no physical abnormalities found.

Other Meds:

Lab Data: ANA 113. CBC with WBC 4.6.

History: Seizures

Prex Illness: None

Prex Vax Illns:

Vaers Id: **319403-2** **Related reports:** 319403-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Jun-2008	19-Jun-2008	0	17-Jul-2008	12-Sep-2008	PA	WAES0806USA07785	24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	3	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Feeling of body temperature change, Headache, Inappropriate schedule of drug administration, Sensation of heaviness

Symptom Text: Information has been received from a consumer concerning her granddaughter a 16 year old female patient with no allergies and a history of seizures who in approximately November 2007, was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot number, route and site of administration not reported). In June 2008 the patient was vaccinated accidently with the fourth dose of GARDASIL vaccine (yeast) 0.5 ml (lot number, route and site of administration not reported) by nurse at office. Concomitant therapy included oxcarbazepine (TRILEPTAL) and therapy unspecified for birth control. On 19-JUN-2008 the patient experienced headaches, a feeling as if her muscles were heavy and hot and cold flash. The patient's headaches and a feeling as if her muscles are heavy and hot and cold flash persisted. The patient sought medical attention. Additional information has been requested.

Other Meds: therapy unspecified, TRILEPTAL

Lab Data: None

History: Convulsion

Prex Illness:

Prex Vax Illns:

Vaers Id: **319405-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	09-Jul-2008	Unknown		16-Jul-2008	24-Jul-2008	IN		24-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB284CA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2492BA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0511X	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Medication error

Symptom Text: None. Pt had chicken pox as infant, was given varicella vaccine today.

Other Meds:

Lab Data:

History: Had chicken pox as infant - gave vaccine in error

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319406-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	24-Jan-2007	Unknown		16-Jul-2008	24-Jul-2008	UT		24-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Chronic leg pain. ? First complain my have preceded (9/7/05) but increased over past 4 checks.

Other Meds:

Lab Data: Evaluate by orthopedics hosp & rheumatology

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **319459-1** **Related reports:** 319459-2; 319459-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Jun-2008	30-Jun-2008	6	17-Jul-2008	18-Jul-2008	NY	WAES0807USA02186	02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Clonus, Convulsion, Headache, Loss of consciousness, Neck pain, Tonic clonic movements

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a third dose of GARDASIL IM. One week after the third dose the patient experienced a seizure. Subsequently, the patient recovered from the seizure. Upon internal review, the seizure was considered to be an other important medical event. Additional information has been requested. 12/31/08-records received for DOS 6/30/08-presented after sudden loss of consciousness with tonic and clonic movements and spontaneous resoltuion. C/O headache not present prior to event, right lateral neck pain present prior to event. Assessment:new onset seizure.

Other Meds: Unknown

Lab Data: Unknown 12/31/08-records received-CT scan normal.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319459-2 (S)** **Related reports:** 319459-1; 319459-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	24-Jun-2008	30-Jun-2008	6	29-Sep-2008	06-Oct-2008	NY		06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Confusional state, Convulsion, Heart rate increased, Hypertension, Inappropriate schedule of drug administration, Loss of consciousness

Symptom Text: 6 days after receiving the 2nd Gardasil vaccine, I had a seizure and was rushed to St. Vincent's hospital. Before the seizure, I did not have any signs or symptoms of anything wrong. I went to school and work as usual up until the event. The seizure took place around 3:00 on June 30, 2008. After receiving treatment (oxygen) from the EMTs, I regained consciousness and was very confused. In the emergency room, I had unusually high blood pressure and rapid heart beat. I was admitted to St. Vincent's hospital (Manhattan) where I had a blood test, EEG, MRI, saw a cardiologist, and received a heart monitor. All tests came back normal, therefore no treatment/medication was administered by my Neurologist.

Other Meds: None

Lab Data: At the request of the attending Neurologist, I had an MRI, heart monitor, blood test, EEG and saw a cardiologist. Upcoming tests include following up with cardiologist and a sleep deprived EEG test per Neurologist recommendation.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **319459-3 (S)** **Related reports:** 319459-1; 319459-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	24-Jun-2008	30-Jun-2008	6	28-Oct-2008	29-Oct-2008	--	WAES0810USA03694	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Confusional state, Convulsion, Heart rate increased, Hypertension, Inappropriate schedule of drug administration, Loss of consciousness, Oxygen supplementation

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 28 year old female patient with no medical history reported and no known drug allergies who on 24-JUN-2008, was vaccinated with her second dose of GARDASIL (Lot # not reported) into the left arm. There was no concomitant medication. On 30-JUN-2008, 6 days after receiving the second dose, the patient had a seizure and was rushed to the hospital. Before the seizure, the patient did not have any signs or symptoms of anything wrong. The patient went to school and work as usual up until the event. The seizure took place around 1500 PM on 30-JUN-2008. After receiving treatment (oxygen) from the EMTs, the patient regained consciousness and was very confused. In the emergency room, the patient had unusually high blood pressure and rapid heart beat. The patient was admitted to the hospital where the patient has a blood test. Electroencephalogram (EEG), Magnetic Resonance Imaging (MRI), saw a cardiologist and received a heart monitor. All test came back normal, therefore no treatment/medication was administered by my neurologist. Upcoming test include following up with cardiologist and a sleep Electroencephalogram (EEG) test per neurologist recommendation. The listing also indicated that one or more of the events was life-threatening. This was originally reported by a consumer. VAERS ID # 319459. No further information is available.

Other Meds: Unknown

Lab Data: diagnostic laboratory, blood test: normal; electroencephalography, normal; magnetic resonance, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319460-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	18-Jul-2008	--	WAES0807USA02185	18-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness

Symptom Text: Information has been received from a physician assistant concerning a female, a patient's friend, who was vaccinated with GARDASIL in a different office and suffered blindness. She recovered a little but still had the symptom. Upon internal review the blindness was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 319461-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	17-Jun-2008	24-Jun-2008	7	17-Jul-2008	18-Jul-2008	FR	WAES0807USA01933	18-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1068U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Contraception, Monoparesis, Pain in extremity

Symptom Text: Information has been received from a gynaecologist concerning a 19 year old female who on 17-JUN-2008 was vaccinated with a first dose of GARDASIL (lot # 1068U; batch number NG42070) IM into the left upper arm on 17-JUN-2008. Concomitant therapy included hormonal contraceptives (unspecified) for systemic use. The patient developed painful monoparesis in the left arm one week post vaccination. The patient was hospitalized from 04-JUL-2008 to 07-JUL-2008. In hospital suspicion of neuritis of brachial plexus with monoparesis of the left arm was diagnosed. Clinical examination revealed weakness of elevation and abduction of the left arm (power degree 4). The MRI and CSF showed normal results. The symptoms were treated with PREDNISOLON and NEXIUM and the symptoms resolved completely within 2 days. The patient was discharged from the hospital completely recovered. The treatment with PREDNISOLON was stopped step by step after discharge. File closed. No further information was available. The other business partners included are: E2008-06375.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: magnetic resonance imaging, 24?Jun08, Comment: normal; cerebrospinal fluid analysis, 24?Jun08, Comment: normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319462-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Apr-2008	25-Apr-2008	0	17-Jul-2008	18-Jul-2008	MO	WAES0807USA01540	18-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal stiffness, Partial seizures, Staring, Unresponsive to stimuli

Symptom Text: Information has been received from a Licensed Practical Nurse (L.P.N.) concerning a 16 year old female patient who on 25-APR-2008 was vaccinated with a first dose of GARDASIL. The nurse reported that patient who was receiving the injection sat up staring ahead. She was not blinking in response to nurse's waving in front of her face. The nurse realized that the patient's arms were stiff. The nurse reported that patient experienced a "focal seizure". She called back and indicated that patient did have an focal seizure. Outcome was unknown. Upon internal review "focal seizure" was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 319463-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	15-May-2008	Unknown		17-Jul-2008	18-Jul-2008	FR	WAES0807USA01408	18-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hemianopia, Multiple sclerosis, Post lumbar puncture syndrome, Visual disturbance

Symptom Text: information has been received from a health authority concerning a 21 year old female who received a third dose of GARDASIL via intramuscular route on 15-MAY-2008. First and second doses had been administered in December 2007 and February 2008 respectively. Early in May 2008, the patient complained of visual disorders with hemianopia at right side. On an unspecified date, she was hospitalized for explorations. MRI found small nodular pictures of white substance evoking multiple sclerosis according to the specialist. Lumbar puncture was performed but results were unknown. Fundus occulis was normal, there was no papillitis. Multiple sclerosis check-up was performed results pending. In mid-June i.e. approximately one and half month after beginning of disorders, ocular effects were resolving. The patient was still hospitalized for post lumbar puncture syndrome. Other business partner numbers included E2008-06370. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, Comment: MRI found small nodular pictures of white substance evoking multiple sclerosis; spinal tap, Comment: Results were unknown; retinal photography, Comment: normal, no papillitis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319482-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	24-Oct-2007	24-Oct-2007	0	17-Jul-2008	18-Jul-2008	FR	WAES0807USA02177	18-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a gynecologist concerning a 24 year old female who on 24-OCT-2007 was vaccinated with a dose of GARDASIL (lot #, route and injection site not reported), while pregnant. The patient's last menstruation was on 01-OCT-2007. The estimated date of delivery was 07-JUL-2008. An intended abortion by the patient after required consultation according to foreign legislation was performed before the gestation week 12 (exact date not reported). The patient's induced abortion was considered to be an other important medical event. Other business partner numbers included: E2008-06182. Additional information is not expected. Case is closed.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 01Oct07)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319515-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	15-Jul-2008	15-Jul-2008	0	17-Jul-2008	25-Jul-2008	CT		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2995BA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Presyncope, Syncope

Symptom Text: Syncope + few seconds. Diaphoresis. Pale. Remained presyncopal/dizzy for 2 hrs after.

Other Meds: oral contraceptives

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319516-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Jul-2008	16-Jul-2008	0	17-Jul-2008	24-Jul-2008	VT		24-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1465U	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0070X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Nausea, Vomiting

Symptom Text: Numbness in face, hands, & abdomen, nausea, vomiting x4.

Other Meds:

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **319533-1 (D)** **Related reports:** 319533-2; 319533-3; 319533-4; 319533-5; 319533-6; 319533-7

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	03-Jun-2008	20-Jun-2008	17	17-Jul-2008	18-Jul-2008	MD		05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0053X	2	Left arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Autopsy, Cardiac arrest, Death, Heart rate irregular, Physical examination normal, Pulmonary oedema, Spleen disorder, Splenomegaly, Supraventricular extrasystoles

Symptom Text: Pt received her 3rd and final dose of HPV vaccine on 6/3/08. Per mother patient was found dead, in bed on 6/22/08, in her dorm room at an out-of-state college. According to the autopsy the patient had been dead for about 48 hours. According to mother autopsy was negative except for splenic inflammation. 8/22/08 Autopsy report also states Final Diagnoses: Cardiac arrest, cause undetermined w/recent history of PAC w/otherwise normal EKG; normal echocardiogram 2/08; no evidence of myocarditis; acute pulmonary edema; slight splenomegaly; cardiac blood neg for ethanol; urine (+) for ethanol=16 mg/dl; liver (+) for acetaldehyde (incidental finding). 3/5/09-records received for DOS 8/22/07-seen for routine visit and first annual pap test..PE normal. First HPV vaccine administered. 2/4/09-records received for DOS 11/20/07-C/O chronic PAC and irregular heart beat.

Other Meds: none

Lab Data: none - apparently healthy young woman 8/22/08-records received-cardiac blood neg for ethanol; urine (+) for ethanol=16 mg/dl; liver (+) for acetaldehyde (incidental finding). 3/5/09-records received-pap smear normal. 2/4/09-records recei

History: reported allergy to penicillin and cephid 3/5/09-records received-Allergic to penicillin.

Prex Illness: none

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319533-2 (D)** **Related reports:** 319533-1; 319533-3; 319533-4; 319533-5; 319533-6; 319533-7

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	03-Jun-2008	23-Jun-2008	20	22-Jul-2008	23-Jul-2008	MD		03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	05334	2	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Do not know what happened. Pt was in college. Went to bed, friends found her dead 3 days later. Provider file report w/ manufacturer as well.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319533-3 (D)** **Related reports:** 319533-1; 319533-2; 319533-4; 319533-5; 319533-6; 319533-7

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	03-Jun-2008	20-Jun-2008	17	22-Jul-2008	23-Jul-2008	MD		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	00534	2	Left arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Death, Dizziness, Fatigue

Symptom Text: CT received her third shot of Gardasil (hpv virus prevention shot) on 6/03/08. On following days, CT complained of feeling tired and faint at times. CT left home on 6/12/08 to return to college and job on campus. She was living with peers in off campus housing. She worked last on 6/19, had dinner with housemates, watched a movie and all went to bed about 10:30 pm. She never came out of her room again alive after that. When she did not appear, housemates assumed she had gone away for the weekend. However, when she did not report to work on 6/23/08, housemates went into her room and found her dead in bed. Autopsy showed she was dead for at least 36 hours prior to being found, but can give no exact date or time of death. It is believed to have been between 6/ 20 and 6/22/08, probably the earlier date.

Other Meds: none

Lab Data: Initial autopsy was performed on 6/24. CT reported to appear to be "healthy". No signs of trauma or foul play. No obvious signs of cause of death. More tests pending.

History: none except allergy to Cefzil and Augmentin which are antibiotics

Prex Illness: none

Prex Vax Illns:

Vaers Id: **319533-4 (D)** **Related reports:** 319533-1; 319533-2; 319533-3; 319533-5; 319533-6; 319533-7

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	03-Jun-2008	18-Jun-2008	15	24-Jul-2008	25-Jul-2008	MD	WAES0807USA02497	25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0053X	2	Unknown	Intramuscular	

Seriousness: DIED, LIFE THREATENING, SERIOUS

MedDRA PT Death, Fatigue, Splenitis, Viral infection

Symptom Text: Information has been received from a physician concerning a 21 year old female with a penicillin allergy and an unremarkable medical history, who on 22-AUG-2007 was vaccinated with the first dose of GARDASIL (lot # 0469U), 0.5 mL intramuscular administration. On 20-NOV-2007, the patient was vaccinated with the second dose of GARDASIL (lot # 654540/1209U), 0.5 mL intramuscular administration. On 03-JUN-2008, she was vaccinated with the third dose of GARDASIL (lot # 0053X), 0.5 mL intramuscular administration. There was no concomitant therapy. On 20-JUN-2008, the patient was found dead in her bed. She had been dead for 48 hours. The patient had complained of fatigue prior to her death. The patient's mother contacted the physician via telephone. The autopsy performed in June 2008 was negative with evidence of inflammation around her spleen caused by a viral infection. The cause of death was inflammation of spleen caused by a virus. The physician considered the events to be life threatening. A lot check has been initiated. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **319533-5 (D)** **Related reports:** 319533-1; 319533-2; 319533-3; 319533-4; 319533-6; 319533-7

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	06-Jun-2008	23-Jun-2008	17	13-Aug-2008	14-Aug-2008	NY		14-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death, Pulmonary oedema

Symptom Text: Found dead.

Other Meds: Multivitamins

Lab Data: Negative autopsy except for acute pulmonary edema.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319533-6 (D)** **Related reports:** 319533-1; 319533-2; 319533-3; 319533-4; 319533-5; 319533-7

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	10-Nov-2008	12-Nov-2008	2	15-Dec-2008	16-Dec-2008	CA		16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: I celebrated my 21st birthday in November 2007. I did not live to see my 22nd. Suddenly, unexpectedly, and inexplicably, I died in bed in June. After an extensive autopsy, the cause of death is still a mystery. My family wants to know what happened to me. My family has concerns about the HPV vaccine, GARDASIL, which I had received only days before my death. They are researching the Vaccine Adverse Event Reporting System for accounts of such deaths. Can you help us find answers...above is one case report. This vaccine is a scam. It does not protect women. It causes infertility, spontaneous abortions, Guillain Barre syndrome. Cardiac impairment and or death, it cause HPV in some! The vaccine industry will be exposed because we the public will not be used and abused by vaccine industry any longer! The CDC and FDA should not be in charge of the VAERS data base when they are promoting their poison in the first place. VAERS is guilty of cover-ups and under reporting. Only 1-10% of victims are reported. That means there are hundreds of HPV vaccine victims not 27 as VAERS suggests! By withholding and suppressing informed consent from people the Pharma industry is violating Constitutional and Civil Rights of the victims. Enough of peddling poison to cull the population and make Pharma rich and further the CDC/other agencies Agenda.

Other Meds:

Lab Data: Autopsies of deceased victims of HPV shot are indisputable. GARDASIL caused death. Sudden disability of victims of HPV shot prove HPV shot caused illness.

History: Healthy girls and young women with no history collapse and die from HPV vaccine. It is the vaccine causing the deaths, illnesses. It is not coincidental. We were told Vioxx was safe too and it killed and crippled many people. As a health professional I am speaking from experience. Vaccines do not prevent disease but they do cause disease. Advances in nutrition, hygiene, availabilit

Prex Illness:

Prex Vax Illns:

Vaers Id: **319533-7 (D)** **Related reports:** 319533-1; 319533-2; 319533-3; 319533-4; 319533-5; 319533-6

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		28-Jan-2009	29-Jan-2009	--	WAES0901USA03297	09-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with GARDASIL (Lot # not reported). After patient received the vaccine, she died. The patient sought unspecified medical attention. The reporting physician considered died after GARDASIL to be immediately life-threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319535-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jul-2008	16-Jul-2008	0	17-Jul-2008	25-Jul-2008	AZ		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2605AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2966AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1854U	2	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Balance disorder, Blood pressure, Cold sweat, Disorientation, Dizziness, Erythema, Gaze palsy, Heart rate normal, Tremor

Symptom Text: Patient given immunizations @ 10:55 and reported felt light headed and loss balance. Face red,hands shaking,cold &clammy, eyes glazed, unware of her surroundings. Doctor responded. Vital signs recorded Q 5 minutes BP 96/56 pulse 72(normal for patient) Oxygen given @ 2 liters Monitored until 11:45 and released to return on 07/17/2008 for follow-up

Other Meds: None

Lab Data: Blood Glucose, oxygen @ 2 liters

History: Sulfa

Prex Illness: None

Prex Vax Illns:

Vaers Id: **319548-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	27-Mar-2008	29-Mar-2008	2	17-Jul-2008	28-Jul-2008	MN		28-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Intramuscular	HEP

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Crying, Depression, Inappropriate schedule of drug administration, Thinking abnormal

Symptom Text: On February 21st of 2008 I received my first hpv and first hepatitis b vaccines and was told to come back in one month for my 2nd hepatiits b shot and then the following month I'd receive my 2nd hpv shot. So on the 27th of March I recieved what I though to be my second hepatitis b shot. With in days I had dropped into a very bad depression. I was crying all the time, could hardly function and had no idea what was causing all of this. I wanted to die and I didn't know why it got so bad I started to call help lines and tried to decide if I should see about getting some medical help. It was the worst I have ever felt in my life, I felt completely out of control. Finally after about 3 weeks of what I can only describe as hell, I started to feel a little better, then I received a bill I was being charged for my 2nd hpv shot not my 2nd hepatitis b! After talking to my mother and putting dates and everything together I believe that my deep depression was soley caused by receiving my 2nd hpv shot a month sooner than I'd expected. We immediatly made an appointment with the clinic to discuss there huge error. They refused to admit any mistake on their part due to that fact that the recommended time inbetween dosing on the hpv serious had change. They would only admit that they should have also given me the 2nd hepitis b shot as well as the 2nd hpv shot I'd received. No one told me that day that the plan had changed that I would be recieving the 2nd hpv shot a month sooner than planned. Not only do I think the clinic was inapt in their communicating my course of treatment but I believe that the 2nd hpv shot sent me into at least 3 weeks of severe depression that with out the help and support of my family and a close friend I don't know if I'd have made it through on my own. After thinking about everything I feel it is my responsiblitiy to tell you the reaction that I had from my 2nd shot, in hopes that maybe others have come forward and it will stop anyone else in the futre from suffering the same horrible side effect.I had

Other Meds: lo-overal

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **319560-1** **Related reports:** 319560-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Jul-2008	11-Jul-2008	0	17-Jul-2008	24-Jul-2008	PR		05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	1	Left arm	Unknown	TDAP
	MNQ	SANOFI PASTEUR	U2545AA		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Rash erythematous, Rash pruritic

Symptom Text: Allergy in the whole body, rashes red and itchy.

Other Meds:

Lab Data: None

History: Mitral valve prolapse

Prex Illness:

Prex Vax Illns:

Vaers Id: **319560-2** **Related reports:** 319560-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Jul-2008	11-Jul-2008	0	18-Jul-2008	28-Jul-2008	PR		07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	1	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	4254599	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Rash generalised

Symptom Text: Rash and redness appeared all over the body.

Other Meds:

Lab Data: none

History: Mitral valve prolapse

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319561-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Jul-2008	17-Jul-2008	0	17-Jul-2008	25-Jul-2008	MN		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1098U	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2966AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy, Injection site pain, Moaning, Syncope

Symptom Text: Patient received, TDAP, Varivax and Gardasil immunization. After receiving Gardasil, patient stated that hurt worse. She then moaned and fell on her side lying on table, eyes rolled back and fainted after 20 seconds. Received orange juice, water and granola bar. Blood pressure taken before patient left was 70/40. Original blood pressure 80/50. Patient was in stable condition upon leaving per doctor.

Other Meds: None

Lab Data: Blood pressure 70/40 at D/C. 60/40 after fainting.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **319562-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	19-May-2008	22-May-2008	3	17-Jul-2008	25-Jul-2008	NJ		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Patient received GARDASIL on 5/15/08. Patient developed intermittent episodes of dizziness starting 5/22/08 continuing daily until 6/12/08. Episodes subsided hen and have not reoccurred. This information reported on 7/17/08 by mother to our office.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319635-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Jul-2008	21-Jul-2008	--	WAES0807USA02672	21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a mother concerning her daughter who on unspecified dates was vaccinated with 3 doses of GARDASIL. Subsequently the patient "has been having seizures since she received the three doses of GARDASIL". The outcome of the seizures was not reported. It was unspecified if the patient sought medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 319637-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-Aug-2007	22-Sep-2007	33	18-Jul-2008	21-Jul-2008	NY	WAES0807USA02471	13-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Disturbance in attention, Epilepsy, Excessive eye blinking, Fall, Grand mal convulsion, Loss of consciousness, Postictal state, Staring, Tremor

Symptom Text: Information has been received from a physician concerning a 16 year old female with a history of wheezing who on 20-AUG-2007 was vaccinated with her first dose of GARDASIL. On 22-SEP-2007 the patient experienced tonic clonic seizure and was hospitalized. On 15-NOV-2007, the patient received the second dose of GARDASIL. The patient was admitted to the hospital for an unspecified period of time on three separate occasions since the onset of the first seizure. The patient has a positive familial history of seizures. The patient's last seizure occurred on an unspecified date in January 2008. Concomitant therapy included folic acid and MINOCIN. No other symptoms and no other treatment reported. Additional information has been requested. 8/11/2008 MR received for multiple DOS 9/22-25/2007, 10/29-11/01/2007, 11/7-12/2007 and ER 1/18/2008 with DX: Epilepsy. Pt presented with 1st seizure 9/22/07. Pt lost consciouness, fell and had generalized convulsion with shaking of upper and lower extremities. Sleepy after. Started on Keppra following EEG. Staring episodes noted with adventitial movements during video. D/C for outpt f/u. Returned again 10/29/07 with 2 episodes of seizure on meds. Recent increase in blinking and decreased attention. Keppra increased. Returned again due to allergic rxn to Keppra. Med changed to Zonegran. ER visit for seizure in school. Dose increased.

Other Meds: folic acid; MINOCIN

Lab Data: None. Labs and Diagnostics: Head CT WNL. Tox screen (-). Video EEGs abnormal.

History: Wheezing. PMH: ADD. Asthma. NKDA. Mom had seizures ages 13-15, cousin w/ seizures, sibling with Chiari malformation

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319640-1** **Related reports:** 319640-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-May-2008	03-Jun-2008	7	18-Jul-2008	21-Jul-2008	OH	WAES0807USA02254	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Fatigue, Loss of consciousness, Memory impairment, Staring, Stomach discomfort, Unresponsive to stimuli

Symptom Text: Information has been received from a registered nurse concerning a 13 year old female with a history of reactive airways disease who on 06-FEB-2008 was vaccinated with the first dose of GARDASIL (Lot number 655327/1287U) 0.5 ml, IM. On 27-MAY-2008, the patient received the second dose of GARDASIL (Lot number 655327/1287U). Concomitant therapy included ORTHO TRI-CYCLEN LO. On approximately 03-JUN-2008, 1 week after the second vaccination, the patient experienced seizure. The patient came into the office on 04-JUN-2008 because the patient had several episodes in a 1 week of dizziness and black outs. Unspecified which week this occurred. The patient continues to have seizures. The last seizure was 3 weeks ago. The patient did not have any problems after the first dose of GARDASIL. The patient's seizure persisted. Upon internal service, the seizure was considered to be an other important medical event. Additional information has been requested. 11/05/2008 MR received for DOS 9/11-13/2008 with D/C DX: Seizure-like activity. Pt presented with increasing staring spells x 2 months, where pt is unresponsive. Pt has no recollection of events. Sick to stomach before and very tired after. Pt dx with Seizure d/o dx June 2008. 12/15/08 Outpt neurology records received with impression ? seizure.

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: electroencephalography; electrocardiogram. Labs and Diagnostics: Labs all WNL. EEG normal. Long-term EEG (+) for intermittent generalized, at times sharply contoured, rhythmic delta activity with frontal predominance.

History: Reactive airways disease. PMH: fx elbow. On OC for dysfunctional uterine bleeding. vocal cord dysfunction, asthma, acid reflux, anemia.

Prex Illness:

Prex Vax Illns:

Vaers Id: **319640-2 (S)** **Related reports:** 319640-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-May-2008	29-May-2008	2	28-Mar-2009	31-Mar-2009	OH		31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Petit mal epilepsy

Symptom Text: 2 days after receiving the second injection in the series of Gardasil, she developed absence seizures. The seizures have been confirmed by EEG and is currently taking Lamictal. She did not receive the 3rd in the series.

Other Meds:

Lab Data: 2 EEGs, blood work, medication, hospitalization for 2 days

History: Asthma, anemia

Prex Illness: None

Prex Vax Illns:

Vaers Id: **319641-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Jul-2008	21-Jul-2008	NY	WAES0807USA02181	21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL by intramuscular injection in to her arm (lot number not reported). Just as the needle was being pulled out of the patient's arm, the patient experienced seizure. Unspecified medical attention was sought. Upon internal review seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319642-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Jul-2008	21-Jul-2008	NJ	WAES0807USA01897	21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paralysis

Symptom Text: Information has been received from a physician stating that one of his colleagues has received a phone call concerning a female patient who on an unspecified date, was vaccinated with GARDASIL. Subsequently, the patient was paralyzed after vaccination. The patient sought for unspecified medical attention. No additional information is available at this time. Upon internal review, paralysis was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319643-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Jun-2008	Unknown		18-Jul-2008	21-Jul-2008	--	WAES0807USA01526	21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter with seizures and no drug allergies, who on 12-JUN-2008 was vaccinated with a 0.5mL dose of GARDASIL. Concomitant therapy included LAMICTAL. Subsequently, the patient experienced an increase in seizures. No laboratory diagnostics were performed. At the time of the report the patient had not recovered. Upon internal review the seizures were considered to be an other important medical event. Additional information has been requested.

Other Meds: LAMICTAL

Lab Data: None

History:

Prex Illness: Convulsion

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319644-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Jul-2008	21-Jul-2008	FR	WAES0807MYS00006	21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a female who in 2008 was vaccinated with two doses of GARDASIL while the patient was in another country. In 2008, after the second dose, the patient experienced seizure. Subsequently, the patient recovered from seizure. The reporter felt that seizure was not related to therapy with GARDASIL. Upon internal review, seizure was considered to be an important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 319645-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		18-Jul-2008	21-Jul-2008	FR	WAES0807AUS00173	21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Alopecia, Asthenia, Catheter placement, Erythema, Impaired work ability, Injection site cellulitis, Oedema peripheral, Renal failure acute, Sepsis, Skin infection, Tenderness, Weight increased

Symptom Text: Information has been received in a newspaper article received from a 23 year old female with a family history of cervical cancer who in 2008 was vaccinated with the third dose of GARDASIL. The patient advised that she had no side effects from the first two doses of GARDASIL. Subsequently after the third dose, the patient's arm became very tender, and the next day the arm started to swell, was extremely red, like a burn. The following day the patient's arm had swollen to double its normal size. The patient was admitted to hospital and was initially diagnosed with cellulitis (infection of the skin) at the injection site. The patient advised that she went downhill dramatically. The patient developed acute renal failure and had to have a catheter inserted. She was placed on massive amounts of antibiotics but was not responding. The patient advised that within days, she went from a minor infection in the skin to major problems. The patient advised that her kidneys shut down and she put on 15 kg practically overnight. The patient also developed septicemia and the specialist in intensive care placed their dialysis unit on standby. After four days, the patient's hair started to fall out but her body finally began to respond to the antibiotics. One week later, they took her off her intravenous fluids and medications and was discharged from hospital. She was instructed to come back every couple of days for blood tests, ultrasounds, etc. The patient advised that the doctors said that what happened to her was not from vaccination with GARDASIL and that it was extremely rare and unusual. The patient did not return to full time work until three months later. Subsequently the patient recovered from the cellulitis at injection site, hair falling out, red arm, like a burn, swollen arm, acute renal failure, septicemia and weight increase of up to 15 kg. but still has soreness in her arm and not much strength. Additional information is not expected.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, results not specified; ultrasound, result not specified

History: Family history of cancer

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319646-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	14-Apr-2008	16-Apr-2008	2	18-Jul-2008	21-Jul-2008	FR	WAES0807AUS00099	21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Coordination abnormal, Dyspnoea, Fatigue, Gait disturbance, Hemiplegia, Impaired work ability, Muscular weakness, Pain, Pleurisy, Syncope

Symptom Text: Information has been received from a 25 year old female as part of a business agreement (manufacturer control # GARD 2008 07 07 001) who on 14-APR-2008 was vaccinated with the first dose of GARDASIL. On 16-APR-2008 (48 hours after the first dose) the patient developed paralysis on her left side and had serious difficulty breathing, to the point of fainting. On 28-APR-2008 (2 weeks later) the patient was still unable to breathe without intense pain and was admitted to hospital. The patient was diagnosed with an inflamed lung lining (pleurisy) but they did not know why her left lung had become inflamed. The patient advised that she also developed extreme fatigue, muscle weakness, difficulty walking and uncoordination, all lasting approximately 1 1/2 months. The patient had various tests which did not come up with any virus. The patient advised that she needed a month off work and at the time of reporting she was still recovering from her other symptoms. The patient believed that the GARDASIL "triggered Guillain-Barre syndrome" although this diagnosis was not confirmed. Upon internal medical review the adverse event of paralysis on left side was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, ??08, negative for any virus

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319647-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	31-Jul-2007	31-Jul-2007	0	18-Jul-2008	21-Jul-2008	FR	WAES0801AUS00010	21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Hepatic haematoma, Inappropriate schedule of drug administration, Live birth, Neonatal disorder, Peritoneal haemorrhage, Physical assault

Symptom Text: Information has been received from a health professional via CSF as part of a business agreement (manufacturer control # GARD 2007 12 21 003) concerning an 18 year old primipara female who on 31-JUL-2007 was vaccinated with the first dose of GARDASIL (invalid Batch # NE58880). On 10-SEP-2007 the patient was vaccinated with the second dose of GARDASIL (invalid Batch # NE58880). On 13-DEC-2007 the patient was inadvertently vaccinated with the third dose of GARDASIL (Lot # 658275/0784U, Batch # J3206, Expiry date 22-MAR2010) while pregnant (gestation unknown). No adverse symptoms were experienced at the time of reporting on 21-DEC-2007. Follow-up information has been received from a completed First Encounter Questionnaire. The date of the patient's last menstrual period was unknown. The patient's pregnancy was confirmed by a urine test. The estimated delivery date is 16-APR-2008 as per the ultrasound. On 07-JUL-2008 a completed "Use in Pregnancy - Pregnancy Outcome Questionnaire" was received from the reporting health professional. It was unknown whether the patient had any diagnostic tests or if the patient had taken any prescription drugs during her pregnancy. It was also unknown whether the patient had any infections/illnesses during her pregnancy, as the patient's pregnancy was not disclosed. On 12-APR-2008, the patient had a liveborn normal female infant at 39+3 weeks from her last menstrual period. The infant did not have any congenital anomalies and weighed at 3175 grams. The infant is slow to feed. Information received on 07-JUL-2008 contained the following adverse experiences: assaulted at 22/40 and developed liver haematoma and hemoperitonium which resolved. Upon internal review, assaulted at 22/40 was considered an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: ultrasound; hemoglobin, 5.6; urine beta-human chorionic gonadotropin, Comment: pregnancy confirmed

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319648-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	05-Dec-2007	05-Dec-2007	0	18-Jul-2008	21-Jul-2008	NY	WAES0712USA08286	21-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from the Merck pregnancy registry for GARDASIL from a physician concerning a 21 year old female who on 05-DEC-2007 was vaccinated with her first dose of 0.5 ml GARDASIL (Lot #659437/1266U) intramuscularly and the patient was pregnant. There was no concomitant medication. LMP was 13-NOV-2007 and on 18-DEC-2007 a pregnancy test was performed and results were positive. The physician reported that the patient became pregnant after her first dose of GARDASIL. No other symptoms were reported. Followup phone call information was obtained from a physician who reported that the patient had not continued in his care and may have terminated the pregnancy. No further information was available. Upon internal review elective termination was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic, 12/18/07, positive

History:

Prex Illness: Pregnancy NOS (LMP = 11/13/2007)

Prex Vax Illns:

Vaers Id: **319654-1 (S)** **Related reports:** 319654-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-May-2008	02-Jul-2008	40	18-Jul-2008	23-Jul-2008	MN		06-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Dyslipidaemia, Hypertriglyceridaemia, Inflammation, Iron deficiency anaemia, Malnutrition, Obesity, Pancreatitis, Pyrexia

Symptom Text: 5 day hospitalization for severe, first-ever pancreatitis. Pt was on Ortho Evra, and had recently - 5/23/08 - completed GARDASIL series. 8/4/08-records received for DOS 7/2-7/7/08- DC DX: Acute pancreatitis possibly secondary to hypertriglyceridemia. Mild iron deficiency anema. Obesity. Protein malnutrition, fevers, elevated inflammatory markers resolving. Dyslipdemia. C/O one day history of severe abdominal pain.

Other Meds: ZOMIG; OrthoEvra

Lab Data: WBC 21.1; ESR 55 8/4/08-records received-total cholesterol 223, triglycerides 260, HDL 62 and LDL 109. CT peripancreatic stranding consistent with pancreatitis. WBC 20,000, hemoglobin 12.5, chemistry normal, LFTs elevated amylase 112, lipa

History: Older sister had pancreatitis at roughly the same age. 8/4/08-records received-PMH: long history of having low blood. Sister recently diagnosed with pancreatitis and DM.

Prex Illness:

Prex Vax Illns:

Vaers Id: **319654-2 (S)** **Related reports:** 319654-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-May-2008	02-Jul-2008	40	17-Sep-2008	18-Sep-2008	--	WAES0808USA04473	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Dyslipidaemia, Hypertriglyceridaemia, Inflammation, Iron deficiency anaemia, Malnutrition, Obesity, Pancreatitis acute, Pyrexia

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act concerning a 16 year old female with low blood who on 23-MAY-2008 completed the series of GARDASIL (lot number 660391/0063X). Concomitant therapy included ORTHO EVRA and ZOMIG. The patient was hospitalized for 5 days, from 02-JUL-2008 to 07-JUL-2008, for severe, first-ever pancreatitis. The diagnosis was Acute pancreatitis possibly secondary to hypertriglyceridaemia. The patient also experienced mild iron deficiency anemia, obesity, protein malnutrition, fevers, elevated inflammatory markers, dyslipidaemia and complained of one day history of severe abdominal pain. On 04-AUG-2008 records received showed the following laboratory test, white blood cell count: 21.1, erythrocyte sedimentation rate: 55, f serum cholesterol test: 223, serum triglyceride test: 260, serum high-density lipoprotein cholesterol test: 62, serum low-density lipoprotein cholesterol test: 109, blood hemoglobin test: 12.5, blood chemistry: normal, hepatic function tests: elevated, serum amylase test: 112, white blood cell count: 20,000, pancreatic abdominal computed axial tomography consistent with pancreatitis. The patients was recovering from elevated inflammatory markers. The patient's older sister had pancreatitis at roughly the same age and was recently diagnosed with pancreatitis and diabetes mellitus. Mild iron deficiency anaemia, acute pancreatitis, severe abdominal pain, dyslipidaemia, hypertriglyceridaemia, elevated inflammatory markers, protein malnutrition, obesity and fever were considered to be immediately life-threatening. The original reporting source was not provided. The VAERS ID # is 319654-1. A standard lot check investigation was performed. All in-process quality checks for the lot # 660391/0063X were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements and wa

Other Meds: ORTHO EVRA; ZOMIG

Lab Data: abdominal computed, ?/?/08 - peripancreatic stranding consistent with pancreatitis; WBC count, ?/?/08, 21.1; erythrocyte, ?/?/08, 55; serum cholesterol, ?/?/08, 223; serum triglyceride, ?/?/08, 260; serum HDL-C, ?/?/08, 62; hepatic function

History:

Prex Illness: Anaemia

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319655-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Apr-2008	14-Apr-2008	0	18-Jul-2008	23-Jul-2008	NY		23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contusion, Parosmia, Rash

Symptom Text: Patient reports several areas of bruising and "smell and dots" which resolved after 1 week.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319656-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	17-Jul-2008	Unknown		18-Jul-2008	24-Jul-2008	FL		24-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Syncope vasovagal

Symptom Text: Vasovagal reaction, sweats. Pt. states she didn't have anything to eat.

Other Meds: LOESTRIN FE

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319679-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	08-Jul-2008	08-Jul-2008	0	18-Jul-2008	25-Jul-2008	OK		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2613AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye rolling, Face injury, Fall, Loss of consciousness, Mouth haemorrhage, Musculoskeletal stiffness

Symptom Text: After receiving the HPV #1, patient passed out falling out of chair and hitting face on exam bed foot stool. Patient eyes rolled in back of head and left side patients body got stiff. Blood in mouth. Patient bit lip causing mouth to bleed. Hit nose on stool. Ambulance called immediately. Gave patient oxygen in office. Checked blood pressure and O2, resp. Everything o.k.

Other Meds:

Lab Data:

History: NKA

Prex Illness: None

Prex Vax Illns:

Vaers Id: **319694-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	15-Jul-2008	16-Jul-2008	1	18-Jul-2008	25-Jul-2008	DC		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Fatigue, Injected limb mobility decreased, Injection site pain, Pain, Pelvic pain

Symptom Text: pain at injection site, limited movement of left arm. body aches, fatigue, difficulty breathing, sharp pains in pelvic area.

Other Meds:

Lab Data:

History: n/a

Prex Illness: n/a

Prex Vax Illns:

Vaers Id: **319697-1** **Related reports:** 319697-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Jun-2008	24-Jun-2008	0	18-Jul-2008	25-Jul-2008	NC		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Syncope

Symptom Text: Pt received HPV and pt. and mother remained in office and during the stay she fainted. Pt. c/o nausea. Dr. Schwanz and clinical assistant remained with and reassessed pt's stauts. Staff offered sips of liquid and she refainted 3 - 5 minutes later and remained with c/o nauesa. Pt. remained assessed at office. Once discard pt went home and remained with c/o nausea throughout the day.

Other Meds: no

Lab Data:

History: nka, no defects or medical condition

Prex Illness: no

Prex Vax Illns:

Vaers Id: **319697-2** **Related reports:** 319697-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Jun-2008	24-Jun-2008	0	18-Aug-2008	02-Oct-2008	NC	WAES0807USA04692	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, Syncope

Symptom Text: Information has been received from a health professional concerning a 15 year old white female, a contact lens wearer, weight 102.2 lb, height 60 inches, who at 09:30 AM on 24-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot#: 659962/1740U) IM in the left arm. After the vaccination the patient and her mother remained in the office. During the stay, the patient fainted. The patient complained of nausea. The physician and clinical assistant reassessed the patient's status. Staff offered sips of liquid. The patient fainted again 3-5 min later and complained of nausea. The patient remained assessed in the office. Once discharged, the patient went home and remained with complaints of nausea. On 25-JUN-2008 the patient recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Contact lens wearer

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319700-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Jan-2008	15-Apr-2008	84	18-Jul-2008	25-Jul-2008	NY		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Migraine, Presyncope, Syncope

Symptom Text: received HPV 10/30/07, 1/22/08, 5/22/08 Developed epsiodes of near syncope and syncope with migraine headaches beginning 4/15/08 She had MRI LP cardiology eval and felt to have status migranosis

Other Meds:

Lab Data: nl mri, nl lp, nl echocardiogram,nl labs

History: asthma-stable

Prex Illness: none also note on 10/30/07 dose she did receive fluvaccine Pasteur U2466AA

Prex Vax Illns:

Vaers Id: **319725-1 (S)** **Related reports:** 319725-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Jul-2008	17-Jul-2008	3	18-Jul-2008	23-Jul-2008	PA		30-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1487U	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2844AA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2546AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Acute respiratory distress syndrome, Breath sounds abnormal, Chest pain, Cough, Dyspnoea, Intercostal retraction, Oxygen saturation decreased, Oxygen supplementation, Pleuritic pain, Pyrexia, Respiratory distress, Somnolence, Stomach discomfort, Tachycardia, Tachypnoea

Symptom Text: Shortness of breath, dry cough, pleural chest pain progressively worse. Developed tachypnea over course of 4 hours refractory to Xopenex and O2 support palliated only with BiPAP. ARDS type picture on chest x-ray. 7/24/2008 D/C summary received for DOS 7/17-20/2008 with D/C DX: Acute Respiratory Distress Syndrome. Pt presented with worsening shortness of breath, dry cough and pleural chest pain which began that am along with sleepiness and upset stomach. Upon arrival in ED O2 sats were in the 80s and pt was in respiratory distress with tachycardia. No improvement with Xopenex nebs and supplemental O2. Transferred to higher level of care. Fever noted on admission. RR in the 50s. PE (+) for accessory mucle use, decreased breath sounds and tachycardia. Pt put on BIPAP with improvement in WOB and RR. Lasix given for pulmonary edema with good effect. Slowly weaned to RA and d/c for outpt f/u.

Other Meds: None

Lab Data: Volatiles, tox screen negative, blood culture negative. Labs and Diagnostics: CXRs c/w bilateral infiltrates, pulmonary edema and acute onset ARDS. CBC with WBCs 18.3 with a left shift-86% segs, 0 bands. Strep (-). Blood cx (-).

History: None PMH: NKDA

Prex Illness: None

Prex Vax Illns:

Vaers Id: **319725-2 (S)** **Related reports:** 319725-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Jul-2008	17-Jul-2008	3	24-Jul-2008	28-Jul-2008	PA		28-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Acute respiratory distress syndrome, Cough, Dyspnoea, Fatigue, Pleural effusion, Pulmonary oedema

Symptom Text: Acute respiratory distress, pulmonary edema and possible pleural effusion. 13 YOF received immunizations on 7/14/08. On 2/15/08 c/o fatigue and stomach ache. Later in the evening found to have coughing, difficulty breathing, labored breathing. on 7/17/08 found to have pulmonary edema, required bilevel pressure support upon transfer to hospital.

Other Meds: No medications prior.

Lab Data: Tox screen, pregnancy test, blood cx's - 7/17/08 negative; CBC on 7/18/08 with WBC 18.3 with 86 segs; CBC on 7/20/08 WBC 10.18 with 58 segs; CXR - BL pulmonary edema with pleural effusions

History: NKDA; no medications prior; no underlying medical problems; kidney infection at 6 months of age; no hx chronic respiratory problems

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319726-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.1	F	17-Jul-2008	18-Jul-2008	1	18-Jul-2008	25-Jul-2008	IN		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2551AA	0	Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC526024EA		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Angioedema

Symptom Text: Severe angioedema

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **319728-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	09-Jul-2008	Unknown		18-Jul-2008	25-Jul-2008	OH		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, No reaction on previous exposure to drug

Symptom Text: Nauseated, light headed. This didn't happen with first 2 shots.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **319730-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Jul-2008	Unknown		18-Jul-2008	25-Jul-2008	OH		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Headache, Nausea, No reaction on previous exposure to drug

Symptom Text: Tired, headache, nausea on 3rd shot only.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319733-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Jul-2008	Unknown		18-Jul-2008	24-Jul-2008	AZ		04-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: None Stated

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319738-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Jul-2008	17-Jul-2008	2	18-Jul-2008	25-Jul-2008	TX		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	0513X	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Injected limb mobility decreased, Injection site pain, Injection site swelling, Pain, Tenderness

Symptom Text: Pain, swelling at injection site, redness, tender to touch, soreness with arm movement. RX-Observe, Ibuprophen, ice pack.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **319746-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	08-Jul-2008	08-Jul-2008	0	18-Jul-2008	24-Jul-2008	CO		31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dehydration, Depressed level of consciousness, Dizziness, Headache, Loss of consciousness, Nausea

Symptom Text: Dizziness, nausea, headache on the evening of the vaccine administration and has occurred with each GARDASIL vaccine but has lasted longer with each vaccine. This incident lasted 8 days required office visit, passed out in office and could not get her to wake up. Started IV fluids transferred to emergency room. She is mildly dehydrated, blood sugar was 60.

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319749-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Jul-2008	18-Jul-2008	0	18-Jul-2008	25-Jul-2008	CA		25-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2936BA	0	Left arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB618AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0570X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2572AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Pain, Pallor

Symptom Text: Patient passed out after the 4th vaccine HPV given. Pale and noted with minor body aching for 2-3 seconds. Regained consciousness right away. Mom to read and observed. Aware. No Ng measure done. Injury - no falls.

Other Meds: N/A

Lab Data: Well teen exam.

History: Depression

Prex Illness: None

Prex Vax Illns:

Vaers Id: **319751-1** **Related reports:** 319751-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	14-Mar-2008	14-Apr-2008	31	18-Jul-2008	24-Jul-2008	IL		24-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Hypoaesthesia, Pain in extremity, Paraesthesia

Symptom Text: Patient developed left arm numbness, tingling, pain and redness from above elbow to mid-forearm. Pt says that it constantly hurts, is worse with movement. Symptoms are unchanged over past few months. No injuries. Pt saw PCP ortho and neurologist about this. They thought she could have had cellulitis, tendonitis, carpal tunnel, blood clot, or nerve damage, but nothing determined.

Other Meds:

Lab Data: Pt states she was told EMG was normal and labs normal except slightly elevated ESR.

History: Bird breeder's lung disease in past year. PSH 11/07 tonsils and adenoids, septoplasty, turbinoplasty.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **319751-2** **Related reports:** 319751-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	14-Mar-2008	14-Apr-2008	31	24-Jul-2008	21-Aug-2008	IL		21-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Hypoaesthesia, Pain in extremity, Paraesthesia

Symptom Text: Patient developed left arm numbness, tingling, pain and redness from above elbow to mid-forearm. Pt says that it constantly hurts, is worse with movement. Symptoms are unchanged over past few months. No injuries. Pt saw PCP , ortho and neurologist about this. They thought she could have had cellulitis, tendinitis, carpal tunnel, blood clot, or nerve damage, but nothing determined.

Other Meds: None

Lab Data: Pt states she was told EMG was normal and labs normal except slightly elevated ESR.

History: bird breeder's lung disease in past year, PSH 11/07 tonsiloadenoids, septoplasty, turbinoplasty

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319779-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Dec-2006	30-Dec-2006	23	17-Jul-2008	01-Sep-2008	MI	WAES0702USA00986	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1161F	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Depression, Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received through the Merck pregnancy registry from a physician concerning an 18 year old female with asthma, an obstetrical history of a prior pregnancy electively terminated in the first trimester, and a medical history of Chlamydia (2004), vulvar intraepithelial neoplasia (VIN III) (treated October 2006) and Cervical intraepithelial neoplasia (CINI), who on 12-OCT-2006 was vaccinated in the left arm with the first dose of GARDASIL (Lot # 653735/0688F) and on 07-DEC-2006 was vaccinated in the left arm with the second dose of GARDASIL (Lot # 654540/1161F). Concomitant therapy included ADDERALL, CELEXA, CATAPRESS, montelukast sodium (MSD), ZOLOFT, and CALAN. Subsequently, the patient informed her physician that she was pregnant. The date of the LMP was 30-DEC-2006 (previously reported as approximately 26-DEC-2006), with an estimated date of delivery of 02-OCT-2007. The patient sought unspecified medical attention. In approximately December 2006 the patient experienced depression. On 03-OCT-2007 the patient delivered a healthy, normal male infant, birthweight 3523 grams and 53.3 cm in length. Apgar score of 3/8/9, taken at 1/5/ and 10 minutes. No further information is available.

Other Meds: ADDERALL XR; CELEXA; CATAPRES; SINGULAIR; ZOLOFT; CALAN

Lab Data: ultrasound, 02/20/07 - no results reported; ultrasound, 05/15/07 - within normal limits; ultrasound, 07/16/07 - within normal limits; serum alpha-fetoprotein, 07/16/07 - normal limits - integrated screen

History: Chlamydia infection; Attention deficit disorder; Vulval intraepithelial neoplasia; Cervical intraepithelial neoplasia

Prex Illness: Pregnancy NOS (LMP = 12/30/2006); Asthma

Prex Vax Illns:

Vaers Id: **319780-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	01-Sep-2008	TX	WAES0703USA00845	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Initial and follow up information has been received from a medical assistant and the patient's mother, concerning her daughter with no known drug allergies or past medical history, who in approximately, October 2006, was vaccinated, intramuscularly with the first dose of GARDASIL. In approximately, February 2007, the patient was vaccinated, intramuscularly with the second dose GARDASIL and on 06-MAR-2007, the patient was vaccinated, intramuscularly with third dose GARDASIL. The specific dates for the first and second dose were not available. Concomitant therapy included an unspecified allergy medication. The patient's mother reported that after the first dose, the patient experienced tenderness in her arm at the injection site. Unspecified medical attention was sought. No product quality complaint was involved. Additional information has requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 319781-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Mar-2007	30-Mar-2007	3	17-Jul-2008	01-Sep-2008	CT	WAES0706USA00021	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0012U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour, Vomiting

Symptom Text: Initial and follow up information has been received through the Merck pregnancy registry for GARDASIL via an obstetrician and a 20 year old white female on methadone maintainence for opiate abuse with a history of an adverse drug reaction to REGLAN, herion abuse, panic attacks, frequent urinary tract infections, pyelonephritis (2002, normal urology on follow up) and one previous pregnancy with first trimester spontaneous abortion. On 23-JAN-2007, she was vaccinated with a first dose of (Lot#655165/1425F). On 27-MAR-2007, she was vaccinated with a second dose of GARDASIL (Lot#655503/0012U). Concomitant therapy include methadone HCl 80 mg daily. Last menstrual period was 30-MAR-2007 (previously reported as LMP 05-APR-2007) and estimated dates of delivery was 04-JAN-2008. On approximately 31-MAY-2007, the patient was informed that she was pregnant. Subsequently, the patient experienced hyperemesis and was treated with ZOFRAN 8 mg prn and TIGAN 300 mg prn. On 07-AUG-2007 the patient had an ultrasound at 18-20 weeks with a result within normal limits. On approximately 01-DEC-2007, the patient's pregnancy was complicated by preterm labor at 35 weeks. On 05-DEC-2007 urine drug screen results were positive for methadone and opiates. On 13-DEC-2007, at 36 6/7 weeks from LMP the patient had a "technically, a pre-term delivery" with a 6 lb. 11 oz. male infant. Apgar score was 9/9. The outcome of the hyperemesis, pre-term labor and pre-term delivery were unknown. Additional information is not expected.

Other Meds: methadone hydrochloride 80 mg

Lab Data: ultrasound, 08/07/07, WNL - 18-20 weeks; beta-human chorionic, 05/31?/07 - positive; Apgar score, 12/13/07, 9/9; urine drug screen, 12/05/07 - positive for methadone and opiates

History: Adverse drug reaction; Urinary tract infection; Pyelonephritis; Opioid abuse; Panic attack; Abortion spontaneous; Pregnancy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319782-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	15-Jan-2007		17-Jul-2008	01-Sep-2008	MD	WAES0706USA00588	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a physician concerning a 17 year old female patient, with asthma and drug hypersensitivities to ibuprofen and BACTRIM, who in January 2007, was vaccinated with the first dose of GARDASIL. Concomitant therapy included DEPO-PRVERA and pre-natal vitamins (started on 24-MAY-2007). On approximately 07-JAN-2007, the patient had her LMP. On 12-APR-2007, the patient was vaccinated with the second dose GARDASIL (Lot# 657621/0387U), with the patient reported as "20 weeks gestation" (estimated date of delivery on 14-OCT-2007). There were no problems reported. On 18-MAY-2007, the patient's pregnancy was confirmed by a pregnancy test. On 24-MAY-2007, 04-JUN-2007 and 07-JUL-2007 the patient had an ultrasound for fetal dates and growth. It also revealed left pyelectasis. On 07-SEP-2007, an ultrasound confirmed that the left pyelectasis had resolved. There were no previous pregnancies, deliveries or spontaneous abortions. On 08-OCT-2007, the patient gave birth to a healthy and normal baby boy. He weighed between 6 to 7.5 lbs. and his apgar score was reported as 8/9. The patient was 38 weeks and 2 days from her last menstrual period. There were no congenital anomalies reported. It was reported that all was fine. Additional information is not expected.

Other Meds: DEPO-PROVERA; vitamins (unspecified)

Lab Data: ultrasound, 05/24/07; ultrasound, 07/27/07; ultrasound, 09/07/07 - Left pyelectasis

History:

Prex Illness: Pregnancy NOS (LMP = 1/7/2007). Asthma; Drug hypersensitity; Sulfonamide allergy; Contraception

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319783-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-May-2007	17-May-2007	2	17-Jul-2008	01-Sep-2008	IA	WAES0706USA03778	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0244U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received for the Merck Pregnancy Registry for the GARDASIL via a medical assistant concerning a 15 year old female with no pertinent medical history who on 15-MAY-2007 was vaccinated intramuscularly with the first 0.5 ml dose of the GARDASIL (Lot # 656051/0244U). Concomitant therapy included PROTONIX, PROZAC, magnesium supplement (unspecified), SEROQUEL and ZONEGRAN. A blood HCG test was performed on 15-MAY-2007 and was negative. The blood HCG test was repeated on 31-MAY-2007 and was positive. An ultrasound was performed on approximately 15-JUN-2007 which showed that the patient is approximately 4.5 to 6.5 weeks pregnant. The patient's last menstrual period was approximately 17-May-2007 and the estimated due date was 21-Feb-2008. The reporter stated that "the patient will not be having a therapeutic abortion." Follow up information has been received from a health professional at the pediatrician's office and from a registered nurse at the obstetrician's office, concerning the outcome of the pregnancy. There were no complications or illnesses during the patient's pregnancy. The health professional and the nurse reported that on 27-JAN-2008, the patient gave birth to a healthy and normal male infant, apgar: 8/1; weight: (3668gms), 8lbs 1oz; length 21; and head circumference: 14. The health professional noted that the infant had no congenital anomalies. The baby however experienced respiratory distress and fever during delivery. No further information was provided. Additional information was provided. Additional information is not expected.

Other Meds: PROZAC; magnesium (unspecified); PROTONIX; SEROQUEL; ZONEGRAN

Lab Data: ultrasound, 06/15?/07 - patient was 4.5 to 6.5 weeks pregnant; beta-human chorionic, 05/15/07 - negative; beta-human chorionic, 05/31/07 - positive;

History:

Prex Illness: Pregnancy NOS (LMP = 5/17/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319784-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	02-Feb-2007	09-Apr-2007	66	17-Jul-2008	01-Sep-2008	TN	WAES0708USA02903	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TTOX	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MMR	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1426F	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received through the Merck Pregnancy Registry from a licensed practical nurse concerning a 16 year old white female with no previous pregnancies, with asthma who on 02-FEB-2007 (previously reported as 09-APR-2007) was vaccinated with a first dose of GARDASIL (lot # 655205/1426F). Concomitant vaccination on 09-APR-2007 included MMR II. Concomitant therapy included albuterol and "quar". The patient was in her first trimester at the time of the vaccination. Unspecified medical attention was sought. No adverse event was reported. It was reported that the patient delivered a healthy and normal baby girl on 13-DEC-2007 at 38 weeks gestation. No further information is available.

Other Meds: (therapy unspecified); albuterol

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319785-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Jun-2007	13-Jun-2007	0	17-Jul-2008	01-Sep-2008	TX	WAES0708USA03004	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Hypertension

Symptom Text: Initial and follow-up information has been received through the pregnancy registry, from a nurse and a consumer concerning her 16 year old daughter with a cold and allergies to AUGMENTIN and erythromiycin and no medical history, who on 13-JUN-2007 was vaccinated with a 0.5mL third dose of GARDASIL. Concomitant therapy included Prenatal vitamins (unspecified), FLOVENT and ROBITUSSIN. Subsequently, after receiving the vaccination, the patient found out that she was 14 weeks pregnant. The patient sought unspecified medical attention. Blood work taken (results unknown). No product quality complaint was involved. On 29-JAN-2008 the patient delivered her baby "a bit early due to high blood pressure" (in the patient). The baby weighed 8 pounds 5 ounces and was healthy and normal. The patient was seen on 13-MAR-2008 and her blood pressure was normal at 116/74. Additional information has been requested.

Other Meds: FLOVENT; ROBITUSSIN; vitamins (unspecified)

Lab Data: diagnostic laboratory - blood work; blood pressure, 01/29?/08 - high; blood pressure, 03/13/08, 116/7

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Allergic reaction to antibiotics; Cold

Prex Vax Illns:

Vaers Id: 319786-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	13-Feb-2007	Unknown		17-Jul-2008	01-Sep-2008	NY	WAES0708USA04865	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0011U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature separation of placenta

Symptom Text: Information has been received from a licensed practical nurse (LPN) concerning a 23 year old female with papilloma viral infection (diagnosed in 2006), peanut oil allergy, egg allergy and allergy to nuts and a history of Papanicolaou smear abnormal, loop electrosurgical excision procedure for the treatment of dysplasia (2007) who on 08-DEC-2006 was vaccinated with her first dose GARDASIL (653978/0955F), 0.5 ml, IM, left deltoid. Concomitant therapy included YASMIN, which was discontinued on approximately 12-FEB-2007. On 13-FEB-2007, the patient received her second dose GARDASIL (lot #654702/0011U), 0.5ml, IM, left deltoid. On that same date, the patient was placed on therapy with YAZ. On 22-JUN-2007, the patient received her third dose of GARDASIL (lot #657868/0523U), 0.5ml, IM, left deltoid. Therapy with YAZ was discontinued (date and reason not reported). On 24-AUG-2007, the LPN reported that the patient was pregnant Last menstrual period reported as 28-JUN-2007, estimated delivery date is 03-APR-2008. Follow up information has been received from a nurse who reported that on an unspecified date the patient had a vaginal preterm delivery at 35 weeks gestation due to a partial placental abruption with pre-term labor. She delivered a healthy, normal male, weighing 6 pounds 4 ounces with good cord blood ph values at delivery. No additional information is expected.

Other Meds: YASMIN; YAZ

Lab Data: beta-human chorionic - positive;

History: Papanicolaou smear abnormal; Loop electrosurgical excision procedure; Dysplasia

Prex Illness: Pregnancy NOS (LMP = 6/28/2007); Papilloma viral infection; Peanut allergy; Egg allergy; Allergy to nuts

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319787-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	14-Aug-2007	14-Aug-2007	0	17-Jul-2008	01-Sep-2008	PA	WAES0708USA05720	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure increased, Drug exposure during pregnancy

Symptom Text: Information has been received from the Merck Pregnancy registry from a nurse concerning a 22 year old female who on 12-JUN-2007 was vaccinated IM with a 0.5 ml first dose of GARDASIL. When the patient received her first vaccination she was not pregnant. On 14-AUG-2007 the patient received the second dose of of GARDASIL (Lot # 658222/0927U). There was no concomitant medication. Subsequently, the patient was pregnant at the time of the vaccination. On 29-AUG-2007 the patient came into the physician office and had a positive pregnancy test. The patient last menstrual period was 21-JUL-2007 and the estimated date of delivery was 26-APR-2008. On 11-APR-2008, the patient gave birth to a healthy female. It was reported that during labor/delivery, the mother developed increased blood pressure. Additional information is not expected.

Other Meds: None

Lab Data: beta-human chorionic 08/29/07 - Positive

History: Pregnancy

Prex Illness: Pregnancy NOS (LMP = 7/21/2007)

Prex Vax Illns:

Vaers Id: **319788-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	04-May-2007	18-Jul-2007	75	17-Jul-2008	01-Sep-2008	CA	WAES0709USA00095	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received via the Merck pregnancy registry, from a physician, concerning a 19 year old female patient with no known allergies and no pertinent history, who on 04-MAY-2007 was vaccinated with the first dose of GARDASIL (lot # not reported). On 18-JUL-2007, the patient had her LMP and was unknowingly pregnant, when on 20-AUG-2007, she was vaccinated with the second dose of GARDASIL (Lot #655617/1447F). The estimated date of delivery was 23-APR-2007. The patient sought unspecified medical attention. Follow up information has been received from a nurse who reported that the patient had a "slightly early" delivery on 07-MAR-2008, approximately 33 weeks from last menstrual period. No problems were reported with mother or baby. No further information was reported regarding the pregnancy outcome. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 7/18/2007)

Prex Vax Illns:

Vaers Id: 319789-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	25-Jul-2007	Unknown		17-Jul-2008	01-Sep-2008	LA	WAES0709USA01334	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Thrombocytopenia, Vaginal infection

Symptom Text: Initial and follow-up information has been received through the Merck Pregnancy registry via a healthcare professional and a physician concerning a 22 year old white female with mild cervical dysplasia and a history of 2 previous pregnancies with full term delivered (January 2002 and August 2004) who on 25-MAY-2007 was vaccinated with the first dose of GARDASIL (lot #653736/0014U). On 25-JUL-2007, the patient was vaccinated with the second dose of GARDASIL (Lot #657872/0515U). Concomitant medications included UNISOM and PREMESIS. On approximately 25-MAY-2007, the patient developed vaginitis and on 25-MAY-2007 was placed on therapy with TINDAMAX. It was reported on 10-SEP-2007, the patient was 6 weeks pregnant. On 20-SEP-2007, ultrasound revealed intra-uterine pregnancy at 7.2 weeks. The patient last menstrual period (LMP) was of 30-JUL-2007 and estimated of delivery was 05-MAY-2008. The patient underwent unspecified blood work (results not reported). Unspecified medial attention was sought. On an unspecified date, the patient developed thrombocytopenia. On 22-APR-2008, 38.1 weeks from LMP, the patient delivered a healthy male infant. Weight was 7 pounds 8 ounces, head circumference was 13 5/8 inches and length was 20.5 inches. Apgar score was 8/9. On 20-MAY, the patient was vaccinated with a third dose of GARDASIL (lot # 660387/1967U). Other medications used this pregnancy included PRIMACARE ONE. Additional information has been requested.

Other Meds: PREMESIS RX; UNISOM (DOXYLAMINE SUCCINATE)

Lab Data: diagnostic laboratory - results not reported; ultrasound, 09/20/07 - IUP at 7.2 weeks; serum alpha-fetoprotein, 12/07/07 - negative; Apgar score, 04/22/08 - 8/9

History:

Prex Illness: Pregnancy NOS (LMP = 7/30/2007); Cervical dysplasia; Hyperemesis

Prex Vax Illns:

Vaers Id: **319790-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Aug-2007	28-Aug-2007	0	17-Jul-2008	01-Sep-2008	PA	WAES0709USA04227	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received from a retired certified medical assistant, who is also the mother of the patient and a member of the certified nurse midwife's office, for the Pregnancy Registry for GARDASIL, concerning a 16 year old female with allergies to sulfa antibiotics and prior history of smoking. On 27-FEB-2007, the patient was vaccinated with her first dose of GARDASIL (Lot #, 654702/00110). On 02-MAY-2007, the patient was vaccinated with her second dose of GARDASIL (Lot # 657617/0384U). On 28-AUG-2007, the patient was vaccinated with her third dose of GARDASIL (Lot # 658556/1060U). Concomitant therapy included TANDEM OB. On 25-SEP-2007 it was reported that the patient was 8 weeks and 6 days pregnant. On 25-SEP-2007, 10-DEC-2007, 10-APR-2008 and on 18-APR-2008 the patient had an ultrasound due to large for gestational age and right testicle hydrocele. On 26-NOV-2007 the patient had an elective serum alpha-fetoprotein test. The patient sought unspecified medical attention in the office. It was reported that on an unspecified date the patient had unspecified blood work and a urine pregnancy test. "As far as the delivery went everything was fine" (no further information was provided). The patient delivered a normal male infant on 04-MAY-2008, weighing 8 pounds and 15 ounces. It was reported that the baby experienced fetal distress during labor and delivery. There were no congenital anomalies, complications or abnormalities. It was reported that the mother experienced a 50 plus pound weight gain. On 04-JUN-2008, the patient went to the office for her postpartum visit (not otherwise specified). On 11-JUL-2008, the infants pediatrician was contacted regarding whether or not the baby had any right testicular hydrocele (earlier identified on a sonogram). He said that after doing several exams on the infant there was no hydrocele noted. It was also reported that he had no access to the prenatal ultrasound reports and was not aware of these findings. Additional information is not expected.

Other Meds: TANDEM OB

Lab Data: diagnostic laboratory; ultrasound, 09/25/07 - LGA hydrocele right testicle; ultrasound, 12/10/07 - LGA hydrocele right testicle; ultrasound, 04/18/08 - LGA hydrocele right testicle; ultrasound, 04/10/08 - LGA hydrocele right testicle; ultra

History:

Prex Illness: Pregnancy NOS (LMP = 7/25/2007); Sulfonamide allergy; Ex-smoker; Vitamin supplementation

Prex Vax Illns:

Vaers Id: 319791-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		17-Jul-2008	01-Sep-2008	NY	WAES0710USA00168	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0210U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Initial and follow up information has bee received from a physician, through the Merck pregnancy registry and from a 26 year old female consumer with no known allergies and no pertinent medical history, who in May 2007 was vaccinated with her first dose of GARDASIL (lot #0210U), and on 22-JUL-207 was vaccinated with her second dose of GARDASIL (lot #0469U). There was no concomitant medication. The patient reported that in September 2007 she was currently 2 months pregnant. Follow up information received from the physician indicated the date of the patient's LMP was 26-JUL-2007, and the estimated date of delivery was 01-MAY-2008. No further details were provided. Follow up information has been received from a medical assistant who reported that on 08-APR-2008 the patient had a normal vaginal delivery of a healthy and normal infant born at 36 5/7 weeks estimated gestational age, pre-term. There was no complications for the baby. Additional information is not expected.

Other Meds: None

Lab Data: beta-human chorionic, 09/??/07

History:

Prex Illness: Pregnancy NOS (LMP = 7/26/2007)

Prex Vax Illns:

Vaers Id: 319792-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Aug-2007	03-Aug-2007	0	17-Jul-2008	01-Sep-2008	--	WAES0710USA03974	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Polyhydramnios

Symptom Text: Initial and follow up information has been received from a nurse and a certified nurse midwife for the Pregnancy Registry for GARDASIL concerning a 15 year old female who on 03-AUG-007 was vaccinated with the first dose of GARDASIL (Lot #, site and route not reported). Concomitant therapy included vaccination with the meningococcal vaccine (unspecified). Subsequently, it was determined that the patient was pregnant (LMP 15-Apr-2007). The patient sought unspecified medical attention. On 25-NOV-2007, '(also reported as 32 weeks gestation), the patient was sent for a amniotic fluid index (AFI) and the prenatal sonogram found that the patient had polyhydramnios. No numeric AFI was reported. On 20-JAN-2008, the patient delivered vaginally at term with "massive polyhydramnios". She delivered a healthy, and normal baby weighing 7 lbs, 6 oz. Both the mother and baby are doing well. Additional information is not expected.

Other Meds:

Lab Data: ultrasound, 11/25/07 - polyhydramnios; serum beta-human - positive

History:

Prex Illness: Pregnancy NOS (LMP = 4/15/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319793-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Sep-2007	14-Sep-2007	0	17-Jul-2008	01-Sep-2008	WI	WAES0711USA00225	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Gestational diabetes, Polyhydramnios, Pre-eclampsia

Symptom Text: Information has been received from a registered nurse through the Merck pregnancy registry concerning an 18 year old female with a family history of diabetes mellitus and familial risk factor (gestational diabetes mellitus, and pre-eclampsia in patient's mother), who on 14-SEP-2007 was vaccinated with her first dose of 0.5 mL GARDASIL (lot #658554/0928U). The patient is now 8 weeks pregnant with last menstrual period 04-Sep-2007 and an estimated due date of 11-JUN-2008. There is no information about the vaccine because it was given at another office. The patient sought medical attention with an exam in the office. Follow up information has been received from the obstetrician/gynaecologist who reported that on 08-JAN-2008, the patient underwent an ultrasound indicated for gestational diabetes mellitus (GDM) and polyhydraminos which showed polyhydraminos. She also had a serum alpha-fetaprotein test, indicated for (GDM) and polyhydraminos, which was negative. On 31-MAR-2008, 09-MAY-2008, 15-MAY-2008 and 30-MAY-2008 the patient underwent ultrasounds indicated for (GDM) and polyhydraminos, all showed polyhydraminos, but otherwise normal. A 35 glucose tolerance test done during the pregnancy was abnormal -1. Gestational diabetes was diagnosed (date not reported). The treatment for the gestational diabetes mellitus included insulin NPH BID and insulin regular daily. The physician reported that the patient underwent several neonatal stress tests (dates not specified) which were normal and reactive. The patient also experienced pre-eclampsia during her pregnancy (date not specified). The physician reported that on 06-JUN-2008, at 38 5/7 weeks from last menstrual period, the patient delivered a normal male infant with apgar: 9/9, weight: 7lbs 11ozs, length: 21 inches, and head circumference: 37 cm. The infant had mild jaundice. Additional is not expected.

Other Meds: Unknown

Lab Data: ultrasound, 05/30/08 - polyhydraminos; ultrasound, 05/15/08 - polyhydraminos; ultrasound, 05/09/08 - polyhydraminos; ultrasound, 03/21/08 - polyhydraminos; fetal nonstress test - normal, reactive; ultrasound, 01/08/08 - polyhydraminos; seru

History: Family history of diabetes; Familial risk factor

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319794-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Aug-2007	17-Aug-2007	0	17-Jul-2008	01-Sep-2008	WI	WAES0711USA04697	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0802U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chlamydial infection, Drug exposure during pregnancy

Symptom Text: Information has been received as part of a pregnancy registry from a registered nurse concerning a 16 year old white female who on 17-AUG-2007, was vaccinated with her first dose of GARDASIL (lot# 658490/0802U), intramuscularly. On 18-OCT-2007 the patient received her second dose of GARDASIL (lot #658556/1060U), intramuscularly. The patient was given two doses of GARDASIL while she was pregnant. It was reported that on 27-NOV-2007 patient was treated 500 mg (two tablets) of ZITHROMAX for chlamydia. She was also started on prenatal vitamins on October 2007 1 tablet daily for pregnancy. No adverse events were reported. On 21-NOV-2007 the patient had a routine ultrasound that showed single IUC, 13 weeks and 5 days. The patient's last menstrual period was estimated to be 15-AUG-2007, " mid August" and her estimated date of delivery is 23-May-2008. In follow up telephone call the nurse reported that the patient delivered a healthy and normal infant on 12-MAY-2008 weighing 8 lb 1 oz "8-1" with apgars of 9/10. The baby's length was 20 inches long. No problem was reported. Additional information is not available.

Other Meds: meningococcal vaccine

Lab Data: ultrasound, 11/21/07 - single IUC, 13 weeks, 5 days; Apgar score, 05/02/08, 9/10

History:

Prex Illness: Pregnancy NOS (LMP = 8/15/2007)

Prex Vax Illns:

Vaers Id: **319795-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		17-Jul-2008	01-Sep-2008	TX	WAES0711USA04758	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Chlamydial infection, Drug exposure during pregnancy, Dyspepsia, Gastrooesophageal reflux disease, Upper respiratory tract infection

Symptom Text: Initial and follow up information has been received through the Merck pregnancy registry for GARDASIL from a Registered Nurse concerning an 18 year old female who in August 2007 was vaccinated with a first dose of GARDASIL. On 08-NOV-2007 the patient was vaccinated with a second dose of GARDASIL and was pregnant. There was no concomitant medication and diagnostic laboratory tests included Complete Blood Count (CBC), Human immunodeficiency (HIV), rubella, Hepatitis B, and antibody type and screen. No results were given. The GARDASIL was given by another physician at another office. The patient experienced chlamydia and upper respiratory infection during her pregnancy (dates unknown). Since 27-NOV-2007 the patient has been prescribed pre-natal vitamins. On 17-DEC-2007 the patient experienced heartburn and was treated with PREVACID and had a maternal serum alpha fetoprotein survery (MSAFP) and the result of the test was negative. On 21-DEC-2007 the patient experienced gastroesophageal reflux disease and was treated with PREVACID. On 18-JAN-2008 the patient had an ultrasound for anatomical survey and the result of the test was unremarkable and within limits. On 17-MAR-2008 the patient experienced anemia and was treated with REPLIVA 21/7). On 25-MAY-2008 the patient delivered a normal, healthy female baby weighing 7 pounds and 14 ounces and length was 20.5 inches. At the time of the report the outcome of the heartburn, gastroesophageal reflux disease, anemia, chlamydia and upper respiratory disease were unknown. Additional information has been requested.

Other Meds:

Lab Data: diagnostic laboratory - HIV test - no results given; diagnostic laboratory - antibody type and screen - no results given; ultrasound, 01/18/08 - unremarkable anatomical survey for pregnancy-WNL; complete blood cell - no results given; serum

History:

Prex Illness: Pregnancy NOS (LMP = 8/27/2007)

Prex Vax Illns:

Vaers Id: 319796-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-May-2007	10-May-2007	0	17-Jul-2008	01-Sep-2008	--	WAES0803USA00968	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0961F		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Gastrooesophageal reflux disease, Haemorrhage, Urinary tract infection

Symptom Text: Information has been received for the Pregnancy Registry of GARDASIL from a Registered Nurse (R.N.) concerning an 18 year old female patient who on 10-MAY-2007 was vaccinated with a dose of GARDASIL (lot # 654389/0961F). In follow up information from the doctor's office it was reported that on 02-OCT-2007 patient had ultrasound (19 weekd pregnancy) for bleeding and result was within normal limit. On 22-OCT-2007 she had a amniocenticsis (at 21weeks pregnancy) and the result was within normal limit. On 23-JAN-2008 she was treated for gastric esophageal reflux disease (GERD) with PRILOSEC twice a day and with KEFLEX twice a day for urinary tract infection. On an unspecified day patient was started with prenatal vitamins. The office learnt about the pregnancy when patient went to the office on 26-JUL-2007. In a follow up telephone call and from the follow up information from the doctor's office it was reported that patient's last menstrual period (LMP) was on 27-MAY-2007 and she delivered a normal male baby on 21-FEB-2008. The apgar score for the baby was 9/9. The baby weighed 7 lb 8 oz. The nurse stated that the baby was "fine". No other information was provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: ultrasound, 10/02/07 - Done in 19 weeks for bleeding (within normal); amniocentesis, 10/22/07 - 21 week routine fetal screen (within normal); Apgar score, 02/21/08, 9/9

History:

Prex Illness: Pregnancy NOS (LMP = 5/27/2007)

Prex Vax Illns:

Vaers Id: 319797-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	03-Mar-2008	03-Mar-2008	0	17-Jul-2008	01-Sep-2008	WI	WAES0803USA04586	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Information has been received from a registered nurse concerning a 24 year old female who on 19-DEc-2007 was vaccinated with a first dose of GARDASIL and on 18-JAN-2008 was vaccinated with a second dose of GARDASIL. On 03-MAR-2008 at 15:24, the patient was inadvertently vaccinated intramuscularly with her third dose of GARDASIL in place of hepatitis B virus vaccine rHBsAg (yeast) (MSD). There were no adverse symptoms. This is not a case of product confusion. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319798-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		17-Jul-2008	01-Sep-2008	AZ	WAES0804USA02881	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0961F	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cardiac disorder, Inappropriate schedule of drug administration

Symptom Text: Initial and follow up information has been received from a medical assistant and a physician concerning an approximately 25 year old female who on 30-OCT-2006 was vaccinated IM with the first 0.5 ml dose of GARDASIL (Lot#653937/0637F). On 02-JAN-2007, the patient was vaccinated IM with the second 0.5 ml dose of GARDASIL (Lot#654389/0961F). In approximately 2007, the patient had a "problem with her heart" between the second and third doses. On 11-APR-2008, she was vaccinated IM with the third 0.5 ml dose of GARDASIL. The patient sought medical attention by an physician other than the reporter. At the time of the report, the patient outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 319799-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	22-Aug-2007	30-Sep-2007	39	17-Jul-2008	01-Sep-2008	--	WAES0805USA04033	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0929U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Drug exposure during pregnancy, Gastrooesophageal reflux disease

Symptom Text: Initial and follow-up information has been received for the Merck Pregnancy Registry for GARDASIL from a certified nurse midwife concerning a 22 year old female with depression, no pertinent medical history and no drug reactions/allergies who on 21-FEB-2007 was vaccinated with a first dose of GARDASIL (lot# 655618/0186U) 0.5 mL IM. On 22-AUG-2007 the patient was vaccinated with a second dose of GARDASIL (lot# 658282/0929U) 0.5 mL IM. The patient became pregnant after two doses of GARDASIL. The patient's date of last menstrual period was 30-SEP-2007. Medical attention was sought. On 05-DEC-2007 an ultrasound was performed for dating and was viable 7.5 "fup" and on 31-JAN-2008 a maternal serum alpha-fetoprotein test (MSAFP) was performed and was within normal limits. No further information was available. The estimated date of delivery is 06-JUL-2008. Follow-up information was received the patient also had a history of papanicolaou smear abnormal. On an unspecified date the patient had anxiety and on 28-FEB-2008 CYMBALTA was prescribed. On an unspecified date the patient had gastrooesophageal reflux disease (GERD) and on 25-MAR-2008 the patient was given PREVACID. Additional information has been requested.

Other Meds: CYMBALTA; PREVACID

Lab Data: ultrasound, 12/05/07 - dating viable 7.5 "FUP"; serum alpha-fetoprotein, 01/31/08 - screening within normal limits

History: Papanicolaou smear abnormal

Prex Illness: Pregnancy NOS (LMP = 9/30/2007); Depression

Prex Vax Illns:

Vaers Id: **319800-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	30-May-2008	30-May-2008	0	17-Jul-2008	01-Sep-2008	MA	WAES0806USA01521	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a registered nurse concerning a 20 year old female with a history of allergic to antibiotics who on 30-MAY-2008 was vaccinated IM with the first dose of GARDASIL (659439/1267U). Concomitant therapy included hormonal contraceptives (unspecified). On 30-MAY-2008 the patient experienced pain, redness and swelling at the injection site. The patient had increased pain, redness and swelling on 05-JUN-2008. The patient sought unspecified medical attention by calling the physician. Patient outcome was not reported. The nurse also reported that "many patients" experience pain related to the administration of GARDASIL. No other information is available at this time. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Allergic reaction to antibiotics

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319801-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	30-Mar-2007	30-Mar-2007	0	17-Jul-2008	01-Sep-2008	IL	WAES0806USA01527	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1161F	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthritis, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a physician concerning a 28 year old female, with no relevant medical history and no known drug allergies, who on 30-MAR-2007 was vaccinated intramuscularly with her first dose of GARDASIL (Lot # 654540/1161F; site not reported). On 01-JUN-2007 the patient was vaccinated intramuscularly with her second dose of GARDASIL (Lot # 0210U; site not reported). On 19-OCT-2007, the patient was vaccinated intramuscularly with her third dose of GARDASIL (Lot # 0530U; site not reported). There was no concomitant medication. On 04-JUN-2008, the patient called the office and stated that "she had arthritis from GARDASIL". The patient sought unspecified medical treatment by calling the office. The patient outcome was not reported. No additional information was provided. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319802-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	30-May-2008	30-May-2008	0	17-Jul-2008	01-Sep-2008	PA	WAES0806USA01530	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from a physician's office manager concerning a 13 year old female with asthma and a history of hypoglycaemia who on 31-OCT-2007 was vaccinated intramuscularly in the left deltoid with her first dose of GARDASIL (Lot # 659437/1266U). On 20-JAN-2008, the patient was vaccinated intramuscularly in the left deltoid with her second dose of GARDASIL (Lot # 659657/1487U). On 30-MAY-2008, the patient was vaccinated intramuscularly in the left deltoid with her third dose of GARDASIL (Lot # 660391/0062X). Concomitant therapy included and albuterol inhaler (unspecified). The office manager reported that on 30-MAY-2008 "the patient experienced a syncopal episode after receiving her third dose of GARDASIL". She reported that the patient collapsed as she attempted to leave the office and hit her head on the wall as she fell. The patient did not lose consciousness. The patient was examined in the office and vital signs monitored (not otherwise specified). It was reported that on 30-MAY-2008, the patient recovered from both events within an unspecified amount of time. There were no other symptoms and no treatment reported. No additional information was provided. Additional information has been requested.

Other Meds: albuterol

Lab Data: None

History: Hypoglycaemia

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **319803-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	06-Jun-2008	06-Jun-2008	0	17-Jul-2008	01-Sep-2008	--	WAES0806USA01610	02-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysgeusia

Symptom Text: Information has been received from a nurse concerning a female who on 06-JUN-2008 was vaccinated with her first dose of GARDASIL (lot# not reported). Concomitant therapy included VARIVAX, for the treatment of prophylaxis (duration and dose not reported) (lot# not reported). Other concomitant therapy included MENACTRA (lot# not reported). On 06-JUN-2008, after receiving the 3 different vaccines, the patient experienced a metallic in her mouth. She brushed her tongue 20 times, but she could still taste it. The patient's metallic taste in her mouth persisted. The patient sought unspecified medical attention on an unspecified date when her mom called the office. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319804-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	17-Jan-2008	17-Jan-2008	0	17-Jul-2008	01-Sep-2008	UT	WAES0806USA01620	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Headache, Pain, Pyrexia

Symptom Text: Information has been received from a physician and healthcare worker concerning a 21 year old female who was vaccinated on 17-JAN-2008 in the left deltoid with her third dose of GARDASIL (lot# 659441/1446U). Concomitant therapy included YAZ. On 17-JAN-2008 the patient felt achy, had a high fever, headache and the chills after receiving her third dose. Subsequently, the patient recovered on 18-JAN-2008 from feeling achy, a high fever, headache and chills. The patient sought unspecified medical attention on an unspecified date. No additional information is expected. This is a consolidation of two reports.

Other Meds: YAZ

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319805-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	09-Jun-2008	09-Jun-2008	0	17-Jul-2008	01-Sep-2008	SC	WAES0806USA01624	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin warm, Somnolence

Symptom Text: Information has been received from a Pharmacist (R.Ph.) concerning a "young lady" who on 09-JUN-2008 was vaccinated with a first dose of GARDASIL (lot # not reported). There was no concomitant medication. The Pharmacist reported that the "young lady received her first dose of GARDASIL at the physician's office around 10 am this morning and slept from around 12 noon to about 4:15 PM". She was awakened by her mother as recommended by the pharmacist to check her status. It was reported that "she felt a little warm". The patient sought medical attention by contacting the pharmacist. The patient's present status was reported as "sleepy". Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **319806-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	01-Sep-2008	--	WAES0806USA01921	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lip swelling

Symptom Text: Information has been received from a Nurse Practitioner concerning a female who was vaccinated with a first dose of GARDASIL (lot # not reported). The nurse reported that the patient "developed swollen lips a few days after receiving her first dose of GARDASIL". It was also reported that the patient had also "just started an unspecified birth control medication". The patient sought unspecified medical attention during a phone call to the office. Patient outcome was not reported. Additional has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319807-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Jun-2008	10-Jun-2008	0	17-Jul-2008	01-Sep-2008	OH	WAES0806USA01942	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0244U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Headache, Musculoskeletal pain, Neck pain, No reaction on previous exposure to drug, Tension headache

Symptom Text: Information has been received from a physician and from Emergency room medical records concerning a 16 year old female with no pre-existing allergies or medial condition, who on 24-APR-2007 was vaccinated intramuscularly into left deltoid with the first dose of GARDASIL (lot# not reported) and on 10-JUN-2008 was vaccinated with the second dose of GARDASIL (lot # 656051/0244U). On 12-JUN-2008 the patient went to the emergency room and had complaints of headache to the right temporal area, described as constant. The symptoms were aggravated by standing or laying for too long. The patient had right neck pain into her shoulder. Examination was positive for right trapezius, pain at rest, pain with movement. The symptoms began two days ago. Chest pain was also noted (onset not reported). The emergency room report noted that there was no dizziness, fever, nausea, paresthesis, sinus congestion, vision changes, vomiting. The severity of the pain in the emergency department was a "10" out of "10." The patient had not had any similar episode in the past. Physical examination in the emergency room showed that the patient was oriented to person, place, time and her mentation was appropriate for stated age. She had excellent breath sounds in all fields with symmetrical chest wall movement and no wheezing, rales of rhonchi. Her heart sounds were normal with no murmurs, rubs or gallop. Vital signs included: B/P 130/93; pulse 81; respirations 18; temperature 98.7 and pulse oximeter 96& on room air. Impression was tension headache. In the emergency room the patient was given MOTRIN 800 mg orally and FLEXERIL 10 mg orally. Her symptoms improved and she was discharged to home in stable condition with instructions on headache, tension muscle contraction headache. Discharged medications included prescriptions for PHENERGAN (twelve) tablets 25 mg, 1 every 6 hours as needed for nausea; TORADOL 1O mg (twelve) tablets, 2 tablets by mouth to start then 1 tablet every 6 hours as needed. She was to follow up with her physician in 2-3 days.

Other Meds: Unknown

Lab Data: blood pressure, 06/12/08, 130/9; pulse oximetry, 06/12/08, 96%; cardiac monitoring, 06/12/08 - Pulse 81 and repeat pulse 82; temperature measurement, 06/12/08, 98.7

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319808-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Apr-2008	Unknown		17-Jul-2008	28-Aug-2008	MD	WAES0806USA01947	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration

Symptom Text: Information has been received from a certified medical assistant concerning a 17 year old female with a history of penicillin allergy who on 27-FEB-2008 was vaccinated with IM with the first dose of GARDASIL (658556/1060U). On 23-APR-2008 the patient was vaccinated IM in the right deltoid with the second dose of GARDASIL (659962/1740U). The medical assistant reports that the patient developed a "knot" at the injection site at an unspecified time period after receiving the second dose. The patient phoned the physician's office on 10-JUN-2008 to report the adverse symptom. No other symptoms or treatments were reported and no other information is available. The patient's "knot" at the injection site has persisted. This is a consolidation of two reports concerning the same patient. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Penicillin allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **319810-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Aug-2007	20-Sep-2007	45	21-Jul-2008	22-Jul-2008	IL	WAES0807USA02139	29-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0012U	2	Unknown	Unknown	

Seriousness: DIED, ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Cardiac arrest, Convulsion, Death, Fall, Mydriasis, Pulmonary congestion, Pulmonary oedema, Pulse absent, Pupil fixed, Respiration abnormal, Syncope, Unresponsive to stimuli, Ventricular fibrillation, Visceral congestion

Symptom Text: Information has been received from a certified medical assistant concerning a 14 year old female who was vaccinated with a first dose of GARDASIL and experienced syncope. She was taken to an emergency room and released. The patient was vaccinated with a second dose of GARDASIL (unspecified time). Subsequently, the patient experienced her first seizure (unspecified time) and was taken to the emergency room (no further details provided). The patient was vaccinated with a third dose of GARDASIL at 15 years old. Approximately 27-JUN-2008, two weeks after the third dose, the patient developed a complication. She was taken to the hospital by ambulance but passed away during the transport from an unknown cause. The physician has asked the mother for the autopsy report. The reporting medical assistant considered the syncope, seizure and "a complication" were considered to be immediately life-threatening and disabling. Additional information has been requested. 2/13/09 Autopsy report received. COD: Seizure Disorder. Summary Diagnoses: Clinical history of seizure disorder. Pulmonary congestion and edema. Passive visceral congestion. 2/20/2009 ER received from CDC. Pt presented to ER via EMS following witnessed seizure activity with fall from standing. Upon EMS arrival pt had agonal respirations and was pulseless in V-fib at 650. Upon arrival in ER unresponsive, pupils fixed and dilated, no cardiac activity. Resuscitation unsuccessful and pt expired.

Other Meds: Unknown

Lab Data: Unknown. Labs and Diagnostics: Tox screen (-).

History: Unknown. PMH: 1 prior seizure 8/2007. 4/28/09 Additional records received from PCP at CDC's request. Pt in for OV 1/30/07 with c/o allergy sx and requesting HPV#1-given 0012U. Returned 3/22/07 for HPV#2-given 1427F with Boostrix AC52B012AA. Mild URI 4/25/07. OV 6/12/07 in F/U to ER visit for seizure on 6/11/07. Syncope noted. Sent for tests. OV 6/28/07 Echo and blood work repor

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319812-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	21-May-2008	21-May-2008	0	21-Jul-2008	22-Jul-2008	--	WAES0807USA02664	22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old white female with mild asthma, and no previous pregnancies, who on 21-MAY-2008 was vaccinated with the first dose of GARDASIL and then discovered that she was pregnant. Concomitant medications included prenatal vitamin with folic acid. The patient's last menstrual period was 02-APR-2008 and estimated date of delivery is 06-JAN-2009. On 23-MAY-2008 ultrasound results showed that the fetus was 5 weeks and there were no problems. On 04-JUN-2008 the patient had a spontaneous abortion at five weeks, four days. At the time of this report the patient's outcome was unknown. Upon internal review, the spontaneous abortion was considered to be an other important medical event. No further information is available.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 05/23/08 - fetus 5 weeks, no problems

History:

Prex Illness: Pregnancy NOS (LMP = 4/2/2008); Asthma

Prex Vax Illns:

Vaers Id: 319813-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-May-2007	15-Jun-2007	31	21-Jul-2008	22-Jul-2008	MO	WAES0807USA02543	14-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Aura, Dysarthria, Headache, Hemiplegia, Immediate post-injection reaction, Migraine, Nausea, Photophobia

Symptom Text: Information has been received from a nurse concerning a 14 year old female who on 15-MAY-2007 was vaccinated with her first dose of GARDASIL. There was no other vaccination to the patient on that day. On 15-MAY-2007, immediately post vaccination, the patient developed slurred speech for 10 minutes, paralysis of left side for 30 to 40 minutes and a migraine. Subsequently, the patient recovered from the events. Unspecified medical attention was sought. Upon internal review, hemiplegia was determined to be an other important medical event. Additional information has been requested. 8/13/08-records received for DOS 8/15/07-neurology clinic visit for evaluation of two spells associated with headache as well as third severe headache in past 3 months. First spell occurred in June of 2007 when her speech became slurred and developed ;numbness or loss of sensation in entire left lower extremity followed by entire left upper extremity. Speech problem resolved within 10 minutes and loss of sensation persisted for 30 minutes and as this was resolving developed a severe headache over left temple migrated to right temple. Felt like bright light burning directly into left side of head, severe photophobia, vomiting and severely nauseous. Evaluated in ED with head CT which was unremarkable. The next episode occurred in July with no speech problems, only sensation loss in left leg and foot and arm. Fell asleep for 2 hours and up awakening no sensory abnormalities. Seen in ED and repeat CT scan. Two weeks prior to this office visit had significant headache and sensory symptoms. PE normal. Consistent with classic migraine with aura.

Other Meds: Unknown

Lab Data: Unknown 8/13/08-records received- head CT which was unremarkable.

History: Unknown 8/13/08-records received-Family history of migraines. Seasonal allergies.

Prex Illness:

Prex Vax Illns:

Vaers Id: **319814-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Jun-2008	30-Jun-2008	19	21-Jul-2008	22-Jul-2008	KS	WAES0807USA02464	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Face injury, Neck pain, Nuclear magnetic resonance imaging brain normal, Pain in jaw, Postictal state

Symptom Text: Information has been received from a physician, who was notified by a patient's mother that her 14 year old daughter, with no previous medical history of seizures reported, who on 11-APR-2008 was vaccinated with the first dose of GARDASIL (Lot # 660387/1967U) and on 11-JUN-2008 was vaccinated with the second dose of GARDASIL (Lot # 659182/1757U). The patient experienced 2 generalized seizures. On 30-JUN-2008, the patient experienced the first seizure at home which lasted for 5 minutes. On 05-JUL-2008, the patient experienced the second seizure with duration for 5 minutes. On 11-JUL-2008, the patient sought medical attention by a phone call. The patient has recovered and is being monitored. Upon internal review, the 2 generalized seizures were considered to be an other important medical events. Additional information has been requested. 8/4/08-records received for DOS 7/5/08-seen in ED for C/O seizure lasting 2 minutes and postictal, hit face during seizure, nose jaw and neck pain. Genrealized seizure. First seizure 5 days ago.

Other Meds: Unknown

Lab Data: None 8/4/08-records received-X-ray of face nasal bone fracture. CT, labs and LP normal. 10/1/08 Reviewed hospital records which consist only of brain MRI, WNL./

History: None

Prex Illness:

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319815-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Mar-2008	Unknown		21-Jul-2008	22-Jul-2008	--	WAES0807USA02411	22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Mobility decreased, Monoplegia, Pain, Physiotherapy

Symptom Text: Information has been received from a consumer concerning her daughter, a 25 year old who in approximately March 2008 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. The consumer reported that her daughter developed paralysis on her right arm, has limited mobility and is in constant pain after getting the first dose of GARDASIL. MRI and physical therapy were performed, however results were not provided. The patient's paralysis on her right arm, limited mobility and constant pain persisted. The patient sought medical attention. Upon internal review, paralysis on her right arm was determined to be an other important medical event. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **319816-1** **Related reports:** 319816-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		21-Jul-2008	22-Jul-2008	AZ	WAES0807USA02253	22-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a physician concerning a 12-14 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL. Concomitant vaccinations received on the same day included MENACTRA and diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (manufacturer unknown). The physician reported that a patient fainted post vaccination with GARDASIL. The patient was vaccinated with her first dose of GARDASIL, on an unknown date, and also with MENACTRA and another vaccine diphtheria (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (manufacturer unknown), on the same day. Immediately post vaccination the patient fainted and had "seizure like activity". The patient sought for medical attention: in the office. At the time of the report, the patient outcome was unknown. There was no product quality complaint. Upon internal review "seizure like activity" was considered to be other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319816-2** **Related reports:** 319816-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		29-Jul-2008	30-Jul-2008	--	200802347	09-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: This case was received from a physician via another manufacturer on 18 July 2008, under reference number WAES0807USA02253. SERIOUSNESS CRITERIA-OTHER: MEDICALLY SIGNIFICANT. The following is verbatim from the other manufacturer's report: "Information has been received from a physician concerning a 12-14 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL. Concomitant vaccinations received on the same day included: MENACTRA and DTaP (manufacturer unknown)." "The physician reported that a patient fainted postvaccination with GARADASIL. The patient was vaccinated with her first dose of GARDASIL, on an unknown date, and also with MENACTRA and another vaccine DTaP (manufacturer unknown) on the same day. Immediately post vaccination the patient fainted and had "seizure like activity". The patient sought for medical attention: in the office." "At the time of the report, the patient outcome was unknown." "There was no product quality complaint." "Upon internal review "seizure like activity" was considered to be other important medical event." "Additional information has been requested."

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 319817-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Nov-2007	01-Dec-2007	30	21-Jul-2008	22-Jul-2008	PA	WAES0807USA02228	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Axillary pain, Chest discomfort, Chest pain, Dyspnoea, Haematoma, Pain in extremity, Pleuritic pain, Pulmonary embolism, Rales, Skin papilloma, Thrombosis

Symptom Text: Information has been received from a mother concerning her 26 year old daughter with no pertinent medical history and no drug reaction allergies who in last May or June 2007 was vaccinated with the first dose of GARDASIL (Lot # not provided), in August 2007 was vaccinated with the second dose of GARDASIL (Lot # Not provided) and in November 2007 with the third dose of GARDASIL (Lot # not provided). Concomitant therapy included hormonal contraceptives (unspecified). The mother reported that in December 2007, the patient developed warts on her foot and she started to experience difficulty in breathing and tightening of the chest this year and on 13-JUN-2008, she was hospitalized for 4 days. The mother noted that the patient was placed on warfarin sodium (manufacturer not provided) that she needs to take for 6 months. Patient still has clots on her lungs. On an unspecified date, a full coagulation panel was performed (results not provided). Additional information has been requested. 07/23/2008 MR received for DOS 6/5-7/2008 with D/C DX: Acute Bilateral Pulmonary Emboli. Oral Contraceptives. Possible Family hx of thrombophilia. Pleuritic pain 2' to acute PE. Pt presented with increasing SOB x 1 week, inability to run usual distance 2' to SOB, recent onset of R-sided back and posterior thorax pain and R axilla pain. Recent calf pain. PE (+) for mild crackles R lung base, anxiety and tearfulness r/t dx. Significant pleuritic pain. Started on Heparin then Coumadin and switched to Arixtra for outpt use. D/C BCPs. Seen in ER on 6/14/08 with DX: Hematoma in SubQ tissue (at Arixtra injection site).

Other Meds: hormonal contraceptives

Lab Data: diagnostic laboratory - full coagulation panel. Labs and Diagnostics: Multiple bilateral PEs noted on CT pulmonary angiogram. D-dimer (+) 1.45. Duplex US of lower extremities (-). Homocysteine 7. Coags (-).

History: None. PMH Lap chole 2004. Oral Contraceptive use. Family hx of DVT and clotting problems. NKDA.

Prex Illness:

Prex Vax Illns:

Vaers Id: **319818-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	03-Jul-2008	03-Jul-2008	0	21-Jul-2008	22-Jul-2008	--	WAES0807USA01802	22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from an office manager concerning a 22 year old female who on 03-JUL-2008 was vaccinated IM with a first 0.5 ml dose of GARDASIL (Lot #660391/0063X). The patient fainted and had a seizure after vaccination. The patient sought unspecified medical attention. On 03-JUL-2008, the patient had recovered. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319819-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		21-Jul-2008	22-Jul-2008	--	WAES0807USA01619	22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a parent concerning her daughter who was vaccinated with GARDASIL (lot #, date not reported). The parent reported that the daughter fainted and "started moving around as though she was going to start convulsing". The second dose of GARDASIL (lot #, and date not reported) was given. It was reported that the patient sought medical attention (office visit). No further information was available. Upon internal review, the patient's convulsion was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 319820-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		21-Jul-2008	22-Jul-2008	--	WAES0807USA01523	22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Stillbirth

Symptom Text: Information has been received from a consumer concerning her approximately 25 year old female friend who was vaccinated with the series of GARDASIL. Subsequently, the patient then became pregnant, and delivered a still born baby. The patient sought unspecified medical attention. The reporter indicated that the patient is now fine and the reporter does not want to provide any further information. No product quality complaint was involved. Upon internal review, still born was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **319821-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	01-Mar-2008		21-Jul-2008	22-Jul-2008	--	WAES0807USA01395	22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraception, Convulsion

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female patient with an irregular heart rate, menstrual issues and migraines who was vaccinated intramuscularly with the third 0.5 mL dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). Subsequently, It was reported that the patient experienced a seizure after her third dose of GARDASIL. The patient sought unspecified medical attention. Diagnostic studies performed included neurological testing and a sleep study but no results were reported. At the time of this report, the patient had not recovered. No product quality complaint was involved. Upon internal review, seizure is considered to be an other important medical event. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: neurological, 03/??/08 - results not reported; sleep study, 03/??/08 - results not reported

History:

Prex Illness: Heart rate irregular; Menstrual disorder; Migraine

Prex Vax Illns:

Vaers Id: 319822-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	06-Jul-2008	06-Jul-2008	0	21-Jul-2008	22-Jul-2008	NJ	WAES0807USA01295	22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Body temperature increased, Immediate post-injection reaction, Musculoskeletal pain, No reaction on previous exposure to drug, Paraesthesia, Pyrexia, Urticaria, Vomiting

Symptom Text: Information has been received from a physician concerning his 19 year old daughter with no medical history and no drug allergies, who on 06-JUL-2008 was vaccinated intramuscularly into the left deltoid muscle with the third 0.5 mL dose of GARDASIL. There was no concomitant medication. On 06-JUL-2008, immediately after the injection, the patient experienced severe pain of the left shoulder, tingling of the left fingers, and a feeling of weakness of the left hand. She then developed localized hives on the left upper arm, a low grade temperature and vomited once. On 07-JUL-2008 the hives, fever and vomiting were resolved, but the pain and tingling persisted. At the time of this report, the outcome of the weakness of the left hand was unknown. It was reported that the first dose of GARDASIL was given in January 2008, and that the patient did not experience any problems after receiving the first or second doses of GARDASIL. No product quality complaint was involved. The reporting physician considered the severe pain of the left shoulder and the tingling of the left fingers to be disabling. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319823-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	31-Dec-2007	31-Dec-2007	0	21-Jul-2008	22-Jul-2008	--	WAES0807USA01279	22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Amnesia, Hypoaesthesia, Paralysis

Symptom Text: Information has been received from a sales representative who was told by health professionals of media reports concerning a 13 year old female, who on 31-DEC-2007 was vaccinated with a first dose of GARDASIL. On 31-DEC-2007 the patient experienced memory loss, numbness of body and paralysis. A pediatrician was told by a consumer that the consumer doubted the validity of the report. It was reported that the patient played soccer, and as a result has a history of concussions. The patient recovered on an unknown date. the event could not be confirmed. No product quality complaint was involved. The memory loss, numbness of body, and paralysis were considered to be disabling. Additional information is not available.

Other Meds: Unknown

Lab Data: Unknown

History: Concussion

Prex Illness:

Prex Vax Illns:

Vaers Id: 319824-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	30-Jan-2008	30-Jan-2008	0	21-Jul-2008	22-Jul-2008	FR	WAES0806USA00535	22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Back pain, Diplopia, Disturbance in attention, Dysarthria, Gait disturbance, Headache, Hyperacusis, Influenza, Meningism, Mental impairment, No reaction on previous exposure to drug, Photosensitivity reaction, Vision blurred

Symptom Text: Initial and follow up information has been received from a physician concerning a 19 year old female with a history of relapsing infections who on 30-JAN-2008 was vaccinated intramuscularly into the upper left arm with her third dose of GARDASIL (Lot # and site not reported). Two days post vaccination the patient complained about headache and asthenia. She was admitted to the hospital for diagnostics (not further specified) and recovered completely within about 1 week. The first and second vaccinations with GARDASIL (Dates, Lot #s, route and sites not reported) were well tolerated. No additional information was provided. In follow up it was reported that on 30-JAN-2008 (also reported as "same day"), she developed meningeal irritation, double and blurred vision, concentration disorder, noise- and photosensitivity, a "dull feeling in head", articulation problems, gait disorder, headache, asthenia and back pain. On 31-Jan-2008 she was admitted to the hospital for diagnostics. Virus diagnostics revealed low-positive antibodies for Influenza B virus. Other virus infections were ruled out. Meningeal irritation due to influenza B virus infection was assumed. A postvaccinal reaction was discussed. A lumbar puncture was performed (normal results) and meningitis could be ruled out. Cranial MRI, abdominal sonography, ECG and neurological examinations showed normal results. Therapy was carried out with unspecified infusions and analgesics. The patient fully recovered and was discharged from the hospital on 06-FEB-2008 (exact duration of symptoms not reported). The file is closed. Other business partner numbers include: E2008-04957. No further information is available.

Other Meds: Unknown

Lab Data: spinal tap, Comment: normal; magnetic resonance imaging, Comment: normal; abdominal ultrasound, Comment: normal; electrocardiogram, Comment: normal; serum influenza B virus Ab, Comment: slightly positive antibodies for Influenza B virus

History: Infection susceptibility increased

Prex Illness:

Prex Vax Illns:

Vaers Id: **319825-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	02-Feb-2007	02-Feb-2007	0	21-Jul-2008	22-Jul-2008	--	WAES0702USA01329	22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a 25 year old female healthcare worker with no medical history or known drug allergies who on 02-FEB-2007 was vaccinated with a first dose of GARDASIL. There was no concomitant medication. The patient stated that she would not complete the vaccine series because she was 4 weeks pregnant. A pregnancy test was performed. The patient's expected delivery date was 19-OCT-2007. The patient sought unspecified medical attention. On approximately 17-MAR-2008, at approximately nine weeks, the patient reported that she had terminated the pregnancy. She did not provide a reason. She reported that she had no complications and was doing well. No product quality complaint was involved. Upon internal review terminated pregnancy was considered to be an other important medical event. Additional information is not expected.

Other Meds: None

Lab Data: beta-human chorionic

History:

Prex Illness: Pregnancy NOS (LMP = 1/12/2007)

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319826-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		21-Jul-2008	22-Jul-2008	FR	WAES0807USA03515	22-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraception, Idiopathic thrombocytopenic purpura, No reaction on previous exposure to drug, Petechiae

Symptom Text: Information has been received from a gynecologist concerning a 14 or 15 year old female who was vaccinated with the first 2 doses of GARDASIL on unspecified dates. These doses were well tolerated. Concomitant therapy included hormonal contraceptives (unspecified). It was reported that the patient was vaccinated with the third dose of GARDASIL (lot#, injection route, and site not reported) on an unspecified date. About 3 weeks post vaccination, the patient presented with generalised petechiae. Diagnosis of immune thrombocytopenia was established. No information regarding personal history (i.e. infection), treatment, duration and outcome was provided. Upon internal review Idiopathic Thrombocytopenia Purpura was considered an other important medical event. Other business partner numbers include E2008-06579. Additional information has been requested.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319836-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Jun-2006	01-Feb-2008	610	21-Jul-2008	28-Jul-2008	--		30-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Biopsy cervix abnormal, Cervix carcinoma, Smear cervix abnormal, Surgery

Symptom Text: I was diagnosis with Cervical Cancer in April 2008. I have gotten a routine thin pap test each year for the last 8 years. February 2008 was my first abnormal pap smear in my lifetime. I received the GARDASIL shot in June of 2006 after hearing and reading about its approval by the FDA. I was the first patient my doctor ever gave the HPV vaccination to. I received all three of the shots and completed the HPV vaccination in November of 2006; each given by my doctor. I had my annual pap smear in February of 2007, and like each pap smear before, it came back negative. When my February 2008 pap smear cam back positive my doctor then did a biopsy which came back with high-grade cells and warranted a Leep procedure. The Leep was performed at a local hospital on March 14, 2008. The pathology results from the Leep came back and showed that within a year of my last normal pap smear and 15 months from the completion of the GARDASIL HPV vaccination, I had full blown cervical cancer. On May 6th of 2008 I had my second surgery, a Cone Biopsy of my cervix by Dr., an oncologist at Cancer Center. My second surgery was performed at another hospital. I will now have to see my Oncologist every three months and wait to see, not 'if', but 'when', my cervical cancer returns. My oncologist would like to do a hysterectomy at this time, but as a 26-year-old who has always wanted children, I have chosen to wait as long as possible before removing my reproductive organs. As a very health conscious and responsible person, I have always researched health care issues and been good to my body. Thinking it was in my best interest of my health and well being, I received the GARDASIL shot in June 2006. It was discovered in March of 2008, followed by my first abnormal pap smear, that I have two of the four HPV strains, 16 and 18, that the shot is suppose to prevent, as well as prevent the onset of HPV symptoms. I now have cervical cancer and I am left wondering what role the GARDASIL HPV vaccination played in the hasty onset of my onset. I wish I ha

Other Meds:

Lab Data: 7/28/08-records received-5/6/08-Cold knife conization of cervix-squamous metaplasia and acute and chronic cervicitis, no dysplasia or malignancy identified. 5/22/08-Stage 1 depth of invasion less than 1mm with margin involvement dysplasia.

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **319837-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	09-Jun-2008	09-Jun-2008	0	17-Jul-2008	28-Aug-2008	RI	WAES0806USA01948	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0802U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a physician concerning a 23 year old female with a history of penicillin allergy who on 09-JUN-2008 was vaccinated IM with the first dose of GARDASIL (658490/0802U). Concomitant therapy included ORTHO TRI-DYCLEN LO. Per the physician the patient developed a "rash" over her entire body 6 hours after administration of her first dose of GARDASIL. The patient sought unspecified medical attention in the physician's office. The patient was prescribed oral prednisone and no additional information was provided. The patient's rash persisted. Additional information is not expected.

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: Unknown

History: Penicillin allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **319838-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	05-Apr-2008	06-Apr-2008	1	17-Jul-2008	28-Aug-2008	--	WAES0806USA01966	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Rash

Symptom Text: Information has been received from a physician concerning a 19 year old female with a history of rhinitis allergic who on 05-APR-2008 was vaccinated IM with 0.5 ml of the first dose of GARDASIL. (lot#659655/1486U, site not reported). Concomitant therapy included CLARITIN and RHINOCORT NASAL SPRAY. On 06-APR-2008, one day after receiving the vaccination, the patient experienced rash with red dots on her chest, itching of arms and itching of chest for 1 to 1.5 weeks. No other vaccinations were given, no change in soaps or laundry products. The patient had sought unspecified medical attention in the doctor's office. Subsequently, the patient recovered. Additional information has been requested.

Other Meds: RHINOCORT; CLARITIN

Lab Data: None

History:

Prex Illness: Rhinitis allergic

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319839-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
34.0	F	08-Feb-2008	Unknown		17-Jul-2008	28-Aug-2008	NJ	WAES0806USA01977	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity, Wrong drug administered

Symptom Text: Initial information and follow up has been received from a physician and 35 year old female who on 08-FEB-2008, was vaccinated intramuscularly in error (the patient was suppose to receive the 2nd dose of hepatitis B) with her second dose of GARDASIL (lot# not reported). Concomitant therapy, in January 2008, included hepatitis B virus vaccine (unspecified manufacturer), for the treatment of prophylaxis (duration and dose not reported). After the first GARDASIL dose, the patient had pain in the opposite arm that lasted 2-3 months (recovered in June 2008). In March or May 2008, the patient went to the doctors office to receive another hepatitis B vaccine and was given another dose of GARDASIL (lot# not reported). The patient does not know if she will complete the GARDASIL or hepatitis B vaccine series. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **319840-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	25-Mar-2008	Unknown		17-Jul-2008	28-Aug-2008	CO	WAES0806USA01985	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a nurse concerning a 23 year old female with a penicillin allergy who on 25-MAR-2008 was vaccinated intramuscularly with her first dose of GARDASIL (lot# 0151X). There was no concomitant medication. On an unspecified date, the patient experienced a rash on her back, arms and neck. Subsequently, the patient recovered after 5 days from the rash on her back, arms and neck. The patient sought medical attention on an unspecified date by calling the office. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **319841-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Mar-2008	15-Mar-2008	0	17-Jul-2008	28-Aug-2008	MD	WAES0806USA02211	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Myalgia, Pyrexia, Vaccine positive rechallenge

Symptom Text: Initial and follow up information has been received from a registered nurse concerning a 15 female with acne who on 15-MAR-2008 was vaccinated IM with a first 0.5ml dose of GARDASIL (Lot#659182/175U). Concomitant therapy BENZACLIN and RETIN-A. The patient developed widespread muscle aching and a low grade fever within hours of receiving her first dose which resolved in 1-2 days with out requiring treatment. On 10-JUN-2008 the patient was vaccinated IM with a second 0.5ml dose of GARDASIL (Lot#660391/0063X). After the second dose, the patient's mother contacted the office by phone to report her daughter's symptoms of muscle aching, low grade fever, as well as left knee pain that occurred within a few hours of the dose. Rest and ibuprofen were prescribed. At the time of the report, the patient had not recovered. The nurse did not known if the patient was scheduled to receive the third dose. Additional information has been requested.

Other Meds: BENZACLIN; RETIN-A

Lab Data: None

History:

Prex Illness: Acne

Prex Vax Illns:

Vaers Id: 319842-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	28-May-2008	29-May-2008	1	17-Jul-2008	28-Aug-2008	TX	WAES0806USA02216	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a licensed vocational nurse concerning a 21 year old female who on 28-MAY-2008 was vaccinated IM with a first 0.5ml dose of GARDASIL in the left arm. Concomitant therapy included PROZAC, WELLBUTRIN and TRI-SPRINTEC. On 29-MAY-2008, within 18 hours of vaccination the patient developed hives to her arms, legs and trunk. The patient had an office visit with her primary physician. At the time of the report the patient was recovering. Additional information has been requested.

Other Meds: WELLBUTRIN; TRI-SPRINTEC; PROZAC

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319843-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	11-Apr-2007	04-Feb-2008	299	17-Jul-2008	28-Aug-2008	NC	WAES0806USA02219	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Vitiligo

Symptom Text: Information has been received from a father concerning his 9 year old daughter who on 23-JAN-2007 was vaccinated with a first dose of GARDASIL. There was no concomitant medication. On 11-APR-2007 she was vaccinated with a second 0.5ml dose GARDASIL. Subsequently, the patient experienced Vitiligo. On 04-FEB-2008 was vaccinated with a third dose of GARDASIL. The patient sought unspecified medical attention. The patient underwent unspecified "labs" (result not reported). At the time of the report the Vitiligo was not recovered. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory - "labs" result not reported

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319844-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	28-Aug-2008	VT	WAES0806USA02240	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a physician concerning a female, her nurse, who in May 2008, was vaccinated intramuscularly with her first dose of GARDASIL (lot# not provided). The nurse stated that the experience with the vaccine was horrible, extremely painful and her arm hurt for 3 days. Subsequently, the patient recovered 4 days after the first dose. The patient sought unspecified medical attention on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319845-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	09-Sep-2008	MO	WAES0806USA02247	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Localised oedema

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot# not reported) on an unspecified date. "1 week later" the patient experienced bilateral axillary neck edema. "The edema lasted a few days and then resolved." No additional AE information was reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319846-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	02-Apr-2008	02-Apr-2008	0	17-Jul-2008	09-Sep-2008	MA	WAES0806USA02255	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning a 21 year old female who on 02-APR-2008 was vaccinated IM with the first dose of GARDASIL vaccine (660387/1967U). the physician reported that the patient experienced nausea and vomiting after administration of the first dose of GARDASIL vaccine. The patient sought unspecified medical attention in the physician's office. Subsequently, the patient recovered from her nausea and vomiting. No additional information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319847-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Mar-2008	30-Apr-2008	60	17-Jul-2008	09-Sep-2008	WA	WAES0806USA02275	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a Licensed Practical Nurse for the Pregnancy Registry for GARDASIL vaccine, concerning a 20 year old female who on 01-MAR-2008 was vaccinated intramuscularly with a 0.5 mL first dose of GARDASIL vaccine (Lot #658556/1060U). On 19-MAY-2008 the patient was vaccinated intramuscularly with a 0.5 mL second dose of GARDASIL vaccine (lot# 660389/1968U). Concomitant therapy included AZOR. It was unspecified if the patient was "currently on" alprazolam. The patient's LMP was reported as 30-APR-2008 (estimated due date 04-FEB-2009). The patient sought unspecified medical attention during an office visit. Laboratory diagnostics studies performed on an unspecified date included an "abnormal PAP." Additional information has been requested.

Other Meds: AZOR

Lab Data: Pap test - abnormal

History:

Prex Illness: Pregnancy NOS (LMP=04/30/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319849-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	01-Apr-2008		17-Jul-2008	09-Sep-2008	MO	WAES0806USA02291	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, No reaction on previous exposure to drug, Rash

Symptom Text: Information has been received from a 19 year old female for the Pregnancy Registry for GARDASIL vaccine (yeast) with an allergic reaction to antibiotics (cephalexin (KEFLEX)) who in March 2008, was vaccinated with her first dose of GARDASIL vaccine (yeast) (lot# not reported). There was no concomitant medication. The patient received the second dose of GARDASIL vaccine (yeast) (lot# not reported) on an unspecified date and was pregnant. The patient's LMP was 01-APR-2008. The day after receiving the second dose of GARDASIL vaccine (yeast), the patient experienced a rash and went to the physician's office. At this time, a urine pregnancy test was conducted and it was positive. The patient's outcome for the rash and pregnancy were not reported. Additional information has been requested.

Other Meds: None

Lab Data: urine beta-human - positive

History: LMP = 4/1/2008, Allergic reaction to antibiotics

Prex Illness: Pregnancy NOS

Prex Vax Illns:

Vaers Id: **319850-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Dec-2007	13-Dec-2007	0	17-Jul-2008	09-Sep-2008	UT	WAES0806USA02306	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1210U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling

Symptom Text: Initial information and follow up has been received from a physician's assistant and registered nurse concerning a white 16 year old female who on 13-DEC-2007 was vaccinated intramuscularly in the deltoid with her first dose of GARDASIL vaccine (yeast) (lot# 655154/1210U). There was no concomitant medication. On 03-JUN-2008 the mother informed the physician that the daughter experienced pain and swelling at the injection site on 13-DEC-2007. The patient was not seen as a result of this occurrence and has not decided not to continue the dosing series. Subsequently, the patient recovered from the pain and swelling at the injection site after 2 days. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **319851-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		17-Jul-2008	09-Sep-2008	PA	WAES0806USA02317	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: Information has been received from a physician concerning an 11 year old female who was vaccinated on an unspecified date with her first dose of GARDASIL vaccine (yeast) (lot# not reported). Subsequently the patient experienced prolonged vomiting. The patient sought medical attention by seeing the physician on an unspecified date. The patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **319854-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Jul-2008	15-Jul-2008	0	21-Jul-2008	24-Jul-2008	VA		30-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB216AA	1	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B020AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Crying, Loss of consciousness, Mental status changes, Syncope, Tremor

Symptom Text: 11 y.o. female client post vaccination found on floor crying, conscious at 20 min. post vaccination. Rescue was called, vital signs were taken. Ct kept immobile until paramedics arrived. BP 100/60, Pulse 72, Resp. 22, PERLA, MAE. Paramedics left clinic at 3:15 pm. with client. 7/23/08-records received for DOS 7/15/08-Impression: convulsive syncope. Episode of syncope versus seizure with documented loss of consciousness followed by convulsive activity noted shortly after receiving vaccination. Collapsed and had generalized shaking with some mental status changes.

Other Meds:

Lab Data: Ct. was taken to hospital 7/23/08-records received-Labs WNL, EKG revealed a QTC interval of 0.45, 0.46. CT scan no abnormality. Neuro exam appropriate. CSF protein 45 glucose 63. EEG mild to moderate abnormal study due to left posterior qu

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **319855-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Jul-2008	15-Jul-2008	0	21-Jul-2008	24-Jul-2008	MA		24-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2550AA	0	Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B019AB	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1978U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope, Vomiting

Symptom Text: Vomited, lightheaded, fainted - also had MENACTRA & tetanus vaccine along with HPV vaccine.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 319856-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Aug-2007	08-Jan-2008	145	21-Jul-2008	29-Jul-2008	AR		29-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2720AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0181U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection, Skin papilloma

Symptom Text: 1-8-08 had wart removed from (R) buttock. MD had tested, biopsy result HPV. Does not know what strand. 7-08 had to have 2nd wart removed. Client and mother concerned the HPV may have been caused by immunization.

Other Meds: None

Lab Data: Biopsy 1-8-08 - HPV

History: None

Prex Illness: N/A

Prex Vax Illns: Uncontrolled screaming and crying after pertussis; faints after as infant~Vaccine not specified (no brand name)~UN~0~In Sibling

Vaers Id: **319860-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Jul-2008	01-Jul-2008	0	21-Jul-2008	25-Jul-2008	IA		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling hot, Presyncope

Symptom Text: 2-3 hours after 1st vaccine Gardasil, started feeling hot, dizzy, light headed, pre-syncope. No LOC.

Other Meds: None

Lab Data: N/A

History: Psoriasis

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319863-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	11-Jul-2008	11-Jul-2008	0	21-Jul-2008	24-Jul-2008	NY		24-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: About 4-5 minutes after GARDASIL vaccine the pt. fainted in the office. It lasted only for few seconds. She was fine in a minute or so & went home after 15 to 20 minutes.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **319865-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	17-Jan-2008	17-Jan-2008	0	17-Jul-2008	17-Sep-2008	NH	WAES0806USA02458	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Injection site discomfort, Nausea, Pain, Vomiting

Symptom Text: Information has been received from a licensed practical nurse concerning a 22 year old female with no allergies, who on 09-AUG-2007 was vaccinated with a first dose of GARDASIL vaccine (lot#, and route not reported). There was no concomitant medication. On 17-Jan-2008, the patient was vaccinated with the second dose of GARDASIL vaccine (lot# 655237/1287U) (route not reported). In the evening of 17-JAN-2008, the patient experienced nausea, body aches, vomiting, and weakness. On 18-JAN-2008, the patient had mild discomfort at the injection site and also vomited in the morning. The reporter noted that the patient's symptoms lasted fro a day and on half and them resolved. On 21-MAR-2008, the patient returned to the office for another vaccination, but the vaccination was not administered due to the adverse reaction on 17-JAN-2008. The office was still deciding if they would administer another dose of GARDASIL vaccine. No other information was available. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319867-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	22-Apr-2008	23-Apr-2008	1	17-Jul-2008	10-Sep-2008	PA	WAES0806USA02499	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Rash, Vomiting

Symptom Text: Information has been received from a physician concerning a female who on 22-APR-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast). On 23-APR-2008 the patient experienced nausea, vomiting, dizziness and an unspecified rash. The patient sought unspecified medical attention. At the time of the report the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319869-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Jan-2008	23-Jan-2008	0	17-Jul-2008	10-Sep-2008	PA	WAES0806USA02500	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Metrorrhagia

Symptom Text: Information has been received from the Merck Pregnancy Registry for GARDASIL vaccine (yeast) via a health professional concerning a 17 year old female with a history of irregular periods (April 2005) and anorexia (March 2006) who on 19-NOV-2007 was vaccinated with a first dose of GARDASIL vaccine (yeast). Concomitant therapy included ethinyl estradiol/norgestimate (ORTHO TRI-CYCLEN). In January 2008, the patient was seen by the physician for metrorrhagia that was resolved. On 23-JAN-2008 the patient was vaccinated IM with a second 0.5 ml dose of GARDASIL vaccine (yeast) and then discovered she was pregnant. Estimated date of last menstrual period was 22-JAN-2008. Gestation at the time of the report was "5 months along." Estimated date of delivery is 28-OCT-2008. At the time of the report the pregnancy outcome was unknown. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN

Lab Data: None

History: Irregular periods, Anorexia

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319873-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Nov-2007	01-Nov-2007	0	17-Jul-2008	10-Sep-2008	NY	WAES0806USA02510	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper

Symptom Text: Information has been received from a physician concerning a 14 year old female who in November 2007, was vaccinated SC with a first 0.5 ml dose of GARDASIL vaccine (yeast) in the abdomen. There was no concomitant medication. The patient reported having pain in her stomach after the first dose that did resolve. On 12-APR-2007 (previously reported as 04-DEC-2007) the patient was vaccinated IM with a second dose of GARDASIL vaccine (yeast) in the arm. She had no adverse effects after the second dose. The patient sought medical attention in the office. Other business partners numbers included: E2008-05747. No further information is expected. This case is closed.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319874-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	10-Sep-2008	--	WAES0806USA02559	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a health professional concerning a female who was vaccinated with a second dose of GARDASIL vaccine (yeast) and fainted. At the time of the report the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319875-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Jun-2008	Unknown		17-Jul-2008	10-Sep-2008	CA	WAES0806USA02562	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 02-JUN-2008 was vaccinated with a second dose of GARDASIL vaccine (yeast). There was no concomitant medication. Subsequently, the patient fainted after the administration. The patient did not sustain any injuries. The patient sought medical attention in the office. At the time of the report the patient had recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **319876-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	12-May-2008	12-May-2008	0	17-Jul-2008	10-Sep-2008	IL	WAES0806USA02564	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Urticaria

Symptom Text: Information has been received from a physician concerning a female who "one month ago," on approximately 12-MAY-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot# and route not reported). The reporter noted that the patient broke out in hives, was dizzy and went to the emergency room. No additional information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319878-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Nov-2007	01-Nov-2007	0	17-Jul-2008	10-Sep-2008	NY	WAES0806USA02670	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Nausea

Symptom Text: Information has been received from a nurse concerning a sixteen year old female patient with no medical history or drug allergies reported, who in November 2007, in France, was vaccinated subcutaneously in the abdomen with a first 0.5 mL dose of GARDASIL vaccine (yeast). There was no concomitant medication. Subsequently the patient complained of having pains in her stomach and nausea after the first dose that did resolve. On 04-DEC-2007 (reported as 12/04/2008), in Geneva, Switzerland, the second dose was given intramuscularly in the arm. No reports of adverse effects were indicated after the second dose. The patient sought unspecified medical attention in the office. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319879-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	10-Sep-2008	MD	WAES0806USA02841	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Immediate post-injection reaction, Injection site anaesthesia

Symptom Text: Information has been received from a nurse practitioner concerning a female (age unreported), with concomitant medication, pertinent medical history and drug reactions/allergies reported as none, who was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 657737/0522U), IM on an unspecified date. The second dose of GARDASIL vaccine (yeast) (lot # 655322/1211U) was given IM on an unspecified date. Immediately after vaccination the patient experienced numbness of the arm where the injections were given following both her first and second dose of GARDASIL vaccine (yeast). The numbness stretched from where the shot was given and all the way down her arm. The patient sought unspecified medical attention. The patient was treated with acetaminophen (TYLENOL) and subsequently recovered approximately 2 days after vaccination. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **319881-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	10-Sep-2008	--	WAES0806USA02846	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: Information has been received from a health professional concerning herself, who, on an unspecified date, was vaccinated IM with a 0.5mL dose of GARDASIL vaccine (yeast). Subsequently, shortly after the vaccination the patient experienced swollen lymph nodes in her legs. A biopsy was performed of the swollen lymph nodes, and the result was negative. At the time of the report, the patient had not recovered. No product quality complaint was involved. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: biopsy - biopsy of lymph nodes was negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319883-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		17-Jul-2008	10-Sep-2008	TX	WAES0806USA02870	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oligomenorrhoea

Symptom Text: Information has been received from the mother of a 26 year old female who, on an unspecified date was vaccinated with her second dose of GARDASIL vaccine (yeast) (Lot #, site and route not reported). Concomitant therapy included hormonal contraceptives (unspecified). The date of the patient's first vaccination with GARDASIL vaccine (yeast) was not reported. The mother reported that "her daughter received her second dose of GARDASIL vaccine (yeast) and her monthly cycle has not ended". No additional information was reported. The patient outcome was not reported. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319884-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Jul-2008	11-Jul-2008	0	21-Jul-2008	29-Jul-2008	WA		29-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister

Symptom Text: 2 1/2 hrs after vaccine given in (L) deltoid pt noted 2 raised "blister-like" bumps on (L) upper arm about 4 inches away from injection site. Pt given Benadryl po and ice pack.

Other Meds:

Lab Data: N/A

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319885-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-Apr-2008	28-May-2008	30	17-Jul-2008	10-Sep-2008	--	WAES0806USA02876	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1424F	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Gait disturbance, Musculoskeletal stiffness, Trismus

Symptom Text: Information has been received from a nurse practitioner concerning a 14 year old female with "high risk human papillomavirus", and a history of genital warts who on 28-APR-2008 was vaccinated with her first dose of GARDASIL vaccine (yeast) (Lot # 654885/1424F, site and route not reported). Concomitant therapy included "DOXY" (not otherwise specified). On 28-MAY-2008, also reported as "2 weeks before 11-JUN-2008", "the patient had trouble walking because of stiff legs and had trouble opening her jaw". When the patient relaxed on her bed, the symptoms went away, but when she started to walk again, the symptoms came back. The patient went to the emergency room and was released (not further specified). The patient outcome was not reported. No further information was provided. Additional information has been requested.

Other Meds: doxycycline

Lab Data: Unknown

History: Genital wart

Prex Illness: Papilloma viral infection

Prex Vax Illns:

Vaers Id: **319888-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Jun-2008	11-Jun-2008	0	17-Jul-2008	10-Sep-2008	--	WAES0806USA02889	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with no medical history and no drug reactions/allergies, who on 06-Nov-2007 was vaccinated with first dose of GARDASIL vaccine (yeast) (lot# unspecified). On 11-Jun-2008, the patient was vaccinated with 0.5ml of second dose of GARDASIL vaccine (yeast) (lot# unspecified). It was reported that "about 12 hours after vaccination", the patient experienced rash on her arms and face. There was no concomitant medication. It was also reported that the patient had no ill effects after vaccination with her first dose of GARDASIL vaccine (yeast). Unspecified medical attention was sought by calling physician. At the time of this report the patient was still recovering from her experiences. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **319890-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	10-Sep-2008	--	WAES0806USA02891	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a consumer concerning her daughter who on unspecified date was vaccinated with GARDASIL vaccine (yeast) (lot# unspecified). It was reported that on unspecified date the patient developed rash. At the time of this report the outcome was unknown. No other information is available. Additional information is not expected.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319892-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Nov-2007	01-Nov-2007	0	17-Jul-2008	10-Sep-2008	--	WAES0806USA02906	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer for the Pregnancy Registry for GARDASIL vaccine (yeast) concerning herself, a 21 year old female, who in November 2007, was vaccinated with her third dose of GARDASIL vaccine (yeast) (lot # unspecified) and realized she was pregnant. Dates and lot numbers of the previous 2 doses were not reported. There was no concomitant medication. Unspecified medical attention was sought. Approximately in April 2008 the 7th month sonogram was performed (date not reported), and the physician noticed that the baby had an echogenic bowel. After this was found, on unspecified date the patient had amincentesis performed and the results were reported as "everything was normal". The patient reported that at the time of this report she was 34 weeks pregnant (estimated LMP is 17-Oct-2007). No further information was provided. No further information is available.

Other Meds: None

Lab Data: ultrasound - 04/01?/08 - baby had echogenic bowel, amniocentesis - 04?/??/08 - "normal"

History: LMP = 10/17/2007

Prex Illness: Pregnancy NOS

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319914-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Jul-2008	12-Jul-2008	1	21-Jul-2008	29-Jul-2008	AL	AL0817	29-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Hypoaesthesia facial

Symptom Text: Pt. called and said she received her 2nd HPV here on 7/11/08 the next morning she began having numbness in her hands and face-lasting from 5-20 minutes, occurs almost daily, denies other symptoms.

Other Meds: topamax,glodon

Lab Data:

History: NKDA,no birth defects,bipolar,psychotic

Prex Illness:

Prex Vax Illns:

Vaers Id: **319933-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		17-Jul-2008	10-Sep-2008	FL	WAES0806USA02922	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a "15 year old" female who on an unspecified date was vaccinated intramuscularly with a 0.5 mL second dose of GARDASIL vaccine (yeast) (lot # not reported). Subsequently the patient fainted after receiving the second dose of GARDASIL vaccine (yeast). The patient sought unspecified medical attention. The physician reported that the patient recovered "the same day as the adverse experience". Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319934-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Jul-2007	Unknown		17-Jul-2008	10-Sep-2008	OH	WAES0806USA02966	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthritis

Symptom Text: Information has been received from a physician concerning an 18 year old female with no medical history and no known drug reactions or allergies who in July 2007 completed three dose series of GARDASIL vaccine (yeast). There was no concomitant medication. It was reported that the patient might have arthritis from GARDASIL vaccine (yeast). Unknown medical attention was sought. Patient outcome was not reported. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319935-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Apr-2008	01-Apr-2008	0	17-Jul-2008	10-Sep-2008	--	WAES0806USA02973	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea, Dizziness, Headache, Nausea, Pain in extremity, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female with no medical history and no known drug reactions or allergies who in April 2008, was vaccinated with the second dose of GARDASIL vaccine (yeast). The day after the second dose of GARDASIL vaccine (yeast) the patient developed bilateral leg pain, headache, nausea, diarrhea, vomiting and felt faint. On an unspecified date the patient recovered from bilateral leg pain, headache, nausea, diarrhea, vomiting and felt faint. Unknown medical attention was sought in the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319936-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Mar-2008	18-Mar-2008	0	17-Jul-2008	10-Sep-2008	PA	WAES0806USA03056	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dysarthria, Memory impairment

Symptom Text: Information has been received from a nurse concerning a 16 year old female with migraine headaches who on 18-MAR-2008 was vaccinated intramuscularly with her first dose of GARDASIL vaccine (yeast) (lot# 659439/1267U). Concomitant therapy included aspirin (+) caffeine (+) cinnamedrine (MIDOL) and ibuprofen. On 18-MAR-2008 the patient experienced dizziness, slurred speech and forgetfulness. Subsequently, the patient recovered on an unspecified date from dizziness, slurred speech and forgetfulness. The patient did not seek medical attention, the AE was discovered during follow up. Additional information has been requested.

Other Meds: MIDOL, ibuprofen

Lab Data: None

History:

Prex Illness: Migraine

Prex Vax Illns:

Vaers Id: **319937-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	13-May-2008	Unknown		17-Jul-2008	10-Sep-2008	--	WAES0806USA03068	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: Information has been received from a nurse practitioner concerning an 18 year old female who on 13-MAY-2008 was vaccinated intramuscularly in the left deltoid with her first dose of GARDASIL vaccine (yeast) (lot# not reported). Subsequently the mother called the office on 04-JUN-2008 because the patient experienced cervical, groin and bilateral axillary lymphadenopathy on an unspecified date. Subsequently, the patient recovered from cervical, groin and bilateral axillary lymphadenopathy on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319938-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Jun-2007	Unknown		17-Jul-2008	10-Sep-2008	FL	WAES0806USA03103	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 25-JUN-2007 was vaccinated with a first dose of GARDASIL vaccine (yeast) (injection site and route not reported). Subsequently the patient broke out in hives. She sought medical attention and was treated with diphenhydramine hydrochloride (BENADRYL). Subsequently, the patient recovered from hives. The patient came in for second dose but it was not given because of the event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319939-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Apr-2008	21-May-2008	30	17-Jul-2008	10-Sep-2008	NC	WAES0806USA03111	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Myalgia

Symptom Text: Information has been received from a physician concerning a 17 year old female with no relevant medical history who on 21-APR-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). There was no concomitant medication. On approximately 21-MAY-2008, also reported as 1 month after the first dose was given, the patient experienced myalgia and arthralgia. The patient's myalgia and arthralgia persisted. No other doses have been given yet. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **319940-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		17-Jul-2008	10-Sep-2008	--	WAES0806USA03127	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site discolouration

Symptom Text: Information has been received from a nurse concerning a 13 year old female who in October 2007, was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot no., route and site of administration were not reported). On an unspecified date, the patient was vaccinated with the second dose of GARDASIL vaccine (yeast) (lot no. and route of administration were not reported) on her left arm. After receiving her second dose, the patient developed a "white ring" at the injection site. This "white ring" area does not tan with sun exposure. Both dosed were given at a location other than this nurse's office. The patient went to office and sought unspecified medical attention. No other information is available at this time. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319941-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Jun-2008	01-Jun-2008	0	17-Jul-2008	10-Sep-2008	CA	WAES0806USA03128	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Myalgia

Symptom Text: Information has been received from a physician concerning a 12 year old female with no pertinent medical history or allergies who in April 2008, was vaccinated intramuscularly with a first dose of GARDASIL vaccine live (yeast) and no problems were reported. "About 2 weeks ago", in June 2008, the patient was vaccinated intramuscularly with a second dose of GARDASIL vaccine (yeast). There was no concomitant medication. The same night of the second vaccination, the patient experienced muscle pain in the legs and arms and had a general feeling of weakness all over. No laboratory or diagnostics studies were performed. The myalgia lasted 48 to 72 hours. Subsequently, the patient recovered from myalgia. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **319942-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	21-May-2008	22-May-2008	1	17-Jul-2008	10-Sep-2008	TX	WAES0806USA03218	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	17574	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Migraine

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female with no medical history and no allergies, who on 21-MAY-2008 was vaccinated in the left deltoid with third dose of GARDASIL vaccine (yeast) (lot # reported as "17574"). Dates and lot #s of previous two doses were not reported was no concomitant medication. It was reported that on 22-MAY-2008 at 10 am, the patient called the office with complaints of migraine. She was advised to take ibuprofen (ADVIL) and go to ER if headache get worse. It was reported that at 11:30 am on the same day, the patient felt better and subsequently recovered from the migraine. It has been determined that WAES No. 0806USA03218 is a duplicate of WAES No. 0805USA04997. Therefore, WAES No. 0806USA03218 is being deleted from our files and the reports consolidated into WAES No. 0805USA04997. No additional information is expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **319943-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		17-Jul-2008	10-Sep-2008	--	WAES0806USA03347	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site irritation

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female who on unspecified date was vaccinated intramuscularly with 0.5ml of GARDASIL vaccine (yeast) (lot# unspecified). It was reported that on unspecified date the patient developed a persistent round circle on her arm at the injection site. At the time of this report, the patient's round circle at the injection site persisted. Unspecified medical attention was sought. No other information is available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319945-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	10-Sep-2008	NC	WAES0806USA03365	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthritis

Symptom Text: Information has been received from a physician concerning a female (demographics not provided) who on unspecified date was vaccinated intramuscularly with first dose of GARDASIL vaccine (yeast) (lot# unspecified). It was reported that on unspecified date the patient developed arthritis. Unspecified medical attention was sought. On unspecified date erythrocyte sedimentation rate test was performed, result was reported as "elevated". At the time of this report, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: erythrocyte - elevated

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319946-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	16-Jun-2008	16-Jun-2008	0	17-Jul-2008	11-Sep-2008	--	WAES0806USA03371	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain, Skin warm, Swelling, Tenderness

Symptom Text: Information has been received from a Medical Assistant concerning a 19 year old female who on 16-JUN-2008 was vaccinated intramuscularly with a 0.5 mL first dose of GARDASIL vaccine (yeast) (lot # 660389/1968U). Concomitant therapy included ethinyl estradiol/norethindrone acetate (LOESTRIN). On 16-JUN-2008 the patient developed left side (face, shoulder, neck and arm) warmth, tenderness, pain and swelling. The patient's left side (face, shoulder, neck and arm) warmth, tenderness, pain and swelling persisted. The patient sought medical attention during an office visit. It was reported that the patient returned to the office "today" (17-JUN-2008 at the time of the report) and was instructed by the Nurse Practitioner to take ibuprofen and call the office if her symptoms persisted. It was reported that the Nurse Practitioner gave the patient a lab order for a SED rate and CBC with differential. Additional information has been requested.

Other Meds: LOESTRIN

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **319947-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	15-Apr-2008	Unknown		17-Jul-2008	11-Sep-2008	--	WAES0806USA03397	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a nurse practitioner concerning a 25 year old female who on 15-APR-2008 was vaccinated intramuscularly with her first dose of GARDASIL vaccine (yeast) (lot# 659964/1978U). Concomitant therapy included hormonal contraceptives (unspecified). Subsequently the patient experienced extreme dizziness for 2-3 days after the dose. The dizziness episodes lasted about 10 minutes each. The second dose has been deferred at this time. The patient sought unspecified medical attention on an unspecified date. Subsequently, the patient recovered from extreme dizziness on an unspecified date. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319948-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	09-Jun-2008	10-Jun-2008	1	21-Jul-2008	25-Jul-2008	TX		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Vaccine-GARDASIL - admin. - 6/9/08 - pt called on 7/7/08 - stating L arm where shot given wnt. to hurt. Advised to take ibuprofen 600 mg TID- heat like compress & recheck if not better. Pt called 7/14/08 cont pain. Appt 7/18/08 pain resolved. Exam neg.

Other Meds: None

Lab Data: None

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319950-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Jul-2008	18-Jul-2008	0	21-Jul-2008	25-Jul-2008	TX		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	19114	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Dizziness, Loss of consciousness, Syncope

Symptom Text: Pt given vaccines at 5:20p. Got up and walked around office. While doing so, asked "should I feel dizzy" and then collapsed into her mother's arms. Was lowered to floor, still unconscious, but readily regained consciousness with ammonia stick. Had pt lay down for ~20 min. BPS: 118/70 and 120/70. Left office at 5:50p. No further sx per mom.

Other Meds: None

Lab Data: Hgb, 14

History: None

Prex Illness: None, but on period

Prex Vax Illns:

Vaers Id: 319956-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Jul-2008	15-Jul-2008	0	21-Jul-2008	25-Jul-2008	IL		25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lip swelling, Pharyngolaryngeal pain

Symptom Text: Pt received second dose of GARDASIL (HPV) & c/o swollen lips, sore throat x 12-15 hours. No shortness of breath.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **319964-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	11-Sep-2008	--	WAES0806USA03398	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a nurse practitioner concerning a female (age unknown) who on an unspecified date was vaccinated intramuscularly with a 0.5 mL first dose of GARDASIL vaccine (yeast) (Lot # unknown). Subsequently, on an unknown date, the patient experienced felt dizzy and light headed for over a week after 1st dose. Therapy with human papillomavirus vaccine was discontinued. Subsequently, on an unspecified date the patient recovered. Unspecified medical attention was sought. No product quality control was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319966-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	11-Sep-2008	GA	WAES0806USA03420	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	HEP	UNKNOWN MANUFACTURER	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Angioedema, Urticaria

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with her first dose of GARDASIL vaccine (yeast). Concomitant suspect vaccination included second of third dose of hepatitis B virus vaccine (unspecified). The physician reported that within 24 hours of vaccination, the patient had hives and then had angioedema of her lips. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319967-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Aug-2007	01-Aug-2007	0	17-Jul-2008	11-Sep-2008	LA	WAES0806USA03433	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning the 16 year old daughter of his receptionist, with polycystic kidney who in August 2007, was vaccinated with the first dose of GARDASIL vaccine (yeast). Concomitant therapy included hormonal contraceptives (unspecified). In August 2007, on an unspecified date, after receiving GARDASIL vaccine (yeast) by injection, the patient experienced "passing out." She received her second dose of GARDASIL vaccine (yeast) on an unreported date in October 2007. Her hormonal contraceptives were discontinued in November 2007. The patient was not given the third dose of GARDASIL vaccine (yeast). She sought unspecified medical attention and had a stress test and an electroencephalogram (EEG) performed, no results were provided. At the time of reporting the patient was still experiencing "passing out." Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: electroencephalography - results not reported, cardiac exercise - results not reported

History:

Prex Illness: Polycystic kidney

Prex Vax Illns:

Vaers Id: **319968-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Oct-2007	15-Oct-2007	0	17-Jul-2008	11-Sep-2008	AL	WAES0806USA03719	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0263U	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse (RN) through a Merck pregnancy registry concerning a 13 year old female with attention deficit/hyperactivity disorder and no known drug allergies and a history of being a rape victim who on 15-OCT-2007 was vaccinated intramuscularly in the right deltoid with a first 0.5 ml dose of GARDASIL vaccine (yeast) (Lot #655849/0263U). On the same day the patient also received concomitant vaccinations of meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA), hepatitis A virus vaccine (manufacturer unknown) and influenza virus vaccine (unspecified). The patient was in her menstrual cycle at the time of vaccination. On 15-JUN-2008 the patient had a normal live birth, female child. Unspecified medical was sought. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Rape victim, LMP = 10/15/2007

Prex Illness: Pregnancy NOS, Attention deficit/hyperactivity disorder

Prex Vax Illns:

Vaers Id: **319969-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Apr-2008	Unknown		17-Jul-2008	11-Sep-2008	--	WAES0806USA03724	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Joint swelling, Oedema peripheral

Symptom Text: Information has been received from a medical assistant concerning a female with no known drug allergies who on 01-APR-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot no. 659962/1740U) 0.5ml via intramuscular route. Site of injection was not reported. The patient developed red ankles and feet with minor swelling after administration of her first dose. On an unspecified date the patient was recovered. The patient sought unspecified medical attention via telephone. No additional information was reported. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319970-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Apr-2008	09-May-2008	38	17-Jul-2008	11-Sep-2008	AL	WAES0806USA03743	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Joint swelling

Symptom Text: Information has been received from a physician concerning a 13 year old female patient with no medical history or drug allergies reported, who in February and April 2008 was vaccinated with the first and second dose of GARDASIL vaccine (yeast), respectively. There was no concomitant medication. On 09-MAY-2008 the patient developed systemic joint tenderness with mild to moderate joint swelling. The patient sought unspecified medical attention. Lyme and magnetic resonance imaging tests were performed with no results reported. The symptoms have been somewhat responsive to prednisone, but return when the prednisone was not used. At the time of this report, the patient has not recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: magnetic resonance - results not reported, Lyme disease assay - results not reported

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **319971-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Jun-2008	17-Jun-2008	0	17-Jul-2008	11-Sep-2008	CT	WAES0806USA03752	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bradycardia, Headache, Hypotension, Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Information has been received from a nurse concerning a 14 year old female who on 17-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot no. not reported) 0.5ml via intramuscular route. Site of injection was not reported. The patient experienced syncope right after receiving initial dose of GARDASIL vaccine (yeast). The patient was placed in a wheel chair and taken to a room in office. Vital signs demonstrated hypotension and bradycardia. The patient passed out several more times during this period in office. The patient was sent to hospital ER in ambulance, but was not admitted as In-Patient. On 18-JUN-2008, the patient recovered from syncope, hypotension, bradycardia and passed out. On the same day, the patient still had a headache. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319972-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	11-Sep-2008	--	WAES0806USA03780	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician assistant concerning a female who was vaccinated with GARDASIL vaccine (yeast) unsure how many doses and had a positive HPV result from a PAP smear test post vaccination. The physician assistant stated the patient became sexually active at this time frame. The patient sought medical attention. No further information is available.

Other Meds: Unknown

Lab Data: cervical smear - HPV positive

History: Unknown

Prex Illness: sexually active

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319974-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	06-May-2008	06-May-2008	0	17-Jul-2008	11-Sep-2008	--	WAES0806USA03791	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Human papilloma virus test positive, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a nurse practitioner concerning a 24 year old female with no relevant medical history who in May 2007 and in July 2007, was vaccinated with a first and second dose of GARDASIL vaccine (yeast) respectively (lot number, injection site and route not reported). On 06-MAY-2008 the patient was vaccine with the third dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). Concomitant therapy included minocycline HCl (MINOCIN). On 06-MAY-2008 the patient had an abnormal PAP test and was positive for the HPV DNA reflex group which tested the 6 high risk types. The patient was diagnosed with low grade lesions or precancer. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: MINOCIN

Lab Data: Pap test - 05/06/08 - abnormal, cervix HPV DNA assay - 05/06/08 - positive

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **319977-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	31-Oct-2007	04-Nov-2007	4	22-Jul-2008	29-Jul-2008	NH		29-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	42507AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	10634	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Back pain, Constipation, Pain, Pyelonephritis, Vomiting

Symptom Text: 10/29/07 - Diagnosed with cystitis, started on Bactrim. 10/31/07 symptoms resolved, afebrile, administered HPV and flu vaccine. 11/6/07 presented to ER with 2-3 days progressive back and abdominal pain, vomiting. Diagnosed with pyelanephtitis. Given IV fluids and antibiotics (Rocephid) and additional PO antibiotics (Augmentin). Returned to ER 11/7/07 continued pain, ? constipation as cause. Prescribed mag citrate. Office follow up 11/9/07 - abdominal and back pain remained unexplained with normal exam, labs, work-up. 11/12/07 patient reported symptoms resolving.

Other Meds: Bactrim; pyridium prescribed 10/29/07.

Lab Data: 10/29/07 - positive urine cx; 11/6/07 - normal CBC, BMP, and Lipase. UA positive WBCs and bacteria. 11/7/07 - renal U.S., abdominal x-ray normal; Normal CBC, CMP. Negative urine HCG.

History: 1. 10/29/07 diagnosed with UTI, symptoms resolved on 10/31/07. 2. Mood disorders.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **319978-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	11-Sep-2008	OH	WAES0806USA03798	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a dose of GARDASIL vaccine (yeast). The patient fainted after she received GARDASIL vaccine (yeast). Subsequently, the patient recovered. Unspecified medical attention was sought. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319980-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	M	18-Jun-2008	18-Jun-2008	0	17-Jul-2008	11-Sep-2008	CA	WAES0806USA03801	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site reaction

Symptom Text: Information has been received from a registered nurse concerning a male patient who on 18-JUN-2008 was vaccinated with a third dose of GARDASIL vaccine (yeast) subcutaneously (lot number and injection site not reported). Subsequently the patient developed an injection site reaction. The injection site reaction went away and at the time of reporting there was a hard area at the injection site. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319982-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	18-Jun-2008	18-Jun-2008	0	17-Jul-2008	11-Sep-2008	NY	WAES0806USA07546	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Diarrhoea, Malaise, Nausea, Nervousness, Vomiting

Symptom Text: Information has been received from a physician and a consumer concerning the 25(also reported as 26) year old female consumer with irritable bowel syndrome who on 18-JUN-2008 was vaccinated intramuscularly with GARDASIL vaccine (yeast). The physician reported that the consumer felt "sick" all night after receiving the dose of GARDASIL vaccine (yeast). There was no concomitant medication. The consumer reported that the same night after receiving the GARDASIL vaccine (yeast), she experienced diarrhea, nausea and "I even threw up a little". The reporter also noted that she was feeling anxious and scared. The consumer sought medical attention with a call to the physician. The consumer reported that she was "feeling a little better but not fully myself." No further information was available. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Irritable bowel syndrome

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319983-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Apr-2008	30-Apr-2008	7	17-Jul-2008	11-Sep-2008	MO	WAES0806USA07577	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Breast discharge, Mastitis

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 23-APR-2008 had a complete physical and was symptom free, she then was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot# not specified). Concomitant therapy included meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA). on approximately 30-APR-2008 the patient developed mastitis (of the breasts) and discharge from her nipples. The patient sought unspecified medical attention and underwent a pelvic sonogram on an unspecified date, the results of which were negative. The physician reported that the patient was treated with unspecified antibiotics. On 27-MAY-2008, the physician reported that the patient was seen for a follow-up office visit and appeared to be fine. Additional information has been requested.

Other Meds:

Lab Data: pelvic ultrasound - 05/??/08 - negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319984-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	18-Jun-2008	18-Jun-2008	0	17-Jul-2008	11-Sep-2008	FL	WAES0806USA07597	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a licensed practical nurse, concerning a patient who received the third dose of GARDASIL vaccine (yeast) on 18-Jun-2008 and passed out. The office reporting the adverse reaction was not the facility that administered the dose. The patient passed out after receiving the dose of GARDASIL vaccine (yeast) for a "short time". The patient received the first dose of GARDASIL vaccine (yeast) on 04-Jan-2008, the second dose on 07-Mar-2008 and the third dose on 18-Jun-2008. There was no concomitant therapies. All doses were administered at another facility. The patient recovered. No other information to report. There was no product quality complaint. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319985-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	11-Sep-2008	VA	WAES0806USA07603	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female (age unreported) who was vaccinated on an unspecified date with a dose of GARDASIL vaccine (yeast). Subsequently the patient experienced a grief syncopal episode. The patient was reported as "fine" and no follow up was needed. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319987-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Dec-2007	28-Jan-2008	42	22-Jul-2008	30-Jul-2008	NH		13-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Muscular weakness, Pain, Physiotherapy

Symptom Text: See attached. 8/11/08-records received-DX Gait disturbance possible lumbar radiculopathy. Plays sports seven days per week very little rest 4-5 hours sleep per night. Aches and pains on and off aggravated bending during field hockey season. Received physical therapy and on 3/11/08 80% improved. on 6/20/08-no longer C/O leg pain.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **319988-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	09-Jul-2008	09-Jul-2008	0	22-Jul-2008	30-Jul-2008	IA		31-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal stiffness

Symptom Text: Reported after receiving 2nd GARDASIL vaccine feeling like she had a stiff neck, arm where vaccine was given felt stiff and back felt stiff. Advised OTC NSAIDS, rest and call if symptoms failed to resolve. Pt did not call back.

Other Meds: NUVA RING contraceptive device

Lab Data: N/A

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: **319990-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Mar-2008	14-Mar-2008	0	17-Jul-2008	11-Sep-2008	NY	WAES0806USA07628	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse for the pregnancy registry for HPV vaccine concerning a 16 year old female who on 20-AUG-2007 was vaccinated with the first dose of GARDASIL vaccine (yeast), 0.5 ml intramuscularly. Concomitant vaccination included meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA). On 14-APR-2008 the patient was vaccinated with the second dose of GARDASIL vaccine (yeast), 0.5 ml intramuscularly. The nurse reported that the patient is now pregnant, on an unspecified date a pregnancy test was done. It was noted that the patient tested positive for HPV during routine PAP test. The patient is not experiencing any known symptoms. The patient's LMP was 01-APR-2008 and EDD 06-JAN-2009. The patient sought medical attention and was seen by the physician. Additional information has been requested.

Other Meds:

Lab Data: beta-human chorionic - positive, Pap test - positive for HPV

History: Pregnancy NOS (LMP = 4/1/2008)

Prex Illness:

Prex Vax Illns:

Vaers Id: **319991-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Oct-2007	01-Oct-2007	0	17-Jul-2008	11-Sep-2008	--	WAES0806USA07672	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Rash papular, Skin discolouration

Symptom Text: Information has been received from a mother concerning her 18 year old daughter who "sometime" in June 2007, was vaccinated with a first dose of GARDASIL vaccine (yeast). "Sometime" in July 2007 she was vaccinated with a second dose of GARDASIL vaccine (yeast). There was no concomitant medications. "Sometime" in October 2007 she was vaccinated with a third dose of GARDASIL vaccine (yeast). In the beginning of October 2007, the patient started to break out in rash on the front of her body and by the end of October she started to develop little bumps on her whole stomach. In December 2007 the bumps spread to her back from her chest down to her stomach. The bumps turned into open sores that were a little larger than a pencil tip but did get to the size of an eraser on a pencil. The sores healed and the patient "has brown spots on her body where the rash had been." The patient was seen and treated by a dermatologist. The patient had a biopsy (results not reported). The patient was treated with a cream (unspecified by reporter). The cream had faded the spots a "little bit" but the patient "still has the marks." At the time of the report the patient was recovering. Additional information has been requested.

Other Meds: None

Lab Data: biopsy - result not reported

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **319992-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Jan-2008	Unknown		17-Jul-2008	11-Sep-2008	AZ	WAES0806USA07677	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a medical assistant concerning a 17 year old female who on 16-JAN-2008 was vaccinated with a second dose of GARDASIL vaccine (yeast). The patient developed a rash, unspecified, after the second dose and went to an urgent care center but was not hospitalized. The doctor's office was notified of the rash when the patient was called by the doctor's office on 17-JUN-2008 to schedule her third vaccination. The doctor's office is awaiting records. At the time of the report, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319993-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	11-Sep-2008	--	WAES0806USA07725	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site pain

Symptom Text: Information has been received from a nurse practitioner concerning an approximately 20 female patients who on unspecified date were vaccinated intramuscularly with 0.5 ml of GARDASIL vaccine (yeast) (dose and lot # unspecified). Immediately post vaccination the patients developed stinging at the injection site. Unspecified medical attention was sought. It was reported that the stinging resolved prior to the patients leaving the office or within 1-5 minutes. No other information is available. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided when available. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **319994-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		17-Jul-2008	11-Sep-2008	--	WAES0806USA07745	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning an 18 year old female with no known drug reactions or allergies who on an unspecified date was vaccinated with the first dose of GARDASIL vaccine (yeast). Concomitant therapy included meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA) (Sanofi Pasteur). The patient fainted 10 minutes after receiving her first dose of GARDASIL vaccine (yeast). There were no injuries. She was walking fairly soon after fainting. She did not say if she will discontinue the series. Unknown medical attention was sought with the doctor. Patient recovered on an unspecified date. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319995-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		17-Jul-2008	11-Sep-2008	OH	WAES0806USA07749	11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Human papilloma virus test positive

Symptom Text: Information has been received from a medical assistant concerning a 15 year old female with no known drug reactions or allergies who was vaccinated with a dose of GARDASIL vaccine (yeast) and now has tested positive for high risk HPV DNA and has an abnormal Pap test. The patient received at least one and possibly two vaccinations with GARDASIL vaccine (yeast) prior to the abnormal Pap and HPV DNA test on 27-MAY-2008. The vaccination with GARDASIL vaccine (yeast) were not administered at the office in the case. The patient had never had an abnormal Pap or positive HPV DNA test in the past. It was unknown whether the patient sought medical attention. Patient outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test - 05/27/08 - abnor, cervix HPV DNA assay - 05/27/08 - posit - high risk HPV DNA

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319996-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	13-Mar-2008	13-Mar-2008	0	17-Jul-2008	12-Sep-2008	--	WAES0806USA07755	12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin papilloma, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a female who on 13-Mar-2008 was vaccinated with first dose of GARDASIL vaccine (yeast) (lot# 655604/0052X) and developed warts on her knees and elbows. It was reported that on 20-May-2008 the patient vaccinated with second dose of GARDASIL vaccine (yeast) (lot# 659182/1757U) and developed warts on her hands and fingers. Unspecified medical attention was sought. The physician reported that the patient will not receive the 3rd dose of GARDASIL vaccine (yeast). The therapy with GARDASIL vaccine (yeast) was determined. At the time of this report the outcome of the events was unknown. No further information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319997-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	12-Sep-2008	WI	WAES0806USA07756	12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rectal haemorrhage

Symptom Text: Information has been received from a Physician concerning a female patient who on an unknown date was vaccinated with a dose of GARDASIL vaccine (yeast). Lot number was not available. Subsequently, the patient experienced rectal bleeding. The patient did seek medical attention with the physician. There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **319998-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-Jun-2007	20-Jun-2008	367	17-Jul-2008	12-Sep-2008	FL	WAES0806USA07767	12-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received from a licensed practical nurse (LPN) concerning an approximately 14 year old female with no pertinent medical history, drug reactions or allergies who on 19-JUN-2007 was vaccinated intramuscularly with a first 0.5 ml dose of GARDASIL vaccine (yeast). On the same day the patient also received secondary suspect vaccinations of varicella virus vaccine live (Oka/Merck) (MSD) and hepatitis A virus vaccine inactivated (MSD). On an unspecified date the patient had a fever of 104F. Subsequently the patient recovered from fever. The patient sought medical attention by calling office. On 20-JUN-2008 the patient was in office for the second dose of GARDASIL vaccine (yeast). Additional information has been requested.

Other Meds: Unknown

Lab Data: body temp - 104 F

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **319999-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		17-Jul-2008	12-Sep-2008	AZ	WAES0806USA07776	12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician and an office manager concerning an approximately 21 year old female who on an specified date was vaccinated intramuscularly with a 0.5 ml first dose of GARDASIL vaccine (yeast) (lot #659653/1448U). After receiving GARDASIL vaccine (yeast) the patient fainted. At the time of the report, it was unknown if the patient had recovered from the event. Unspecified medical attention was sought. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320001-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	12-Sep-2008	--	WAES0806USA07917	12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: Information has been received from a registered nurse concerning a female patient who was vaccinated with GARDASIL vaccine (yeast). The patient experienced faint and injured head on floor. Subsequently, the patient recovered from faint and injured head on floor. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320002-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Jun-2008	19-Jun-2008	0	17-Jul-2008	12-Sep-2008	PA	WAES0806USA07826	12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	3	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Decreased appetite, Feeling of body temperature change, Headache

Symptom Text: Information has been received from a nurse concerning a 16 year old female with no pertinent medical history or drug reactions/allergies reported who on 21-SEP-2007 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot# 658560/1062U) 0.5 ml IM and was vaccinated with a second (lot# 658560/1062U) and a third dose (lot# 659055/1522U) of GARDASIL vaccine (yeast) 0.5 ml IM on unspecified days. On 19-JUN-2008 the patient was vaccinated with a fourth dose of GARDASIL vaccine (yeast) (lot# 659964/1978U). Concomitant therapy included ethinyl estradiol/norgestimate (ORTHO-CYCLEN). The patient was experiencing headache, muscle heaviness, hot and cold flashes and a decrease in appetite. The patient sought medical attention by calling the physician. Additional information has been requested.

Other Meds: ORTHO-CYCLEN

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **320004-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	17-Jun-2008	Unknown		17-Jul-2008	12-Sep-2008	AZ	WAES0806USA07873	12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Syncope

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female who on 17-JUN-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) by intramuscular injection (lot number, injection site not reported) and a dose of diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (manufacture unknown). Subsequently the patient experienced faint. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320005-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		17-Jul-2008	12-Sep-2008	--	WAES0806USA07898	12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician concerning an 11 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported), and the patient did not experience any difficulties after that. On an unspecified date the patient was vaccinated with a second dose of GARDASIL vaccine (yeast) by intramuscular injection (lot number and injection site not reported). The patient also received 2 other vaccines (name not known) minutes prior to GARDASIL vaccine. Within 30 seconds following the vaccination of GARDASIL vaccine, the patient "passed out". Unspecified medical attention was sought. The patient recovered after 30-40 seconds. The patient's mother stated that the patient would not receive the third dose. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320006-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	19-Jun-2008		17-Jul-2008	12-Sep-2008	IL	WAES0806USA08058	12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oedema peripheral

Symptom Text: Information has been received from a physician concerning a 15 year old female who on an unspecified date was vaccinated with a third dose of GARDASIL vaccine (yeast) 0.5 ml (lot# 0152X). Concomitant therapy included albuterol sulfate (VENTOLIN (albuterol sulfate)), "topical acne medicine" dermatologic (unspecified) and fluticasone propionate (FLOVENT). On 19-JUN-2008 the patient experienced leg edema. The patient was brought to emergency room on 20-JUN-2008 but was not admitted to the hospital. The patient's leg edema persisted. Additional information has been requested.

Other Meds: VENTOLIN (ALBUTEROL SULFATE), dermatologic (unspecified), FLOVENT

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320007-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-May-2008	10-May-2008	0	17-Jul-2008	12-Sep-2008	IL	WAES0806USA08095	12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who on 10-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). On 10-MAY-2008 the patient had an injection site reaction (local reaction with erythema) for a few days. Subsequently, the patient recovered from local reaction with erythema for a few days. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320008-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Jan-2008	Unknown		17-Jul-2008	12-Sep-2008	VA	WAES0806USA08115	12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Human papilloma virus test positive, Smear cervix abnormal

Symptom Text: Information has been received from a licensed practical nurse concerning a 19 year old female patient who in January 2008, was vaccinated with the first dose of GARDASIL vaccine (yeast). The patient was HPV positive and had an abnormal PAP since receiving GARDASIL vaccine (yeast). In May 2008 the patient was vaccinated with the second dose of GARDASIL vaccine (yeast). The patient's HPV positive and abnormal PAP were persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear - abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320009-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Nov-2007	01-Nov-2007	0	17-Jul-2008	15-Sep-2008	GA	WAES0806USA08130	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a nurse concerning a 11 year old female who in November 2007 was vaccinated with a first dose of GARDASIL vaccine (yeast) IM. Since November 2007, the patient had not gotten her period until recently after receiving her third dose of GARDASIL vaccine (yeast) in May of 2008. The date of the second vaccination was not provided. the patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320010-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Jun-2008	18-Jun-2008	0	17-Jul-2008	15-Sep-2008	NY	WAES0806USA08142	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Hypotension, Inappropriate schedule of drug administration, Syncope vasovagal

Symptom Text: Information has been received from a physician concerning an overweight 15 year old female with anxiety and no drug reactions/allergies history reported who on 18-JUN-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) 0.5 ml IM (lot# 660555/0279X). Concomitant therapy included diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid. On 18-JUN-2008 the patient became lightheaded, diaphoretic and hypotensive after her first dose of GARDASIL vaccine (yeast). The patient had a consult with a cardiologist due to these adverse experiences and was diagnosed with a vasovagal response to the immunizations. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Anxiety, Overweight

Prex Vax Illns:

Vaers Id: **320011-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Jun-2008	21-Jun-2008	0	17-Jul-2008	15-Sep-2008	CA	WAES0806USA08146	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 12 year old female who on 21-JUN-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) in the right arm (route not reported. There was no concomitant medication. On 21-JUN-2008 the patient experienced numbness and parathesias. The symptoms were a little better when the patient got home. The patient sought medical attention in the office. Additional information has been requested. 9/2/08 WCC received from PCP dated 6/21/2008 which states mother refused HPV vaccine. TDaP, Menactra and Varicella vax rec'd on that date. 9/26/2008 Per office RN pt recently in for 2nd HPV vax, no reported problems. Case closed.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **320012-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	Unknown	01-Jun-2008		17-Jul-2008	15-Sep-2008	--	WAES0806USA08149	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Injected limb mobility decreased, Similar reaction on previous exposure to drug

Symptom Text: Information has been received from a nurse practitioner concerning a 24 year old female with penicillin allergy and allergic reaction to antibiotics who on an unspecified date was vaccinated with a first dose of GARDASIL vaccine (yeast) IM. On 20-JUN-2008, the now 25 year old patient was vaccinated with a second dose of GARDASIL vaccine (yeast) IM. Concomitant therapy included "Mercet birth control" (hormonal contraceptives (unspecified)). The patient was unable to lift her arm above shoulder level after being immunized with the second dose of GARDASIL vaccine (yeast). The patient also suffered from severe bilateral back pain after receiving the second dose of GARDASIL vaccine (yeast). The nurse practitioner reported that the patient had experienced mild symptoms after the first dose of GARDASIL vaccine (yeast), but the symptoms were much more pronounced with the second dose. The nurse practitioner reported that the patient was seen in the office on 23-JUN-2008 and was treated with acetaminophen (TYLENOL) for the pain. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy, Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **320014-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Jun-2008	14-Jun-2008	1	17-Jul-2008	15-Sep-2008	NJ	WAES0806USA08226	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthma, Axillary pain, Lymphadenopathy

Symptom Text: Information has been received from a physician concerning a 15 year old white female student with asthma who on 13-JUN-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot# 660391/0063X) intramuscularly into left deltoid. Suspect therapy given the same day included a first dose of meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA) (lot #0063X) IM into left deltoid. On 14-JUN-2008 the patient developed left axillary adenopathy, left axillary pain and also asthma exacerbation. There was no illness at the time of vaccination. It was unknown by the reporter if the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320015-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	15-Sep-2008	OH	WAES0806USA08301	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a dose of GARDASIL vaccine (yeast). The patient fainted after she received GARDASIL vaccine (yeast). Subsequently, the patient recovered. Unspecified medical attention was sought. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320016-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	15-Sep-2008	OH	WAES0806USA08302	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a dose of GARDASIL vaccine (yeast). The patient fainted after she received GARDASIL vaccine (yeast). Subsequently, the patient recovered. Unspecified medical attention was sought. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320017-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	15-Sep-2008	OH	WAES0806USA08303	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Hyperhidrosis, Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a dose of GARDASIL vaccine (yeast). The patient fainted after she received GARDASIL vaccine (yeast). She became hot and sweaty after fainting. Subsequently, the patient recovered. Unspecified medical attention was sought. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320018-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	15-Sep-2008	OH	WAES0806USA08304	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Hyperhidrosis, Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a dose of GARDASIL vaccine (yeast). The patient fainted after she received GARDASIL vaccine (yeast). She became hot and sweaty after fainting. Subsequently, the patient recovered. Unspecified medical attention was sought. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320019-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-May-2008	20-Jun-2008	31	17-Jul-2008	15-Sep-2008	--	WAES0806USA08311	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Concussion, Fall, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with a history of "small septal defect" and no drug reactions/allergies who on 20-JUN-2008 was vaccinated intramuscularly in the right arm with first dose of GARDASIL vaccine (yeast) (lot # unspecified). Concomitant therapy included hormonal contraceptives (unspecified). It was reported that the patient fainted and fell off exam table seconds post vaccination. Upon further examination by physician, the patient was determined to have a concussion. Unspecified medical attention was sought. It was reported that the patient was getting worse and the physician will be scheduling CT scan if symptoms won't subside. At the time of this report the patient has not recovered from her experiences. No further information is available.

Other Meds: hormonal contraceptives

Lab Data: None

History: small septal defect

Prex Illness:

Prex Vax Illns:

Vaers Id: **320024-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Jun-2008	23-Jun-2008	0	17-Jul-2008	15-Sep-2008	CA	WAES0806USA08334	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Syncope

Symptom Text: Information has been received from a physician concerning an 18 year old female who on 23-JUN-2008 was vaccinated IM in the arm with the first dose of GARDASIL vaccine (yeast). On 23-JUN-2008 the patient fainted and fell to ground. On 23-JUN-2008 the patient recovered from fainting. Unknown medical attention was sought. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320025-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Jun-2008	20-Jun-2008	0	17-Jul-2008	15-Sep-2008	TX	WAES0806USA08339	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Pyrexia

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with no medical history and an allergy to sulfa medications who on 17-May-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (no lot number provided). On 20-JUN-2008 the patient received the second 0.5 ml dose of GARDASIL vaccine (yeast) (no lot number provided). Other therapy included "SYMBIAX". Since receiving the second dose on 20-JUN-2008 she has had a fever and was extremely tired. The patient's fever and extremely tired persisted. Laboratory diagnostics studies performed reported as "lab." At time of reporting patient had not recovered. Unknown medical attention was sought. Additional information has been requested.

Other Meds:

Lab Data: lab

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320026-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Jun-2008	22-Jun-2008	2	17-Jul-2008	15-Sep-2008	--	WAES0806USA08341	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper

Symptom Text: Information has been received from an 18 year old female consumer who on 20-JUN-2008 was vaccinated intramuscularly with a 0.5 mL first dose of GARDASIL vaccine (yeast) (lot # not reported). Concomitant therapy included "birth control pills" (hormonal contraceptives (unspecified)). the patient states that she "experienced stomach pains after getting vaccinated" (onset reported as 22-JUNE-2008). The patient sought unspecified medical attention and provided a urine sample (nor further specified). The patient reported that she was recovering from the stomach pains. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: diagnostic urinalysis

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320027-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-Jun-2008	Unknown		17-Jul-2008	15-Sep-2008	MD	WAES0806USA08362	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning an 18 year old female who on 19-JUN-2008 was vaccinated with a second dose of GARDASIL vaccine (yeast) (route and administrating site not reported) (lot# 660393/0067X). Following her second dose of GARDASIL vaccine (yeast) the patient experienced nausea and vomiting for three hours. Subsequently the patient recovered from the nausea and vomiting. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320028-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	15-Sep-2008	FL	WAES0806USA08383	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Injection site erythema, Injection site swelling, Vomiting

Symptom Text: Information has been received from a healthcare worker concerning a female patient who was vaccinated with the first and second doses of GARDASIL vaccine (yeast). The patient experienced feeling faint, with vomiting, dizziness, and an injection site reaction with swelling and redness after each dose. The patient recovered from feeling faint, with vomiting, dizziness, and an injection site reaction with swelling and redness. Injection were administered at another location. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320029-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	02-Jun-2008	02-Jun-2008	0	17-Jul-2008	15-Sep-2008	MA	WAES0806USA08389	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Injection site pain

Symptom Text: Information has been received through the Merck pregnancy registry from a 25 year old female patient with no allergies and a history of three surgical procedures to remove skin cancer and gall bladder removed who on 02-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). There was no concomitant therapy. The patient was pregnant. The patient experienced the only adverse side effect as some pain in her arm in the area of the injection site. There was no fever or sickness. This only lasted fro a few days and the patient was fine now. The patient sought medical attention. Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic - pregnancy

History: Cholecystectomy, Skin cancer

Prex Illness:

Prex Vax Illns:

Vaers Id: **320030-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Jun-2008	10-Jun-2008	0	17-Jul-2008	15-Sep-2008	--	WAES0806USA08390	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dizziness postural, Headache

Symptom Text: Information has been received from a licensed visiting nurse (LVN) concerning a 15 year old female with allergic rhinitis and a history of headache and meningitis (at 7 years of age) who on 25-MAR-2008 (Lot 659657/1487U), 10-JUN-2008 and 24-JUN-2008 (Lot #660391/0063X) was vaccinated IM with 0.5 mL doses of GARDASIL vaccine (yeast). Concomitant therapy included mometasone furoate (NASONEX). On 24-JUN-2008, after vaccination, the patient became dizzy/lightheaded upon standing and also developed a headache. The patient was treated with ibuprofen (MOTRIN) 800 mg for the headache. The patient did not require hospitalization, but was seen in the office. At the time of this report, the patient's dizziness/lightheadedness and headache persisted. Additional information has been requested.

Other Meds: NASONEX

Lab Data: None

History: Headache, Meningitis

Prex Illness: Rhinitis allergic

Prex Vax Illns:

Vaers Id: **320032-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-May-2008	07-May-2008	0	17-Jul-2008	15-Sep-2008	NC	WAES0806USA08391	24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1800U	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Asthma, Autoimmune disorder, Cardiac disorder, Dizziness, Dyspnoea, Eyelid oedema, Fatigue, Headache, Pallor, Presyncope, Tremor, Upper respiratory tract congestion, Ventricular extrasystoles

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with chronic asthma who on 14-APR-2008 or on 16-APR-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). Concomitant therapy included montelukast sodium (MSD). The consumer reported that her daughter developed cardiac and auto immune issues after getting the first dose of GARDASIL vaccine. The patient was taken to the ER but not hospitalized. The patient had already seen a cardiologist and would be seeing a rheumatologist. On an unspecified date the patient had a stress test done (results not provided). The patient sought medical attention. Additional information has been requested. 9/17/08-cardiology consult notes received for DOS 6/11/08-Impression:rare, uniform premature ventricular contractions (PVCs). Mild mitral valve regurgitation without prolapse. Referred for C/O premature ventricular contractions. Over past two months C/O severe fatigue. On 5/23/08 episode of shakiness, dizziness and shortness of breath. Presyncope, headaches and pallor. 9/23/08-records received for DOS 1/28/08-well visit with PMH asthmatic. 4/29/08-chest congestion face swelling with puffy eyelids. Assessment sinusitis. 5/1/08-asthma attack, asthma exacerbation. 5/7/08-seen for C/O low right side of head pain possible muscle spasm in neck. Mild hyperplasia. Swollen nasal mucosal. Received first Gardasil vaccine. 5/22/08-C/O feeling weak, fatigue, lack of energy.

Other Meds: SINGULAIR

Lab Data: Unknown 9/17/08-records received-ANA positive. Electrocardiogram rare uniform premature ventricular contractions. Echocardiogram normal sinus rhythm with rare uniform premature ventricular contractions followed by compensatory pauses. 9/2

History: 9/17/08-records received-PMH: breathing difficulties related to molds and asbestos. Hepatitis secondary to mononucleosis at 10 years of age. Visual difficulties. Strabismus surgery. Tympanostomy tube placement. Unexplained thrombocytosis. Weight bearing and ambulating difficulties. 9/23/08-records received-PMH asthmatic.

Prex Illness: Asthma chronic

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320033-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	15-Sep-2008	MS	WAES0806USA08405	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Human papilloma virus test positive

Symptom Text: Information has been received from a physician concerning a female who on unspecified dates was vaccinated with the three doses of GARDASIL vaccine (yeast). The physician reported that the patient tested negative twice for HPV before receiving GARDASIL vaccine. After her three injections, the patient tested positive for HPV. On an unspecified date the patient had a "Reflex Test" with WCP lab; which revealed she was a patient that had "ASCUS (abnormal undetermined cells)". The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: serum octavalent HPV 16 - "ASCUS (abnormal undetermined cells)"

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320036-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Jun-2008	10-Jun-2008	0	17-Jul-2008	15-Sep-2008	--	WAES0806USA08556	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a nurse concerning a 14 year old female with no relevant medical history who on 10-JUN-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number 660387/1967U) by intramuscular injection (injection site not reported). There was no concomitant medication. On 10-JUN-2008, after receiving the vaccine, the patient became dizzy. It was reported that the patient's dizziness improved after stopping therapy and that the patient had recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **320037-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	23-Apr-2008	23-Apr-2008	0	17-Jul-2008	15-Sep-2008	MI	WAES0806USA08567	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Malaise, Pyrexia

Symptom Text: Information has been received from a health professional concerning a 21 year old female with a history of Raynaud's Syndrome who on 23-APR-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number 659439/1267U) (injection site and route not reported). Concomitant therapy included amphetamine aspartate/amphetamine SO4/dex (ADDERALL TABLETS), lisdexamfetamine dimesylate (VYVANSE) and desogestrel/ethinyl estradiol (MIRCETTE). After receiving the first dose of vaccine, the patient developed a fever and "felt sick". Subsequently the patient recovered from the events. On 16-JUN-2008 the patient was vaccinated with a second dose of GARDASIL vaccine (yeast) 0.5 ml by intramuscular injection (injection site not reported). Five minutes after the second dose, the patient developed a three inch round, red, swollen area at injection site. Unspecified medical attention was sought. Subsequently, the patient recovered from the event. Additional information has been requested.

Other Meds: ADDERALL TABLETS, MIRCETTE, VYVANSE

Lab Data: None

History: Raynaud's syndrome

Prex Illness:

Prex Vax Illns:

Vaers Id: **320038-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	07-Jun-2007		17-Jul-2008	16-Sep-2008	KS	WAES0806USA08578	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Central nervous system lesion, Malaise, Mydriasis, Optic neuritis, Syncope

Symptom Text: Information has been received from a healthcare worker concerning her 18 year old daughter with irritable bowel and a history of attention deficit disorder who on unspecified date was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). The patient felt sick after the vaccination. On an unspecified date, the patient was vaccinated with a second dose of GARDASIL vaccine (yeast) by intramuscular injection (lot number and injection site not reported). Concomitant therapy included amphetamine aspartate/amphetamineS04/dex (ADDERALL TABLETS) and birth control pill. On 07-JUN-2007 the patient experienced faint and shortly afterwards she developed a problem with her eye; it became dilated more than the other. The caller took her daughter to an optometrist who performed some tests that came back abnormal and determined it was optic neuritis. The caller went to other specialists to find out if it was MS related and the patient had an MRI done which came back abnormal and showed 11 to 14 lesions on her brain, spine tap came back negative. A MS specialist did not feel it was MS however suggested not receiving the 3rd dose and determined it was probably a response to the vaccine. The patient's optic neuritis persisted. The caller also mentioned that her daughter also had a behavioral problem on Periaction when she was little. Additional information has been requested.

Other Meds: ADDERALL TABLETS, hormonal contraceptives

Lab Data: magnetic resonance - abnormal, computed axial, spinal tap - negative

History:

Prex Illness: Attention deficit disorder, Irritable bowel

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320039-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Feb-2008	Unknown		17-Jul-2008	16-Sep-2008	TN	WAES0806USA08599	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Menstrual disorder

Symptom Text: Information has been received from a certified medical assistant concerning a 17 year old female with no pertinent medical history and no allergies who in December 2007, was vaccinated with the first dose of GARDASIL vaccine (yeast). In February 2008 the patient was vaccinated with the second dose of GARDASIL vaccine (yeast). There was no concomitant medication. The patient's mother asked if there have been reports of increase of frequency in the menstrual cycle. The patient's cycle was usually every 32 to 35 days but now it was every 27 days. On 25-JUN-2008, the patient was vaccinated with the third dose of GARDASIL vaccine (yeast). The patient's increase of frequency in the menstrual cycle persisted. The patient sought medical attention in office. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320042-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	24-Jun-2008	25-Jun-2008	1	17-Jul-2008	15-Sep-2008	RI	WAES0806USA08603	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Feeling abnormal, Headache, Loss of consciousness, Myalgia, Syncope

Symptom Text: Information has been received from a registered nurse concerning a 22 year old female with penicillin allergy who consumes alcohol and has no other pertinent medical history who on 24-JUN-2008 was vaccinated with third dose of GARDASIL vaccine 1 dose. On 24-JUN-2008, the patient experienced black out. On 25-JUN-2008 morning, the patient was not feeling right and felt dizzy. The patient was bending over at work and then fainted. The patient came to the office 1/2 hour after fainting with a chief complaint of fatigue, myalgia, headache and dizziness. The patient had no symptoms in the office and was not treated. On 25-JUN-2008, the patient recovered from black out, not feeling right, faint, fatigue, myalgia, headache and dizziness. No further information is available.

Other Meds:

Lab Data: diagnostic laboratory - carotid arteries without bruit (murmur); diagnostic laboratory - lungs clear-normal; electrocardiogram - normal; vital sign - normal

History:

Prex Illness: Penicillin allergy; Social alcohol drinker

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320045-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Apr-2008	12-Apr-2008	0	22-Jul-2008	30-Jul-2008	NY		31-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2425AA	0	Right arm	Intramuscular	
	IPV	SANOFI PASTEUR	A01692	2	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0924U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope, Syncope vasovagal

Symptom Text: Fainting (vaso-vagal) about 10-15 after administration of vaccines: followed by

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320053-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jun-2008	01-Jun-2008	0	17-Jul-2008	15-Sep-2008	OH	WAES0806USA08613	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a certified medical assistant concerning a female who in June 2008 was vaccinated with the first dose of GARDASIL vaccine. The patient had "trouble getting shots." Post vaccination the patient was monitored for approximately 15 minutes and when the patient to the reception area the patient fainted. Subsequently, the patient recovered from faint. The patient sought medical attention at the office. This is one of several reports from the same source. Additional information ahs been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320055-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Oct-2007	02-Oct-2007	0	17-Jul-2008	15-Sep-2008	MD	WAES0806USA08614	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Pallor

Symptom Text: Information has been received from a nurse concerning a 14 year old female with no pertinent medical history or drug reactions/allergies reported who on 22-MAY-2007 was vaccinated with a first dose of GARDASIL vaccine (lot# 657736/0389U) 0.5 mL IM. The patient, on 02-OCT-2007 was vaccinated with a second dose of GARDASIL vaccine (lot# 658558/1061U) 0.5 mL IM. On 25-JUN-2008, the patient became dizzy, pale and diaphoretic after a third dose of GARDASIL vaccine (lot# 660555/0279X) 0.5 mL IM. Subsequently, the patient recovered from dizzy, pale and diaphoretic. The patient sought medical attention in the office, the events occurred in the physician's office. Additional information has been requested. This is one of several reports from the same source.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320057-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	23-Jun-2008	23-Jun-2008	0	17-Jul-2008	15-Sep-2008	TX	WAES0806USA08624	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a medical assistant concerning a 25 year old female who on 23-JUN-2008 was vaccinated with a first dose of GARDASIL VACCINE 0.5 mL IM. The patient started getting a rash on her arms, but not around the injection site. On 25-JUN-2008, the patient called the office to report that the rash was all over her body and progressing. BENADRYL was recommended to the patient to treat the rash; however she reported that it did not seem to help. The patient was scheduled to be seen in the office on 26-JUN-2008 for an unrelated reason (sonogram). The patient's rash persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320058-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Oct-2007	Unknown		22-Jul-2008	23-Jul-2008	FR	WAES0807USA03469	23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0233U	1	Right arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Amenorrhoea, Convulsion

Symptom Text: Information has been received from a health authority concerning a 14 year old female who on 15-OCT-2007 was vaccinated with a second dose of GARDASIL (lot # 1475F, batch # NF37120) into the upper arm. In October 2007 (exact date not reported), the patient experienced persisting amenorrhea. On 22-MAY-2008 the patient had a seizure cerebral "for minutes". The patient was hospitalized (date not reported). The final outcome of the cerebral seizure was not reported. the amenorrhea was ongoing at the time of reporting. The patient was vaccinated with a first dose of GARDASIL (lot # 0233U, batch # NF46740) into the right upper arm on 10-AUG-2007. No adverse effect occurred. Other business partner numbers included E2008-06547 and PEI2008010062. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320059-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-May-2008	23-May-2008	0	17-Jul-2008	15-Sep-2008	--	WAES0806USA08649	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Pallor

Symptom Text: Information has been received from a physician assistant concerning a 15 year old female who on 23-MAY-2008 was vaccinated with a first dose of GARDASIL vaccine and included hepatitis A virus vaccine (manufacturer unknown). The physician assistant reported that the patient received the first vaccination with GARDASIL VACCINE on 23-MAY-2008 and passed out. The patient became pale in color and passed out while sitting on the examination table. The patient was treated with cold compresses and recovered after an unspecified time frame. The patient was asked to wait in the office after recovery, but mother needed to leave. There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 320060-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	01-Apr-2008		22-Jul-2008	23-Jul-2008	NC	WAES0807USA03323	23-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain lower, Body temperature increased, Menorrhagia, Muscle spasms, Oral contraception, Ovarian cyst, Syncope, Thrombosis

Symptom Text: Information has been received from a female concerning her 13 year old granddaughter with no pertinent medical history and no history of drug reactions or allergies who on unspecified dates was vaccinated with the complete series of GARDASIL. There was no concomitant medication. Subsequently, in April 2008, the patient experienced severe pain on the bottom of her stomach on both sides and she was having blood clots. Because of these symptoms, the patient was hospitalized for 4 days. The patient also developed cyst. Ultrasound was performed (results not reported). As of 16-JUL-2008, the patient was at home but still complaining about severe pain in the lower part of her stomach and still has blood clots. This is one of three reports from the same source. (WAES: 0807USA03551 and 0807USA03552). Additional information has been requested. 8/21/08-ER records for DOS 4/2-4/4/08-presented with C/O abdominal pain and cramping. Menses began 3-4 days prior. Pale diaphoretic. Impression:abdominal pain, syncope. Temperature elevated. Urine culture E. coli. Seen in OB/GYN office 4/8/08-C/O continuous bleeding and abdominal pain. Follicular cyst of ovary. 6/4/08-continues to have heavy bleeding with cramps.Prescribed Ortho Nuvum 1/35. Seen on 7/15/08-last period without problems no longer taking birth control pills. Office did not administer Gadasil to client.

Other Meds: None

Lab Data: None 8/21/08-records received-Pelvic ultrasound demonstrated ovarian cyst. CT abdomen and pelvis negative.

History: None

Prex Illness:

Prex Vax Illns: Abdominal pain, Clot blood~HPV (Gardasil)~UN~17~In Sibling

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320061-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Jun-2008	23-Jun-2008	0	17-Jul-2008	15-Sep-2008	--	WAES0806USA08651	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician's assistant concerning a 14 year old female who on 04-DEC-2007 was vaccinated with the first dose of GARDASIL vaccine, on 07-FEB-2008 was vaccinated with the second dose of GARDASIL vaccine and on 23-JUN-2008 was vaccinated with the third dose of GARDASIL vaccine. There was no concomitant medication. The patient had no problems reported with the first or second dose of GARDASIL vaccine, but on 23-JUN-2008 while walking out the waiting room following the third dose passed out. The patient did not hit her head and was not passed out for very long. The patient was treated with cold compresses. No other supportive measurements were needed. The patient recovered at the office after an unspecified time. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320063-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Jul-2008	16-Jul-2008	0	22-Jul-2008	23-Jul-2008	TX	WAES0807USA03300	23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Fall, Musculoskeletal stiffness, No reaction on previous exposure to drug, Tremor, Urinary incontinence

Symptom Text: Information has been received from a nurse concerning a 16 year old female who on unspecified dates was vaccinated with the first and second doses of GARDASIL. The first and second doses did not cause symptoms. On 16-JUL-2008 the patient was vaccinated with the third dose of GARDASIL. Concomitant therapy included VAQTA (manufacturer unknown). The patient experienced "seizure-like symptoms within 30 seconds of her third dose". The symptoms were falling on a table, mild shaking including her legs, hand stiffening and urinating on herself. On an unspecified date the patient was recovered. The patient saw the doctor and sought unspecified medical attention. Upon internal review seizure-like symptoms were considered to be other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320064-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	06-May-2008	07-May-2008	1	17-Jul-2008	15-Sep-2008	PA	WAES0806USA08744	31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Swelling face, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 24 year old old female who on 06-MAR-2008 was vaccinated with a first dose of GARDASIL vaccine (lot # not reported). On 06-MAR-2008, the patient was vaccinated intramuscularly with a second dose of GARDASIL vaccine (lot # not reported). The physician reported that "the patient received two doses of GARDASIL vaccine and experienced swelling of her jaw the night of vaccine both times. The 1st dose was given when she was 24 year sold and the 2nd dose was given when she was 25 years old. The swelling resolved in a few days without treatment for both instances." The patient sought unspecified medical attention during an office visit. No other details were reported by the physician. Additional information has been requested. Follow-up information was received from a physician, concerning the now 25 year old white female patient with no previous medical history and pre-existing allergies reported. The physician reported that on 06-MAY-2008, the patient was vaccinated with the second dose of GARDASIL. The next morning the patient had noted swelling and tenderness of right jaw. The patient were to the reporter's office later on 07-MAY-2008, and still had mild fullness at right jaw area, but no mass or oro-pharyogeal swelling. Left deltoid injection site was not swollen. Swelling jaw improved during the course of the day. The patient indicated similar swelling of jaw "a few days after" her first dose of GARDASIL. In both cases, swelling resolved spontaneously. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320065-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jun-2007	Unknown		17-Jul-2008	15-Sep-2008	--	WAES0806USA08748	19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Sexual abuse

Symptom Text: Information has been received from a Nurse Practitioner concerning a female who on an unspecified date in June 2007, reported as "about 1 year ago," was vaccinated with a first dose of GARDASIL vaccine (lot # not reported). It was reported that, on an unspecified date post first vaccination, the patient was sexually assaulted after her first dose of GARDASIL vaccine. "No adverse effect" was reported. Patient outcome was not reported. Additional information has been requested. Initial and follow up information has been received from a nurse practitioner and the physician's office concerning a female who on an unspecified date in june 2007, reported as "about 1 year ago", was vaccinated with a first dose of GARDASIL (lot # not reported). It was initally reported that the patient on approximately "25 or 25-JUN-2008", was vaccinated with a second dose of GARDASIL (lot # not reported) and on an unspecified date post first vaccination, the patient was sexually assaulted after her first dose of GARDASIL. "No adverse effect" was reported. Patient outcome was not reported. In follow up it was reported that there was no adverse drug related event. It was reported that the patient did not receive the second or third dose as scheduled. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 320066-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	01-Jan-2008	12-Jun-2008	163	17-Jul-2008	15-Sep-2008	--	WAES0806USA08763	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Muscle spasms

Symptom Text: Information has been received through the Merck pregnancy registry from a 26 year old female with no history of drug reactions or allergies and a history of light cramping when menstrual period starts who in November 2007 was vaccinated with the first dose of GARDASIL vaccine and in January 2008 was vaccinated with the second dose of GARDSIL vaccine. About 2 weeks ago (on approximately 12-JUN-2008), the patient experienced cramping, which is "stronger than the usual light cramping" she had before her period starts." This cramping did not fade away, but is "off and on." On 25-JUN-2008, the patient was vaccinated with the third dose of GARDASIL vaccine 0.5 mL (lot 655327/1287U). There was no concomitant medication. On 26-JUN-2008, the patient found out that she was pregnant by a pregnancy test. On 26-JUN-2008, the patient was approximately five weeks gestation. Last menstrual period was approximately 20-MAY-2008, estimated due date 24-FEB-2009. She will not get any more doses. The patient's cramping persisted. The patient sought medical attention with a telephone call. No further information is available.

Other Meds: None

Lab Data: beta-human chorionic 06-25/08 - positive

History: Menstrual cramps

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320067-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Jul-2007	Unknown		17-Jul-2008	15-Sep-2008	--	WAES0806USA08764	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Smear cervix abnormal

Symptom Text: Information has been received from a nurse practitioner concerning a 25 year old female who in the summer of 2007, was vaccinated with a first dose of GARDASIL vaccine (lot number, injection site and route not reported). On 20-MAR-2008, the patient was vaccinated with a second dose of GARDASIL vaccine (lot number, injection site and route not reported). After receiving the 2 doses of vaccine, the patient developed a abnormal PAP smear. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear - abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320068-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Jun-2008	26-Jun-2008	0	17-Jul-2008	15-Sep-2008	PA	WAES0806USA08766	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a consumer concerning her 14 year old daughter with sulfonamide allergy who on 26-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine. At the same time the patient was vaccinated with the second dose of varicella virus vaccine live (MSD). The consumer reported that the patient had blood drawn for routine blood work after receiving the vaccinations and the patient fainted approximately 20 minutes immediately after the blood was drawn. Subsequently, the patient was recovered. The patient sought unspecified medical attention at the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory 06/26/08 - blood drawn

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320069-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jun-2008	18-Jun-2008	2	17-Jul-2008	15-Sep-2008	--	WAES0806USA08770	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: Information has been received from a medical assistant concerning a 14 year old female with type 1 diabetes mellitus and no known drug allergies who on 13-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine. On 16-JUN-2008 the patient was vaccinated with the second dose of GARDASIL vaccine. The patient was vaccinated at another facility. On 18-JUN-2008, the patient experienced vomiting. Subsequently, the patient recovered from vomiting. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Type 1 diabetes mellitus

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320071-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Apr-2008	Unknown		17-Jul-2008	15-Sep-2008	KS	WAES0806USA08771	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Gingival erythema, Gingival swelling, Pharyngolaryngeal pain, Pyrexia, Stomatitis, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 16 year old female with seasonal allergies and a sulfonamide allergy who on 14-APR-2008 was vaccinated with the first dose of GARDASIL vaccine, lot # not specified. Concomitant therapy included ALLEGRA and VYVANSE. On an unspecified date in April 2008, the patient experienced low grade fever and sores on tongue after receiving her first dose of GARDASIL vaccine. The patient did not seek medical attention related to this and recovered at an unspecified time. On 16-JUN-2008, the patient received her second dose of GARDASIL vaccine, lot # not reported. The day after receiving the vaccine the patient developed a fever that lasted 3 - 4 days, a sore throat, sores on her mouth, tongue and inside of her lips, and red swollen gums. The patient was evaluated in the office and is recovering. Additional information has been requested.

Other Meds: ALLERGRA; VYVANSE

Lab Data:

History:

Prex Illness: Seasonal allergy; Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **320072-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	14-Mar-2008	Unknown		17-Jul-2008	15-Sep-2008	--	WAES0806USA08773	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1264U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Herpes zoster

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female with amoxicillin allergy and no pertinent medical history who on 10-SEP-2007, 12-NOV-2007 and 14-MAR-2008 was vaccinated with a first, second and third 0.5 mL doses, respectively, of GARDASIL vaccine (Lot #658488/0930U, 658558/1061U, 658488/1264U respectively). There was no concomitant medication. After receiving the third dose of GARDASIL vaccine the patient experienced unnamed symptoms. Subsequently, the symptoms cleared and then after an unknown time she experienced the symptoms again. Her family doctor diagnosed shingles for both occurrences. At the time of the report, the patient had recovered from shingles. The patient was seen in office. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **320073-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Jun-2008	26-Jun-2008	3	17-Jul-2008	15-Sep-2008	OH	WAES0806USA08775	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a nurse concerning an 18 year old female with no pertinent medical history, drug reactions or allergies who on 23-JUN-2008 was vaccinated with a first dose of GARDASIL vaccine. There was no concomitant medication. "3 days later," on 26-JUN-2008 the patient called the office to report she was dizzy. At the time of the report, the patient was recovering from being dizzy. The patient sought medical attention by calling the office. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320074-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	--	WAES0806USA08787	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Metrorrhagia

Symptom Text: Information has been received from a pharmacist concerning a 21 year old female patient with no pertinent medical history and no allergies who was vaccinated with GARDASIL vaccine (yeast). There was no concomitant medication. The patient has been experiencing "spotting" during menstrual cycle. The pharmacist did not know the history of the "spotting". The patient is not known to be on birth control. The patient's spotting during menstrual cycle persisted. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 320075-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
39.0	F	28-May-2008	25-Jun-2008	28	22-Jul-2008	23-Jul-2008	FR	WAES0807USA02911	23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0569U	1	Gluteous maxima	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Back pain, Dysuria, Inappropriate schedule of drug administration, Incorrect route of drug administration, Malaise, Pyelonephritis acute, Pyrexia

Symptom Text: Information has been received from a health professional concerning a 39 year old female with hypothyroidism who on 25-MAY-2008 was vaccinated with the first dose of GARDASIL (lot number not reported) without any adverse events. On 25-JUN-2008 was administered the second dose of GARDASIL (lot # 0569U; batch # NG39340) in the buttocks. On 07-Jun-2008, laboratory evaluation revealed white blood cell count 7,040; blood neutrophil count 69%; blood lymphocyte count 16%; and blood monocyte count 13%. On 25-JUN-2008, after vaccine administration, the patient started with general malaise. On 30-JUN-2008, the patient began to have lumbar pain, the patient went to the hospital where she was diagnosed with lumbago, the patient was given analgesics to treat lumbar pain. By 01-JUL-2008, the patient presented a high fever (39 C). She was hospitalized on 3-JUL-2008, where she was diagnoed with an acute right side pyelonephritis and febrile syndrome. On 03-JUL-2008, laboratory evaluation on admission revealed red blood cell count 4,700,000; hemoglobin test 15.1; hematocrit 41.2; white blood cell count 11,800; neutrophil count 87.4%; lymphocyte count 4.9%; monocyte count 6.9%; platelet count 229,000; serum glucose test 94; blood urea test 17.8; serum creatinine test 0.9; serum sodium test 136; serum potassium 4.3; serum C-reactive protein test 2.2. On 03-JUL-2008, urine tests revealed: urine culture Isolated bacteriae, urocultive: mixed flora; red blood cell count 11-20; and white blood cell count 50-100. On 07-JUL-2008, his urinalysis was normal. Per hospital discharge report received on 11-JUL-2008 the patient, a 39 year old female was hospitalized through the emergency room, with clinical symptoms that had been going on for 6 days after being administered the second dose of vaccine. The symptoms were lumbar pain on the right side, that ceased after treatment with analgesics, but later on reappeared accompanied with fever (39C), dysuria and general malaise. According to the hospital report, the patient was firstly treated with

Other Meds: Unknown

Lab Data: urinary tract infection prophylaxis, 03Jul08; abdominal X-ray, no liathiasis; urological examination, bladder and kidneys appear to be normal, no expanding urine tract; WBC count, 07Jun08, 7040; lymphocyte count, 07Jun08, 16%; monocyte coun

History:

Prex Illness: Hypothyroidism

Prex Vax Illns:

Vaers Id: **320077-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Nov-2007	01-Mar-2008	107	22-Jul-2008	23-Jul-2008	FR	WAES0807USA02904	23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0253U	2	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Hypoaesthesia, No reaction on previous exposure to drug

Symptom Text: Information has been received from a health authority concerning a 14 year old female who on 24-APR-2007, was vaccinated with the first dose of GARDASIL (LOT # 1314F and BATCH # NF12410), intramuscular administered and was well tolerated. On 17-JUN-2007, was vaccinated with the second dose of GARDASIL and was well tolerated. On 15-NOV-2007, was vaccinated with the third dose of GARDASIL (LOT # 0253U and BATCH # NF58540), intramuscular administered into the left upper arm. In March 2008, the patient experienced numbness of fingers II-V up to the metacarpophalangeal joints of the left hand. On 18-MAY-2008, the patient experienced dizziness. She was hospitalized for diagnostics. Borreliosis, multiple sclerosis, transverse myelitis, disturbance of the static sense and "cardiac causes" were ruled out. At the time of the report dizziness had improved, but has not recovered. The patient's numbness of fingers II-V up to the metacarpophalangeal joints of the left hand outcome was not reported. Numbness of fingers II-V up to the metacarpophalangeal joints of the left hand and dizziness were considered to be an other important medical events. Other business partner numbers included: E2008-06466. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320078-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Nov-2007	06-Feb-2008	76	22-Jul-2008	23-Jul-2008	FR	WAES0807USA02874	23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1518F	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Adenovirus infection, Dizziness, Headache, Meningism, Nausea, Pharyngeal erythema, Pyrexia, Syncope, Tonsillitis, Vomiting

Symptom Text: Information has been received from a paediatrician concerning a 14 year old female who on 22-NOV-2007 was vaccinated with the first dose of GARDASIL (lot # 1518F; batch NF27880). This dose was well tolerated. On 05-FEB-2008, she received the second dose of GARDASIL (lot # 0467U; batch NG14300) intramuscular administration, into the deltoid muscle. On 06-FEB-2008 the patient experienced headache, nausea, vomiting (once), dizziness, fever up to 39.4 C and syncope. The patient was hospitalized the same day because meningitis the course of the febrile infection was suspected. By discharge summary it was reported that the patient showed meningism but CSF was normal. Additionally, she had a red pharynx and tonsils. Adenovirus infection of the upper respiratory tract was diagnosed. Laboratory tests included: Adenovirus serum immunoglobulin M (IgM) test = 13 U and serum immunoglobulin G (IgG) test = 24 U; serum C-reactive protein test = 5.9 mg/l; cerebrospinal fluid = Normal; serum Borrelia burgdorferi antibody test = Negative; X-ray of the paranasal sinuses and the lung = Normal. The patient recovered and was discharged from hospital on 10-FEB-2008. Case closed. Other business partner numbers included: E200806392. No further information is available.

Other Meds: Unknown

Lab Data: X-ray, ??Feb08, normal for paranasal sinuses and lungs; Serum C-reactive protein, ??Feb08, 5.9 mg/l; Serum immunoglobulin M test, ??Feb08, 13 U, normal range: <8.5 - for adenovirus; Serum immunoglobulin G test, ??Feb08, 24 U, normal range:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320080-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		22-Jul-2008	23-Jul-2008	--	WAES0807USA01852	23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Meningitis viral

Symptom Text: Information has been received from a nurse concerning an 11 or 12 year old daughter of a co-worker who was vaccinated with the first dose of GARDASIL. The patient, was diagnosed of "viral meningitis" after receiving the first dose and was hospitalized for a few days. The nurse reported that the patient was home as of 10-JUL-2008, but she still had left over symptoms. The patient had not recovered. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320081-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Jan-2008	30-Jun-2008	151	22-Jul-2008	23-Jul-2008	FR	WAES0807USA02905	23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0513U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, No reaction on previous exposure to drug, Paralysis

Symptom Text: Information has been received from a gynecologist, concerning a 17 year old female patient with history of neurodermatitis and allergies (not otherwise specified) was vaccinated with her first dose of GARDASIL (Batch# NF37120, Lot # 1475F) into the upper arm on 08-AUG-2007. The second dose of GARDASIL was given into the upper arm on 04-OCT-2008. No adverse effect occurred for both vaccinations application. The third dose of GARDASIL (Batch # NG16040, Lot #0513U) route not reported was given the upper arm on 31-JAN-2008. Five months post vaccination, approximately 30-JUN-2008, the patient experienced paralysis of the left foot with loss of strength of elevator toes. ENG (electroneurography) showed changes (not specified). CT is planned. Concomitant therapy included hormonal contraceptives (unspecified) for systemic use. The patient's paralysis persisted. Symptoms were ongoing at the time of reporting. Paralysis was considered an Other Important Medical Event. Other business partner numbers included: E2008-06469. No further information is available.

Other Meds: hormonal contraceptives (unspecified), Unk - Unk

Lab Data: electroneurography, showed changes not specified

History: Neurodermatitis; Hypersensitivity

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320082-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	24-Jan-2008	11-Feb-2008	18	22-Jul-2008	23-Jul-2008	FR	WAES0807USA02877	23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0476U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Facial paresis, No reaction on previous exposure to drug

Symptom Text: Information has been received from a gynecologist concerning a 25 year old female smoker with penicillin allergy and multiple allergies (pollen, coat of animals, mites and herbage) who on 27-NOV-2007, was vaccinated with the first dose of GARDASIL and was well tolerated. On 24-JAN-2008, was vaccinated with the second dose of GARDASIL (LOT # 0476U and BATCH #NG14300) into the upper arm. Concomitant therapy included hormonal contraceptives for systemic use (unspecified). On approximately 11-FEB-2008, 18 days post vaccination, the patient experienced left-sided facial paresis and was hospitalized on date not reported. On approximately, 03-MAR-2008, the patient recovered completely from facial paresis after 3 weeks. Other business partner numbers included: E2008-06458. Additional information has been requested.

Other Meds: hormonal contraceptives (unspecified), Unk - Unk

Lab Data: Unknown

History:

Prex Illness: Smoker; Penicillin allergy; Multiple allergies

Prex Vax Illns:

Vaers Id: **320083-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	29-May-2008	29-May-2008	0	22-Jul-2008	23-Jul-2008	SC	WAES0807USA02502	23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a physician through the Merck pregnancy registry for GARDASIL concerning a 27 year old female who on 29-MAY-2008, was vaccinated with the first dose of GARDASIL, 0.5ml, IM and is now pregnant. On 08-MAY-2008, the patient had her last menstrual period (LMP) (estimated date of delivery 12-FEB-2009). On 14-JUL-2008, the patient was experiencing a miscarriage. The patient sought medical attention at the physician's office. On 14-JUL-2008, the patient was scheduled for a Dilation and Curettage (D&C) procedure. At the time of reporting, the outcome was unknown. Upon internal review, miscarriage was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 5/8/2008)

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320084-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	21-Feb-2007	28-Feb-2007	7	22-Jul-2008	23-Jul-2008	IL	WAES0704USA00393	23-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0014U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received from a registered nurse for the Pregnancy Registry of GARDASIL concerning a 21 year old female with no pertinent medical history or drug reactions or allergies who on 21-FEB-2007 was vaccinated with GARDASIL, lot# 653736/0014U (first dose). Concomitant therapy included YASMIN. As of 02-APR-2007 the patient was pregnant (LMP = 28-FEB-2007, estimated delivery date = 05-DEC-2007). There were no adverse experiences related to this event. The patient sought unspecified medical attention (not further specified). Follow-up information indicated that the patient terminated the pregnancy at less than 12 weeks. Upon internal review the elective termination was considered to be an other important medical event. Additional information is not expected.

Other Meds: YASMIN

Lab Data: serum beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = 2/28/2007)

Prex Vax Illns:

Vaers Id: **320087-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Jun-2008	25-Jun-2008	0	17-Jul-2008	16-Sep-2008	PA	WAES0806USA08792	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 25-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (yeas). On 25-JUN-2008 the patient experienced periodic numbness in arm after vaccination. The patient experienced three episodes of numbness in the arm that received the vaccine. The patient recovered from periodic numbness in arm. The patient sought medical attention by telephone call. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320088-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	MN	WAES0806USA08820	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a female between 16-20 years of age, who on an unspecified date was vaccinated with GARDASIL vaccine (yeast). The nurse practitioner reported that within the last 4-6 months the patient had experienced fainting and dizziness after receiving GARDASIL vaccine (yeast). It is unclear if the fainting occurred after all three dose or not. At the time of the report the patients had recovered; she was fine before leaving the office after receiving the vaccine. The patient did not seek medical attention. This is one of several reports received from the same source. Attempts are being made to obtain additional identifying information to distinguish the individual patients. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320089-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	25-Jun-2008	26-Jun-2008	1	17-Jul-2008	16-Sep-2008	PA	WAES0806USA08826	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a 11 year old female who on 25-JUN-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) in the deltoid region of her arm. On 26-JUN-2008 the patient developed a rash from the wrist to the elbow on the arm in which she received the GARDASIL vaccine (yeast). The patient was treated with diphenhydramine hydrochloride (BENADRYL). The patient sought medical attention by telephone call. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320090-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	MN	WAES0806USA08827	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a female between 16-20 years of age, who on an unspecified date was vaccinated with GARDASIL vaccine (yeast). The nurse practitioner reported that within the last 4-6 months the patient had experienced fainting and dizziness after receiving GARDASIL vaccine (yeast). It is unclear it the fainting occurred after all three dose or not. At the time of the report the patients had recovered; she was fine before leaving the office after receiving the vaccine. The patient did not seek medical attention. This is one of several reports received from the same source. Attempts are being made to obtain additional identifying information to distinguish the individual patients. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 320091-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	26-Dec-2007	26-Dec-2007	0	17-Jul-2008	16-Sep-2008	--	WAES0806USA08831	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Malaise, Oedema peripheral, Pain in extremity, Pyrexia

Symptom Text: Information has been received from a nurse concerning her daughter, an 18 year old female who on approximately 26-DEC-2007 was vaccinated with a first dose of GARDASIL vaccine (yeast) (route and administrating site not reported). The patient experienced soreness, redness and swelling in her arm as well as a fever that lasted for a few days. It was noted that the patient did not feel well for a period of approximately one week. Subsequently, the patient recovered from soreness, redness and swelling in her arm and fever. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320092-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Jun-2008	26-Jun-2008	0	17-Jul-2008	16-Sep-2008	TX	WAES0806USA08836	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Gaze palsy, Muscle rigidity, Nervousness, Syncope, Tremor

Symptom Text: Information has been received from a nurse concerning a 14 year old female with no known drug allergies who on 26-JUN-2008 was vaccinated intramuscularly into the left deltoid with the first 0.5 ml dose of GARDASIL vaccine (yeast) (lot no. 660393/0067X). At the same time the patient was vaccinated with hepatitis A vaccine (inactive) (HAVRIX). The patient told the nurse that she was nervous about shots. The patient was sitting on the table and a few minutes after GARDASIL vaccine (yeast) was administered the patient slumped down onto the table and her legs and arms were rigid and shaking. The patient's sister said her eyes rolled to the back of her head, The patient fainted and her hair was over her face. The patient was out for approximately two to three minutes. When the patient came to she said to nurse "did I fall asleep?" The patient was monitored at the office and fully recovered. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **320093-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	AZ	WAES0806USA08863	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Headache, Local reaction, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 12 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL vaccine (yeast) (route and administrating site not reported). The patient experienced arm pain, weakness, headache and local reaction after administration. The patient's sister also had an adverse experience after vaccination with GARDASIL vaccine (yeast) (WAES# 0806USA08872). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: Headache~HPV (no brand name)~1~15~In Sibling|Local reaction~HPV (no brand name)~1~15~In Sibling

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320094-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	AZ	WAES0806USA08868	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a physician concerning her daughter who was vaccinated with a first dose of GARDASIL vaccine. Subsequently, the patient experienced arm soreness. Subsequently, the patient recovered from arm soreness. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320095-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	MN	WAES0806USA08869	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Stomach discomfort

Symptom Text: Information has been received from a registered nurse concerning a female (age not reported who on an unspecified date was vaccinated with the first dose of GARDASIL vaccine (lot not reported). Subsequently, the patient felt sick to her stomach but did not faint. The patient's status was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320096-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	AZ	WAES0806USA08872	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Headache, Local reaction, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 15 year old female who was vaccinated with a first dose of GARDASIL vaccine (yeast). Subsequently the patient experienced arm pain, weakness, headache and local reaction. At the time of report, no outcomes were reported. The physician also reported that the patient's sister experienced the same symptoms after received GARDASIL vaccine (yeast) (WAES# 0806USA08863). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: Headache~HPV (no brand name)~1~12~In Sibling|Local reaction~HPV (no brand name)~1~12~In Sibling

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320097-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jun-2008	01-Jun-2008	0	17-Jul-2008	16-Sep-2008	OH	WAES0806USA08925	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a certified medical assistant concerning a female who in June 2008 was vaccinated with the second dose of GARDASIL vaccine. The patient had "trouble getting shots or giving blood." The patient laid down for 15 minutes post vaccination and was monitored. When the patient walked down the hall way the patient fainted, and it took the patient about 30 second to revive. Smelly salts were place under the patient's nose. Subsequently, the patient recovered from faint. The patient sought medical attention at the office. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320098-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Jul-2008	16-Sep-2008	MD	WAES0806USA08926	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Pallor

Symptom Text: Information has been received from a nurse concerning an unspecified number of patients who were vaccinated with a first dose of GARDASIL vaccine (yeast). The patients became dizzy, pale and diaphoretic after receiving a dose of GARDASIL vaccine (yeast). Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320099-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	AZ	WAES0806USA08928	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician and an office manager concerning an approximately 20 year old female who on an specified date was vaccinated intramuscularly with a first 0.5 mL dose of GARDASIL vaccine (Lot #660555/0279X). After receiving GARDASIL vaccine the patient fainted. At the time of the report, it was unknown if the patient had recovered from the event. Unspecified medical attention was sought. This is one of several reports received from the same source. Additional information ahs been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320100-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	21-Jun-2008	Unknown		17-Jul-2008	16-Sep-2008	MA	WAES0806USA08932	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site inflammation, Injection site pruritus, Injection site swelling, Oedema peripheral

Symptom Text: Information has been received from a pharmacist concerning a 23 year old female who on approximately 21-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (dose, route, and lot # not specified). On approximately 21-JUN-2008, the patient developed itching, redness, swelling, and inflammation at the injection site that went away on an unspecified date. On an unspecified date the injection started swelling again and spread to the elbow from the upper arm. The patient sought medical attention by phone call to the office. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320101-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Feb-2008	01-Feb-2008	0	17-Jul-2008	16-Sep-2008	FL	WAES0806USA09142	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received regarding a case in litigation. An X-ray technician reported that her colleague with no relevant medical history or allergies in October 2007, was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). In November 2007, the patient was vaccinated with a second dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). Concomitant therapy included ethinyl estradiol (+) etonogestrel (NUVARING). In February 2008, also reported as soon after third dose, the patient had a positive PAP with abnormal cells. The patient sought unspecified medical attention. The patient's positive PAP with abnormal cells persisted. This is case 2 of 2. Additional information has been requested.

Other Meds: NOVARING

Lab Data: cervical smear - 02/??/08 - positive with abnormal cells

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **320102-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Jun-2008	25-Jun-2008	15	17-Jul-2008	16-Sep-2008	--	WAES0807USA00024	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Malaise, Myalgia, Pain

Symptom Text: Information has been received from a nurse, who is the mother of the patient, concerning her 16 year old daughter who on an unspecified date was vaccinated with the first dose of GARDASIL vaccine. On 10-JUN-2008, she was vaccinated with the second dose of GARDASIL vaccine, (lot # not reported), IM. Concomitant therapy included MENACTRA. The nurse reported that her daughter developed headache, muscle aches and pain on 25-JUN-2008. On 29-JUN-2008, she had taken her daughter the patient to a urgent care facility because she still wasn't feeling well. The nurse reported that her daughter had blood work performed and it was determined that she had a low white blood count; it was suspected she could have a virus, but they were not sure. No further information was provided. Additional information has been requested.

Other Meds:

Lab Data: hematology 06/29/08 - low white blood count

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320103-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	06-Mar-2008	Unknown		17-Jul-2008	16-Sep-2008	--	WAES0807USA00047	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Libido decreased

Symptom Text: Information has been received from a 24 year old female consumer with PAXIL allergy and no pertinent medical history who on 06-MAR-2008 was vaccinated with the first dose of GARDASIL vaccine 0.5 mL IM. There was no concomitant therapy. The patient experienced a diminished sex drive soon after starting therapy. On 06-MAY-2008, the patient was vaccinated with the second dose of GARDASIL vaccine 0.5 mL IM. There was no concomitant medication. On 06-MAY-2008, the patient experienced diminished sex drive much more soon after starting therapy. The patient's diminished sex drive persisted. The patient did not seek medical attention. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320104-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	IL	WAES0807USA00052	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Loss of consciousness

Symptom Text: Information has been received from a physician concerning a female (age unreported) who was vaccinated with a dose of GARDASIL vaccine (yeast), lot number not reported. Within five minutes the patient passed out for an extended period of time, hit her head on the wall and went to the emergency room. This is one of 2 reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320105-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	30-Jun-2008	30-Jun-2008	0	17-Jul-2008	16-Sep-2008	IL	WAES0807USA00058	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood glucose increased, Condition aggravated

Symptom Text: Information has been received from a consumer concerning her daughter a 13 year old female patient with type 1 diabetes mellitus, who at 30-JUN-2008 8:45 AM was vaccinated with the first dose of GARDASIL vaccine. Concomitant therapy included HUMALOG and LANTUS. On 30-JUN-2008, the patient experienced an elevation of blood glucose level (270mg/dl at 10 AM) (Home monitor). The patient had eaten usual breakfast prior to receiving vaccine in the morning. The patient did not seek medical attention, but would call physician. Additional information has been requested.

Other Meds: LANTUS; HUMALOG

Lab Data: blood glucose 06/30/08 27 mg/dl

History:

Prex Illness: Type 1 diabetes mellitus

Prex Vax Illns:

Vaers Id: **320106-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	29-May-2008	29-May-2008	0	17-Jul-2008	16-Sep-2008	PA	WAES0807USA00062	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Hypoaesthesia, Injection site anaesthesia, Paraesthesia

Symptom Text: Information has been received from staff from a physician's office concerning an 18 year old female with severe allergies to numerous things (dogs, cats, doxycycline, sulfa, cefprozil (CEFZIL) and diphtheria toxoid (+) pertussis acellular 5-component vaccine (+) tetanus toxoid (ADACEL)) who on 29-MAY-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) by intramuscular injection in the arm (lot number not reported). Concomitant therapy included drospirenone (+) ethinyl estradiol (YASMIN), cetirizine hydrochloride (ZYRTEC) and pseudoephedrine HCl (SUDAFED). Almost immediately after receiving the vaccine, the patient experienced numbness and tingling in her arm where the injection was given. The patient also experienced redness underneath her eyes which described as red streaks (one going vertically and the other horizontally). The patient also had a reaction to diphtheria toxoid (+) pertussis acellular 5-component vaccine (+) tetanus toxoid (ADACEL), but specifics were unknown. Unspecified medical attention was sought. Subsequently, the patient recovered from all the events. Additional information has been requested.

Other Meds: ZYRTEC, YASMIN, SUDAFED

Lab Data: None

History:

Prex Illness: Hypersensitivity, Sulfonamide allergy, Drug hypersensitivity

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320107-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	--	WAES0807USA00064	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain

Symptom Text: Information has been received from a nurse practitioner concerning an 18 year old female with allergy to VICODIN who on 08-JAN-2008 was vaccinated with the third 0.5 mL dose of GARDASIL vaccine. It was unknown when she received the first and second 0.5 mL doses of GARDASIL vaccine. There was no concomitant medication. The patient began to experience back pain after receiving the second dose. At the time of this report, the patient's back pain persisted. The patient sought unspecified medical attention at the practice. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **320108-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Apr-2008	01-Apr-2008	0	17-Jul-2008	16-Sep-2008	CA	WAES0807USA00071	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a medical assistant concerning an approximately 17 year old female with allergy to FLONASE who in April 2008, was vaccinated with the first 0.5 mL dose of GARDASIL vaccine. Concomitant therapy included diclofenac. The patient complaint of pain during administration of her first dose. The outcome was not reported. The patient sought unspecified medical attention during office visit. Additional information has been requested.

Other Meds: diclofenac

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **320109-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	--	WAES0807USA00073	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning her 19 year old female cousin who on an unspecified date was vaccinated with a first dose of GARDASIL vaccine. Concomitant medications were not reported. A nurse reported that her cousin received the first dose of GARDASIL vaccine and fainted in the waiting room. She recovered in 5 minutes. She had no reaction to her second vaccination with GARDASIL vaccine. Medical attention was sought: in office. There is no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320111-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	NJ	WAES0807USA00093	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection, Smear cervix abnormal

Symptom Text: Information has been received from a nurse concerning a female who was vaccinated with GARDASIL vaccine. It was unknown how many doses of GARDASIL vaccine the patient had received. The patient who had a normal PAP prior to vaccination had an abnormal PAP and was positive for HPV. At the time of this report, the patient was not recovered. The patient sought unspecified medical attention at office. No further information is available.

Other Meds: Unknown

Lab Data: Pap test - abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320116-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	CO	WAES0807USA00306	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash pruritic

Symptom Text: Information has been received from a physician concerning a female with a history of hives from penicillin who on an unspecified date was vaccinated with the first dose of GARDASIL vaccine. Later in that day the patient developed a rash, slightly raised if scratched, pruritic, over her trunk and arms. Subsequently, the patient recovered from rash which lasted for 5 to 7 days. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Hives

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **320118-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	MN	WAES0807USA01310	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a female between 16-20 years of age, who on an unspecified date was vaccinated with GARDASIL vaccine. The nurse practitioner reported that within the last 4-6 months the patient had experienced fainting and dizziness after receiving GARDASIL vaccine. It is unclear if the fainting occurred after all three doses or not. At the time of the report the patient had recovered; she was fine before leaving the office after receiving the vaccine. The patient did not seek medical attention. This is one of several reports received from the same source. Attempts are being made to obtain additional identifying information to distinguish the individual patients. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320119-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Jul-2008	19-Jul-2008	1	22-Jul-2008	31-Jul-2008	MA		31-Jul-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0279X	0	Left arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B019AA	0	Left arm	Unknown	
VARCEL	MERCK & CO. INC.	1996U	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Decreased appetite, Erythema, Somnolence

Symptom Text: Approximately 6 x 18 cm area of mild erythema underside of upper arm where given, decreased appetite, somnolence.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320120-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	MN	WAES0807USA01311	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a female between 16-20 years of age, who on an unspecified date was vaccinated with GARDASIL vaccine. The nurse practitioner reported that within the last 4-6 months the patient had experienced fainting and dizziness after receiving GARDASIL vaccine. It is unclear if the fainting occurred after all three doses or not. At the time of the report the patient had recovered; she was fine before leaving the office after receiving the vaccine. The patient did not seek medical attention. This is one of several reports received from the same source. Attempts are being made to obtain additional identifying information to distinguish the individual patients. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320122-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	MN	WAES0807USA01312	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a female between 16-20 years of age, who on an unspecified date was vaccinated with GARDASIL vaccine. The nurse practitioner reported that within the last 4-6 months the patient had experienced fainting and dizziness after receiving GARDASIL vaccine. It is unclear if the fainting occurred after all three doses or not. At the time of the report the patient had recovered; she was fine before leaving the office after receiving the vaccine. The patient did not seek medical attention. This is one of several reports received from the same source. Attempts are being made to obtain additional identifying information to distinguish the individual patients. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320130-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	M	04-Apr-2008	04-Apr-2008	0	22-Jul-2008	31-Jul-2008	PA		31-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back injury, Fall, Neck injury, Syncope

Symptom Text: Upon receiving the first dose of the HPV vaccine, I fainted in the doctor's waiting room. I fell straight backwards and hit my back/neck on a couch in the waiting room. I have since had problems with my neck and back.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320133-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Jul-2008	16-Jul-2008	0	22-Jul-2008	25-Jul-2008	MI		21-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Burning sensation, Conversion disorder, Dyskinesia, Headache, Movement disorder, Muscle twitching, Oedema peripheral, Pain in extremity, Paraesthesia, Swelling face

Symptom Text: Patient received Gardasil vaccine on 7/16/2008 and subsequently was noted to have jerking movements; patient also complained of tingling and pain with her extremities. Patient was subsequently hospitalized where she was evaluated and monitored. 8/21/08-ED records received for DOS 7/22/08-Presented with C/O burning sensation in chest, headache and feeling funny. facial swelling and hand swelling began yesterday. Pain in both legs with headache. Movement disorder twitching movements. Neuro consult observed episodes of shoulder shrugging. Impression: conversion disorder.

Other Meds: Albuteral prn

Lab Data: CT head negative for acute events.

History: Allergies to eggs and tomatoes, and environmental allergens. Medical history includes asthma, hypertension, obesity, sinus disease, and granulosis cell tumor of the right ovary status post salpingo-oophorectomy. 8/21/08-records received- PMH: morbidly obese, asthma granulosis cell tumor of the right ovary status post salpingo-oophorectomy.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320155-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Jul-2008	15-Jul-2008	0	22-Jul-2008	31-Jul-2008	KS		31-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TD	UNKNOWN MANUFACTURER	NULL		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	NULL	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blindness, Convulsion, Dizziness, Headache, Incontinence, Visual field defect, Vomiting

Symptom Text: Approximately 10 minutes after the shot, while still in the doctors office, patient experienced a seizure, incontinence, headache, temporary peripheral vision loss in right eye, vomiting, dizziness. Required emergency room visit via ambulance. Received anti-nausea drugs via IV to end vomiting. Released from the hospital later that night.

Other Meds: None

Lab Data: Received CT Scan, Blood Work at hospital

History: Allergy to Suprax

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320168-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
44.0	F	05-May-2008	16-May-2008	11	17-Jul-2008	16-Sep-2008	NY	WAES0806USA02234	02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0955F	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blister, Micturition urgency, Muscular weakness, Pain in extremity, Pollakiuria, Urinary tract infection

Symptom Text: Information has been received from a licensed practical nurse concerning a female in her "late 30's or early 40"s" who was vaccinated with a dose of GARDASIL vaccine. The nurse reported that the patient "may have Guillain-Barre syndrome." The patient contacted the office by phone. At the time of the report, the outcome of the patient was unknown. No product quality complaint was involved. Upon internal review possible Guillain-Barre syndrome was considered to be an other important medical event. Additional information has been requested. 12/19/08-records received-C/O weakness of muscles on 5/16/08 after Gardasil vaccine. 2/28/08 C/O increase in urge and frequency of urination for 24 hours. Suprapubic pain. DX UTI. 8/13/07 C/O foot pain/blisters after walking Gardasil vaccine adminsitered 11/15/07 lot #0955F left deltoid., 1/7/08 2nd Gardasil lot#0955F left deltoild and 3rd on 5/5/08 lot#1446U left deltoid.

Other Meds: Unknown

Lab Data: Unknown 12/19/08-records received

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320169-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	--	WAES0806USA03453	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injury

Symptom Text: Information has been received regarding a case in litigation concerning a female (age unreported) who was vaccinated with a dose of GARDASIL vaccine (yeast). Subsequently the patient experienced a "serious personal injury." Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320170-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	26-Mar-2008	26-Mar-2008	0	17-Jul-2008	16-Sep-2008	MD	WAES0806USA08354	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a laboratory assistant concerning an 18 year old female patient who on 26-MAR-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot #659964/1978U) and on 26-MAR-2008 she received her second dose of GARDASIL vaccine (yeast) (lot # 660393/0067X). Concomitant therapy included meningococcal ACYW conj vaccine (dip toxoid). The reporter reported that the patient fainted briefly after receiving the first dose of GARDASIL vaccine (yeast). She recovered from the fainting on the same day. She did not faint after the second injection. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320171-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	IL	WAES0806USA08937	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Loss of consciousness

Symptom Text: Information has been received from a physician concerning a female (age unreported) who was vaccinated with a dose of GARDASIL vaccine, lot number not reported. Within five minutes the patient passed out for an extended period of time, hit her head on the wall and went to the emergency room. This is one of 2 cases from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320172-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	10-Mar-2008	Unknown		17-Jul-2008	16-Sep-2008	--	WAES0806USA08945	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hepatic enzyme increased

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female with no pertinent medical history and no allergies who on 26-DEC-2007 was vaccinated with the first dose of GARDASIL vaccine (lot# 655327/1287U) 0.5mL IM. On 10-MAR-2008, the patient was vaccinated with the second dose of GARASIL vaccine (lot# 0151X) 0.5mL IM. Concomitant therapy included minocycline (manufacturer unknown). The patient was on minocycline for about a year and this was recently discontinued because of the liver test: In June 2008, the patient had elevated liver enzymes. The patient had no symptoms but the liver function test was done because patient was worried family history of diseases. The patient sought medical attention. Additional information has been requested.

Other Meds: minocycline

Lab Data: hepatic function tests 06/08 - elevated liver enzymes

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320173-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Apr-2008	Unknown		17-Jul-2008	16-Sep-2008	MO	WAES0806USA08953	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Mastitis

Symptom Text: Information has been received from a physician concerning a 14 year old female with drug hypersensitivity to PANCOF and with no known pertinent medical history who on 23-APR-2008 was vaccinated with a first and only dose of GARDASIL vaccine IM (lot# 654272/0073X). Concomitant therapy included MENACTRA. The patient developed mastitis after receiving GARDASIL vaccine. A sonogram was performed. The patient was treated with an antibiotic (unspecified). The patient was recovering. The patient sought medical attention by seeing the physician. Additional information has been requested.

Other Meds:

Lab Data: ultrasound - mastitis

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320174-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	23-Jun-2008	23-Jun-2008	0	17-Jul-2008	16-Sep-2008	WA	WAES0806USA08975	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Urticaria

Symptom Text: Information has been received from a licensed practical nurse concerning a 26 year old female with no known pertinent medical history or drug reactions/allergies who on 23-JUN-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) 0.5 ml IM in her arm. There was no concomitant medication. Later on 23-JUN-2008 the patient began to experience itching which developed into hives that night. No lab or diagnostic studies were performed. The patient took oral diphenhydramine hydrochloride (BENADRYL). The patient called the office on 25-JUN-2008 to report this reaction. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320175-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Apr-2008	22-Apr-2008	0	17-Jul-2008	16-Sep-2008	CA	WAES0806USA08982	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Panic attack, Syncope

Symptom Text: Information has been received from a consumer concerning her approximately 19 year old daughter with no known drug allergies and a history of infectious meningitis during infancy and epilepsy (seizure-free for eight years) who on 22-APR-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). There was no concomitant medication. On approximately 22-APR-2008 the patient fainted after administration of her first dose. On approximately 24-APR-2008, "two days later", the patient experienced "panic attack" followed by two weeks of generalized anxiety. On 08-MAY-2008 patient was recovered. The patient sought unspecified medical attention via telephone. No further information is available.

Other Meds: None

Lab Data: None

History: Infectious meningitis, Epilepsy

Prex Illness:

Prex Vax Illns:

Vaers Id: 320176-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Jun-2008	26-Jun-2008	2	17-Jul-2008	16-Sep-2008	NY	WAES0806USA08993	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning an approximately 19 year old female with no known allergies and a history of folliculitis due to Razor who on 24-JUN-2008 was vaccinated with the third dose of GARDASIL vaccine (lot no. 660391/0063X). There was no concomitant medication. On approximately 26-JUN-2008, "approximately two days later," the patient developed raised spots on her forearms and legs. The patient was treated with oral BENADRYL and she was recovering from the symptom. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Folliculitis

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320177-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Dec-2006	Unknown		17-Jul-2008	16-Sep-2008	--	WAES0806USA08995	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0954F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a nurse practitioner (NP) concerning an approximately 19 year old female with no known drug allergies who on 09-DEC-2006 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL vaccine (yeast) (lot no. 653938/0954F). On 03-MAR-2007 the patient was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL vaccine (yeast) (lot no. 655503/0012U). On 06-JUL-2007 the patient was vaccinated intramuscularly with the third 0.5 ml dose of GARDASIL vaccine (yeast) (lot no. 658094/0524U). The patient claimed that she was not sexually active prior to the completion of the GARDASIL vaccine (yeast) series. On an unspecified date the patient tested positive for "low grade squamous intraepithelial lesion for SIN 1". The patient was recovering from the symptoms. The patient was seen by the nurse practitioner to seek unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test - positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320178-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	07-Apr-2008	07-Apr-2008	0	17-Jul-2008	16-Sep-2008	--	WAES0806USA09011	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy, Pharyngolaryngeal pain

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female with no relevant medical history or allergies who on 07-APR-2008 was vaccinated with a first dose of GARDASIL vaccine by intramuscular injection (lot number 659964/1978U) (injection site not reported). There was no concomitant medication. About one hour post vaccination, the patient developed swollen neck glands and a sore throat. Unspecified medical attention was sought. The symptoms lasted for several days and then resolved. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320179-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Jul-2008	16-Sep-2008	FL	WAES0806USA09019	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site rash

Symptom Text: Information has been received from a registered nurse (RN) concerning a female who was vaccinated with a second dose of GARDASIL vaccine (yeast). There was no concomitant medication. A "few" days later, the patient experienced rash and pain in the injection site arm. At the time of report, no outcomes were reported. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320180-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	11-Jun-2008	18-Jun-2008	7	17-Jul-2008	16-Sep-2008	--	WAES0806USA09025	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site induration, Injection site pain, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female with hypertension and no allergies who on 08-APR-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number 659182/1757U) without incidence (injection site and route not reported). On 11-JUN-2008 the patient was vaccinated with a second dose of GARDASIL vaccine (yeast) (lot number 660391/0063X) 0.5 ml intramuscularly in the left arm. Concomitant therapy included vitamins (unspecified), citalopram hydrobromide (CELEXA) and lisinopril (manufacturer unknown). A week later the patient vomited once (but also mentioned that it was hot at her work and the air conditioner was not working). The patient also complained of a hard sore area at the injection site. The reporter mentioned that the area was about the size of a dime and dark purple in color. "It looks like a bruise." There was no fever, rash or redness noted at the site. Unspecified medical attention was sought. At the time of reporting, the patient was recovering from all the symptoms. Additional information has been requested.

Other Meds: lisinopril, vitamins (unspecified)

Lab Data: None

History:

Prex Illness: Hypertension

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320181-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Mar-2008	01-Jun-2008	92	17-Jul-2008	16-Sep-2008	FL	WAES0806USA09141	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Human papilloma virus test positive

Symptom Text: Information has been received regarding a case in litigation. A consumer with hypothyroidism reported that she in September 2007, was vaccinated with a first dose of GARDASIL vaccine (lot number, injection site and route not reported). In December 2007, the patient was vaccinated with a second dose of GARDASIL vaccine (lot number, injection site and route not reported). In March 2008, the patient was vaccinated with a third dose of GARDASIL vaccine 0.5 mL by intramuscular injection (lot number and injection site not reported). Concomitant therapy included NUVARING and levothyroxine. The patient reported she had a normal PAP smear prior to the vaccination. In the beginning of June 2008, the patient had a positive HPV test with squamous dysplasia. The test included HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59 and 68. The patient sought unspecified medical attention. The patient's events persisted. This is case 1 of 2. Additional information has been requested.

Other Meds: NUVARING; levothyroxine sodium

Lab Data: cervical smear 06/08 - squamous dysplasia; cervix HPV DNA assay 06/08 - positive

History:

Prex Illness: Hypothyroidism

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320207-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Jun-2008	18-Jun-2008	0	23-Jul-2008	24-Jul-2008	TX	WAES0807USA03351	24-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Fall, Gaze palsy, Musculoskeletal stiffness

Symptom Text: Information has been received from a physician concerning a 11 year old female with no pertinent medical history, drug reactions or allergies who on 18-JUN-2008 was vaccinated with a first 0.5 ml dose of GARDASIL (Lot #660389/1968U). There was no concomitant medication. On 18-JUN-2008, within a minute of receiving the vaccination, the patient experienced a seizure like episode. While sitting on the examination table the patient became very stiff and her eyes rolled back into her head. The patient then fell backwards, from the sitting position, onto the examination table. The patient recovered within two minutes. The patient was at the office. Upon internal review, the "seizure-like episode" was determined to be an other important medical event. Follow-up information was received via phone call from a nurse on 18-JUL-2008. She reported that no labs were performed. The patient recovered. She had no further information to add. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320209-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Jan-2008	Unknown		23-Jul-2008	24-Jul-2008	CO	WAES0807USA02938	07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Headache

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL IM. Subsequently, the patient experienced headaches and seizure. The patient sought unspecified medical attention. At the time of reporting, the outcome was unknown. Upon internal review seizure was considered to be an other medical event. Additional information has been requested. 7/30/08-records received-70/29/07-menstrual cramps better. 1/25/08-birth control Mircette and second HPV vaccine given. 4/28/08-C/O 4 month history of headaches, wakes up in morning with pounding headache, worsens as the day progresses. 5/6/08-Headaches remain same. 6/2/08-continues with headachs and pain behind eyes.

Other Meds: Unknown 7/30/08-records received-7/14/07-prescribed Yaz for painful cramps. 1/25/08-birth control Mircette and second HPV vaccine given.

Lab Data: Unknown 7/30/08-records received-5/20/08 CT brain normal.

History: Unknown 7/30/08-records received-7/14/07-prescribed Yaz for painful cramps.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320210-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	15-Jun-2008	15-Jul-2008	30	23-Jul-2008	24-Jul-2008	--	WAES0807USA02927	24-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Convulsion, Head injury, Urinary incontinence

Symptom Text: Information has been received from a registered pharmacist a concerning a 19 or 20 year old of age female pharmacy technician who on an unspecified date was vaccinated with a first dose of GARDASIL and on approximately 15-JUN-2008, one month ago, was vaccinated with the second dose of GARDASIL. On 15-JUL-2008, the patient experienced a seizure after administration of second dose of GARDASIL. The technician hit her head and urinated on herself during the seizure. The seizure occurred while she was working. Paramedics treated her. At the time of reporting, she was alert and improving (recovering). The pharmacist did not know if she was hospitalized. The seizure was considered to be disabling by the reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320211-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-May-2008	11-Jun-2008	34	23-Jul-2008	24-Jul-2008	--	WAES0807USA02899	03-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1976U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Convulsion, Dyskinesia, Gaze palsy, Staring, Syncope

Symptom Text: Information has been received from a neurologist concerning a 16 year old female with a history of urinary tract infection, a few weeks before reporting, treated with unnamed medication, who in May 2008, was vaccinated with the first dose of GARDASIL. There was no concomitant medication. In approximately June 2008, two weeks later, the patient had a syncopal episode, rose to her feet and had another syncope. This was immediately followed by a seizure with starting, rolling of her eyes, jerking of all limbs lasting for a moment or two. This was followed by confusion. An electroencephalogram was performed and resulted negative. She is scheduled for a computed tomography of her brain. The physician referred her to the neurologist for medical attention. Upon internal review, seizure was considered to be an other medical important event. Additional information has been requested.

Other Meds: None

Lab Data: Electroencephalography, negative. 7/29/08-CT scan 6/24/08-normal 7/28/08-Per CDC-This is a report of seizure 2 weeks after the first dose of HPV4. CT scan on 24JUN08 was normal.

History: Urinary tract infection

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320212-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	11-Jul-2008	11-Jul-2008	0	23-Jul-2008	24-Jul-2008	FL	WAES0807USA02459	24-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0847X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness

Symptom Text: Information has been received from a physician concerning a 21 year old female with no pertinent medical history and no drug reactions/allergies, who on 11-JAN-2008 was vaccinated with the first dose of GARDASIL and on 11-Jul-2008 was vaccinated with the third dose of GARDASIL (Lot # 659968/0847X). There was no concomitant medication. The patient went into a seizure episode a minute after administration at the physician's office, and became unconscious for about 30 seconds. Patient was extremely nervous about receiving shots. Subsequently, the patient recovered before leaving the office. Upon internal review, seizure episode was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320219-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Jan-2008	24-Apr-2008	86	23-Jul-2008	24-Jul-2008	IN		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Cholecystitis, Fatigue, Infectious mononucleosis, Lymphadenopathy, Nausea, Pancreatitis acute, Pharyngolaryngeal pain, Vomiting

Symptom Text: Pt received 1st GARDASIL 11-7-07, 2nd GARDASIL 1-29-08, DX with Pancreatitis 5-7-08. x\x of pancreatitis 4-24-08. Recovered 5-21-08 DX with cholecystitis on 5-23-08. 5/7/08 also dx with mono. 08/26/2008 MR received for DOS 5/7-8/2008 with D/C DX: Acute Pancreatitis. Nausea with vomiting. Abdominal pain. Mono. Mesenteric lymphadenopathy. Pt presented to ER with 2 wk hx of nausea with vomiting, fatigue and sore throat. Initially dx with H pylori, now with worsening LUQ pain, N&V. Increased lipase and amylase on labs. Tx with IV hydration and abx. Improved and d/c next day.

Other Meds: YAZ; Albuterol inhaler

Lab Data: Labs and Diagnostics: Lipase >2000, Amylase 251-both reduced by d/c. Anion gap 14. Glucose 111. GFR 79. CBC with WBCs 17. CT of abdomen and pelvis (+) for mesentaric lymphadenitis. US of GB (-). EBV IgG>4000. EBV nuclear antigen >1000. T

History: NKA. PMH: none. NKDA

Prex Illness: None

Prex Vax Illns:

Vaers Id: 320257-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	03-Nov-2007	27-Nov-2007	24	23-Jul-2008	25-Jul-2008	PA		07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UKNOWN	0	Right arm	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Erythema, Fatigue, Fluid retention, Insomnia, Joint swelling, Musculoskeletal stiffness, Polyarthritis, Weight increased

Symptom Text: Approximately 3 weeks after receiving vaccine, began to rapidly retain fluid and have swollen joints. Very tired. Before seeking medical attention gained approximately 15-20 lbs of fluid. Went for blood work to administering facility, several batches of tests. Was referred to rhematologist, began prednisone. Again, many batches of tests, no conclusive diagnosis. Advised vaccine company of reaction, was told not fault of vaccine. Still undiagnosed, going to clinic August 22. Taking Plaquenil now, and very high doses of motrin with little to no effect. Do not have RA antibodies or other factors, only high inflam. levels. 8/4/08-records received-presented on 2/4/08-C/O pain and swelling in joints which began 2 weeks after Gardasil injection on 12/4/07-noted minimal myalgias and arthralgias and in January 2008 significant pain right wrist, hands, elbows, shoulders, ankles and knees. Morning stiffness and 24 pound weight gain with puffiness around ankle. C/O fatigue, poor sleep secondary to pain. PE: erythema over PIP and MCP, joint swelling. Impression:acute onset inflammatory polyarthritis involving small joints of hands, wrists, feet and ankles. Arthralgia in knees, elbows and shoulders. 2/13/08-Stiffness improved, 8 pound weight loss. 4/7/08-Stiffness much less intense, minimal swelling, tapering steroids. Assessment self limited arthritis resolving slowly. Viral illness versus poststrep inflammatory polyarthritis versus a more chronic process such as rheumatoid arthritis or other autoimmune diseases.

Other Meds: zyrtec, nuva ring, topical duac and tazorac at time of vaccine

Lab Data: Every blood test possible related to rhematology, xrays, etc. 8/4/08-records received-Labs elevated AST at 40, ALT elevated at 51, rheumatoid factor negative. H and H 12.9 and 37.2. ANA negative.

History: allergic to sulfa 8/4/08-records received-PMH:anemia, eczema, acne. Right knee surgery with patellar replacement. Birth control pills. Allergic to sulfa.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **320266-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	21-Jul-2008	22-Jul-2008	1	23-Jul-2008	01-Aug-2008	WA		01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB222AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1968U	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1513U	1	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site pain

Symptom Text: Localized redness, induration, and mild pain at site of injection 24-48h post injection. No fever, chills, adenopathy or signs/symptoms of anyphylaxis. Induration measured 10cm. Symptoms controlled with OTC antihistamines and analgesics.

Other Meds: None

Lab Data: None indicated

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **320267-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Jul-2008	23-Jul-2008	0	23-Jul-2008	01-Aug-2008	FL		01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	MSD1061U		Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2620AA		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Cold sweat, Heart rate decreased, Hyperhidrosis, Syncope

Symptom Text: Pt receive HPV vaccine fainted, skin sweaty and clammy, BP dropped, and also pulse. B/P checked along with pulse.

Other Meds: N/A

Lab Data:

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320275-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jul-2008	02-Jul-2008	0	23-Jul-2008	31-Jul-2008	HI		01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2561AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea

Symptom Text: complained of feeling nauseous few minutes after immunization given. Rested for about 10 minutes and drank some water than felt better and left clinic with family.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320276-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-Jul-2008	21-Jul-2008	0	23-Jul-2008	31-Jul-2008	FL		01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB235BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2774AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Fainted after GARDASIL injection. No seizure activities seen.

Other Meds: None

Lab Data:

History: None

Prex Illness: fainted

Prex Vax Illns:

Vaers Id: **320278-1** **Related reports:** 320278-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Jul-2008	16-Jul-2008	0	23-Jul-2008	01-Aug-2008	WY		01-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB222AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1758U	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B015AA		Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1807U	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Respiratory rate increased

Symptom Text: Patient was diagnosed with rapid breathing during immunizations. Patient received TDAP, HPV, HEP A, and Varicella. Directly after immunization patient listed to right wedged between arm of chair and back of chair. Lost consciousness. I placed her in an upright seated position, talked to her until she became responsive and alert.

Other Meds: None listed

Lab Data: None

History: None listed

Prex Illness: None listed

Prex Vax Illns:

Vaers Id: **320278-2** **Related reports:** 320278-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Jul-2008	16-Jul-2008	0	29-Jul-2008	08-Aug-2008	WY		08-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1807U	1	Left arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB222AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1758U	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B015AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Immediate post-injection reaction, Loss of consciousness, Respiratory rate increased

Symptom Text: Patient was anxious with rapid breathing during immunizatios. Directly after immunizations patient listed to the right wedged between arm of chair and back of chair and lost conscousness. I placed her in an upright seated position and talked to her until she became responsive and alert. Patients father and sister were present during complete process.

Other Meds: none listed/revealed

Lab Data: none

History: none listed/revealed

Prex Illness: none listed/revealed

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320279-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Jul-2008	Unknown		23-Jul-2008	01-Aug-2008	MN		01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2384BA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1758U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: Patient was given on extra dose of meningococcal vaccine - No adverse effect reported at this time.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320280-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-Jul-2008	21-Jul-2008	0	23-Jul-2008	01-Aug-2008	PA		01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Migraine, Nausea, Vertigo, Vomiting

Symptom Text: Severe migranous headache with vertigo, nausea and vomiting 3 hours after GARDASIL injection. Improved with rest in dark room and Ibuprofen; She does admit to similar headache in past on 2 occasion in last 2 years. This was more severe

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320282-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Jul-2008	17-Jul-2008	10	23-Jul-2008	01-Aug-2008	PA		01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Grand mal convulsion

Symptom Text: Patient had a known seizure disorder in past. Had been seizure-free for over a year and was discharged from her neurologist. She received her first HPV on 7-7-08. She had a seizure on 7-17-08. It was her typical tonic-clonic seizure.

Other Meds:

Lab Data: None done at time of event. Will have EEG 7-28-08 and see neurologist.

History: Seizure disorder; asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320283-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Jan-2008	09-Jan-2008	1	23-Jul-2008	01-Aug-2008	NY		01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2771AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0927U	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0495U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Oedema peripheral

Symptom Text: Patient complained of swelling of left arm and numbness after receiving immunization

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320299-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	03-Apr-2008	Unknown		23-Jul-2008	01-Aug-2008	IA		01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Diarrhoea, Dizziness, Headache, Nausea

Symptom Text: Dizziness, weak, nausea, diarrhea, headache.

Other Meds:

Lab Data: N/A

History: N/A

Prex Illness: Nothing at this time

Prex Vax Illns:

Vaers Id: **320307-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Jun-2008	26-Jun-2008	2	24-Jul-2008	21-Aug-2008	PA		21-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2632AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cellulitis, Injection site erythema, Injection site pain, Injection site warmth, Pain in extremity

Symptom Text: Patient arrived 6-26 for PPD reading. C/O left arm pain and redness from MENACTRA given 2 days prior. Seen by doctor who noted +4 cm irregular shaped erythematous, tender, warm area at injection site over left deltoid. No streaking. Diagnosis cellulitis and not a local reaction. Treated with OMNICEF 300 mg BID till gone #20. Return 2 days if no better.

Other Meds: PPD

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320310-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Jul-2008	15-Jul-2008	1	23-Jul-2008	01-Aug-2008	KS		01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB519AA	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0928U	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Hypoaesthesia, Injected limb mobility decreased, Oedema peripheral, Skin warm

Symptom Text: little bump on (L) deltoid 3x3 mm Red area 7x6mm. This area is 9 mm above the main area of redness and warmth. An area of slight swelling, warm and redness is 70 x 58 mm. States arm is numb, hurts to move the arm pain with both lateral and verticle movement. Tx ice pack

Other Meds: PPD

Lab Data:

History: Hay fever, pork, rate, and birth defects, with medical conditions

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320314-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Jul-2008	17-Jul-2008	1	23-Jul-2008	01-Aug-2008	MA		01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	AC52B020AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Injection site swelling

Symptom Text: 1 day after Tdap T increased 100.3 pos local 3 cm swelling at the (L) site Tdap (R-HPV)

Other Meds: None

Lab Data: None

History: ADHD

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320319-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Aug-2007	27-Nov-2007	98	23-Jul-2008	01-Aug-2008	NJ		08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0263U		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Acute tonsillitis, Adenoidectomy, Anxiety, Constipation, Diarrhoea, Dizziness, Dysmenorrhoea, Ear pain, Fatigue, Headache, Hearing impaired, Infectious mononucleosis, Injection site pain, Irritable bowel syndrome, Lymphadenopathy, Malaise, Menorrhagia, Menstruation irregular, Oral contraception, Pharyngolaryngeal pain, Road traffic accident, Streptococcal infection, Stress, Tonsillectomy, Vomiting, Weight decreased

Symptom Text: GARADASIL injections- 8/21/07, 10/18/07 and 2-21-08. (1) soreness of arm around injection site; (2) abdominal pain (moderate) into the following day after injections each time. (Enough to stay in bed the next day after each injection). (3) Ha's -not constant but several times a month since September 2007. (4) Dizziness-off and on since September 2007 (5) Severe infections -strep throat 11/07, 12/07, 1/08, 5/08. Constant sore throats, ear pain, ear infections, hearing issues. (6) mono 1/08 (7) chronic fatigue since September 2007, gradually has gotten worse. (8) severe abdominal pain since 2/28/08-7 days after 3rd vaccine injection. Comes and goes-lasts 8 hrs or so -has to lay still in bed when gets pain. (9) vomiting/diarrhea/constipation off and on since 2/28/08. (10) constant "does not feel good" since 9/07-gradually has gotten worse. (11) increased in bleeding with periods 11/07, 12/07, 1/08, 2/08 bad cramping-spot bleeding between periods, was on BC Pills same one from around spring 2006 until 2/08 when gyn. changed them. Periods not as bad now. 9/2/08-records received-11/27/07-C/O sore throat. 1/5/08-fever 101, throat raw dry and tight, glands are swollen, vomiting mucus, slight cough. Acute tonsillitis. 1/11/08-fever, throat better, rules out URI. 1/29/08-Passed out . 3/18/08 status post mono, spleen enlarged, severe stomach pains, swollen lymph nodes. Status post MVA. 5/13/08-stressed out about school, anxiety. 6/3/08-IBS, pain with decreased appetite. Vague abdominal pain. Impression: Anxiety, recommend counseling. 6/10/08-C/O throat pain, ear ache. No abdominal pain. 9/10/08-records received for office visit 5/12/08-C/O abdominal pain and recent onset of constipation. 1/08 C/O intermittent abdominal pain in different areas of abdomen including epigastric area. Since the MVA C/O upper back and shoulder pain and headaches. Weight loss. C/O early satiety. 1/11/08 mono spot positive. Yasmin birth control pills. Victim of bullying at school. visit 7/17/08-Continues with same complaints. 6/23/08 required to

Other Meds:

Lab Data: 9/3/08-records received-1/28/08-CT abdomen mild splenomegaly. 1/17/08-alk phos 345, ALT/ 74, AST 62, Hgb 939. 6/23/08-tonsillectomy hyperplasia and chronic inflammation of tonsils. 1/3/08-CT abdomen status post MVA unremarkable. 9/10/08-rec

History: (1) s/p spontaneous Pneumothorax x 2 2/06 and 3/06. s/p arthroscopic surgery (L) lung (to remove fibrosis taper of (L) lung. (2) s/p MVA 12/26/07 Allergic to PCN. Prior to 9/07 was healthy, active teenager. School, sports, work, etc. As of 9/07 always tired, Missed 50 (+) (-) days of senior year in school-quit sports, clubs, and missed work. Missed senior prom and graduation ceremo

Prex Illness:

Prex Vax Illns:

Vaers Id: **320327-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Apr-2008	16-Apr-2008	0	23-Jul-2008	05-Aug-2008	HI		05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	10616	0	Left arm	Intramuscular	VARCEL
	MNQ	SANOFI PASTEUR	U2405AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Pain

Symptom Text: Pain, numbness to arm after GARDASIL shot. Numbness spread to arm and lasted about 2 wks.

Other Meds:

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320331-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Jul-2008	18-Jul-2008	1	24-Jul-2008	28-Jul-2008	VA		13-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2619AA	0	Left arm	Unknown	
HPV4	MERCK & CO. INC.	0072X	0	Right arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024EA		Left arm	Unknown	
VARCEL	MERCK & CO. INC.	0445X	1	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Body temperature increased, Cellulitis, Induration, Pain, Pain in extremity, Skin warm, Swelling

Symptom Text: 24 hours after HPV inject - pain/swell; 48 hours after HPV inject - 102/ increased swell; 72 hours after HPV inject; admitted for suspected cellulitis; 96 hours after HPV inject - discharged PO Cephalexin. 8/12/08-records received for DOS 7/20-7/21/08-DX: cellulitis vs allergic hypersensitivity. Developed palpable lump in upper arm with fever, pain and warmth and induration. Treated with antibiotics.

Other Meds:

Lab Data: CBC; blood cult -> neg 8/12/08-records received-Blood culture no growth.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320343-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Apr-2007	15-Aug-2007	134	24-Jul-2008	25-Jul-2008	CA	WAES0805USA05983	25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0961F	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Drug exposure during pregnancy, Eclampsia, Inappropriate schedule of drug administration, Live birth

Symptom Text: Initial and follow up information has been received from a medical assistant and a physician through the Merck Pregnancy Registry for GARDASIL concerning a 16 year old female with no previous pregnancies and no significant past medical history who on 31-Jan-2007, 03-Apr-2007 and 25-Oct-2007 was vaccinated intramuscularly with first, second and third 0.5ml doses, respectively, of GARDASIL (lot #s: 653937/0637U, 654389/0961F, 658560/1062U) while pregnant. The patient's last menstrual period (LMP) was 15-AUG-2007 with an estimated delivery date of 15-MAY-2008. The patient took prenatal vitamins (unspecified) one daily from October 2007 to May 2008. On 10-JAN-2008 and 14-MAY-2008 the patient underwent routine ultrasound which were normal per patient. On 15-MAY-2008 at 40-41 weeks from the LMP, the patient delivered a normal liveborn male, weighing 7lbs, 4 ozs., length: 21 in; head circumference: 14 in. On approximately 15-MAY-2008, after delivery the patient experienced "eclampsia-seizure xl". Upon internal review, the patient's "eclampsia-seizure" was considered to be an other important medical event. Additional information is not expected.

Other Meds:

Lab Data: ultrasound, 01/10/08, Normal per patient; ultrasound, 05/14/08, Normal per patient

History:

Prex Illness: Pregnancy NOS (LMP = 8/15/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320345-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Feb-2008	14-Jul-2008	164	24-Jul-2008	25-Jul-2008	--	WAES0807USA02843	25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from the mother of a 17 year old female with no known drug allergies and no pertinent medical history, who in February 2008 was vaccinated with the second dose of GARDASIL (lot # not provided), 0.5 mL intramuscularly. There was no concomitant therapy. The mother reported that on 14-JUL-2008, her daughter fainted and convulsed after receiving GARDASIL. The patient sought unspecified medical attention. No lab diagnostics studies were performed. The patient recovered on 14-JUL-2008. Upon internal review, convulsions was considered to be an other important medical event. No further information is available as the mother declined to give her physician's information.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 320346-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	21-Apr-2008	05-May-2008	14	24-Jul-2008	25-Jul-2008	NY	WAES0807USA02910	25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U		Unknown	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Back pain, Foreign body trauma, Headache, Vertigo, Vomiting

Symptom Text: Information has been received from a physician concerning a 19 year old female with vertigo, headache and on 20-APR-2008, the patient swallowed ring in tongue who on 21-APR-2008, was vaccinated with GARDASIL (LOT # 659964/1978U), 0.5ml, IM. Concomitant therapy included ORTHO TRI-CYCLEN LO) and Tdap. On 05-MAY-2008, the patient experienced vomiting, abdominal pain and back pain. The mother of the patient called office for medical attention. Emergency room did blood work and Computerized Axial Tomography scans (CAT), results not reported. On an unspecified date, the patient experienced a possible urine infection. On 22-MAY-2008, the patient recovered from vomiting, abdominal pain and back pain. The outcome of the possible urine infection was not reported. The physician felt that the vomiting, abdominal pain, back pain, and urine infection were disabling and other important medical events. The physician felt that the possible urine infection was serious (other important medical event) because the patient needed unspecified antibiotics for the possible urine infection. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: Unknown

History: General symptom

Prex Illness: Vertigo; Headache

Prex Vax Illns:

Vaers Id: **320347-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		24-Jul-2008	25-Jul-2008	WA	WAES0807USA03390	25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a certified medical assistant concerning a 16 year old female with morphine allergy and no relevant medical history who was vaccinated with GARDASIL during the first trimester of her pregnancy. The vaccine was provided at another location. Dose, route of administration and lot number were not provided. There was no concomitant medication. Ultrasounds, fetal echo, pulmonary function tests were performed and no results were provided. Prenatal testing revealed that the fetus had multiple skeletal abnormalities (dysplasias) and was not expected to survive after delivery. The patient contacted the physician to seek unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound; pulmonary function test; echocardiogram

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **320348-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	05-Jun-2008	05-Jun-2008	0	24-Jul-2008	25-Jul-2008	NJ	WAES0807USA03810	25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Fall, Headache, Impaired work ability, Neck pain, Syncope

Symptom Text: Information has been received regarding a case in litigation from a nurse concerning a 22 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL (lot number, injection site and route not reported). On 05-JUN-2008 the patient was vaccinated with a second dose of GARDASIL (lot number 659182/1757U) by intramuscular injection (injection site not reported). A minute or two later, the patient fainted and fell off the table. Ice was applied to her head, blood pressure was taken and she was sent to the Emergency Room. She had a computed tomography of her neck which was negative. She was given an unnamed medication for pain in head and neck. The patient took three days off from work. The patient taking three days off from work was considered disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: computed axial, 06/05/08, neck, negative; blood pressure, 06/05/08

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320349-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Apr-2008	Unknown		24-Jul-2008	25-Jul-2008	TX	WAES0807USA03903	25-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Fall, Hypoaesthesia, Loss of consciousness, Muscle fatigue, Paraesthesia, Syncope

Symptom Text: Information has been received from a registered nurse (R.N.) concerning her 15 year old daughter with no pertinent medical history, drug reactions or allergies who "three months ago", on approximately 18-APR-2008 was vaccinated with a dose of GARDASIL. There was no concomitant medication. "Approximately two months ago", in approximately May 2008, the patient began to experience numbness and tingling in her hands. On 16-JUL-2008 the patient experienced two episodes of syncope during which she lost consciousness and hit the floor. On 17-JUL-2008 the patient noted that all of her muscles felt tired. Allergy tests were performed (results not provided). At the time of the report, the patient's event persisted. The patient did not seek medical attention. The reporter considered numbness and tingling in hands, syncope and muscles tired to be immediately life-threatening. Additional information has been requested.

Other Meds: None

Lab Data: allergy test, results pending

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **320354-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Apr-2008	Unknown		24-Jul-2008	21-Aug-2008	NY		21-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menorrhagia

Symptom Text: Hypermenorrhea (menstrual periods every 2 weeks) after her first dose of GARDASIL 04/01/08.

Other Meds:

Lab Data: Awaiting evaluation by the gynecologist.

History: Recurrent UTIs

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320355-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Jul-2008	23-Jul-2008	0	24-Jul-2008	21-Aug-2008	FL		17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Breath sounds abnormal, Gaze palsy, Glasgow coma scale, Grand mal convulsion, Somnolence, Tremor

Symptom Text: Approximately 12-14 hours status post HPV administration patient had grand mal seizure requiring EMS transport and ER evaluation for 6-8 hours. 7/30/08 ER rec received for DOS 7/24/08 with DX: Seizures. Pt presented via EMS following an episode of seizure-like activity consisting of arms shaking and eyes rolling back in the head on the day of 2nd HPV4 vax. Drowsy on exam, coarse respirations noted in upper lobes, otherwise WNL. GCS 15.

Other Meds: None

Lab Data: CT head/Chest. Labs and Diagnostics: drug screen (-). CT brain WNL. CXR (-) for acute disease. Possible scoliosis.

History: mild learning disorder. PMH: migraines. NKDA

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320359-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	23-Jul-2008	23-Jul-2008	0	24-Jul-2008	21-Aug-2008	MO		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fear of needles, Vomiting

Symptom Text: Pt had friend come with her as pt stated she was "really afraid" of shots. Had topical anthesia applied to upper arms - secured by transparent covering. Cleaned site with alcohol, gave shot. Pt slumped on self and friend. Pt stated she was not nauseated and then vomited. Applied cold compress to neck and forehead. Led to chairs in hall where pt drank water and held compresses. Stated she felt better and was advised to sit in lobby 10 min.

Other Meds: birth control pills

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **320373-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	08-Jul-2008	Unknown		24-Jul-2008	21-Aug-2008	PA		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1495U	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2573AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0279X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Inappropriate schedule of drug administration, Oedema peripheral, Skin warm

Symptom Text: Right upper arm red & swollen & warm to touch. TYLENOL & PRELONE

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320388-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-May-2008	07-May-2008	0	24-Jul-2008	21-Aug-2008	WI		21-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1797U	1	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site cellulitis, Injection site erythema, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: Received HPV IM in left deltoid on 5-7-08. Developed redness, swelling, hot to touch & pain at site and surrounding area. Within a week of administration sought medical treatment for cellulitis at injection site. Treated with antibiotic. Condition resolved. Urgent care treatment was 5/09/08.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320396-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Mar-2008	15-Apr-2008	39	24-Jul-2008	01-Aug-2008	PA		20-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB171AA	1	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1657U	1	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0802U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Epilepsy, Eye rolling, Grand mal convulsion, Somnolence

Symptom Text: 4/15/08 Seizure occured at bedtime. Taken to E.D., CT scan done. 5/15/08 Seizure occured at bedtime. Taken to another Hosp. EEG showed mildly abnormal brain activity. Possibly hormonal trigger. Prescribed seizure medication, Kepra. Continues to be followed medically. 8/15/08-records received-4/21/08-The EEG was performed after one episode of generalized tonic-clonic seizure on 4/8/08. Presented to ED on 5/17/08-after seizure at home, eyes rolled back, sleepy afterward. Similar episode last month during her period. 5/22/08-neurology consult exam essentially normal. Impression: generalized epilepsy.

Other Meds:

Lab Data: CT scan. EEG, and others 8/15/08-records received-CT scan showed mild asymmetry of ventricles, left frontal lobe single punctate lesion in white-gray matter junction in front area. EEG abnormal tracing due to generalized epileptiform disch

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320400-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Jul-2008	03-Jul-2008	0	24-Jul-2008	01-Aug-2008	MD		01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	AHAVB265AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1804U	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness, Syncope

Symptom Text: Approximately 5 minutes after HPV, VZV, Hep A administered patient had syncopal episode, fell back, brief loss of consciousness, recovered fully

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320409-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	24-Jul-2008	24-Jul-2008	0	24-Jul-2008	01-Aug-2008	SC		01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dysphagia, Eye swelling, Eyelid ptosis, Hypoaesthesia

Symptom Text: I recieved the first shot of the Gardasil series today, within 3 hours I felt very dizzy/lightheaded, it became hard to swallow, the arm that the shot was administered (left arm) became numb with a burning sensation, and my left eye felt swollen and droopy/puffy. I took benadryl, fell alseep for 2 hours, woke up and felt somewhat better. My arm still feels a little wierd though.

Other Meds: Microgestin, Multivitamin

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320438-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Aug-2007	30-Jun-2008	327	25-Jul-2008	28-Jul-2008	FR	WAES0807USA02088	28-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1475F	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Hypoaesthesia, Paralysis

Symptom Text: Information has been received from a gynecologist and nurse concerning the nurse's 17 year old, vegan (since 1 year), daughter with neurodermatitis and allergies who on 08-AUG-2007 was vaccinated with her first dose of GARDASIL (lot# 1475F, batch #NF37120), into the upper arm. The second dose of GARDASIL, (lot # 1536F, batch # NG01520), was given on 04-OCT-2007, into the upper arm. The first and second doses of GARDASIL were well tolerated and no adverse effect occurred for both vaccinations. Concomitant therapy included hormonal contraceptives (unspecified). The third dose of GARDASIL, (lot # 0513U, batch#NG16040), route not reported was given on 31-JAN-2008, into the upper arm. Subsequently, the patient complained about numbness feeling in one foot. Neurological examination was without pathological findings. The mother discussed a possible circulation disorder because of intake of hormonal contraceptives and veganism. Follow-up information was reported by the gynaecologist that 5 months post vaccination (approximately 30-JUN-2008), the patient developed paralysis of the left foot with loss of strength of elevator toes. Electroneurography (ENG) showed changes (not specified). cat (CT) scan was planned. Symptoms were ongoing at the time of reporting. The reporter considered paralysis and asthenia to be other important medical events. This is a consolidation of two reports concerning the same patient. Other business partner numbers included: E008-05546. No further information is available.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: electroneurography, changes (not specified)

History:

Prex Illness: Vegan; Neurodermatitis; Hypersensitivity

Prex Vax Illns:

Vaers Id: **320439-1 (S)** **Related reports:** 320439-2; 320439-3; 320439-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Jun-2008	30-Jun-2008	14	25-Jul-2008	28-Jul-2008	PA	WAES0807USA03571	22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Unknown	Intramuscular	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Brain oedema, Dysarthria, Encephalitis, Headache, Lethargy

Symptom Text: Information has been received from a registered nurse concerning a 13 year old female patient who on 16-JUN-2008 was vaccinated with the first dose of GARDASIL (Lot # 660387/1967U) IM. There was no concomitant medication. On 30-JUN-2008 the patient experienced headache, lethargy, slurred speech and brain swelling. The patient was diagnosed with acute cerebellitis (cerebellar encephalitis). The patient took an overseas trip when these symptoms occurred and was hospitalized. The patient will be on IV Acyclovir for 3 weeks and has been on Dexamethasone but is being weaned off. The patient was on acetazolamide and that was subsequently discontinued. The patient will be on ceftriaxone for 2 weeks and doxycycline for 28 days. The patient was considered to be recovering. The plan by the hospital was to discharge the patient on 17-JUN-2008 and have her on a flight back home by 19-JUL-2008 and to be directly admitted to a pediatric hospital. Lab Diagnostics studies performed were 3 MRIs to monitor brain swelling, serology for Lyme's disease IGG, mycoplasma IGM, mumps IGG and IGM, rubella IGG and IGM, varicella IGG and IGM, parvovirus IGG and IGM, HSV IGG and IGM, however not results were reported. Acute cerebellitis was considered to be immediately life-threatening. The patient sought medical attention, called the physician's office. Follow-up information was received which reported that on 19-JUL-2008, the patient was admitted to the hospital. The patient was subsequently discharged from the hospital on 22-JUL-2008. It was reported that the patient was sent home with a PICC line for antibiotics for the next several weeks. The registered nurse stated that the patient was stable. The registered nurse reported that the physician felt that the patient's Encephalitis was related to GARDASIL (Lot # 660387/1967U) vaccination. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **320439-2 (S)** **Related reports:** 320439-1; 320439-3; 320439-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Jun-2008	12-Jun-2008	0	30-Jul-2008	31-Jul-2008	PA	WAES0807USA04340	22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Ataxia, Decreased appetite, Depressed level of consciousness, Dysarthria, Encephalitis, Fatigue, Gait disturbance, Headache

Symptom Text: Information has been received from a registered nurse concerning a 13 year old female with herpes who on 12-JUN-2008 was vaccinated with a first 0.5 ml dose of GARDASIL by intramuscular injection (lot number and injection site not reported). Concomitant therapy included ceftriaxone sodium, acyclovir and doxycycline. Subsequently the patient experienced headache and fatigue. The patient left and on 30-JUN-2008, her condition dramatically worsened. The patient was stumbling around and slurring her words. She was admitted to the hospital on 30-JUN-2008 and diagnosed with cerebritis. She remained an inpatient until 18-JUL-2008 and returned. On 19-JUL-2008, th patient was admitted to the hospital. She remained in hospital and then was discharge with a percutaneously inserted central venous catheters (PICC) line. The patient was tested for lime disease (result not specified). The diagnosis was acute disseminated encephalitis. According to the reporter, headache, fatigue, stumbling around, slurring her words, cerebritis and acute disseminated encephalitis were considered to be immediately life-threatening and caused hospitalization. Additional information has been requested. 08/29/2008 MR received for DOS 7/19-21/2008 with DX: Acute cerebellitis. Pt presented to foreign hospital 7/5/08 with onset of slurred speech and ataxia following several day hx of H/A, decreased appetitite, decreased interaction and exhaustion beginning 6/30/08. Pt admitted to for 2 weeks prior to transfer. When well enough to travel, returned home for remainder of tx. ID consult with impression: Acute cerebellitis ? viral, ?post-vaccine, ?2' to infection. Pt tx with abx, antivirals and steroids. PICC line placed for tx. By d/c walking unaided, with normal speech.

Other Meds: Acyclovir; Ceftriaxone sodium; Doxycycline

Lab Data: diagnostic laboratory, lime disease tests. Labs and Diagnostics: MRI brain abnormal, repeat 7/20/0 WNL. Mycoplasma IgM (+) initially, now 437. CBC with WBCs 16.01. Blood cx (-). Q-fever, EBV, Lyme all (-).

History: PMH: none

Prex Illness: Herpes virus infection

Prex Vax Illns:

Vaers Id: **320439-3 (S)** **Related reports:** 320439-1; 320439-2; 320439-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	20-Jun-2008	25-Jun-2008	5	07-Aug-2008	08-Aug-2008	--	WAES0807USA05583	22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Ataxia, Blood cyanide, Blood lead, Demyelination, Dysarthria, Headache, Malaise, Mental impairment, Skin lesion, Somnolence, Speech disorder, Vasculitis

Symptom Text: Information has been received from a physician concerning a 13 year old female who on 20-JUN-2008 was vaccinated with GARDASIL. Approximately two weeks after vaccination with GARDASIL, the patient travelled to another country. Approximately two weeks prior to travelling to another country, the patient had attended a picnic in a wooded area and one of the other people at the picnic had developed a skin lesion and was commenced on antibiotic treatment for Lyme disease. Subsequently, on 25-JUN-2008 the patient experienced headache, ataxia, dysarthria, malaise, mental impairment and somnolence and on 05-JUL-2008 she was hospitalised. The report description was as follows: "Five days of intermittent headache, 5 days of malaise, 2 days of dysarthria and ataxia, drowsiness, slow mentation. Never febrile, no rash, purely cerebellar signs, no bulbar signs, speech is dysarthric and very slow with poverty of words. There is no dysphasia". The patient had no significant medical history. Laboratory tests results were as follows (dates of tests and units not specified): C-Reactive protein - <3; white blood cells and differential were normal; creatinine and liver function tests were all normal; haemoglobin - 128; platelets - 223. On 05-JUL-2008 a magnetic resonance imaging scan showed features corresponding most closely with cerebellitis (cerebellar encephalitis). No associated cerebral encephalitis. Mass effect protruding inferior cerebellar tonsillar ectopia. No hydrocephalus. On 07-JUL-2008 an MRI showed acute cerebellitis. The differential diagnosis is quite wide and includes lead and cyanide toxicity, demyelination, vasculitis, childhood viral illnesses and a manifestion of acute disseminated encephalomyelitis. The patient was discussed with a paediatric neurologist. Treatment was as follows: "She was commenced on acyclovir, dexamethasone 4mg every six hours since 05-JUL-2008 and added on 07-JUL-2008 were ceftriaxone 2g twice daily (for Lyme disease) and ampicillin 2g every four hours (for Listeria, seems

Other Meds: Unknown

Lab Data: magnetic resonance, 07/05/08, features correspond most closely with cerebellitis; magnetic resonance, 07/07/08, acute cerebellitis; WBC count, ?/?/08, white blood cells and differential normal; hemoglobin, ?/?/08, 128; hepatic function test

History:

Prex Illness: Lyme disease

Prex Vax Illns:

Vaers Id: **320439-4 (S)** **Related reports:** 320439-1; 320439-2; 320439-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	20-Jun-2008	05-Jul-2008	15	21-Sep-2008	24-Sep-2008	PA		24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cerebellar ataxia, Fatigue, Foreign travel, Headache, Malaise

Symptom Text: Report from a Foreign Regulatory agency, pt vaccinated in home country,who became ill while on holiday. Suspect Gardasil, administered on 20Jun 2008. symptoms began in another country early JULY, admitted to hospital 5 July 2008. Cerebellar ataxia, frontal headache, fatigue, malaise. NO signs of infection , no rash/diarrhoea, no visual disturbance, no urinary incontinence, no other symptoms. Hospital doctor and health dept doctor were in touch with CDC and FDA and patient's personal paediatrician, all in early July 2008.

Other Meds:

Lab Data: Lyme disease serology NEG (tested x2 in another country, x1 at home) Positive serology for Q fever, mycoplasma and rickettsiae, but NO RISING TITRES, therefore considered false positives.

History: No allergies

Prex Illness:

Prex Vax Illns:

Vaers Id: **320441-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	16-May-2008	14-Jun-2008	29	25-Jul-2008	28-Jul-2008	FR	WAES0807USA03933	28-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mononucleosis syndrome

Symptom Text: Information has been received from a health authority agency concerning a 20 year old female who on 16-MAR-2008 was vaccinated with the first dose of GARDASIL IM. No adverse event. On 16-MAY-2008, the patient was vaccinated with the second dose of GARDASIL IM. (Lot UNK and site of administration UNK). On 14-JUN-2008, the patient experienced mononucleosis syndrome, confirmed by lab test. She is recovering at time of report. Mononucleosis syndrome was reported as an other important medical event. Other business partner number included E2008-06782. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, mononucleosis syndrome confirmed.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320446-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Nov-1991	16-Nov-2007	5845	25-Jul-2008	21-Aug-2008	AZ		21-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2367AA		Right arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB207AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0929U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: GARDASIL 9-12-07, 11-15-07 Patient reports fainting day after receiving GARDASIL. (reported 07/22/2008).

Other Meds:

Lab Data: Seek medical attention if symptoms return

History: Penicillin allergy; knee burn

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320449-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Jul-2008	17-Jul-2008	3	25-Jul-2008	21-Aug-2008	CT		21-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2937BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1757U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Epistaxis, Facial bones fracture, Loss of consciousness, Nasal oedema, Skin laceration

Symptom Text: 7/17/2008 4 AM (approximately) patient went to the bathroom to check and wash her eyes, as she picked up her head, she felt dizzy and started to see black, woke up in hallway. Hit right side of face and nose, cut to nose and mouth and confirmed broken nose (hospital ER visit at 4 PM on 07/17/08). Also swelling, bleeding to nose.

Other Meds:

Lab Data:

History:

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320450-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	07-Jul-2008	07-Jul-2008	0	25-Jul-2008	21-Aug-2008	NC		21-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0513X	1	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2937AA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2619AA	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB235BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Dizziness, Headache, Hypotension, Nausea

Symptom Text: Administered vaccines (Hep A, MENACTRA, GARDASIL, varicella, TDap) to patient. Approximately 10-15 minutes later, patient stood up to leave and began feeling faint, hypotensive, abdominal pain, headache, dizziness, nauseous. Bolused with 1 liter of LR symptoms resolved completely within 5 hours.

Other Meds:

Lab Data:

History: Allergy to penicillin

Prex Illness: Child had complaint of cough, fever

Prex Vax Illns:

Vaers Id: 320451-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Nov-2007	03-Nov-2007	-18	25-Jul-2008	21-Aug-2008	WI		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Anorexia, Weight decreased

Symptom Text: Mother reports abdominal pain, loss of appetite and weight loss for 4-5 months following vaccine. Labs unremarkable. Patient recovered without sequelae. Mother requested form sent.

Other Meds: albuterol

Lab Data: labs unremarkable

History: Exercise-induced asthma

Prex Illness: sinusitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320453-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Jul-2008	14-Jul-2008	0	25-Jul-2008	21-Aug-2008	PA		07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2351AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Pyrexia, Urticaria

Symptom Text: Shot given at 10 AM. 10 hours later developed fever, chills, & urticarial type rash 2-3 cm proximal to injection site.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320457-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Jul-2008	15-Jul-2008	0	25-Jul-2008	21-Aug-2008	KS		22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Dizziness, Dyspnoea, Vaccine positive rechallenge

Symptom Text: Patient came in complaining of chest pain, difficulty breathing and light headedness. Patient evacuated to emergency room. Had similar reactions with first doses but less severe, not reported.

Other Meds: ORTHO TRICYCLINE, LEVEMIR, NOVOLOG

Lab Data:

History: Diabetes type I

Prex Illness:

Prex Vax Illns: OCT 4 2007~HPV (Gardasil)~1~0~In Patient

Vaers Id: **320477-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	11-Jul-2007	Unknown		25-Jul-2008	01-Aug-2008	MI		01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0962F	0	Right arm	Intramuscular	TDAP

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event

Symptom Text: Physician stated in note "pros & cons [of getting HPV vaccine] discussed, due to risky lifestyle she will go ahead & start series." No known adverse events reported.

Other Meds:

Lab Data: No testing performed.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320480-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Jul-2007	30-Oct-2007	92	25-Jul-2008	30-Jul-2008	NC		20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Asthenia, Diarrhoea, Dizziness postural, Headache, Juvenile arthritis, Mental status changes, Musculoskeletal stiffness, Myalgia, Neck pain, Nuchal rigidity, Pain in extremity, Pharyngolaryngeal pain, Photophobia, Pyrexia, Rash, Rash maculo-papular, Vomiting

Symptom Text: 3 MONTHS AFTER PATIENT RECEIVED VACCINE, SHE CAME TO CLINIC C/O FEVER, JOINT PAINS, SORE THROAT AND HEAD ACHE. STARTED ON ANTIBIOTICS. PT. CLINICAL STATUS GOT WORSE, FEVER PERSISTED, NUCAL RIGIDITY AND PHOTOPHOBIA. REFERED TO WAKE MED HOSP TO R/O MENINGITIS. 7/29/08-records received for ED visit 11/2/07-presented with fevers since 10/28/07-initially seen by PCP on 10/30/07 for sore throat and antibiotics but did not start treatment until 11/1/07-on 10/30/07-developed diffuse rash and seen at another ED where antibiotic was changed, patient did not start the treatment-returned to PCP on 11/1/07- with C/O worsening sore throat and diffuse upper abdominal pain, temp 104 and now at ED 102.9. Mild frontal headache and 1 episode of emesis. PE:tonsils mildy erythematous, diffuse maculopapular rash to arms and legs and fine papular rash to bilateral inner thighs and trunk. 8/5/08-records received for DOS 11/2-11/12/07-DC DX: Fever, myalgias, weakness, rash, proteinuria. Presented with one week history of fevers, stiff neck for 3 days and rash for 3 days. Sore throat for 5 days. Abdominal pain and diarrhea, bilateral wrist pain, full body myalgias and vomiting on 10/31 and 11/1/07. Leg pain, dizziness when standing and intermittent servere headaches for past 5 days. Transferred to another facility. 08/18/08-records received for DOS 11/23-11/26/07-DC DX: Stil's Disease/Systemic onset JRA.presented with C/O headache, altered mental status. New onset of neck pain associated with headace. Head bobbing tremor noted. Symptoms could be related to Prednisone.

Other Meds:

Lab Data: RMSF,PARVO 19 AND EBV TITERS NEGATIVE, PROTEINURIA AND HEMATURIA. ANA,Ds DNA,ANCA, ANTI DNA ANTIB AND RA ALL NEGATIVE. 7/29/08-records received-Potassium low 3.3, calcium low 8.4, WBC 11.0. urine occasional casts, mono spot test negative,

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320485-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	24-Jul-2008	24-Jul-2008	0	25-Jul-2008	01-Aug-2008	NC		01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2774AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Urinary incontinence, Vomiting

Symptom Text: Client became nauseated, vomited, felt faint and dizzy and urinated on self.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **320510-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Jul-2008	26-Jul-2008	0	25-Jul-2008	22-Aug-2008	IL		22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Syncope

Symptom Text: Patient fainted. At first felt like she was going to vomit then fainted. Gave Pt water and assisted to chair.

Other Meds:

Lab Data:

History: Penicillin

Prex Illness:

Prex Vax Illns:

Vaers Id: **320513-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	24-Jul-2008	24-Jul-2008	0	25-Jul-2008	22-Aug-2008	NC		22-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0096X	1	Right arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0571X	2	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2633AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Fainted 10-15 minutes after receiving vaccines. Pt tried to get up and fainted again. After 30-45 minutes of observing pt, she was released. Pt's blood pressure, blood sugar and pulse all were normal.

Other Meds: None

Lab Data: blood pressure, blood sugar and pulse all normal

History:

Prex Illness: Pt in for a well child Physical

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320514-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Jul-2008	25-Jul-2008	0	25-Jul-2008	22-Aug-2008	NC		22-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB235BA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B020AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0571X	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2656AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Pallor

Symptom Text: Within minutes of receiving vaccines patient felt very dizzy and turned pale. we observed patient for 20-30 minutes and at that time patient was able to leave and felt better. This is the 1st time pt has had this kind of reaction.

Other Meds: Aleve PRN

Lab Data:

History: no known drug allergies

Prex Illness: well child physical

Prex Vax Illns:

Vaers Id: **320515-1** **Related reports:** 320515-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Jun-2008	07-Jun-2008	1	25-Jul-2008	22-Aug-2008	WA		01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Chest pain, Headache, Hypoaesthesia, Injected limb mobility decreased, Malaise, Pain in extremity, Palpitations, Pruritus, Tenderness, Ventricular extrasystoles, Vomiting

Symptom Text: Injection given 6/4/08 - Onset of symptoms on 6/7/08 - not feeling well, itching. By 6/24/08 numbness in left leg and arm, itching and chest pain. Today 7/25/08, same symptoms of chest pain and numbness in both arms and legs. 9/22/2008 MR received from PCP beginning 6/11/2008 with pt c/o R arm pain, vomiting, H/A and upper arm numbness. Unable to lif arm. PE WNL except pt is anxious. Pain meds given. Several Cardiol consults 7/1,8,&22/2008 with c/o palpitations. Later had episodes of chest pain. Impression: Palpitations-uncertain etiology. Probably benign ventricular ectopy. Seen 7/28/08 with c/o intermittant bilateral arm and leg pain with numbness since 6/08. PE (+) for tenderness. Referred to orthopedics.

Other Meds: None

Lab Data: No. Labs and Diagnostics: ECG Sionus rhythm with PVCs and PACs. Holter monitor (+) PVCs.

History: PMH: migraines. Allergic to pantoprazole and Clonidine.

Prex Illness: None

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 320515-2 **Related reports:** 320515-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Jun-2008	11-Jun-2008	5	24-Oct-2008	23-Jan-2009	WA		23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	2	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Burning sensation, Hypoaesthesia, Pain in extremity

Symptom Text: (R) arm pain/burning numbness, tingling; leg pains since June '07 - Ibuprofen and TYLENOL with codeine. Neuro and Ortho evaluation.

Other Meds: MAXALT; Trimeth-Sulfa; Ibuprofen; Albuterol

Lab Data: CRP, ESR, CBC - normal

History: See attached document

Prex Illness: Acute sinusitis; Reactive airways disease

Prex Vax Illns:

Vaers Id: **320517-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	22-Jul-2008	24-Jul-2008	2	25-Jul-2008	22-Aug-2008	NC		22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2888AA	0	Right arm	Unknown	
	HEPA	MERCK & CO. INC.	AHAVB211AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0279X	0	Right arm	Intramuscular	
	MEN	UNKNOWN MANUFACTURER	U2541AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Induration, Oedema peripheral, Skin warm

Symptom Text: Varivax vaccine given on 7/22/08 in left arm. Since came in on 7/24/08 with 5.5 x 8 cm swollen warm, induration. no vesicles. No assessment revealed. Motrin as recommendation. Benadryl, topical cool compresses, monitor size.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320518-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	23-Jul-2008	24-Jul-2008	1	25-Jul-2008	22-Aug-2008	TX		22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0088X	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2573AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Pruritus

Symptom Text: 7-24-08 noticed swelling in L arm. Redness, itchy today. No swelling elsewhere.

Other Meds: No meds

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320519-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Jul-2008	22-Jul-2008	0	25-Jul-2008	22-Aug-2008	FL		22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Hyperhidrosis, Malaise, Nausea, Pallor, Panic reaction, Visual disturbance

Symptom Text: Less than five mins after admin GARDASIL pt c/o not feeling well (nauseous). Had pt sit then pt started panicking saying she could see stars, everything was getting dark. Pt was pale, diaphoretic and clammy. We had pt lie down and checked bld pressure. Had pt stay for 20 minutes. Pt soon improved.

Other Meds:

Lab Data: blood pressure checked

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **320525-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	31-Mar-2008	Unknown		25-Jul-2008	22-Aug-2008	WI		22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Dose 3 was given too soon. It will be repeated per CDC guidelines.

Other Meds:

Lab Data: None

History: Morphine, bee stings

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320526-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Jun-2008	Unknown		25-Jul-2008	22-Aug-2008	WI		22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Dose 3 was given too early. It will be repeated by CDC guidelines.

Other Meds:

Lab Data: None

History: minocycline/doxycline

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320527-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Jun-2008	Unknown		25-Jul-2008	22-Aug-2008	WI		22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Dose 3 was given too soon. It will be repeated per CDC guidelines.

Other Meds:

Lab Data: None

History: NKA

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320528-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	30-Jan-2008	Unknown		25-Jul-2008	22-Aug-2008	WI		22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Dose 3 was given too early. It will be repeated per CDC guidelines.

Other Meds:

Lab Data: None

History: NKA

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320557-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		28-Jul-2008	29-Jul-2008	IL	200802361	29-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Oedema peripheral, Swelling face

Symptom Text: Initial report received on 22 July 2008 from a health professional. A 14-year-old female patient (Initials not provided), with "unknown" past medical history, had received on an unspecified date, a dose of ADACEL vaccine, MENACTRA vaccine and GARDASIL vaccine (manufacturer MERCK). The lot numbers, routes and sites of administration were not provided for any of the vaccines. At an unspecified amount of time later, after receiving the three vaccines, the patient was described as "blowing up like a balloon" with swelling of the face and legs. The patient was admitted to the hospital (date not specified); however, treatments received and diagnostic tests performed were not provided. At the time of this report, the recovery status of the patient was "unknown."

Other Meds: "Unknown"

Lab Data: "Unknown"

History: "Unknown"

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320559-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		28-Jul-2008	29-Jul-2008	--	WAES0806USA08705	29-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, ER VISIT, SERIOUS

MedDRA PT Death

Symptom Text: Initial and follow up information has been received from a physician, who was told by one of his patients, that the mother of a consumer was told by a neurologist that there were 4,400 kids who have died following vaccination with GARDASIL. No product quality complaint was involved. Attempts are being made to verify the existence of patients. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320560-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		28-Jul-2008	29-Jul-2008	TX	WAES0807USA04414	29-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Skin laceration, Syncope

Symptom Text: Information has been received from a physician concerning a 17 year old female on an unknown date was vaccinated with the second dose of GARDASIL. After getting the second dose, the patient fainted and hit her head (causing a gash on her head). The patient sought medical attention. The patient's outcome was not reported. Patient fainted and hit her head (causing a gash on her head) were considered to be disabling by the reporting physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320561-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jan-2007	27-May-2008	512	28-Jul-2008	29-Jul-2008	NC	WAES0807USA04489	29-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anal haemorrhage, Anogenital warts, Proctalgia

Symptom Text: Information has been received from a physician concerning a 17 year old female with pollen allergy who in approximately 2007 was vaccinated with two doses of GARDASIL. On 10-JUN-2008, the patient was taken to the ER with a complaint of anal pain and bleeding starting about 1-2 weeks before the ER visit. The patient was diagnosed with severe anal warts. On an unspecified date, the patient had a PAP test performed (results not provided). Out patient surgery was done with good results. The patient missed school as a result of the surgery. On an unknown date the patient recovered. The reporting physician considered the severe anal warts to be disabling and an other important medical event. The physician noted the mother of the patient believed that her daughter's anal warts were caused by GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pollen allergy

Prex Vax Illns:

Vaers Id: **320565-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		28-Jul-2008	29-Jul-2008	--	WAES0807USA04330	29-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a licensed practical nurse (L.P.N.) concerning a female who on an unspecified date was vaccinated intramuscularly with a 0.5 ml dose of GARDASIL. After receiving a dose of GARDASIL, the patient fainted and seized. The patient was taken to the emergency room as the result of fainting episode. It was reported that vaccination with GARDASIL was discontinued and then the adverse events improved. The outcome of the events was unspecified by the reporter. The reporter considered syncope and seizure to be other important medical events. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320566-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	21-Mar-2008	21-Mar-2008	0	28-Jul-2008	29-Jul-2008	FR	WAES0807USA04446	29-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Eye rolling, Loss of consciousness, No reaction on previous exposure to drug

Symptom Text: Information has been received from a health professional concerning her daughter, a 21 year old female who in January 2008, was vaccinated with the first dose of GARDASIL (Lot # and Batch # not reported), on her left deltoid by intramuscular route without any reactions. On approximately 21-MAR-2008, the patient was vaccinated with the second dose of GARDASIL (Lot # and Batch # not reported) on the deltoid by intramuscular route. It was reported that after vaccine administration the patient started feeling dizzy and then suffered an episode of loss of consciousness with the rolling of eyes back into her head. According to the reporter this event lasted for a few seconds, after which the patient recovered. The patient continued feeling dizzy until next morning. No medications were administered to treat event, as the patient recovered quickly. At this time, no other information has been reported. Case is closed. Other business numbers included: E2008-06942. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320571-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Jul-2008	24-Jul-2008	0	28-Jul-2008	06-Aug-2008	FL		06-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Hypotension, Nausea, Syncope vasovagal

Symptom Text: h/a, nausea, hypotension,vasovagal syncope

Other Meds:

Lab Data: N/A

History: Amoxil

Prex Illness: headache

Prex Vax Illns:

Vaers Id: **320574-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-Jul-2008	28-Jul-2008	0	28-Jul-2008	07-Aug-2008	VA		07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	007OX	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2657AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Pallor, Syncope

Symptom Text: Within a minute of receiving vaccines, pt had a brief syncopal episode. Appeared pale and diaphoretic. Allowed pt to lie down, and gave her a sugared beverage. Pt's color returned within a few minutes, and pt left office independently ambulatory within 15 minutes.

Other Meds: None at time (takes PRN OTC Mucinex for allergy relief)

Lab Data: N/A

History: Seasonal allergies

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320589-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Jul-2008	25-Jul-2008	0	28-Jul-2008	07-Aug-2008	AZ		07-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0133X		Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0171X		Left leg	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB223AA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient had a Brief syncopal episode that lasted approximately 5-10 seconds. Patient was layed done and after approximately 3-5 min patient felt better and went home with parents. It was also a very hot day and warm in the store.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320590-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Jul-2008	24-Jul-2008	0	28-Jul-2008	07-Aug-2008	IN		07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2616AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Fall, Laceration, Syncope

Symptom Text: Pt received vaccines (MCV4 & Gardasil) at 1250 at our satellite clinic in Dale at the North Spencer Community Action Center, waited for copy of immunization record and experienced syncopal episode when walking out of clinic door at approximately 1300. Pt slowly collapsed, and fell approximately 2 feet to the ground from a concrete ramp. Sister was walking in front of pt. when incident occurred. Two 3" superficial scrapes noted on L lower arm. Sister states she believes pt. hit head on ramp railing and on the ground. Head examined; No hematoma noted; denied head or neck pain. Blood pressure 80/50 @ 1301. Cool cloths to face & neck. Placed in flat position. Opened eyes immediately. Walked with assist of 2 nurses up ramp and into the office, placed in chair with feet elevated and cool cloths placed on neck & face. Drank soft drink without nausea or vomiting. Alert & oriented to time, place & person. Moves all extremities without difficulty. Left office @ 1330 with mother & sister. B/P 110/60.

Other Meds:

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: 320598-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	11-May-2007	22-May-2007	11	29-Jul-2008	01-Aug-2008	NM		04-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Aggression, Arthralgia, Complex partial seizures, Confusional state, Convulsion, Crying, Dizziness, Epilepsy, Fatigue, Feeling abnormal, Grand mal convulsion, Immediate post-injection reaction, Irritability, Myalgia, Nausea, Pain, Postictal state, Somnolence, Syncope, Tremor, Unresponsive to stimuli

Symptom Text: SYNCOPE, NAUSE, DIZZINESS AT TIME OF INJECTION. FATIGUE, "BRAIN FOG", IRRITABILITY AND MUSCLE ACHES AND SORENESS IN JOINTS WITHIN HOURS OF INJECTION AND CONTINUING TO DATE. SEIZURES, WITH NO PREVIOUS HISTORY, WITHIN MONTHS OF VACCINE, NO EXPLANATION AND CONTINUE TO DATE. PATIENT IS ON MEDICATIONS TO CONTROL SEIZURES AT THIS TIME. PATIENT REQUIRED TO EMERGENCY ROOM VISITS AT TIME OF BOTH GRAND MAL SEIZURES. 9/22/2008 Office records received from Neuro consult beginning 11/27/07. Pt presented after 1st generalized seizure on 11/24/07. Seizure lasted ~45 minutes with post ictal sleepines, then confusion, combativeness and tearfulness. Seen 12/7/07 following 2nd similar seizure, again during sleep. Placed on lamictal. Pt continued to have brief complex partial seizures. Report from 2nd neurologist also included. Seen 1/2/2008. DX: New onset epilepsy. 10/29/2008 MR received for ER visit 12/2/2007 with DX: seizure. Pt presented after 2nd seizure. Found unresponsive, shaking all over. Pain 4-10/10. D/C on Cerebyx.

Other Meds:

Lab Data: CBC, CT SCAN, MRI SCAN, TOXICOLOGY SCREEN, MULTIPLE EEGS. CONTINUED BLOOD WORK TO DATE. Labs and Diagnostics: EEG WNL initially then slightly abnormal. 24 hr ambulatory EEG unremarkable.MRI brain WNL.

History: PMH: none. Family hx of seizure. On oral contraceptives for acne

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 320607-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-May-2008	11-May-2008	3	28-Jul-2008	01-Aug-2008	WI		06-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C2767AA	5	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Body temperature increased, Chills, Joint injury, Leukopenia, Loss of consciousness, Malaise, Nausea, Pain in extremity, Pyrexia, Rash, Splenomegaly, Syncope, Thrombocytopenia

Symptom Text: 3 days after shots did not feel well. Then following day fever developed, next day she fainted in the shower (5/13/08). In the ER she had low WBC - platelet count and admitted for work up - in w/u splenomegaly. 8/4/08-records received for DOS 5/13-5/15/08-DC DX: Syncopal episode. leukopenia. Thrombocytopenia. Splenomegaly. C/O nausea, chills and leg pain on 5/11/08, followed by not feeling well, temperature 100.8. Fainting with loss of consciousness and hit elbow now swollen and tender. Developed rash on back.

Other Meds: SINGULAIR daily prn with ZYRTEC

Lab Data: WBC decreased 2/02 lowest; plts 74,000 was lowest; ultrasound showed enlarged spleen - 158 cm 8/4/08-records received-CT scan head negative. X-ray normal. WBC 2.67. Platelet count 91,000. Monospot negative. Abdominal US for C/O left upper

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320610-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Jul-2008	21-Jul-2008	0	28-Jul-2008	07-Aug-2008	SC		07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B021AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2560AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0387U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Swelling face

Symptom Text: Mom states child received vaccines around 3:30 pm, had some facial swelling and itching. Called on call doctor, advised Benadryl 50 mg and all symptoms were gone in 2 hours.

Other Meds: Claritin 10mg 1 QD

Lab Data: None done

History: Allergies to dust, mold and grass; asthma

Prex Illness: Anemia dx 7/21/08

Prex Vax Illns:

Vaers Id: 320616-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	22-Jul-2008	22-Jul-2008	0	28-Jul-2008	07-Aug-2008	NJ		07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Communication disorder, Crying, Headache, Hyperhidrosis

Symptom Text: Immediately after vaccination started crying, sweating and not communicating well. Complained of headaches. Symptoms continued for 30 minutes until transported to ED.

Other Meds:

Lab Data: HR: 90; BP 110/70; SpO2 100% on room air.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320626-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	23-Jul-2008	23-Jul-2008	0	28-Jul-2008	07-Aug-2008	MS		07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1263U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness, Gaze palsy, Loss of consciousness, Pallor

Symptom Text: Pt received 2nd dose of GARDASIL and TB skin test became pale, eyes rolled upwards and was briefly unconscious but responded quickly, BP decreased 42/10 but gradually became WNL. Last BP 100/58. She also c/o dizziness. Color gradually returned and pt remained responsive.

Other Meds: Received STU PPD (LFA) (Tubersol) at time of incident

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320628-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		28-Jul-2008	07-Aug-2008	NJ		07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Reaction to previous exposure to any vaccine

Symptom Text: I just know a "possible" reaction. Above child's "friend" came to clinic today. She stated that above child had a reaction to HPV vaccine. Nurse called mother, mother said child was fine. Then when nurse questioned further, mother stated child had a facial problem after HPV #2. Nurse then asked mother if that had happened with vaccine #2 why didn't the mother tell us before vaccine #3 on 5-6-08. There is a question sheet initialed by nurse that child had no reactions to vaccines before. I spoke to mother today, she said she will come tomorrow at 9AM and I hope to get the complete story at that time. I then plan to report about on a VAERS form and to notify all supervisors, PBH and the county. (See above note written today in slot 10-29-07). I obtained lot # from computer for HPV #1, lot was (1425F). It was given 10-30-07. I was off. Nurse was covering clinic. I initialed nurse's initials with MMC. After on that dates line RN. 7-24-08 Mother did not come to clinic on 7-24-08 therefore I called VAERS and completed attached form.

Other Meds: None

Lab Data: Per phone call to mother, child went to hospital.

History: Parent had denied all other medical problems for child.

Prex Illness: None

Prex Vax Illns:

Vaers Id: 320635-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	18-Jan-2008	04-Feb-2008	17	28-Jul-2008	06-Aug-2008	MA		14-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Ataxia, Breast cyst, Diarrhoea, Diplopia, Dizziness, Ear, nose and throat examination, Headache, Immediate post-injection reaction, Labyrinthitis, Nystagmus, Ophthalmological examination normal, Positive Rombergism, Skin papilloma, Syncope, Vertigo, Vomiting

Symptom Text: Pt experienced syncope immed after vaccine on 1/18. On 2/4, pt developed dizziness, vertigo, vomiting. Dizziness, vertigo, headaches continue to persist. She has had - MRI. Normal visual exam. - ENT eval. Continues to be symptomatic. 8/13/2008 Office records received. Pt fainted following HPV4 vax on 1/18/2008. Returned 2/7/2008 with several day hx of vomiting and diarrhea with syncopal episode that am. Assessment: vomiting and fainting probably due to viral infection. To increase fluids. Seen again 2/12/08 with dizziness reported since 2/4/08 (worse on change of position and/or on feet) and 2 syncopal episodes. PE (+) for ataxia and (+) Romberg and mild horizontal nystagmus. DX: Labyrithitis. Seen again 2/28/08 with same sx slightly improved with Antivert. DX Labyrithitis. Vertigo. 3/13/08 seen for vertigo. 3/26/08 HPV #2. Seen 6/25/08 with dx diplopia, 7/21 with vertigo and 7/25 with plantar warts and cystic breast mass.

Other Meds:

Lab Data: cranial MRI & MRA. Labs and diagnostics: brain MRI WNL

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320685-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Apr-2008	09-Apr-2008	0	29-Jul-2008	30-Jul-2008	CA	WAES0805USA05684	30-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner for the Pregnancy Registry for GARDASIL concerning a 16 year old female with no medical history, and no drug reactions/allergies, who on 09-APR-2008 was vaccinated intramuscularly with her first 0.5ml dose of GARDASIL (lot# 659964/1978U) while pregnant. It was reported that the patient was "9 weeks pregnant on 22-May-2008" (estimated LMP = 19-Mar-2008). The patient has no symptoms. Unspecified medical attention was sought by calling the office. No further information available. In follow-up information it was reported that date of last menstrual period was 19-MAR-2008 and the estimated delivery date was 24-DEC-2008. On 16-JUN-2008 the patient had an elective termination of pregnancy. It was reported that LMP was 19-MAR-2008, so the patient was approximately 13 weeks. It was unknown if the products of conception were examined and it was unknown if the fetus is normal. Upon internal review elective termination was determined to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 3/19/2008)

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320693-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Sep-2007	17-Sep-2007	0	29-Jul-2008	30-Jul-2008	IA	WAES0807USA04077	30-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Labour complication

Symptom Text: Information has been received from a licensed practical nurse concerning a 16 year old female with allergy to codeine and no pertinent medical history who on 17-SEP-2007 was vaccinated with GARDASIL (lot#: 658558/1061U) 0.5ml IM. Concomitant therapy included ALDOMET. Subsequently, she became pregnant. Her LMP was 10-SEP-2007. The estimated due date was 16-JUN-2008. The patient delivered a baby on 20-JUN-2008. She had a cesarean section because of "failure to descend". The delivery was successful. A cervical smear (PAP smear) was performed (results not reported). The patient was seen by a physician. Upon internal review, failure to descend, the indication for cesarean section, was considered to be an other important medical event. Additional information has been requested.

Other Meds: ALDOMET

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 9/10/2007); Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320694-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Jul-2008	07-Jul-2008	0	29-Jul-2008	30-Jul-2008	--	WAES0807USA04072	30-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse concerning a 15 year old female with no past history of seizures and no history of drug reactions or allergies who on approximately 07-JUL-2008 was vaccinated with the first dose of GARDASIL. Right after the vaccination the patient experienced convulsions. The patient "improved" the same day. subsequently, the patient recovered from convulsion. The patient sought unspecified medical attention. Upon internal review, convulsion was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320695-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		29-Jul-2008	30-Jul-2008	--	WAES0807USA04901	30-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician who received an e-mail that was addressed to all physicians from another physician, a pediatric neurologist. He stated in e-mail that one of his patients experienced seizures after GARDASIL. The patient outcome was not reported. Upon internal review, seizures were considered to be an other important event. Additional information has been requested. This is one of several reports received from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320696-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	01-Feb-2008		29-Jul-2008	30-Jul-2008	--	WAES0807USA04580	30-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Cellulitis, Morphoea

Symptom Text: Information has been received from a physician concerning her niece, a 16 year old female who on unspecified dates was vaccinated with the first and second doses of GARDASIL, 0.5 ml. In February 2008, the patient experienced cellulitis type skin condition. She was seen by a dermatologist and she was hospitalized a few times with diagnosis of Morphea, an autoimmune disease. In March 2008, the patient was vaccinated with the third dose of GARDASIL, 0.5 ml, with no additional reaction or exacerbation of symptoms noted. At the time of report, the patient had not recovered. No additional information at this time. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320697-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		29-Jul-2008	30-Jul-2008	--	WAES0807USA04195	30-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician who received an e-mail that was addressed to all physicians from another physician, a pediatric neurologist. He stated in e-mail that one of his patients experienced seizures after GARDASIL. The patient outcome was not reported. Upon internal review, seizures were considered to be an other important event. Additional information has been requested. This is one of several reports received from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 320698-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	18-Jun-2008	22-Jun-2008	4	29-Jul-2008	30-Jul-2008	IL	WAES0807USA04045	13-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Aphthous stomatitis, Gingival swelling, Gingivitis ulcerative

Symptom Text: Information has been received from a nurse concerning a her daughter 19 year old with "allergic sulfa" and no pertinent medical history who on 18-JUN-2008 was vaccinated with a first dose of GARDASIL. Concomitant therapy included TRI-CYCLEN and montelukast sodium (MSD). The nurse reported that her daughter developed swelling of the gums and cankers sores in the mouth following vaccination with GARDASIL. The daughter's gums swelled and she developed cankers sores 4 days after the first vaccination with GARDASIL. The daughter was treated by a dentist for the gum swelling and cankers sores. The gum swelling was characterized as necrotizing gingivitis. The canker sores developed over a period of 5 days and totaled 7. The gum swelling and canker sores made it hard to eat and the daughter did not eat any solid food for one week. Swelling of the gums and cankers sores in the mouth and necrotizing gingivitis was considered to be disabling. No lab diagnostics were performed. On 06-JUL-2008 the patient recovered. There was no product quality complaint. Additional information has been requested. 8/11/08-records received for DOS 6/28/08 college physical exam normal no complaints.

Other Meds: TRI-CYCLEN; SINGULAIR

Lab Data: None

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **320699-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-Jun-2008	23-Jun-2008	3	29-Jul-2008	30-Jul-2008	FR	WAES0807USA03954	30-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal stiffness, Polyarthritis

Symptom Text: Information has been received from a Health Authority (BGAR2008/103) concerning a 15 year old female who on unreported dates was vaccinated with the first and second dose of GARDASIL without any adverse event. On 20-JUN-2008, the patient was vaccinated with the third dose of GARDASIL via intramuscular route (lot number and route and administration unknown). On 23-JUN-2008, the patient experienced a stiff neck during 1 day (cessation date: 24-JUN-2008) and acute polyarthritis. At the time of the report the patient was recovering from polyarthritis. Some lab test were performed and the relevant Test/Laboratory data included: Serum C-reactive protein (CRP)=0.2, Erythrocyte sedimentation rate (sed)=9; Enterovirus polymerase chain reaction (PCR): Negative; Viral serology: negative. Stiff neck and acute polyarthritis were considered as other important medical event. Other business partner numbers included: E2008-05708. No additional information is available.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, viral serology negative; Diagnostic laboratory test, WBC, 71; Enterovirus PCR, negative; Serum C-reactive protein, 0.2; Erythrocyte sedimentation rate, 9

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320700-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		29-Jul-2008	30-Jul-2008	OR	WAES0807USA03800	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1426F	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Depression, Grand mal convulsion, Staring

Symptom Text: Information has been received from a physician concerning a 12 year old female with family history of seizure who on unspecified dates was vaccinated with the first, second and third doses of GARDASIL. The patient did not have any problems after the first and second dose of GARDASIL. The patient had a seizure 30 days after receiving the third dose of GARDASIL. The patient sought unspecified medical attention. On an unspecified date, the patient recovered. The physician did not feel the seizure was related to GARDASIL. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested. 8/8/08-records received- ED report 1/4/08-presented to ED first seizure 12/26/07-C/O feeling tired. Seizure generalized tonic-clonic lasting 5 minutes. Postictal. Abrasion to tongue. Headache after seizure. Confusion lasting half hour. Neurology consult 1/10/08-the two seizures occurred while playing karaoke. Subsequent seizure with forced eye closure while on the computer. Impression-cryptogenic generalized seizure disorder with multifocal and generalized discharges on EEG. Indeterminate staring spells probably atypical absence seizures. Depression.

Other Meds: Unknown

Lab Data: Unknown 8/8/08-records received-EEG:Partial seizure disorder. Labs:microcytic anemia. MRI brain normal.

History: Unknown 8/8/08-records received-PMH: GERD. Migraines. Asthma. Premature 1 month early. Family history of pseudoseizures.

Prex Illness:

Prex Vax Illns:

Vaers Id: **320701-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		29-Jul-2008	30-Jul-2008	--	WAES0807USA03785	30-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a physician who received an e-mail that was addressed to all physicians from another physician, a pediatric neurologist. The e-mail stated that the NVIC reported that 82 patients developed syncope and seizures after injection of GARDASIL. The patients sought medical attention. The patients' outcomes were not reported. The reporting physician who was not the physician of any of these patients expressed concern that GARDASIL was not safe. Upon internal review, seizures were considered to be an other important event. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. This is one of several reports received from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320702-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Apr-2008	02-Jun-2008	60	29-Jul-2008	30-Jul-2008	CA	WAES0807USA03673	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	2	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Convulsion, Dizziness, Loss of consciousness, Nausea, Vision blurred

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who on 21-MAY-2007, was vaccinated with the first dose of GARDASIL (Lot # and Batch # not provided). Date of second dose not reported. On 03-APR-2008, was vaccinated with the third dose of GARDASIL (Lot # and Batch # not provided). On 02-JUN-2008, about two months after completion of the GARDASIL series, the patient experienced seizure. The patient sought for medical attention at physician's office. On unspecified date, the patient recovered from seizure. Upon internal review, seizure was considered to be other important medical event. Additional information has been requested. 8/26/08 Reviewed ER medical records of 5/31/2008. FINAL DX: new onset seizures Records reveal patient experienced an initial seizure w/LOC, dizziness, nausea, weakness, blurry vision while in restaurant.

Other Meds: Unknown

Lab Data: Unknown LABS: CBC & UA WNL. Chemistry: sodium 134(L), potassium 3.4(L), chloride 99(L). CT head (done at another facility) WNL.

History: Unknown PMH: asthma. Received HPV#1 5/21/07, lot # 0389U, IM LA; HPV#2 8/14/2007, lot #0525U, IM LA

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320703-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	10-Jul-2007	01-Sep-2007	53	29-Jul-2008	30-Jul-2008	FR	WAES0807USA03624	30-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1024F	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Arthritis, Facial paresis, Musculoskeletal discomfort, Musculoskeletal pain

Symptom Text: Information has been received from a patient's mother concerning her daughter (age not reported) who on 11-SEP-2007 was vaccinated with the second dose of GARDASIL (Lot # 1475F, Batch # NF37120, route and site not reported). In September 2007 (exact date not reported), the patient experienced shoulder pain. Arthritis was diagnosed by a physician. In October 2007 and December 2007 pain in the knee and the left hip, in the fingers and toes followed. X-ray and rheumatological investigation showed normal results. Despite ongoing arthritis, on 08-JAN-2008, the patient was vaccinated with the third dose of GARDASIL (Lot # 0277, Batch # NG00020, route and site not reported). In April 2008, the patient developed left facial paresis and was hospitalized for 13 days. MRI and lumbar puncture were normal. Thereafter facial paresis meanwhile resolved but reoccurred in June 2008. The patient was again hospitalized for 12 days. CSF showed a non-specific inflammation. At the time of the reporting, the patient was not recovered. The mother turned to several doctors and asked whether the symptoms could be side effects of the GARDASIL vaccination, the treating physicians however did not confirm this suggestion. It is to be noted that the patient was vaccinated with the first dose of GARDASIL (Lot# 655671/1024F, Batch # NE51790, route and site not reported) and no adverse effect occurred. Other business partner numbers included: E2008-06673. Additional information has been requested.

Other Meds: Unknown

Lab Data: X-ray, showed normal results; magnetic resonance imaging, normal; spinal tap, normal; cerebrospinal fluid analysis, showed a non-specific inflammation

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320704-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Nov-2007	Unknown		29-Jul-2008	30-Jul-2008	FR	WAES0807USA04443	30-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Injected limb mobility decreased

Symptom Text: Information has been received from a gynecologist concerning a 20 year old female who in November 2007, was vaccinated with a first dose of GARDASIL. On 15-JUL-2008 the gynecologist was informed by the patient that following the vaccination, she could not move her arm. The patient was hospitalized. Neurological examinations revealed no findings. A hospital letter was not available. Duration of hospitalization was not reported. The patient recovered completely within approximately 4 weeks. Other business partner numbers included E2008-06755. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320705-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		29-Jul-2008	30-Jul-2008	FR	WAES0807USA04141	30-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hidradenitis

Symptom Text: Information has been received from a physician concerning a female with no medical history who had well tolerated paediatric vaccines. On an unspecified date she was vaccinated with her first dose of GARDASIL. 15 days post the vaccination she developed VERNEUIL'S DISEASE. The reporter saw the patient for the first time 2 months before 20-JUL-2008 and she already had drains applied by a surgeon. The patient was treated with unspecified homeopathic treatment. The reporter considered the case as medically significant. At the time of the report the patient had not recovered. Other business partner numbers included: E2008-06930. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **320709-1** **Related reports:** 320709-2; 320709-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Jun-2007	28-Mar-2008	275	29-Jul-2008	01-Aug-2008	--		20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Arthritis, Arthropathy, Chest pain, Costochondritis, Depression, Erythema, Fatigue, Gait disturbance, Headache, Heat rash, Hypoaesthesia, Impaired work ability, Labyrinthitis, Musculoskeletal pain, Musculoskeletal stiffness, Myalgia, Neck pain, Paraesthesia

Symptom Text: Gradual progression of symptoms since receiving the third booster of the GARDASIL vaccine in January of 2008. Initial Labrynthitis diagnosed by student health center and costochrondritis in late March. Followed by extreme exhaustion and a diagnosis of depression. Fatigue increased. Tempromandibular Joint problems, severe headaches, and neck pain began in Spring. Hip and knee pain followed in April and has worsened to limping and sharp pain. Shoulder pain. Redness and stiffness of the hands followed in early May, followed by ankles. Also, in May, I started experiencing numbness intermittently in my hands. I am seeing a rheumatologist who is treating the symptoms and has made no diagnosis at this time. I am no longer able to work a full day and have spent most of my summer on the sofa. 8/18/08-records received for DOS 6/25/08-presented with C/O arthralgias and myalgias that began in March 2008 noted pain over right trochanteric bursa and pain when walking or standing for periods of time. Participating in spinning class. Stiff and achy in morning. Some numbness and tingling. Color changes in fingertips when exposed to cold. Heat rash on chest. Costochondritis. Pain in chest, headaches. DOS 7/16/08-follow up visit. Improvement in symptoms after Medrol dospak. Assessment:potential inflammatory arthritis.

Other Meds: LEXAPRO 20mg once daily since March 2008; ZYRTEC 10mg as needed for allergies since 2001; Nuva Ring contraceptive device

Lab Data: RA factor; ANA; Sed rate; CBC; UA all tested normal date 06/11/2008 8/18/08-records received- X-ray of shoulder normal.ANA negative, sedimentation rate 4, rheumatoid factor negative, chemistry and CBC normal. Urinalysis unremarkable.

History: Mother has Rheumatoid Arthritis; Allergies (Seasonal); Non-smoker; Moderate Alcohol use; Ovarian Cysts 8/18/08-records received-PMH: asthma and frequent canker sores. Family history of rheumatoid arthritis.

Prex Illness:

Prex Vax Illns:

Vaers Id: **320709-2** **Related reports:** 320709-1; 320709-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	17-Jan-2008	08-Jul-2008	173	18-Aug-2008	30-Sep-2008	MO	WAES0807USA05144	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Fatigue, Gait disturbance

Symptom Text: Information has been received from a physician concerning an approximately 21 year old female who on 27-JUN-2007 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 658094/0524U) intramuscular administration. On 27-AUG-2007 the patient received the second dose of GARDASIL vaccine (yeast) (lot # 658554/0928U) intramuscular administration. On 17-JAN-2008, the patient received the third dose of GARDASIL vaccine (yeast) (lot # 659439/1267U), intramuscular administration. On 08-JUL-2008, the patient's mother called the office stating that the patient had joint pain and fatigue and was limping. She was seen by a rheumatologist and tests were negative for rheumatoid arthritis. At time of reporting, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320709-3** **Related reports:** 320709-1; 320709-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		16-Mar-2009	31-Mar-2009	MO	WAES0902USA04073	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthritis, Body temperature increased, Costochondritis, Dizziness, Fatigue, Labyrinthitis, Nausea, Neck pain, Pain, Pain in jaw, Paraesthesia, Pyrexia, Weight decreased

Symptom Text: Information has been received from a dentist concerning her 21 year old daughter with a medical history of mononucleosis and sulfonamide allergy who in July 2007, was vaccinated with a first dose of GARDASIL (lot # 658094/0524U). The patient received a second and third dose of GARDASIL (lot # 659439/1267U). Concomitant therapy included montelukast sodium (MSD), (dose, duration and indication not reported) and NUVARING. After received all 3 doses the patient experienced arthritis symptoms, tiredness, weight loss, general achy feeling (neck and jaw pain), tingling in her arms and hands, and dizziness. The reporter also stated that she had inflammation in the cartridge in her chest. She was at some point diagnosed with labyrinthitis. Her physician prescribed her some steroids and other non steroidal medication (unspecified which ones) and she felts a little better and was able to go back to school. The reporter also mentioned that after each dose the patient experienced minor problems like dizziness, nausea and temperature but did not have joint pain until after the third dose. The patient had blood work, urine tests, thyroid tests, serum antinuclear antibodies tests (ANA), RA and x rays, everything came back normal. The patient sought unspecified medical attention. At the time of this report the patient had not recovered. Additional information has been requested.

Other Meds: NUVARING; SINGULAIR

Lab Data: diagnostic laboratory - normal; X - ray - normal; hematology - normal; urinalysis - normal; thyroid function test - normal; serum ANA - normal

History:

Prex Illness: Infectious mononucleosis; Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320711-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Jun-2007	01-Mar-2008	271	29-Jul-2008	01-Aug-2008	NY		10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Emotional disorder, Sciatica, Urticaria

Symptom Text: After receiving third injection of GARDASIL there was an acute pain in lower back. Persistent to this date. Sibling-sister-has same acute symptom. Diagnosed as sciatica but not convinced due to the events for two sisters with same symptoms. 7/31/08-records received for DOS 6/25/07-emotional problems, lower back leg pain, sciatica. HPV#1 received 4/9/07, HPV#2 6/4/07, vaccine administration GYN office. Office visit 7/9/07-still C/O back pain getting worse. 12/28/07-hives and itching for 2 months, urticaria. 3/21/08-C/O back pain on and off last seen for this complaint was 7/9/07.

Other Meds:

Lab Data: Diagnosed as sciatica but not convinced due to the events for two sisters with same symptoms.

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320718-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Feb-2008	15-Feb-2008	0	29-Jul-2008	08-Aug-2008	PA		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	1	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2181AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C2844AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Lacrimation increased, Rhinorrhoea, Swelling face

Symptom Text: Runny nose, puffy face/eyes watery and difficulty breathing. Mother gave Benadryl and patient was ok. Child was recently diagnosed with Latex allergy.

Other Meds: Clarinex

Lab Data: N/A

History:

Prex Illness: Stuffy nose and cough

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320719-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Jul-2008	15-Jul-2008	0	29-Jul-2008	08-Aug-2008	TX		08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2624AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB233AA	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Immediate post-injection reaction, Muscle contractions involuntary, Syncope

Symptom Text: Receiving immunizations, stood up and collapsed in syncopal episode. Did not loose consciousness but appeared to have muscular contractions/seizure in (R) arm for 15 seconds. Had seizures in the past but not connected w/immunization. No seizures or medication in several years. Mother called PCP during episode and was to take client to PCP when they left health dept.

Other Meds: None

Lab Data: Parents had MRI, EEG week of 7/15. Dr. ruled out seizure. Diagnosed event as post vaccine reaction. Advised to not received HPV doses #2 and 3.

History: seizures prior to 3 years ago

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320727-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Jul-2008	28-Jul-2008	0	29-Jul-2008	08-Aug-2008	IL		08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	00734	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: dizziness, lightheadedness and nausea lasting approximately 90 minutes. Symptoms occurred around 10 p.m. Vaccine given around 2 p.m.

Other Meds: Yasmin

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320729-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-Jul-2008	28-Jul-2008	0	29-Jul-2008	08-Aug-2008	TX		08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Unknown	
	TD	UNKNOWN MANUFACTURER	NULL		Left arm	Unknown	
	VARCEL	UNKNOWN MANUFACTURER	NULL	1	Right arm	Unknown	
	MEN	UNKNOWN MANUFACTURER	NULL		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Chills, Confusional state, Convulsion, Dyspnoea, Hypoaesthesia, Lip swelling, Musculoskeletal discomfort, Musculoskeletal stiffness, Syncope

Symptom Text: Patient receive this vaccine. A few short seconds later patient fainted and looked to be having a seizure. She came out of this seizure and/or fainting spell confused numbness of a part of the body, a brief loss of memory, sparkling or flashes,appeared to be confused or dazed and was not be able to respond to questions or direction and was having difficulty breathing; swelling of her lips. Her fingers where very stiff and she complain that she couldn't close her hands. She said her muscle in her legs felt strange. After about 15 min. Patient sat up and her teeth started chattering.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320731-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	25-Jul-2008	25-Jul-2008	0	29-Jul-2008	08-Aug-2008	WI		08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness transient, Dizziness, Musculoskeletal pain, Pain in extremity, Pallor, Tinnitus

Symptom Text: At the time of the injection I got very dizzy lost the color in my face had ringing in my ears that lasted about 15 minutes. I also lost my vision for a few seconds. About 6 hours after the injection I have pain in my left shoulder and left upper are that has not subsided as of 07/29/2008.

Other Meds: Singular, Clexa

Lab Data:

History: Amoxicillin, Penicillin, Sulfa, Codeine, Pollens, Grass, Mushrooms, Rag weed, Hay, Mold, Pine Trees

Prex Illness: Nope

Prex Vax Illns:

Vaers Id: **320732-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	06-Apr-2007	11-Apr-2007	5	29-Jul-2008	08-Aug-2008	MA		08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0960K	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Rash, Skin irritation, Swelling face, Urticaria

Symptom Text: 5 days following the HPV vaccine patient experienced skin irritation on face, neck, and back. Pt. went to emergency room 4/12/07 and treated for allergic reaction with prednisone and benadryl. Pt. did not fill prescription and rash became worse so pt. came to doctor's office 4/13/07 and prescribed longer course of prednisone over 10 days and benadryl. At 4/13/07 visit, pt. had wheals over neck, back, bilateral cheeks, forehead and facial swelling. Pt. has been recommended to not receive further doses of HPV vaccine.

Other Meds:

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320736-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Jul-2008	28-Jul-2008	18	29-Jul-2008	08-Aug-2008	AL		08-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0067X	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB291AA	0	Left arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB452AA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2580AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Injury

Symptom Text: ER visit due to injured arm; Pregnancy confirmed at ER Visit 7-28-08

Other Meds: NONE

Lab Data: Ultrasound gestational age 26-27 weeks; HCG Quant 3475

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320738-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	23-Jul-2008	23-Jul-2008	0	29-Jul-2008	08-Aug-2008	CA		08-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	UNKNOWN MANUFACTURER	NULL	1	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	
PPV	UNKNOWN MANUFACTURER	NULL	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion, Immediate post-injection reaction, Pain in extremity, Rash erythematous, Syncope

Symptom Text: Varicella and Pneumococcal injections given in Left arm at approximately 1:45pm on July 23. No adverse effects noted. Nurse left to draw Gardasil vaccine and it was given approximately five minutes later in Right arm. Syncope immediately after Gardasil injection, followed by a tonic clonic seizure. Red non-raised rash present on neck and chest. Given benadryl. Pain in right arm still present 6 days after injection.

Other Meds: None

Lab Data:

History: Bee sting allergy. Some mild food allergies. RAST test confirms negative allergy to eggs.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320739-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		29-Jul-2008	08-Aug-2008	TX		08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site warmth, Nausea, Pyrexia

Symptom Text: Fever> 102, large area of redness and heat to administration site, with nausea

Other Meds: Dapsone

Lab Data: none

History: psoriasis

Prex Illness: none

Prex Vax Illns: fever, swelling~HPV (Gardasil)~1~20~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320750-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	23-Jun-2008	23-Jun-2008	0	29-Jul-2008	01-Aug-2008	NJ		12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Confusional state, Depressed level of consciousness, Foaming at mouth, Gaze palsy, Grand mal convulsion, Staring

Symptom Text: 3 hrs after #2 HPV, pt became confused, then had generalized tonic/clonic seizure. Had played in Lacrosse tournament and had had less sleep than usual in the prior 48 hours. 8/11/08 MR received for DOS 6/23-24/2008 with DX: Seizure. Pt presented to ER after 2 episodes of flailing limbs, frothing at the mouth and eyes rolled back on the day of HPV vax #2. Pt had been staring and "out of it" for 20" prior to seizure activity. Confused state for ~15 min after. PE WNL. Started on IV Dialantin with no further seizures. D/C on po Depakote.

Other Meds: none

Lab Data: Labs and Diagnostics: EEG WNL.

History: Previous seizure 8/25/07, EEG abnormal. PMH: 1 seizure 8/2007. NKDA.

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320751-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	14-Jul-2008	16-Jul-2008	2	29-Jul-2008	01-Aug-2008	OH		09-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	00724	2	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Erythema, Flushing, Induration, Joint range of motion decreased, Oedema peripheral, Pain in extremity, Purulence, Pyomyositis, Pyrexia, Soft tissue aspiration, Tenderness, Vomiting

Symptom Text: Ok at beginning but then became sore. Increased symptoms 7/17 - swollen oval reddish circle, painful, fever. Taken to ER. CT then MRI. Fluid collection. Transferred to hospital. IV mbx then evacuation of fluid collection/abscess. Diagnosis - pyomyositis. 9/12/2008 MR received for DOS 7/18-24/2008 with DX: Pyomyositis. Pt presented to local hospital with increased swelling and tenderness of the L deltoid, fever and emesis. Transfered for eval and tx. PE (+) for 8x4 cm markedly indurated, swollen, erythematous area on L deltoid as well as redness to the face/chest. Decreased ROM of shoulder. US guided soft tissue fluid collection and aspiration (+) for purulent material. Tx with vancomycin.

Other Meds: None

Lab Data: 7/18 WBC 13.7 80% nat, 9% lymph - 7/21 CRP 7.2 - 7/22 abscess clx negative - 7/24 CRP 1.51 - 7/26 CRP ESR 24 blood clx negative. Labs and Diagnostics: CBC with WBCs 13.9. CT scan shows SubQ infiltration, no abscess. MRI (+) for inflammat

History: None. PMH: none

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320753-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	23-Jul-2008	23-Jul-2008	0	29-Jul-2008	08-Aug-2008	CA		04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0540X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1740U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site swelling

Symptom Text: HPV#3 given on 7/23/08 in office. Pt reports vaccine site red, swollen and itchy. Started evening of 7/23/08. treatment was ice and BENADRYL as needed. Patient recovered.

Other Meds: oral bcp's

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **320754-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	07-May-2008	07-May-2008	0	29-Jul-2008	07-Aug-2008	NC	NC08087	07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	SANOFI PASTEUR	U2356BA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0063X	2	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB233AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Pt was given DTaP instead of Tdap.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320760-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Jan-2008	16-Feb-2008	31	29-Jul-2008	08-Aug-2008	FL		06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1501U	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1210U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Patient had her 1st menses 10/08 - had a cycle 11/08 and 12/08. HPV given 1-16-08 - no menses since.

Other Meds:

Lab Data: None

History: No known

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320761-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	22-Jul-2008	22-Jul-2008	0	29-Jul-2008	07-Aug-2008	--		07-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1758U	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B023AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0104X	1	Left arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U2569AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site irritation, Injection site pain, Injection site swelling

Symptom Text: SQ site on L arm with approx 2 1/2 in by 1 1/4 in red, puffy slightly firm to touch raised area. Stings. Pt reports started burning/stinging a few hrs after inj. Pt instructed to start BENADRYL q 8 hours x24-48 hours. Topical hydrocortisone, cool compresses x15 min q 2-4 hours.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320773-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	21-Jul-2008	21-Jul-2008	0	29-Jul-2008	08-Aug-2008	RI		08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2623AA	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Concussion, Head injury, Loss of consciousness, Malaise

Symptom Text: Patient was given vaccs/was told to stay seated for a little while afterwards/started not feeling well-got up and passed out hitting back of head on floor-went to E.R. and diagnosed with a concussion.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **320774-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	23-Jul-2008	23-Jul-2008	0	29-Jul-2008	07-Aug-2008	MN		07-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0334X	1	Left arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B020AA		Left arm	Unknown	
MNQ	SANOFI PASTEUR	U2580AA	0	Right arm	Unknown	
HPV4	MERCK & CO. INC.	0843X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Developed hives, according to mom, within 2 hrs of receiving vaccines.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320775-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Jul-2008	24-Jul-2008	0	29-Jul-2008	08-Aug-2008	PA		08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction

Symptom Text: GARDASIL given and approx 30 sec later felt faint-recovered by lying down

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320778-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	03-Apr-2007	04-May-2007	31	29-Jul-2008	08-Aug-2008	MI		11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0210U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Arthralgia, Asthma exercise induced, Confusional state, Diarrhoea, Dysarthria, Speech disorder, Upper respiratory tract infection, Vomiting

Symptom Text: Memory loss. Will wake up in morning and not know where she is. Will be talking and wrong words come out. Will be driving somewhere and won't know where she's going. 8/4/08-GYN notes received from DOS 10/24/07-7/17/08-chlamdyia infection. Patient feels she has issues with blood sugar will see PCP 9/11/08-records received-office visit 5/4/07-C/O exercise induced asthma. Office visit 5/10/07-C/O acute right knee pain. 7/11/07-office visit follow up for asthma, 8/30/07-GI complaints vomiting and diarrhea.10/9/07-C/O left hip pain for a few months. Lump above left hip present for some time. 2/13/08-Acute upper respiratory infection. 7/21/08-stress reaction in proximal tibial knee possible osteomalacia.7/24/08-difficulty with memory for about 1 year, trouble finding work, slurred speech once happening more frequently.

Other Meds: YASMIN

Lab Data: pt complained of trouble with her "Blood sugar" 9/11/08-records received-8/29/08-MRI brain showed cystic lesions with subtle signal alternations, suspicious for DNET. Bone density study revealed osteopenia of spine. x-ray of knee probable

History: 9/11/08-records received-History of knee injury. Longstanding history of migraines with aura light sensitivity and irritability.

Prex Illness:

Prex Vax Illns:

Vaers Id: **320779-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Jul-2008	25-Jul-2008	0	29-Jul-2008	07-Aug-2008	OR		07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2774AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1904U	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Vision blurred

Symptom Text: 8:55AM client had immunizations, 9:00AM client was standing beside mother while checking out of clinic. Became pale and sat down on floor; pale skin, eyes non focusing, able to talk. Had no bkft, recovered in 5 mins.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **320783-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Jul-2008	22-Jul-2008	0	29-Jul-2008	07-Aug-2008	AZ		07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0524X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0928U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Pain, Pain in extremity, Sensation of pressure

Symptom Text: Immediately after vaccine had shooting pain in left arm, within an hour pt c/o pain in both legs that felt like pressure pain becoming shooting pain into lower leg and foot. Pt told to rest and given ibuprofen, pain resolved w/in 2-3 hrs. Some dizziness. No fainting.

Other Meds: None

Lab Data: None

History: ADHD-not on meds at time of vaccine

Prex Illness: Alopecia-mild

Prex Vax Illns:

Vaers Id: **320784-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	25-Jul-2008	25-Jul-2008	0	29-Jul-2008	08-Aug-2008	MN		08-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0605X	1	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2966AA	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB238AA	0	Right leg	Intramuscular	
MNQ	SANOFI PASTEUR	U2580AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Mydriasis

Symptom Text: Immediately after receiving the 5th shot, patient's body slouched over while in sitting position. When attempting to lay her down on her back, her arms and legs began a jerking movement, head turned to the right and pupils dilated. Episode lasted 3-5 seconds. Patient didn't remember the episode when asked. Physician was called into room and patient was assessed by doctor. Patient was observed for 30 minutes, and had full recovery by the time she left the clinic.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320789-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	M	23-Jul-2008	Unknown		29-Jul-2008	08-Aug-2008	MA		08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Patient given HPV instead of Menactra by accident.

Other Meds:

Lab Data:

History: NKDA, none

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320796-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
30.0	F	01-May-2008	Unknown		29-Jul-2008	08-Aug-2008	TX		08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Inappropriate schedule of drug administration, Presyncope

Symptom Text: I completed my series of the GARADASIL vaccines last month. I have no idea if I am having a side effect from the vaccine but over the last 3 weeks I have been having the occasional dizzy spells. I have never had an actual syncopal episode, just the near syncopal episodes. I am an ER nurse and am familiar with the fact that many people try to relate medical problems to sides effects of their medications. I know that many people have reported unusual symptoms after receiving GARDASIL so I thought I would mention my near syncopal episodes although they may not be related. I have never had any serious medical or health problems though. I did have a thorough lab work up back in January after I turned 30, and my lab work was perfect. I have not had any labs tests done since then.

Other Meds:

Lab Data:

History: NKDA. Not pregnant. No medical problems. I take a multivitamin but no other medications. I have one D&C when I was 25 years old and one LEEP done in April this year. No major surgeries.

Prex Illness:

Prex Vax Illns:

Vaers Id: **320832-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	26-Jun-2008	26-Jun-2008	0	30-Jul-2008	31-Jul-2008	OK	WAES0807USA04782	31-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Disorientation, Face injury, Fall, Mouth injury, Oxygen supplementation, Syncope, Tooth fracture

Symptom Text: Information has been received from a physician concerning a 13 year old female with no pertinent medical history and no history of drug reaction or allergies who three to four weeks ago (on approximately 26-JUN-2008 to 03-JUL-2008) was vaccinated with MENACTRA, then she received the first dose of GARDASIL (lot#: 660391/0063X). Immediately after the GARDASIL injection, she fainted. She hit her nose on a foot stool connected to the exam bed. Oxygen was started, blood pressure and oximetry were within normal range. She did not recall where she was but knew her name. She was transported to the hospital by ambulance where an X-ray of nose was negative. She also hit her lip and cracked one tooth. She was later seen by a dentist and the tooth was cemented. The reporter's office called the patient 24 hours later and she was oriented and remembered the situation in the office. Subsequently, the patient recovered. The reporter considered fainting and cracking one tooth to be other important medical events. Additional information has been requested.

Other Meds: Unknown

Lab Data: pulse oximetry, 06/26/08, normal; X-ray, 06/26/08, negative (nose)

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **320833-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		30-Jul-2008	31-Jul-2008	--	WAES0807USA04948	31-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a 15 year old female who on an unspecified date was vaccinated with her third dose of GARDASIL. Subsequently the patient experienced a seizure. At the time of the report, it was unknown if the patient had recovered from the seizure. Upon internal review, seizure was determined to be an other important medical event. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320834-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	22-May-2008	22-May-2008	0	30-Jul-2008	31-Jul-2008	--	WAES0807USA04758	31-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner for the pregnancy registry for GARDASIL, concerning a female patient with a history of miscarriage who on 22-MAY-2008 was vaccinated with a dose of GARDASIL (lot # 660389/1968U) intramuscularly. The nurse practitioner reported that on 05-JUN-2008, the patient had a miscarriage. The last menstrual period and weeks gestation was not reported. It is unknown if the patient sought medical attention. A lot check has been initiated. Upon internal review, miscarriage was considered an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Miscarriage

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320835-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Jul-2008	20-Jul-2008	4	30-Jul-2008	31-Jul-2008	NY	WAES0807USA04519	04-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Conjunctivitis, Convulsion, Cyanosis, Foaming at mouth, Grand mal convulsion, Loss of consciousness, Paralysis, Tachycardia, Tongue biting

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female with history of syncope who on 16-JUL-2008 was vaccinated with the first dose of GARDASIL (Lot No. 659962/1740U) IM. After the first dose of GARDASIL, on 20-JUL-2008, the patient experienced a seizure. The seizure lasted 3 minutes. The patient went to the emergency room for an evaluation but was not admitted. Subsequently, the patient recovered. Upon internal review, seizure was considered as an other important medical event. Additional information has been requested. 8/26/08 Reviewed ER medical records of 7/20/08. FINAL DX: seizure, conjunctivitis Records reveal patient experienced grand mal seizure lasting approx 3 min & had transient inability to move arms & legs. Tachycardic in ER otherwise stable. D/C to home & referred to neuro for outpatient w/u. 9/2/08 Reviewed neurological consult records of 7/21/2008. FINAL DX: none provided Records reveal patient exprienced witnessed passing out at a friends house after a sleep over. Had generalized tonic-clonic seizure w/foaming at the mouth, cyanosis, bit her tongue & lasting approx 3 minutes. CT scan reviewed & concurred WNL. Suggested MRI/MRA of brain & EEG.

Other Meds: Unknown

Lab Data: LABS: CBC & chemistry WNL. CT of head WNL. Drug screen & UA neg.

History: Syncope PMH: vasovagal responses: one several years prior after head injury & one approx 1 year prior when was overheated. Family hx: brain aneurysm, muscular dystrophy, thyroid disease.

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320836-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Apr-2008	29-Apr-2008	0	30-Jul-2008	31-Jul-2008	CA	WAES0807USA04386	31-Jul-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a 16 year old female with no pertinent medical history who on 29-APR-2008 was vaccinated intramuscularly with the 0.5 ml second dose of GARDASIL. There was no concomitant medication. The physician reported that the patient had seizures after her second dose of GARDASIL. On 14-JUN-2008 the patient was taken to the emergency room and had repeated seizures since. The patient is now under the care of a neurologist. The patient's seizures persisted. Upon internal review, seizures were determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **320838-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Jun-2008	27-Jun-2008	17	30-Jul-2008	31-Jul-2008	CA	WAES0807USA04084	20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Convulsion, Dizziness, Fatigue, Orthostatic hypotension, Tremor, Vision blurred

Symptom Text: Information has been received from a physician concerning a 16 year old female with no pertinent medical history and no history of drug reactions or allergies who on 18-JUN-2007 was vaccinated with the first dose of GARDASIL and on 10-JUN-2008 was vaccinated with the second dose of GARDASIL. On 10-JUN-2008 the patient was also given MENACTRA. Ten days after the second dose of GARDASIL (on 20-JUN-2008) the patient experienced joint pain and fatigue. Seventeen days after the second dose of GARDASIL (on 27-JUN-2008) the patient had a seizure. No adverse events reported after the first dose of GARDASIL was given. The patient sought medical attention by calling the physician's office. The physician reported that she noticed that patients who are given GARDASIL and MENACTRA usually have more side effects. She further stated she would not be administering the two vaccines together from now on. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested. 8/12/08-records received for DOS 6/27/08-Syncope. Presented after 1 episode found on floor with legs shaking. Vision blurred. Now continues with fatigue and dizziness. Impression: syncopal event induced seizures due to orthostatic hypotension.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **320841-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		30-Jul-2008	31-Jul-2008	FR	WAES0807USA04727	01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hodgkins disease

Symptom Text: Information has been received from a consumer adolescent female who in 2007 was vaccinated with a first dose of GARDASIL (batch number, route and site of administration not reported). Approximately one month after the vaccination, she was diagnosed with Hodgkin's lymphoma. She received chemotherapy (not specified) and no further doses of GARDASIL were administered. She recovered on an unspecified day. The event Hodgkin's lymphoma was considered to be other medical event. The other business partner numbers included: E200807007. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320843-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Jul-2008	14-Jul-2008	0	30-Jul-2008	11-Aug-2008	MT		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	MERCK & CO. INC.	0006U	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0389U	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Pallor

Symptom Text: Sitting in waiting room- starting feeling "like I'm going to pass out." Pale and sweaty. Patient laid down for app. 15 min. Felt better. Did state she had not eaten this AM.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **320845-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Mar-2008	Unknown		30-Jul-2008	11-Aug-2008	TN		23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB216AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1740U	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Patient given Hepatitis A #2 and HPV #3 on 3-28-08. Patient had positive pregnancy test 4-7-08.

Other Meds:

Lab Data:

History: NKA/none

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320865-1** **Related reports:** 320865-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-May-2008	23-May-2008	0	30-Jul-2008	11-Aug-2008	VA		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U(2/10/10)	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2582AA 5/12/09	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Disorientation, Erythema, Fatigue, Loss of consciousness, Nausea, Pallor, Rash macular, Vomiting

Symptom Text: Our daughter began throwing up in the school bathroom and passed out wihtin 90 minutes of receiving the vaccine. They loaded her in a wheelchair and took her to the nurse's office. She was pale, her skin was red and blotchy and her blood pressure had dropped significantly. She was disoriented and extremely nauseous. The immediate symptoms lasted for about 30 minutes with fatigue and naseua lasting for several hours.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **320865-2** **Related reports:** 320865-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-May-2008	23-May-2008	0	04-Aug-2008	12-Aug-2008	VA		19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2582AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Loss of consciousness, Vomiting

Symptom Text: One hour after meningitis and GARDASIL vaccines administered pt vomited and BP dropped, she passed out. (5/23/08) No redness for either site, no difficulty breathing.

Other Meds: none

Lab Data:

History: allergic rhinitis

Prex Illness: none

Prex Vax Illns:

Vaers Id: **320869-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	18-Mar-2008	25-Apr-2008	38	30-Jul-2008	11-Aug-2008	CA		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	?	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin papilloma, Vaccine positive rechallenge

Symptom Text: After second vaccine patient developed one wart on hand. It was treated and resolved. After third vaccine, patient broke out prolifically with warts across knuckles and fingers of both hands. Multiple treatments have not been successful.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320873-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Jul-2008	29-Jul-2008	1	30-Jul-2008	11-Aug-2008	WA		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: urticaria. RX benadryl prn

Other Meds:

Lab Data: none

History:

Prex Illness:

Prex Vax Illns: urticaria~HPV (Gardasil)~1~16~In Patient

Vaers Id: **320877-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Apr-2008	01-May-2008	30	30-Jul-2008	01-Aug-2008	CA		01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Aplastic anaemia, Contusion, Erythema, Fatigue, Night sweats, Rash generalised

Symptom Text: Tiredness, Night Sweats, Bruiseing, small red dots all over her body...they diagnosed her with having Aplastic Anemia.

Other Meds:

Lab Data: Aplastic Anemia

History: None

Prex Illness: None

Prex Vax Illns: Tiredness, night Sweats, bruising...~HPV (Gardasil)~NULL~12~In Patient

Vaers Id: **320892-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Aug-2007	Unknown		30-Jul-2008	08-Aug-2008	IA	IA08010	08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0127U	0	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0244U	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal distension, Abdominal pain upper, Dizziness, Headache, Myalgia, Oral intake reduced, Syncope, Tremor, Weight decreased

Symptom Text: Pt. received GARDASIL dose #1, #2, & #3 - after #3 pt. experienced stomach pain, protruding stomach, trouble after eating. Four times in the morning pt. walking to bathroom - lightheaded, fainted. Frequent c/o HA, pain in muscle mostly R leg, hands trembling. Pt. lost weight due to inability to eat because of pain. ER visit -> bloodwork, check for ulcer, UA tests within normal limits. Sxs continued. Then went to regular Dr. - went to GI specialist/surgeon. Scheduled upper & lower CAT scan of abd. Test NL expect showed ovarian cysts. Mom said news showed a story about a girl with similar symptoms. "I'm 100% convinced it's from the shot" per mom.

Other Meds: None

Lab Data: multiple tests - nothing showed up

History: NO -- Allergic to Z-PAC, amoxicillin

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320895-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Jul-2008	25-Jul-2008	1	30-Jul-2008	08-Aug-2008	MI		08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: C/o hives that started 36 hours after receiving GARDASIL. Pt also changed eye medication on that day from TOBRADEX ointment to TOBRADEX drops. Has h/o hives frequently gets them with viruses, "these are worse". Not ill. Tried BENADRYL & CLARITIN which did not help. Seen in office on 7/29/08 - for urticaria possible allergic rxn to GARDASIL or TOBRADEX drops. Rx given for hydroxyzine 25mg one Q6 hours prn, may also try ZYRTEC, prn QD.

Other Meds: TOBRADEX eye drops

Lab Data: None

History: Strabismus (s/p surgery 6/2008)

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320896-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Feb-2008	19-Feb-2008	1	30-Jul-2008	08-Aug-2008	DE		12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia, Syncope, Weight decreased

Symptom Text: Patient fainted after receiving GARDASIL #2. Patient complained of tingling & numbness of both legs below the knees ~1 day after GARDASIL #2. 8/4/08-records received -7/2/07-C/O chronic shoulder pain. 4/9/08-C/O tingling in legs from knees down. Exercising with 16 pound weight loss, possible reduced potassium intake. 4/30/08-continues with C/O tingling in both legs. 6/25/08-neurology consult-C/O pins and needles in bilateral lower extremities. Swims and runs competitively. C/O developed in March 2008. PE WNL except for minimally decreased pinprick sensation in lateral aspect of both feet.

Other Meds: None

Lab Data: CBC, CMP, Lyme titres, EMG, MRI of spine - all tests negative 8/4/08 records received-Electrodiagnostic studies normal. CBC WNL, Lyme titer negative. MRI lumbar spine normal.

History: Mild interm. asthma, recurrent urticaria 8/5/08-records received-Family history of multiple sclerosis.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320909-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		31-Jul-2008	01-Aug-2008	--	WAES0807USA04740	01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: DIED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Death, Fatigue, Injection site pain, Viral infection

Symptom Text: Information has been received from a physician concerning a 22 year old female who on an unspecified date was vaccinated with her third dose of GARDASIL. Subsequently the patient experienced soreness at the injection site and fatigue. The outcome of soreness at the injection site and fatigue was not reported. Two months after receiving her third dose of GARDASIL, the patient died. The cause of death was "viral insult to the heart". Unspecified medical attention was sought. Follow-up information was received via telephone call from the physician. The patient was a family member. She did not have the vaccination dates or lot numbers since she did not give them. The physician reported that the patient's mother thought that the patient died related to GARDASIL. She did not have the cause of death. The physician refused to provide patient information, information was gave to the coroner. The physician considered "viral insult to the heart" to be immediately life-threatening and disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320910-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		31-Jul-2008	01-Aug-2008	--	WAES0807USA04504	01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, LIFE THREATENING, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a physician concerning his patient's daughter who on an unspecified date was vaccinated with a dose of GARDASIL. The patient's mother told to the physician that her daughter died in her dorm room 4 days after receiving the dose. The physician did not have much information because he did not administer the vaccine and the patient's daughter was not his patient. The reporter did not know the name of the physician who administered the vaccine. The physician considered the event to be life threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 320915-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Mar-2008	04-Jun-2008	79	31-Jul-2008	01-Aug-2008	FR	WAES0807USA04909	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Confusional state, Disorientation, Gait disturbance, Hallucination, visual, Irritability, Nervous system disorder, Personality change, Retrograde amnesia, Sensorimotor disorder, Somnolence

Symptom Text: Initial and follow-up information has been received from a pediatrician concerning a 14 year old female with pollen allergy who on 17-MAR-2008 was vaccinated with the first dose of GARDASIL intramuscular into the upper arm, which was well tolerated. On 13-MAY-2008 was vaccinated with the second dose of GARDASIL intramuscular into the upper arm. On 04-JUN-2008 the patient experienced neurological into the upper arm. On 04-JUN-2008 the patient experienced neurological and sensoriomotor disorder including somnolence, personality change, gait instability, disorientation. The patient was hospitalized and received LORAZEPAM 0.7 mg. There were no inflammatory signs and EEG was normal and she recovered after two days. Information from the hospital form 04-JUN-2008 to 06-JUN-0208 was provided, which reported that after the patient's presentation to the outpatient department due to personality changes, the patient was decelerated, whiny and confused with visual hallucinations. Laboratory findings show benzodiazepine in urinary drug screening. Toxicology established LORAZEPAM of 0.18 ng/ml (therapeutic range: (0.08-0.25 ng/ml). The following day the patient was awake and orientated but retrograde amnesia persisted. An intake of LORAZEPAM was denied by the patient and the benzodiazepine level could not explain the remarkable clinical symptoms and the retrograde amnesia of the patient on the day of admission. The suggestion of the physicians to refer the patient to a child psychiatrist was rejected by the mother. The patient was discharged on 06-JUN-2008. The mother was advised of the necessity of further clinical diagnostics in an outpatient department. Other business partner numbers included: E2008-05763. Additional information has been requested.

Other Meds: LORAZEPAM

Lab Data: electroencephalography, normal; urine drug screen, 04Jun08, 0.18 ng, 0.08-0.25, For LORAZEPAM

History:

Prex Illness: Pollen allergy

Prex Vax Illns:

Vaers Id: **320916-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Jul-2008	26-Jul-2008	1	31-Jul-2008	11-Aug-2008	VT		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Rash

Symptom Text: Rash on various parts of body right thumb swollen.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320917-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Apr-2008	09-May-2008	14	31-Jul-2008	01-Aug-2008	OR	WAES0807USA05097	01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse for the pregnancy registry for GARDASIL concerning an 18 year old female with a history of chickenpox disease at age 5 and no allergies who on 25-APR-2008 was vaccinated with the first dose of GARDASIL 0.5 ml IM. The patient at the time of vaccination of the first dose indicated she was not pregnant. On approximately 09-MAY-2008, the patient found out she was pregnant. The patient started at an unspecified date and went to the hospital. The hospital informed her on 01-JUN-2008 the patient had a miscarriage. On 25-JUL-2008 the patient was vaccinated with the second dose of GARDASIL 0.5 ml IM. The patient sought medical attention and told the nurse at an office visit. Upon internal review, miscarriage was determined to be an other important medical event. Additional information has been requested

Other Meds: Unknown

Lab Data: beta-human chorionic

History: Chickenpox

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320918-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		31-Jul-2008	01-Aug-2008	--	WAES0807USA05148	01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Coma

Symptom Text: Information has been received from a vaccine specialist and a nurse practitioner (N.P.) concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL. Subsequently, on an unspecified date following vaccination with GARDASIL, the patient fell into a coma. The outcome of the patient was not reported. Upon internal review, coma was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320920-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		31-Jul-2008	01-Aug-2008	--	WAES0807USA04763	01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a 15 year old female who on an unspecified date was vaccinated intramuscularly with her third 0.5 ml dose of GARDASIL. Subsequently the patient experienced seizures. At the time of the report, the patient's seizures persisted. Unspecified medical attention was sought. Upon internal review, seizure was determined to be an other important medical event. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 320921-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	15-May-2008	30-Jun-2008	46	31-Jul-2008	01-Aug-2008	FR	WAES0807USA04733	01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blister, Dysgeusia, Facial paresis

Symptom Text: Information has been received from a general practitioner concerning a 22 year old female, with no relevant medical history reported, who on 15-MAY-2008 was vaccinated with the first dose of GARDASIL (lot # not reported) into the deltoid muscle. On 30-JUN-2008, she presented at the physician with vesicles on the tongue. Herpes virus infection was suspected (not confirmed). On 08-JUL-2008, she presented again with signs of facial paresis right (not specified). On 09-JUL-2008, she was admitted to hospital. The patient reported about taste disorder of the right half of the tongue ("bitter taste") having started 1,5 weeks before hospitalization, a "strange feeling" of the right half of the face. She couldn't close her right eye completely and during tooth brushing water run out on her mouth. Cerebral MRI showed inflammatory signs in the course of the right facial nerve. CFS showed normal results. Diagnosis of incomplete facial paresis right was established. Herpes virus IgM titres were negative. Prophylactic therapy with Aciclovir I.V. was initiated, but discontinued due to intolerance to this drug. Thereafter the patient was treated with prednisone. Logopedic therapy as carried out. On-17-jul-2008, the patient was discharged from hospital. She recovered completely (exact duration of symptoms not reported). A role of the vaccine was not discussed by the hospital physicians. Other business partners number included: E2008-06951. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, cerebral MRI: inflammatory signs in the course of the right facial nerve; diagnostic laboratory test, CSF: normal; diagnostic laboratory test, Herpes simplex virus IgM titres: Negative; diagnostic laboratory test

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 320922-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Jul-2008	23-Jul-2008	0	31-Jul-2008	01-Aug-2008	FL	WAES0807USA04755	13-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Eye rolling, Somnolence, Tremor

Symptom Text: Information has been received from a medical assistant concerning a 12 year old female with no pertinent medical history, drug reactions or allergies who in the morning of 23-JUL-2008 was vaccinated intramuscularly with a first dose of GARDASIL (Lot #63/0067X). In the afternoon of 23-JUL-2008, the patient was found by her sister on her bed having a seizure. The patient was taken to the emergency room. On the same day the patient recovered from seizure and was released from the emergency room. It was reported that vaccination with GARDASIL was discontinued. Follow-up information was received via telephone call on 28-JUL-2008 from the medical assistant. She did not know if the patient ate before or after the vaccination. She stated that the seizure occurred at night time. The patient went to the emergency room at a children's hospital. Diagnostic test and treatment from the hospital was not available. The patient was referred to a neurologist but there was no information from that appointment yet. The patient was suppose to return to the office after the neurology consult, but an appointment had not been scheduled. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested. 8/11/08-records received-presented to ED 7/24/08-C/O seizure like activity this evening, arms shaking and eyes rolling in back of head. Drowsy. DX: Seizure.

Other Meds: Unknown

Lab Data: Unknown 8/11/08-records received-Brain CT normal.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **320924-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-May-2008	20-May-2008	0	31-Jul-2008	01-Aug-2008	PA	WAES0807USA04477	01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Immediate post-injection reaction, Tonic clonic movements, Unresponsive to stimuli

Symptom Text: Information has been received from a physician concerning a 17 year old white female student with a history of syncope (February 2006), who after a check-up on 20-MAY-2008 was vaccinated with the first dose of GARDASIL (lot # 660387/1967U) into her left deltoid (route not reported). After vaccine was administered, the patient experienced dizziness then had a seizure with tonic movements. She was unresponsive 30-45 seconds then returned to baseline. After 10-15 minutes, the patient went to the waiting room. While talking to her, she stated "I can't hear you" and had another seizure lasting approximately 10-15 seconds. 911 was called. The patient was transferred to the emergency room (ER) via ambulance. She recovered and was referred to neurology. No testing was done in the ER. The patient was seen and discharged by the hospital's ER physician. Upon internal review, seizure with tonic movements and seizure were considered to be other important medical events. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Syncope

Prex Illness:

Prex Vax Illns:

Vaers Id: **320925-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	10-Dec-2007	18-Jan-2008	39	31-Jul-2008	01-Aug-2008	PA	WAES0807USA04054	03-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Aura, Contusion, Convulsion, Dizziness, Menstruation irregular, No reaction on previous exposure to drug, Pain, Paraesthesia, Syncope

Symptom Text: Information has been received from a licensed practical nurse concerning a 12 year old female with no known allergies or pertinent medical history who on 14-SEP-2007 was vaccinated in right arm with first dose of GARDASIL. (Lot# 658558/1061U). On 10-DEC-2007 was vaccinated in left arm with second dose of GARDASIL (Lot # 659055/1522U). There was no illness at the time of vaccination. The nurse reported the following the second vaccine of GARDASIL on 18-JAN-2008 the patient experienced seizure and on 05-FEB-2008 the patient experienced seizure. The patient did not receive other injections on or near those dates. Electroencephalogram (EEG) was performed (Unequivocal result). The patient is now on unspecified medication. On unspecified date the patient recovered. The patient sought medical attention "required emergency room/doctor visit". Upon internal seizures were determined to be an other important medical event. Additional information is not expected. 8/8/08-records received-presented to ED 1/18/08-passed out/seizure, head injury. Seizure occurred while walking to school. Bump on forehead. PE normal. Impression: Seizure activity. Contusion of forehead. 8/27/08-records received for DOS 2/15/08-has had only 1 menarche times 1 lasted for 1 day but none since last Gardasil vaccination. PE:normal. Assessment:one-time seizure versus syncope. multiple neurocutaneous lesions. Second seizure 3/4/08. 4/21/08-felt aura, dizzy and body tingled all over. Whole body aching afterwards. 9/2/08-records received for DOS 2/15/08-pediatric neurology clinic as a follow up to 1 time seizure-like episode. DX: One-time seizure. Versus syncope. Multiple neurocutaneous lesions.

Other Meds: Unknown

Lab Data: electroencephalography, Unequivocal result 8/8/08-records received-MRI brain normal.EEG on 1/22/08-borderline abnormal EEG somehwhat prominent sharp activity seen bilaterally left more than right. No clear cut spike discharges are noted. F

History: None 8/27/08-records received-PMH:headache once per month. Head trauma. Eczema.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320926-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-May-2008	01-May-2008	0	31-Jul-2008	01-Aug-2008	CA	WAES0807USA04840	01-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a 19 year old female, for the Pregnancy Registry for GARDASIL concerning herself with a history of ruptured spleen several years ago which was healed and no known drug reactions/allergies who in early May 2008, was vaccinated with a dose of GARDASIL. There was no concomitant medication. Subsequently the patient learned that she was pregnant. Her last menstrual period was on 09-MAY-2008 and the estimated delivery date was 13-FEB-2009. On 03-JUL-2008 the patient was hospitalized at a local hospital and had a miscarriage. The patient also sought medical attention in the physician's office. The patient's miscarriage was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic, ?/?/08 - confirmed

History: Splenic rupture

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320930-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Jul-2008	23-Jul-2008	0	31-Jul-2008	11-Aug-2008	MD		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2994BA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2994BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncopal episode 3-5 minutes after administration of TDap, Menactra and Gardasil, which lasted about 30 seconds. After episode she was fine.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: Syncopal episode~Tdap (no brand name)~~0~In Sibling|Syncopal episode~Meningococcal (Menactra)~~0~In Sibling

Vaers Id: 320931-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	25-Jul-2008	25-Jul-2008	0	31-Jul-2008	11-Aug-2008	--		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope after injection of HPV, was fine afterward. Had had no breakfast, food or drink this AM.

Other Meds:

Lab Data: EKG- normal

History: possible though unlikely allergy to Suprax 2000.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320932-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	24-Jul-2008	24-Jul-2008	0	31-Jul-2008	11-Aug-2008	NC		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB2680A	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1740U	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1907U	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site warmth, Local reaction

Symptom Text: Pt had a large local reaction. This included a 10 cm red indurated area with warmth and firmness at injection site. Patient improving with Benadryl.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320933-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		31-Jul-2008	11-Aug-2008	WI		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2553AA	0	Right arm	Intramuscular	TD
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site warmth

Symptom Text: redness, warmth started 1 day after immunization; only the menactra site was involved

Other Meds: Enbrel, Fioride, MV

Lab Data:

History: Juvenile Rheumatoid Arthritis

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320938-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	30-Jul-2008	30-Jul-2008	0	31-Jul-2008	11-Aug-2008	VA		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain, Pharyngitis, Pharyngolaryngeal pain, Pyrexia

Symptom Text: Patient started aching all over, fever increased to 102 during night. Also complained of sore throat in office the next day. Was evaluated by doctor on 7-31-08. Diagnosed with pharyngitis and possible adverse reaction to GARDASIL.

Other Meds: Taking Acutane

Lab Data: Rapid strep - negative

History: Allergies to Ephedrine. Treatment for acne.

Prex Illness: No

Prex Vax Illns:

Vaers Id: **320940-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Jul-2008	24-Jul-2008	0	31-Jul-2008	11-Aug-2008	MN		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Injection site pain, Injection site swelling, Oxygen saturation, Pallor, Presyncope

Symptom Text: About 17 minutes after the HPV vaccine administered, patient felt uncomfortable in the arm beneath her injection. She then said her arm mildly hurt and thought it looked swollen. Patient then felt it was hard to breathe. She became pale. She was close to fainting. After about 5 minutes she stated it felt better. Initial O2 sats were 99-100 d. She rested for 20 minutes and drank some mountain dew and was able to go home without difficulty.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320941-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	28-Jul-2008	28-Jul-2008	0	31-Jul-2008	11-Aug-2008	NE		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C274AA		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2543AA		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1978U		Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	0097X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Oedema peripheral, Rash

Symptom Text: Temperature, left arm swollen with rash.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **320942-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	30-Jul-2008	30-Jul-2008	0	31-Jul-2008	11-Aug-2008	CT	CT200805	11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1912U	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC525024CA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: Patient fainted in reception waiting to go home. She hit her head on the floor and had to be taken to ER for evaluation.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320953-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	29-Jul-2008	30-Jul-2008	1	31-Jul-2008	11-Aug-2008	CA		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Hypoaesthesia, Vision blurred, Visual disturbance, Visual field defect

Symptom Text: 07/30/08 8:00 pm patient started to experience some visions changes (blurry vision, seeing spots, decreased peripheral vision), at about 10:00 pm she had severe headache and numbness to bilateral hands and arms. Severe headache continued till about 2:00 am. Medicated with Tylenol 100 mg and Motrin.

Other Meds: Birth control pills

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320963-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Jul-2008	30-Jul-2008	0	31-Jul-2008	11-Aug-2008	AZ		11-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2572AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0063X	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B016BA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Feeling abnormal, Loss of consciousness, Pallor, Syncope

Symptom Text: ABOUT 4 MINS. AFTER IMMS. WE'RE GIVEN PT. LOOKED VERY WHITE AT THE FACE AND SHE REPORTED THAT SHE FELT FUNNY, WALKED TO HER MOTHER, AND THEN SHE FELL OUT WHILE IN HER MOTHER'S ARMS. SHE WAS OUT FOR ABOUT 2 SECONDS SHE CAME BACK RIGHT AWAY. I PLACED HER IN A CHAIR SHE REPORTED THAT SHE FELT FINE, PT. THEN WAS PLACED ON THE TABLE WITH HER MOTHER AT HER SIDE TO CALM DOWN, SHE DID GET A LITTLE EXCITED AFTER THE SYNCOPE EPISODE COOL CLOTH WAS APPLIED TO HER FOREHEAD SO THAT SHE FELL A LITTLE BETTER. DR. EXAMINED PATIENT AFTER EPISODE PATIENT WAS CLEARED BUT STILL HAD TO WAIT THE 15-20 MINS. STILL.

Other Meds:

Lab Data:

History: ASTHMA 3/04 ALLERGIC RHINITIS 3/04 HISTORY OF UTI 3/05

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **320970-1 (S)** **Related reports:** 320970-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	27-Jun-2008	27-Jun-2008	0	31-Jul-2008	05-Aug-2008	SD		13-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	1	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Dehydration, Muscle spasms, Oedema peripheral, Pain in extremity, Peripheral coldness, Petechiae, Pharyngitis, Skin discolouration, Tonsillitis

Symptom Text: Bad leg cramps and swelling in both legs. 8/11/08-records received for DOS 7/2-7/3/08-DC DX: Resolved leg pain. Petechial rash stopped to spread. Pharyngitis, tonsillitis resolving. Dehydration resolved. Presented with severe leg cramping, cold to lower extremities and bluish lower extremities. Developed rash day before admission. Sore throat, erythematous and swollen.

Other Meds:

Lab Data: 8/11/08-records received-WBC 14.1.

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **320970-2 (S)** **Related reports:** 320970-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	27-Jun-2008	27-Jun-2008	0	04-Aug-2008	05-Aug-2008	--	WAES0807USA05565	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Bacterial infection, Infectious mononucleosis, Movement disorder, Pain in extremity, Screaming, Splenomegaly

Symptom Text: Information has been received from a mother concerning her daughter, with no pertinent medical history and no drug reactions/allergies who on an unspecified date was vaccinated with the first dose of GARDASIL and on 27-JUN-2008 was vaccinated with the second dose of GARDASIL. There was no concomitant medication. The mother reported that the same night (on 27-JUN-2008) her daughter received the second dose of GARDASIL she began to develop leg pain. By 02-JUL-2008 the pain worsened and her daughter was screaming and could not move her legs. She was taken to the office of the Physician Assistant. Unknown blood work was done and she was diagnosed as having a "blood bacterial infection". she was given 2 double strength TORADOL for pain. Blood tests revealed that she had mononucleosis which had not been reported previously recognized with an enlarged spleen. She was taken to the ER and then admitted to the hospital where she received potassium and unspecified antibiotics. She was discharged on 03-JUL-2008 and prescribed MOTRIN and antibiotics. At the time of the reporting she was recovering. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory, 07/02/08 - blood test: mononucleosis; diagnostic laboratory, 07/02/08 - blood work: blood bacterial infection

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **320979-1** **Related reports:** 320979-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Jun-2008	30-Jul-2008	47	31-Jul-2008	11-Aug-2008	MI		11-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2428AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	08020	0	Right arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB377AA	2	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B015AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: 06-13-2008 Patient was in clinic for first HPV vaccine & other vaccines. A pre-administration urine pregnancy test was negative/ vaccine was given. Then on 7-30-2008, patient returned for HPV #2 and reports she is 3 months pregnant and says she knew that at the time of first vaccine, but did not report pregnancy. No additional vaccines given and no known effect at this time.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **320979-2** **Related reports:** 320979-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Jun-2008	13-Jun-2008	0	02-Apr-2009	03-Apr-2009	--	WAES0807USA05719	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female with no relevant medical history or allergies who on 13-JUN-2008 was vaccinated with a first 0.5 ml dose of GARDASIL intramuscularly (lot number and injection site not reported). There was no concomitant medication. Subsequently the patient was found to be pregnant. No problems reported. Unspecified medical attention was sought. Follow-up information was received from the nurse practitioner concerning the female patient. The nurse practitioner reported that they administered vaccine only and they are not primary provider. The nurse practitioner also reported that the pregnancy was electively terminated. Upon internal review, electively terminated pregnancy was considered to be an other important medical event. Additional information is not expected.

Other Meds: None

Lab Data: Urine beta-human

History:

Prex Illness: Pregnancy NOS (LMP = 5/21/2008)

Prex Vax Illns:

Vaers Id: **320981-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	31-Jul-2008	31-Jul-2008	0	31-Jul-2008	11-Aug-2008	IL		11-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0070X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2621AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B016BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Dizziness, Dyskinesia, Gaze palsy, Heart rate normal, Hypotonia, Nausea, Pallor, Unresponsive to stimuli

Symptom Text: With patient sitting in chair, Boostrix and Gardasil were administered simultaneously by the nurses. When Menactra was then administered, pt. had following symptoms for 1 minute - eyes rolled back, color became ashen, arms jerked twice, pt. was non-responsive and slumped in chair. Pt. then responded to verbal questions. She shook her head, "Yes", when asked if she was dizzy and nauseated. Pt followed verbal commands and was assisted to exam table and laid down. B/P - 94/64. Pulse - 68, regular. Cool compress applied to forehead. Pt. stated she felt better and drank approx. 3 ounces of water. Pt. rested on exam table for 20 minutes. At 11:50am - B/P - 96/52. Pulse - 64. Pt. was assisted from table and was able to walk without assistance. No further complaints voiced. Pt. left office, accompanied by mother.

Other Meds: None.

Lab Data: None.

History: None.

Prex Illness: None.

Prex Vax Illns:

Vaers Id: **320988-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	10-May-2008	20-May-2008	10	31-Jul-2008	11-Aug-2008	MI		22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Left arm	Intramuscular	
	TD	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Chills, Cough, Decreased appetite, Dizziness, Fatigue, Headache, Influenza, Myalgia, Pharyngitis streptococcal, Pharyngolaryngeal pain, Pyrexia, Rhinorrhoea, Syncope, Viral infection, Vitreous floaters, Vomiting, Weight decreased

Symptom Text: 5/20/08 - fever 103 and vomiting, 5/22/08 weak strep response and antibiotic given and got better, 5/25 101 fever and ER visit, high wbc count dx acute viral syndrome. After this extreme fatigue, anxiety, syncope (x2)in June and July, lightheadedness, weight loss (10 #), decreased appetite and floater in vision. 8/18/08-records received for DOS 5/25/08-presented to ED with C/O cough, sore throat, fever, chills, muscle aches and "flu" started 5 days agao. Diagnosed with Strep 4 days ago. Today developed fever. Nasal discharge. Moderate frontal headache. Impression:Acute viral syndrome.

Other Meds: none

Lab Data: 5/22 weak positive strep test, 5/25 increased wbc count, negative mono test, negative chest xray, 7/25 workup for syncope - all labs normal, eeg normal. Completing EKG at a future date. 8/18/08-records received-CBC normal, WBC 12.8, chemi

History: acne and seasonal asthma 8/18/08-records received-PMH: Asthma.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **320990-1 (S)** **Related reports:** 320990-2; 320990-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Dec-2007	08-Jan-2008	12	31-Jul-2008	06-Aug-2008	AZ		13-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446O	1	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Epilepsy, Fall, Grand mal convulsion

Symptom Text: Had seizure - grand mal - 11 days after GARDASIL. Diagnosed idiopathic generalized epilepsy, CT scan - NL. 11/10/08-EEG report received for DOS 1/10/08-first seizure 1/8/08-with fall to floor and generalized tonic clonic seizure.

Other Meds: None

Lab Data: Hosp for uncontrolled seizures, CT scan - NL, EEG - abnl - epilepsy 11/12/08-records received-EEG results:abnormal in presence of recurrent abortive bursts of 3Hz generalized spike-wave discharges. During hyperventilation, the bursts would

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320990-2** **Related reports:** 320990-1; 320990-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Dec-2007	27-Dec-2007	0	12-Aug-2008	13-Aug-2008	--	WAES0808USA01034	13-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 20-JUN-2007 was vaccinated with a first dose of GARDASIL (lot number, injection site and route not reported). On 27-DEC-2007 the patient was vaccinated with a second dose of GARDASIL by intramuscular injection (injection route not reported). On 08-JAN-2008, also reported as 11 days post-second dose, the patient experienced generalized seizure. On 08-JAN-2008, the patient went to emergency room. While at ER, an EEG was scheduled, a CT scan was actually performed and the results were unspecified. The physician reported that the patient's seizures were currently being controlled by a combination of medications, KEPPRA and other unspecified medication. The physician reported that the patient's last seizure was on 30-MAY-2008. The patient's outcome was not specified. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Computed axial, 08/01/08, unspecified

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **320992-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-Jul-2008	17-Jul-2008	10	31-Jul-2008	11-Aug-2008	NV		24-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1267U		Unknown	Intramuscular	
MNQ	SANOFI PASTEUR	U2548AA		Unknown	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B021CB		Unknown	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB280AA		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contusion, Idiopathic thrombocytopenic purpura, Injury

Symptom Text: Increased and very large bruises noted by patient - worse than her usual "easy bruising" around 1 1/2 week after shots. CBC showed ITP. Platelets = 22 on 7/21/08. Immunizations given 7/7/08. 9/15/08-records received-Outpatient infusion documentation received-treated with WINRho.9/22/08-records received for DOS 7/7/08-received vaccination. Regular periods. Begin BCP ortho-tri-cyclen.. Period 5-7 days heavy with clots. 7/28/08-Increased bruising and very large ones from minor trauma today. Symptoms began about 1 1/2 week ago with larger and more bruises. Feels fine. After vaccination on 7/7/08 felt little under the weather for 2 days.

Other Meds:

Lab Data: Differential normal. 9/15/08-records received-Platelets ranged from 16,000 to 166,000 on 8/9/08. 9/22/08-records received-Von Wilebrand's panel negative.

History: DUB; Acne; started on ortho tri-cyclen 7/7/08. PMH: migraines.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **320996-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Jul-2008	23-Jul-2008	1	31-Jul-2008	11-Aug-2008	PA		20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB2846A	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0067X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy, Headache, Migraine, Pyrexia

Symptom Text: Pt developed high fever for 48 hours of 104 degrees F. With high fever, pt had headache that then developed to migraine 3-4 days after HAV and HPV given. Symptoms continued despite high dose Motrin and Fioricet therapy until 7/30/08. Headache resolved but pt developed new onset of Bell's Palsy - sent to ED. 8/18/08-records received for DOS 7/31/08-DX: Bell's palsy. Presented to ED with C/O right sided facial droop.

Other Meds: None

Lab Data: 8/18/08-records received-CSF protein increased 48, Lyme total CSF 1.61, CSF RBC 5792, segmented neutrophils increased 63.6, Lyme EIA IGM 5.71, Lyme WB IGM positive, CSF culture negative. CT brain unremarkable.

History: None 8/18/08-records received- PMH: migraines.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321008-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Aug-2007	20-Feb-2008	177	01-Aug-2008	04-Aug-2008	FR	WAES0807AUS00277	04-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0734U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Central nervous system lesion, Headache, Paraesthesia

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form concerning a 16 year old female with a history of vague episode of paraesthesia (2004) who on 27-AUG-2007 was vaccinated with the first dose of GARDASIL (Lot No. 655743/0313U, Batch No. J1022, Expiry date, 08-AUG-2009). On 25-OCT-2007, she was vaccinated with the second dose of GARDASIL (Lot No. 657874/0582U, Batch No. J2299, Expiry date 26-FEB-2010). On approximately 18-FEB-2008, she was vaccinated with the third dose of GARDASIL (Lot No. 658214/0734U, Batch No. J2895, Expiry date 13-MAR-2010). On 20-FEB-2008 the patient experienced headache, central nervous system lesion and paraesthesia. It was described that approximately 2 days post vaccination with the third dose of the vaccine, the patient developed headache then 2 days later developed spinal sensory syndrome and paraesthesia. The patient was referred to a neurologist who identified particularly aggressive multiple lesions. On 20-JUN-2008, the patient's outcome was unknown. The agency considered that headache, central nervous system lesion and paraesthesia were possibly related to therapy with GARDASIL. The original reporting source was not provided. The agency considered the events to be serious for the following reason: medically significant. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Paraesthesia

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321010-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-Mar-2008	05-Apr-2008	9	01-Aug-2008	04-Aug-2008	FR	WAES0807USA05445	04-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Carcinoma in situ, Cervical conisation

Symptom Text: Information has been received from a general practitioner concerning an 18 year old adult female who on 27-MAR-2008 was vaccinated with her second dose of GARDASIL IM. 9 days later on 05-APR-2008 a cervical smear performed revealed a carcinoma in situ. The patient was treated with conization on 05-MAY-2008 and recovered without any sequelae. She had no concomitant treatment. Upon internal review, the event was considered to be an other important medical event. Other business partner numbers include E2008-07096. Additional information is requested.

Other Meds: Unknown

Lab Data: Cervical smear, 05Apr08, revealed a carcinoma in situ.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 321011-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	15-May-2008	30-Jun-2008	46	01-Aug-2008	04-Aug-2008	FR	WAES0807USA05433	04-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blister, Dysgeusia, Facial paresis, Feeling abnormal, Tongue disorder

Symptom Text: Information has been received from a general practitioner concerning a 22 year old female who on 15-MAY-2008 was vaccinated with her first dose of GARDASIL IM. On 30-JUN-2008 the patient presented at the physician with vesicles on the tongue. Herpes virus infection was suspected (not confirmed). On 08-Jul-08 she presented again with signs of facial paresis right (not specified). She was admitted to hospital on 09-JUN-08. The patient reported about taste disorder of the right half of the tongue ("bitter taste") having started about 1.5 weeks before hospitalization, a "strange feeling" of the right half of her face. She couldn't close her right eye completely and during tooth brushing water ran out of her mouth. Cerebral MRI showed inflammatory signs in the course of the right facial nerve. CSF showed normal results. Diagnosis of incomplete facial paresis right was established. Herpes virus IgM titres were negative. HSV and VZV IgG titres were positive in blood and "borderline" positive in CSF. Prophylactic therapy with Acyclovir I.V. was initiated, but discontinued due to intolerance to this drug. Thereafter the patient was treated with prednisone. Logopedic therapy was carried out. The patient was discharged from hospital on 17-Jul-2008. She recovered completely (exact duration of symptoms not reported). A role of the vaccine was not discussed by the hospital physicians. Other business partner numbers include E2008-06951. Additional information is expected.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, inflammatory signs of the right facial nerve; CSF VZV IgG Ab, positive; serum Herpes simplex virus IgG antibody, positive; serum Herpes simplex virus IgM antibody, negative; cerebrospinal fluid culture, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321012-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Jun-2008	25-Jun-2008	0	01-Aug-2008	04-Aug-2008	FR	WAES0807USA05388	04-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Hyperhidrosis, Loss of consciousness, Malaise, Nausea, Pallor, Syncope, Tonic clonic movements

Symptom Text: Information has been received from a local health authority (Reference number MA20081115) concerning a 14 year old female, with no relevant medical history, who on 25-JUN-2008 was vaccinated with the first dose of GARDASIL, (Lot #, Batch # not reported) via intramuscular. On 25-JUN-2008, 10 minutes after receiving the vaccination, the patient experienced syncope with loss of consciousness, malaise, tonic clonic movements, nausea, pallor, sweating and asthenia. On 25-JUN-2008, she was admitted in paediatrics emergency service, but there was no hospitalization. She had recovered without any sequelae within a few minutes. There was no post-critical status, no hypotonia, no confusion and no disorientation. Clinical examination was normal. Electrocardiogram and electroencephalography were also normal. Syncope with loss of consciousness, malaise, tonic clonic movements, nausea, pallor, sweating and asthenia were considered to be other important medical events. Other business partner numbers included: E2008-07113. Additional information has been requested.

Other Meds: Unknown

Lab Data: electrocardiogram, 25Jun08, normal; electroencephalography, 25Jun08, normal; diagnostic laboratory test, 25Jun08, Clinical examination: normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **321013-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Feb-2008	01-Feb-2008	0	01-Aug-2008	04-Aug-2008	FR	WAES0807USA04728	04-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Eating disorder, Gastritis, Gastrointestinal disorder, Nausea, Peripheral vascular disorder, Vomiting, Weight decreased

Symptom Text: Information has been received from a gynaecologist concerning a 15 year old female who in December 2007 was vaccinated with the first dose of GARDASIL (lot # not reported). Toleration was not reported. In February 2008, the patient received the second dose of GARDASIL (lot # not reported), intramuscular administration into her deltoid muscle. After the second vaccination, the patient experienced gastrointestinal and eating disorders and weight loss of 5 kg. She also experienced nausea, vomiting, and a peripheral circulatory disorder. Gynaecological examination and sonography of abdomen were normal. The patient was referred to a consultant for internal medicine. She was hospitalized on an unspecified date. According to the family physician, mild gastritis was diagnosed. The complaints were ongoing at the time of reporting. Other business partner numbers included: E2008-06318. No further information is available.

Other Meds: Unknown

Lab Data: gynecological examination, ??Feb08, Normal; abdominal ultrasound, ??Feb08, Normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321014-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	10-Jul-2007	Unknown		01-Aug-2008	05-Aug-2008	FR	WAES0807USA05412	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1024F	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Facial paresis, No reaction on previous exposure to drug

Symptom Text: Information has been received from a patient's mother that her daughter (age not reported) with arthritis who on 10-JUL-2007 was vaccinated with the first dose of GARDASIL (lot number 655671/1024F, batch number NE51790) which was well tolerated. On 11-SEP-2008, the patient was vaccinated with the second dose of GARDASIL (lot number 1475F, batch number NF37120), and experienced arthritis after that. On 08-JAN-2008, the patient was vaccinated with the third dose of GARDASIL (lot number 0277U, batch number NG00020) despite ongoing arthritis (see case E2008-07128). In April 2008, the patient developed left facial paresis and was hospitalized for 13 days. MRI and CSF results were normal. Facial paresis resolved but relapsed in JUN-2008. The patient was again hospitalized for 12 days. This time, CSF showed non-specific inflammation. At the time of reporting, the patient was not recovered. The mother turned to several doctors and asked whether the symptoms could be side effects of the HPV vaccine, the treating physicians however did not confirm this suggestion. The other business partner numbers included: E2008-06673.

Other Meds: None

Lab Data: magnetic resonance imaging, ??Apr08, normal; magnetic resonance imaging, ??Jun08, normal; spinal tap, ??Jun08, normal; X-ray, normal results; CSF plasmacyte observation, ??Apr08, normal; CSF plasmacyte observation, ??Jun08, non-specific inf

History:

Prex Illness: Arthritis

Prex Vax Illns:

Vaers Id: 321015-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Jul-2008	25-Jul-2008	0	01-Aug-2008	05-Aug-2008	PA	WAES0807USA05050	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 25-JUL-2008 was vaccinated with GARDASIL, (Lot # 660553/0070X), 0.5 ml, IM. Concomitant therapy included "Sulodine". On 25-JUL-2008, within minutes after being vaccinated, the patient fainted and then had a seizure. She was revived and almost immediately fainted again. The physician states that the patient has recovered. No other information was available. Upon internal review, seizure was considered as other important medical event. Additional information has been requested.

Other Meds: (therapy unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321016-1 (S)** **Related reports:** 321016-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Feb-2008	18-May-2008	88	01-Aug-2008	05-Aug-2008	--	WAES0807USA04553	16-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Axillary vein thrombosis, Coagulation factor V level, Contraception, Oedema peripheral, Pain in extremity, Skin discolouration

Symptom Text: Information has been received from a consumer concerning a 17 year old female with sulfur allergy and asthma who on 11-JUL-2007 was vaccinated with the first GARDASIL (lot # 657868/0523U), on 05-SEP-2007 with the second dose of GARDASIL (lot # 658490/0802U) and on 20-FEB-2008 with the third dose of GARDASIL (lot # 657868/0523U). Concomitant therapy included montelukast sodium. On 18-MAY-2008, the patient experienced blood clot at the injection site after getting the third shot of GARDASIL vaccine and was hospitalized for one day. On an unspecified date the patient recovered from blood clot at the injection site. The laboratory diagnostics study performed was blood work, factor 5 test (results not reported). The patient sought medical attention. Additional information has been requested. 10/16/08-records received for DOS 5/15-5/16/08-DC DX: Right axillary venous thrombosis. Etiology may be a hypercoagulable state from the NuvaRing versus a hypercoagulable syndrome or thrombophilia. Presented with 1 week history of pain in right arm and mild discoloration to right arm with subsequent swelling.

Other Meds:

Lab Data: None 10/16/08-records received-Doppler study revealed clot in right axillary area. D-dimer 905.

History: 10/16/08-records received-PMH: asthma.

Prex Illness: Sulfonamide allergy; Asthma

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321016-2** **Related reports:** 321016-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	--	WAES0807USA03611	07-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Thrombosis

Symptom Text: Information has been from a registered nurse concerning a female who was vaccinated with the third dose of GARDASIL. Subsequently the patient experienced blood clots three months after receiving the third dose of GARDASIL. The dates of administration and lot number were not known. No additional was provided. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321017-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	29-May-2008	05-Jun-2008	7	01-Aug-2008	05-Aug-2008	FR	WAES0807USA04445	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1068U	2	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hypoaesthesia, Inappropriate schedule of drug administration

Symptom Text: Information has been received from an agency (HA ref# PEI2008010529) concerning a 28 year old female who on 08-NOV-2007 was vaccinated with the first dose of GARDASIL (Lot # not reported). On 24-JAN-2008, the patient was vaccinated with the second dose of GARDASIL (Lot # not reported). No adverse effect occurred after the first and second doses of vaccination. On 29-MAY-2008, the patient was vaccinated with the third dose of GARDASIL (Batch # NG42070; Lot # 1068U) into the left arm. On 05-JUN-2008, the patient experienced numbness of the left arm. On an unspecified date the patient was hospitalized, and was diagnosed with "Suspicion of muscle disease of the left upper arm". Cardiac infarction was ruled out. At the time of the report the patient had not recovered. Other business partners included: E2008-06888. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321018-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		01-Aug-2008	05-Aug-2008	--	WAES0807USA04440	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	UNK	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia, Pharyngeal hypoaesthesia

Symptom Text: Information has been received from a nurse practitioner concerning an approximately 13 year old female patient who was vaccinated with a dose of GARDASIL. Following vaccination the patient experienced numbness and tingling in the throat. The patient received other vaccinations at the same visit. The nurse practitioner administered epinephrine and the patient recovered. It was unknown if the patient sought medical attention. Upon internal review numbness and tingling in the throat treated with epinephrine was determined to be an other important medical event. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321019-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	19-May-2008	Unknown		01-Aug-2008	05-Aug-2008	FR	WAES0807MYS00008	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bone neoplasm malignant, Chemotherapy

Symptom Text: Information has been received from a health professional (nurse) concerning a 19 year old female who on 19-MAy-2008, was vaccinated with the first dose of GARDASIL, 0.5mL, intramuscular injection. In July 2008, the nurse followed-up with the patient regarding the second dose. However, the nurse was told by the husband that the patient was undergoing chemotherapy for bone cancer at another hospital. The nurse does not known when the patient was diagnosed with bone cancer. The nurse also does not know if the patient was on any concomitant medications. The patient was married without children. The reporter felt that bone cancer was not related to therapy with GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 321038-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Aug-2007	06-Aug-2007	5	01-Aug-2008	07-Aug-2008	NH		29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	2	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Cerebrovascular accident, Coma, Convulsion, Diabetes mellitus, Endotracheal intubation, Extubation, Facial paresis, Gastrointestinal tube insertion, Grand mal convulsion, Haemorrhage intracranial, Headache, Hemiparesis, Mouth injury, Nausea, Sinus disorder, Steroid therapy, Subarachnoid haemorrhage, Thrombectomy, Thrombosis, Tinnitus, Tongue biting, Visual disturbance

Symptom Text: Following the vaccine a blood clot formed in my brain. I suffered a stroke and a seizure. An emergency thrombectomy was attempted. I was in a coma for two weeks, followed by months of PT and OT. I still suffer from seizures. 9/26/08 Reviewed hospital medical records of 8/9-8/29/2007. FINAL DX: superior sagittal sinus thrombosis; bilateral frontal hemorrhage. Records reveal patient experienced progressively worsening HA x 3 days w/visual changes, tinnitus & nausea. Tx w/Benadryl, steroids & ASA at outlying hospital. Developed right side facial & limb weakness, had generalized tonic-clonic seizure & was intubated prior to transfer. Had tongue laceration. Tx w/anticoagulant drip, antiseizure meds, antibiotics & steroids. Interventional radiology debulked clot but unable to reestablish blood flow. Developed steroid induced diabetes & tx w/insulin. Neuro & clinical exam slowly improved. Extubated 8/22 & on tube feedings until 8/28 when transitioned to PO. Transferred to inpatient rehab.

Other Meds: oral contraception

Lab Data: hypercoagulation panel was negative LABS: CT of head w/bilateral ICH w/SAH extension. CTA w/SSS thrombosis. Hypercoagulation panel (-). Blood c/s neg. Sputum c/s w/pseudomonas & staph. Urine c/s w/e.coli. Echocardiogram WNL. EEG W

History: none PMH: contraception. Non-smoker. Overweight. Migraines.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **321044-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Apr-2008	16-Apr-2008	2	01-Aug-2008	11-Aug-2008	TN		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Decreased appetite, Diarrhoea, Dizziness, Fatigue, Feeling cold, Headache, Menstrual disorder, Mood altered, Muscle spasms, Muscular weakness, Nasal congestion, Orthostatic hypotension, Pain, Pain in extremity, Palpitations, Vision blurred, Weight decreased

Symptom Text: Fatigue, weight loss of 16 pounds, bilateral leg pain. 8/22/2008 MR received from PCP. OV 5/21/2008 for c/o 16lb wt loss over the past 6 weeks and fatigue. ROS (+) for headache, blurred vision, orthostatic hypotension, heart palpitations, muscle cramps, diarrhea after eating full meals, bilateral leg aches and weakness, dizziness on arising, decreased appetitite. Pt describes not feeling fun and decreased participation in activities. Feels cold and having difficulty with menstual cycles. PE (+) for nasal congestion. Assessment: Weight loss-sinusitis vs depression vs chronic inflammatory process. OV 7/10/08 still c/o muscle weakness in upper thighs since 3rd Gardasil. Other sx improving.

Other Meds:

Lab Data: Labs and Diagnostics: LDH 186. CRP <0.1. Echo WNL for age with trivial pericardial effusion. Free T4 0.97. TSH 0.91. EBV IgGAB (+), IgM (-). CBC and chem unremarkable.

History: Coronary cameral fistula . PMH: Family hx of anxiety, depression, Bipolar d/o. NKDA

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321045-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	29-Jan-2007	01-Mar-2007	31	01-Aug-2008	11-Aug-2008	KY		14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0011U	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	W976AB	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Alopecia, Hyporeflexia, Joint range of motion decreased, Joint swelling, Musculoskeletal stiffness, Neck pain, Rash, Rheumatoid arthritis, Skin infection, Skin lesion, Synovitis

Symptom Text: Developed a progressive symmetrical arthritis. Diagnosed Rheumatoid Arthritis in September 2007. Symptoms began probably in Spring. Treatment is ongoing. 8/18/2008 PCP recs received with vax rec. Seen for WCC 1/29/07 with normal exam, no concerns. RTO 6/6/07 with c/o rash x 4wks. Light brown rash of circular lesions noted on upper back, chest. ? skin infection tx with Loprox. HPV #2 given. 10/10/2008 Rheumatology consult records received with DX: Rheumatoid Arthritis. Seen 10/15/07 with c/o joint pain and swelling, morning stiffness and decreased ROM mainly in the fingers, toes and hands with (+) RF and CCP. PE (+) for joint swelling and tenderness, DTRs +1 in upper extremities. Having difficulty with Ultimate Frisbee and climbing bunk bed. Return visit 11/16/07 with increased # of joints affected. PE (+) for significant synovitis, knees now affected. Seen 3/27/08 with neck pain, likely muscular and mild hair loss. Tx: Plaquenil, Mtx, and TNF inhibitors with some relief.

Other Meds: PPO

Lab Data: Elevated sedimentation rate and CRP, Rheumatoid factor and anti CCP positive 60s. Labs and Diagnostics: RF 65, ANA (-), CRP 1.29, ESR 22, anti-CCP > 60. Parvo B19 IgG 5.16, IgM 0.13.

History: None. PMH: none, tonsillectomy as child. NKDA

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321047-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Apr-2008	07-Apr-2008	0	01-Aug-2008	11-Aug-2008	IN		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site urticaria

Symptom Text: Pt returned for 3rd dose of GARDASIL (HPV) vaccine and reported on questionnaire that she broke out in hives around injection site after 2nd dose on 4.07.08, relieved with ice pack. Denied any difficulty breathing. Indicated allergy to honey on 4.07.08. This writer decided not to give 3rd dose.

Other Meds:

Lab Data: None

History: Allergy to honey

Prex Illness: None

Prex Vax Illns:

Vaers Id: **321048-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Jun-2008	13-Jun-2008	10	01-Aug-2008	11-Aug-2008	AL		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	MERCK & CO. INC.	AHBVB360AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1788U	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0820U	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Headache sent to Neurologist

Other Meds: Femlin, lexapro

Lab Data: Neurologist

History:

Prex Illness: Headache

Prex Vax Illns: HA~HPV (no brand name)~3~16~In Patient

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321052-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	28-Jul-2008	28-Jul-2008	0	01-Aug-2008	11-Aug-2008	TX		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1777U	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1967U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Chills, Dizziness, Oral intake reduced

Symptom Text: While in waiting area had asked for something to drink and couldn't drink water, chills and weak. Escorted to treatment room complaint of dizziness. Vital signs monitored and assessed patient while in room.

Other Meds:

Lab Data: B/P 133/90, 80 pulse

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321053-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-Jul-2008	28-Jul-2008	0	01-Aug-2008	11-Aug-2008	AZ		11-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1758U	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2658AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0525X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Loss of consciousness, Muscle twitching, Paraesthesia

Symptom Text: Pt became dizzy with tingling sensation "all over" 1-2 minutes post injections. Pt proceeded to lose consciousness for 3-5 sec. with 1-2 secs. of twitching. Pt regained consciousness immediately post injections and appears alert & oriented at this time. HR-76 Resp Rate-20 B/P-120/78. Waited 20 minutes after injections.

Other Meds: Walgreen's multi-symptom cold medicine

Lab Data:

History: None known

Prex Illness: Cold symptoms with cough

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321076-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	31-Jul-2008	31-Jul-2008	0	01-Aug-2008	11-Aug-2008	MN		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Syncope

Symptom Text: Patient waited for 15 minutes, did not have symptoms. Drove home, started having symptoms of fainting and dizziness. Parent reported that the child barely made it home without passing out. Had a difficult time getting out of the vehicle. Parent report that the child was feeling better later in the day.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321079-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Aug-2008	01-Aug-2008	0	01-Aug-2008	11-Aug-2008	FL		11-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	02540AA	1	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2997AA	1	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0525X	2	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0229X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Fall, Laceration, Muscle twitching, Sluggishness, Unresponsive to stimuli

Symptom Text: Approximately 1 minute after vaccination, patient fell forward onto floor and severed lip. Immediately began to twitch. Patient appeared to be having seizure-like movements similar to absence seizure. She was not verbally responsive however, patient was breathing spontaneously. The patient was moved from the floor into a chair after 5 minutes and was able to maintain eye contact. It took her approximately 10 minutes to respond verbally to her mother's commands. The patient and parent were in the examination room more than 30 minutes after the incident, however patient remained sluggish.

Other Meds: None

Lab Data: none

History: Atopic Dermatitis

Prex Illness: None

Prex Vax Illns:

Vaers Id: **321085-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Aug-2008	01-Aug-2008	0	01-Aug-2008	11-Aug-2008	NC		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0847X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Loss of consciousness, Pallor

Symptom Text: Became pale diaphoretic, and passed out. Was out for a minute. Layed on floor for 10 min and recovered well. Went home from clinic after 15 more minutes of recovery.

Other Meds:

Lab Data: NA

History: NA

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321086-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-May-2008	30-May-2008	1	01-Aug-2008	11-Aug-2008	IA		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	HEP

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Cold sweat, Dizziness, Hyperhidrosis, Peripheral coldness, Retching, Syncope

Symptom Text: The vaccine was given at approximately 5:00pm without incident. At 6:00am the next morning, the patient awakened with what she described as the worst stomach ache she'd ever had. She quickly became cold, clammy, diaphoretic, light-headed, faint and began retching. After about 15 minutes, this all passed and she felt OK.

Other Meds: none

Lab Data: None

History: none

Prex Illness: no

Prex Vax Illns:

Vaers Id: **321100-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Dec-2007	15-Dec-2007	0	01-Aug-2008	11-Aug-2008	MI		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Disturbance in attention, Dizziness, Feeling abnormal, Head discomfort, Headache, Heart rate increased, Hypoaesthesia, Hypoaesthesia facial, Migraine, Paraesthesia, Swelling, Thinking abnormal, Vaccine positive rechallenge, Visual disturbance

Symptom Text: A day or two after receiving the first Gardasil shot, I experienced a headache on the left side of my head, concentrated in the mid-to-frontal lobe. The headache improved a bit with over-the-counter medication. About two weeks after receiving the shot, I was sitting in class when all of a sudden my right hand went numb and a portion of my right lip and chin. It was very difficult to comprehend the instructor and I could not spell any of the notes I was taking down. The episode lasted only about 10 to 15 minutes. After this episode, I continued to have the headaches-it felt like the left side of my head was heavy and full. The left part of my neck and scalp were also enlarged. After this, I went to my primary care physician, not thinking that the shot and headache were related. The headaches alarmed me because in the past I had headaches very rarely, and never a migraine. My physician diagnosed me with migraines and gave me a prescription medication for tension headaches. She said that if the medication did not work, I should get a CT scan of my head. In the next three months I continued having the headaches-they came on in episodes: first I would start to not think as clear and my hands and arms would sometimes start tingling or feeling numb. During a few of the episodes there were changes in the vision of my right eye-blurs of color. I would take the migraine medicine and the symptoms improved within an hour. I also had a rapid heart rate, and when I worked out, often felt dizzy. A weird effect: when I drank coffee, the headache would become severe- I used to drink at least two cups of coffee a day with out much effect. In March, I received a second Gardasil shot and the severe headache returned as in the first time and I was very dizzy and a bit faint (I realize that some of these minor side effects are listed in the Gardasil info pamphlet). I decided to get the CT scan and the results were normal. I felt reassured by these results and the fact that the symptoms improved over the next few month

Other Meds: birth control

Lab Data: Ct scan-normal

History: asthma

Prex Illness:

Prex Vax Illns:

Vaers Id: 321102-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Sep-2007	15-Sep-2007	10	01-Aug-2008	11-Aug-2008	WI		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Convulsion, Disorientation, Epilepsy, Fall, Gaze palsy, Musculoskeletal stiffness, Postictal state, Tongue biting, Tremor, Urinary incontinence

Symptom Text: Allison received the series of Gardasil vaccines beginning 6/07. The second vaccine was administered 9/5/07. Ten days following Allison had a seizure for the first time in her life. There is no family history of seizures. Allison was taken to the hospital, had a follow up appointment with her pediatrician and referred to a neurologist (Dr. Inglese). Testing completed at that time was within normal expectations. A second seizure occurred in January '08. After additional testing recommended by another neurologist in the same practice (Dr. Sosa), Allison has now been diagnosed with a seizure disorder and is taking medication to prevent the seizures from reoccurring. The Gardasil vaccine was the only difference from her normal routine and without the family history of seizures, I question the vaccine. 8/19/2008 MR received from consulting neurologist including ER record from 9/15/2007 and OVs to 6/18/2008 with DX: Primary Generalized Epilepsy. Pt had 1st seizure 9/15/2007. Pt's eyes glassed over and pt developed full body shaking and stiffening. Pt fell off couch, bit tongue and was incontinent of urine. PE WNL except bite on tongue. DX: Seizure-new onset. Neuro consult 9/20/07 notes equivocal EEG, but will not start meds at this time. 2nd seizure 1/17/2008 lasting 2-3 minutes with post ictal confusion and disorientation. Started on anti-seizure med. F/U 2/22/08 now dx with generalized epilepsy, most likely juvenile myoclonic epilepsy without myoclonus. F/u 6/18/08 no further seizures.

Other Meds: none at the time of the vaccine or seizure

Lab Data: CT Scan, EEG, Ambulatory EEG, MRI, blood and urine samples. Labs and Diagnostics: EEG abnormal. Head CT unremarkable. CBC and Chemistries WNL. MRI brain WNL with inflammatory changes c/w chronic sinusitis in L frontal and ethmoid sinuses.

History: none. PMH: headaches, T&A, chin injury/chipped tooth. Family hx of seizure in maternal 2nd cousin

Prex Illness: none

Prex Vax Illns:

Vaers Id: **321108-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Aug-2008	01-Aug-2008	0	01-Aug-2008	11-Aug-2008	AZ		12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1264U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Incorrect dose administered, Overdose

Symptom Text: Patient was given a fourth dose of HPV gardisil inadvertently because documentation in patient's chart was done poorly. Patient has not had any adverse reaction to date but the CDC asked us to fill out an adverse event about the incident.

Other Meds: None

Lab Data: none

History: NKDA

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321117-1** **Related reports:** 321117-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Apr-2008	14-Jun-2008	46	02-Aug-2008	12-Aug-2008	CA		09-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	1237AA	1	Right arm	Unknown	HPV4
	HPV4	MERCK & CO. INC.	144W	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Grand mal convulsion

Symptom Text: My daughter is 16 yrs old and on Feb 27, 2008 had her first HPV vaccine and the second one April 24, 08. On June 14-08 I heard my dog barking in the living room I went to see what he was barking at and I found my daughter lying on the carpet having a seizure. At the time this was happening I did not know she was having a seizure because she doesn't have a history of seizure problems. I thought my daughter was dying in my arms of course I dialed 911 and she was taken to the Emergency room. We have under gone several tests CAT scan, EEG, MRI, spinal tap, blood work and currently seeing a neurologist. The test have came back all negative and now she has to take medicine for epilepsy. The first medicine the ER put her on was phenytoin sodium. Now she is taking Keppra., I had ask her primary doctor if there could be some connection to having taking the HPV vaccine her answer was that there has been no evidence or research to prove that the HPV vaccine can cause seizures. The doctor also said she probably has epilepsy. Wow this has been my daughter's doctor since she was 5 yrs old. My daughter is an outgoing teenager who has plans to graduate from high school and go on to a 4 year college. She is active in sports and plays the violin. I would definitely like to know why the medical field will not even consider that the HPV vaccine may have cause the complications. 11/19/08 MR received from PCP which include neuro consult. Seen 6/16/08 in F/u for ER visit 6/14/08 with DX: Seizure/Probable Epilepsy. Started on phenytoin in ER. Seen 7/10/08, now on Keppra. Seen for brownish scaley macules on back, chest, neck. Dx: Seizure d/o. Tinea versicolor. Seen 7/14/08 for c/o back pain. PE (+) for decreased ROM upon flexion. Dx: Muscle spasm. Neuro consult dated 6/24/08 for eval of generalized tonic-clonic seizure on 6/14/08 and another on the morning of the exam. No memory of event. Headache and tiredness after. PE WNL. Sent for MRI. 12/2/08 Additional records received from Neuro. No new codes.

Other Meds:

Lab Data: All test came back normal. Labs and Diagnostics: Spinal tap unremarkable. EEG WNL. MRI brain. CBC WNL. ANA (-). ESR 2

History: n/a

Prex Illness: no

Prex Vax Illns:

Vaers Id: **321129-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		01-Aug-2008	04-Aug-2008	FR	WAES0807USA05810	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Tongue paralysis, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician (reference # RA-026-2008) concerning a 15 year old female who on an unspecified date in February 2008, was vaccinated with the first dose of GARDASIL (lot # not reported) intramuscularly. The patient had tongue paralysis after this dose on an unspecified date in FEB-2008. On an unspecified date in APR-2008, the patient received the second dose of GARDASIL (lot # not reported) intramuscularly, site of injection not reported. On an unspecified date after vaccination the patient had tongue paralysis. The patient was submitted to a neurological examination with electroencephalogram (EEG). It was reported that she had recovered on an unspecified date. Additional information received reported that upon a phone conversation with the parent, the EEG was normal. Neurological exam was normal. The physician considered the event as not related to the vaccine. According to the physician the adverse event was associated with the patient's fear of needles and medical intervention in general, leading psychological factor triggering this event. The third dose of GARDASIL was scheduled. Upon internal review tongue paralysis was considered to be an other important medical event. Other business partner numbers include E2008-05126. Additional information was not available.

Other Meds: Unknown

Lab Data: neurological examination, ??Apr08, normal; electroencephalography, ??Apr08, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321133-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-Mar-2008	05-Mar-2008	0	01-Aug-2008	11-Aug-2008	TX		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site atrophy

Symptom Text: Muscle/tissue atrophy at injection site almost immediately apparent - after 5 months approximately has not resolved. Patient had Kenalog injection 2 days prior at another injection site.

Other Meds: YAZ; Claritin; Adderall

Lab Data: None

History: NKDA; Seasonal allergies

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321138-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Jul-2008	24-Jul-2008	1	01-Aug-2008	11-Aug-2008	SC		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Headache, Vomiting

Symptom Text: Gardasil administered on 07/23/08. Patient developed headache, vomiting and diarrhea early AM on 07-24-08. Came to see MD on 07-24-08 and saw that per vaccine information the symptoms could be related to shot.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321140-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	29-Jul-2008	29-Jul-2008	0	01-Aug-2008	11-Aug-2008	CA		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Partial seizures

Symptom Text: Partial seizure immediately after vaccine given.

Other Meds: KARIVA

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321147-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Aug-2008	01-Aug-2008	0	01-Aug-2008	11-Aug-2008	WA		11-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB222AA	1	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1905U	1	Right arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B015AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Angioedema, Lip swelling

Symptom Text: Angioedema of upper lip.

Other Meds:

Lab Data: No

History: H/O mild asthma

Prex Illness: No

Prex Vax Illns:

Vaers Id: 321165-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Oct-2007	02-Nov-2007	32	04-Aug-2008	05-Aug-2008	FR	WAES0807AUS00283	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Altered state of consciousness, Convulsion, Headache, Leukoencephalomyelitis, Personality change

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form concerning a 21 year old female with a history of relapsing-remitting multiple sclerosis with two episodes of diplopia in October 2004 and February 2007, who on 01-AUG-2007 was vaccinated with the first dose of GARDASIL. On 01-OCT-2007 the patient was vaccinated with the second dose of GARDASIL. On 02-NOV-2007 the patient developed leukoencephalomyelitis and was hospitalised. It was described that the patient developed acute disseminated encephalomyelitis (ADEM) with rapid onset of personality change, headache, generalised seizure and altered conscious state. Magnetic Resonance Imaging (MRI) was done which showed confluent carotid enhancing white matter lesions. The patient was treated with 5 day intravenous methylprednisolone and oral steroid trial. At the time of reporting to the agency on 18-JUL-2008, the patient had recovered from the leukoencephalomyelitis. The agency considered that leukoencephalomyelitis was possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, Comment: confluent carotid enhancing white matter lesions

History: Relapsing-remitting multiple sclerosis; Diplopia

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321166-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	13-May-2008	Unknown		04-Aug-2008	05-Aug-2008	CA	WAES0807USA04374	28-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U		Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a female (age unknown), who was vaccinated with a dose of GARDASIL. Subsequently, the patient experienced seizure like symptoms. The patient sought unspecified medical attention from the physician. The physician reported that the patient was not going to continue the rest of the series. The patient recovered on an unspecified date. The physician considered the seizure like symptoms to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321167-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		04-Aug-2008	05-Aug-2008	--	WAES0807USA04805	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Paralysis

Symptom Text: Information has been received from a physician concerning a 13 year old female, the daughter of a friend, who on an unspecified date was vaccinated with a first dose of GARDASIL (route and administration site not reported). Subsequently the patient developed intermittent paralysis. The patient was recovering from the intermittent paralysis. The patient was seen by her physician. Upon internal review the intermittent paralysis was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 321168-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	26-Mar-2007	01-Jul-2008	463	04-Aug-2008	05-Aug-2008	FR	WAES0807USA05391	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1475F	2	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Kidney fibrosis, Kidney transplant rejection, Lymphocytic infiltration, Nephritis interstitial, No reaction on previous exposure to drug, Tubulointerstitial nephritis

Symptom Text: Information has been received from a health authority (HA ref no. PEI2008010664), concerning an 18 year old female patient, who underwent renal transplantation in 2005, was vaccinated with the third dose of GARDASIL (Batch #NF37120) into the left upper arm (route not reported) on 28-SEP-2007. Beginning July 2008, the patient developed interstitial nephritis (transplant kidney). The patient was hospitalized. Laboratory testing revealed the following values at peak on 08-JUL-2008: Urea 170mg/dL (normal: 10-50), creatinine 5.19 mg/dL (normal <1.20) and CRP 21.9 mg/L (normal 0.0-5.0). An acute transplant rejection was also considered by the reporter and is also consistent with the result of the renal biopsy was provided (performed on 10-JUL-2008). The pathologist found extensive plasma-lymphocytic infiltrates, mild eosinophila, interstitial edema and signs of multifocal tubulitis. Mild interstitial fibrosis was seen. The pathologist diagnosed acute rejection type 1 B according to the Banff classification (2005). There was no sign for a vascular transplant rejection. The final outcome was not reported. the first dose of GARDASIL (Batch #NE24240 and Lot #654884/0902F) and the second dose of GARDASIL (Batch #NE51790 and Lot #655671/1024F) were given IM into the left upper arm on 26-MAR-2007 and 25-JUN-2007, respectively, without problems. This case is closed. Other business partner numbers included: E200807013. No further information is available.

Other Meds: Unknown

Lab Data: renal biopsy, ext plasma-lymphocytic infiltrates, mild eosinophilia, interstitial edema/ signs of multifocal tubulit; serum C-reactive protein, 08Jul08, 20.7 mg/L, 0.0-5.0; serum C-reactive protein, 08Jul08, 21.9 mg/L, 0.0-5.0; serum blood

History: Renal transplant

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321169-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	27-Jun-2008	27-Jun-2008	0	04-Aug-2008	05-Aug-2008	--	WAES0807USA05565	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Bacterial infection, Infectious mononucleosis, Movement disorder, Pain in extremity, Screaming, Splenomegaly

Symptom Text: Information has been received from a mother concerning her daughter, with no pertinent medical history and no drug reactions/allergies who on an unspecified date was vaccinated with the first dose of GARDASIL and on 27-JUN-2008 was vaccinated with the second dose of GARDASIL. There was no concomitant medication. The mother reported that the same night (on 27-JUN-2008) her daughter received the second dose of GARDASIL she began to develop leg pain. By 02-JUL-2008 the pain worsened and her daughter was screaming and could not move her legs. She was taken to the office of the Physician Assistant. Unknown blood work was done and she was diagnosed as having a "blood bacterial infection". she was given 2 double strength TORADOL for pain. Blood tests revealed that she had mononucleosis which had not been reported previously recognized with an enlarged spleen. She was taken to the ER and then admitted to the hospital where she received potassium and unspecified antibiotics. She was discharged on 03-JUL-2008 and prescribed MOTRIN and antibiotics. At the time of the reporting she was recovering. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory, 07/02/08 - blood test: mononucleosis; diagnostic laboratory, 07/02/08 - blood work: blood bacterial infection

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321170-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		04-Aug-2008	05-Aug-2008	FR	WAES0807USA05652	05-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Neck pain, No reaction on previous exposure to drug, Visual disturbance

Symptom Text: Information has been received from a general practitioner concerning an adolescent female who was vaccinated with the first dose of GARDASIL which was well tolerated. The patient was vaccinated with the second dose of GARDASIL (lot #, route, injection site not reported) several months ago. After vaccination, exact onset not reported, the patient developed unspecified vision disorder, diffuse neck pain and headache. The patient was hospitalized. Lumbar puncture was carried out, Guillain-Barre syndrome was excluded. "Increased inflammation parameters" in CSF were detected. The outcome was not reported. Other business partner number include: E2008-07140. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, increased inflammation parameters in CSF

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321182-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	20-Dec-2007	21-Dec-2007	1	04-Aug-2008	11-Aug-2008	GA		11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Migraine, Neurological examination

Symptom Text: Since having all three GARDASIL shots my daughter has suffered from severe migraines and had to a neurologist to get them under control and now has to take daily medication.

Other Meds:

Lab Data:

History: none

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321183-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	18-Apr-2008	01-May-2008	13	04-Aug-2008	11-Aug-2008	LA		14-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Cough, Epistaxis, Headache, Migraine, Multiple allergies, Neurological examination normal, Ophthalmological examination normal, Pain, Pharyngolaryngeal pain, Sinusitis, Sneezing, Upper respiratory tract infection

Symptom Text: My daughter was given the final GARDASIL shot, for a month or so after she suffered from migraines and body aches. 8/12/08 Reviewed PCP medical records of 10/9/2007- 4/25/2008. FINAL DX: none provided. Records reveal pt c/o of cough, sore throat & possible dyslexia on 10/9/2007. Dx w/URI. Had right ankle sprain 11/2007. Dx w/URI on 12/13/2007. HA & cough 1/2008, injured wrist at school & went to ER 2/08 where dx w/wrist sprain, continued w/intermittent but almost daily HA & stomach ache, allergies. On 4/18/08 dx w/HA & allergies. Referred to Neuro & Ophtho, both exams (-). Developed cough & nosebleeds w/sneezing. Dx w/sinusitis. VAX: HPV #3, lot #1968U given IM LA on 4/18/2008; HPV #2, lot #1062U given on 12/13/2007 IM LA; HPV #1, lot # 0522U given on 10/9/2007 IM LA; & Fluzone #2437AA given 10/9/2007 IM RA.

Other Meds:

Lab Data: Had blood work, ct scan, saw several specialists over the course of a month. LABS: CT scan of head (-). Cholesterol 180 (H). ALT 29(H)

History: Only pre-existing conditions were mild pollen allergies, which gave her nose bleeds, and allergic to albuterol.

Prex Illness: HA & allergies

Prex Vax Illns:

Vaers Id: **321188-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Jul-2008	29-Jul-2008	0	04-Aug-2008	12-Aug-2008	MA		12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure normal, Dyskinesia, Heart rate normal, Hyperhidrosis, Oxygen saturation normal, Pain, Postictal state, Somnolence, Syncope

Symptom Text: After HPV, pt. had fainting episode with brief jerking generalized lasted for a few seconds. Laid down. Diaphoretic. Responded to voice, flat voice, but sleepy. O2 sat OK. P 66, BP WNL, +c/o pain with light touch. Postictal x10 min. Then alert to date, day events.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 321192-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	25-Jul-2008	26-Jul-2008	1	04-Aug-2008	12-Aug-2008	NY		12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Body temperature increased, Chest discomfort, Headache, Lymph node pain, Myalgia, Pharyngolaryngeal pain

Symptom Text: Increased temp. 101.5 degrees --> 102 degrees orally, chest heaviness. Severe muscle & joint pain, tender lymph nodes, sore throat, headache.

Other Meds: ORTHO TRICYCLEN OC

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321199-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Jul-2008	21-Jul-2008	0	04-Aug-2008	12-Aug-2008	PA		12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB284CA		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2632AA		Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024EA		Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1559U	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1486U		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient received her vaccines and did not wait the recommended 15 minutes at the office. At ~10:30 upon reaching the parking lot patient suffered brief syncopal episode per mom's report. No fall or injuries sustained.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321215-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Apr-2008	01-Apr-2008	0	04-Aug-2008	12-Aug-2008	NJ		12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Muscle twitching, Pain in extremity, Paraesthesia, Pyrexia

Symptom Text: Today when secretary called mother to remind her of child's appt 8-4-08 for GARDASIL #3. Mother told secretary that child had left arm pain after vaccine on same day and "tingling of fingers" on left hand. That night child had fever. The next day child had a very bad headache and "muscle twitches" in back. Patient refused next GARDASIL vaccine.

Other Meds: None known

Lab Data: None known

History: None

Prex Illness: None (per pre vaccine questionnaire

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321218-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Jul-2007	13-Aug-2007	21	04-Aug-2008	12-Aug-2008	NE		09-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	C2770AA		Right arm	Unknown	
HPV4	MERCK & CO. INC.	0384U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Arthralgia, Dizziness, Fatigue, Joint stiffness, Juvenile arthritis, Oedema peripheral, Osteopenia, Pain in extremity, Pyrexia, Soft tissue disorder

Symptom Text: Pt had severe fatigue, fever, stomach aches, dizziness. She missed 20 days of school in 2007/2008 during her 3 series of shots. In March 2008, she was diagnosed with Juvenile Rheumatoid Arthritis, which can be set off by a live virus. She had symptoms through all 3 shots until March of 2008. 8/15/08 Reviewed PCP medical records of 9/1994-5/2008. FINAL DX: polyarticular juvenile inflammatory arthritis. Records reveal patient experienced usual state of good health on 7/23/2007. Next office note is for 3/6/08 for bilateral hand pain she had for 4-5 mo. Had been seeing podiatrist for ankle pain that patient experienced for several months. Exam at that time revealed diffuse fusiform swelling symetrically of both hands esp in PIP joints of fingers. Referred to rheumatologist & consultant records included. Symptoms at that time included pain & stiffness in multiple joints incl hands, wrists & ankles w/stiffness esp bad in mornings. Started on methotrexate. Referred for second opinion which is also included. Missed 20 days of school due to current symptoms. Agreed w/diagnosis. Increased meds & referred to PT/OT. Returned to initial rheumatologist for continued f/u. Minimal improvement & started Humira & serial labs.

Other Meds:

Lab Data: LABS: RF (-). ESR 34 (H), CRP 1.2 (H). X-rays of hands revealed soft tissue swelling & osteopenia.

History: None PMH: Eczema. Family hx RA, psoriasis, Crohn's disease & kidney stones.

Prex Illness: None

Prex Vax Illns: Same~HPV (Gardasil)~UN~13~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321221-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Jul-2008	29-Jul-2008	0	04-Aug-2008	12-Aug-2008	NC		12-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2614AA	0	Right arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB238AA	0	Left arm	Unknown	
HPV4	MERCK & CO. INC.	0070X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Cold sweat, Dizziness, Eye rolling, Flushing, Heart rate normal, Immediate post-injection reaction, Musculoskeletal stiffness, Pallor, Unresponsive to stimuli

Symptom Text: Patient received at 4:45 pm HPV #1. Immediately she stiffened and eyes rolled back. This lasted one minute. Patient could not respond. On exam had face with extreme palor and BP 100/64. Patient laying down. Patient was always on exam table. Then became flushed but skin was cool and clammy. Patient then could talk and said she "felt very faint". Heart rate was normal throughout. Benadryl 12.5/5 10 ml PO given by mouth. Patient aware of surroundings color improved, flushing resolved. Repeat BP was106/70. Current time is 5:12 pm. Event lasted about 22 minutes. Patient is able to drink a soda. Is sitting up and talking. Last BP was 100/60 sitting up. End time is 5:17. Repeat BP - this time standing up at 5:20 BP 100/60. Patient alert - says feels fine. Patient will go home.

Other Meds: Imitrex this am

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **321224-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	04-Aug-2008	04-Aug-2008	0	04-Aug-2008	12-Aug-2008	GA		12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Pt. was checking out after vaccine given and became faint. Skin dry, no pallor noted. BP 100/52. After remianing in office for an additional 15 minutes, felt fine and left office, Will return in 4 months for last injection.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321258-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Aug-2008	Unknown		04-Aug-2008	12-Aug-2008	IN		12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	2	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2570AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Local reaction, Pain, Tenderness

Symptom Text: Localized pain and tenderness (severe) Rt. arm.

Other Meds:

Lab Data:

History: allergic to sulfa, penicillin

Prex Illness:

Prex Vax Illns:

Vaers Id: **321262-1** **Related reports:** 321262-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Jul-2007	01-Aug-2007	7	04-Aug-2008	12-Aug-2008	IL		17-Mar-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0930U	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U23179BA	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2758AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Adverse drug reaction, Angiopathy, Chest pain, Cognitive disorder, Dizziness, Dysuria, Headache, Hypertonic bladder, Intervertebral disc disorder, Loss of consciousness, Mydriasis, Neurogenic bladder, Optic neuritis, Paraesthesia, Urinary incontinence, Visual disturbance, Visual field defect

Symptom Text: 8/07 - bladder symptom - later diagnosed as neurogenic bladder; 9/07 - Optic neuritis /Headaches; 10/07 - cognitive decline; Possible diagnosis - Multiple Sclerosis 8/26/08 Reviewed neurologist medical records of 11/1/07-7/14/2008 which included ophtho & PCP medical records. FINAL DX: optic neuritis & MS Records reveal patient experienced left eye dilated, HA w/sharp pains. Had been seen by ophtho whose records are also included for decreasd color & peripheral vision. Seen in ER for chest pain, dark vision, dizziness & had passed out x 2. Had used imitrex & Topamax for HA & then developed chest pain. Initial neuro consult had been done prior to ER for HA. ER Dx: adverse effects of medication; vascular HA; chest pain secondary to AE of medication. D/C to home. Developed hand/foot tingling & dysuria w/overactive bladder. By 3/2008 HA had almost completely resolved but continued w/bladder frequency & stress urinary incontinence. Referred to urogynocologist & dx w/neurogenic bladder. Referred to second opinion neuro & uro.

Other Meds: Allegra D; Prevacid

Lab Data: MRI x3, EEG, Evoked potentials, extensive blood work, urodynamics testing LABS: MRI/MRA of brain & spine c/w optic neuritis; thoracic spine w/multiple small Schmorl's nodes. Renal US WNL. Voiding cystourogram abnormal. EEG mildly abn

History: Seasonal allergies, History lactose intolerance/GERD/Entrobacter coli 4/06 PMH: GERD. Irregular menses. Allergies: environmental allergies, shrimp & crab. Family hx of heart disease.

Prex Illness:

Prex Vax Illns:

Vaers Id: **321262-2** **Related reports:** 321262-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Jul-2007	01-Aug-2007	6	07-Aug-2008	08-Aug-2008	IL	WAES0808USA00236	11-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL. Concomitant vaccinations included MENACTRA and DTaP (unspecified). But it was unknown at the time of report if the other vaccinations were administered at the same time. On an unspecified date, the patient developed multiple sclerosis (MS). Upon internal review, multiple sclerosis was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321265-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	03-Jul-2008	14-Jul-2008	11	04-Aug-2008	12-Aug-2008	NY		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Contusion, Dyspnoea, Fatigue, Idiopathic thrombocytopenic purpura, Lupus-like syndrome, Petechiae, Steroid therapy

Symptom Text: sudden onset bilat arthralgia; PE-neg labs-decreased platelet; refer hematologist decreased C3-C4-prednisone therapy increased DS DNA; refer rheumatologist 8/15/08 Reviewed PCP medical records which consisted of consultant records & labs. FINAL DX: ITP & probable drug induced lupus Heme/onc records reveal patient experienced joint aching & bruising. Tx w/steroids. Rheumatology records reveal patient evaluated for possible lupus erythematosus. Patient experienced extreme joint pain & fatigue that started several weeks after vaccinations. Then developed petechia on hands & feet which resolved w/steroids. ALso w/mild dyspnea.

Other Meds: ORTHOTRICYCLEN LO

Lab Data: PE-neg labs-decreased platelet; decreased C3-C4; increased DS DNA LABS: 7/16 WBC 3.9(L), H/H 12/35(L), plts 26K(L), ESR 23(H). C-3 57(L); C-4 5.0(L). Initial ANA (+) w/homogeneous pattern. RF (-). Alk Phos 41(L) Cardiac CRP 10.8 (H)

History: Nutrasweet PMH: Metrorrhagia. Contraception. infectious mononucleosis 2006. Seizure after receiving nutrasweet in childhood. anal fissure 2006. Family hx of lupus, RA, cancer & HTN.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321266-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Jul-2008	31-Jul-2008	1	04-Aug-2008	12-Aug-2008	IA	IA08012	12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	2641AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Reports developed sharp pain at collarbone region. States was constant yesterday but today is only when laughs or takes a deep breath.

Other Meds: none

Lab Data: none

History: (See #18)

Prex Illness: none acute-mom stated has cyst on ovary getting checked out on Monday 8/4

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321267-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Jul-2008	21-Jul-2008	0	04-Aug-2008	12-Aug-2008	TX		12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Malaise, Pyrexia

Symptom Text: High fever, 101-102 with malaise and fatigue for 36 hours beginning the night after vaccine given that morning.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321268-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Aug-2007	15-Aug-2007	1	04-Aug-2008	11-Aug-2008	AR	AR0833	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB106DA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Asthma, Bronchitis, Chest pain, Cholecystectomy, Cough, Dizziness, Gastroenteritis, Headache, Musculoskeletal chest pain, Pharyngolaryngeal pain, Pleurisy, Pyrexia, Wheezing

Symptom Text: Received Hep A and HPV vaccine on 08/14/07. On 8/15 she began c/o pain (R) side. Saw doctor. Pts LFT's were elevated. Pain continued. Saw doctor again in Dec 2007 and LFT's were still elevated. Ultrasound showed sluggish gall bladder. Gall bladder removed on March 14, 2008. Still has pain. Surgeon told pt it could be the shots. 8/26/08 Reviewed PCP medical records of 8/13/07-7/29/2008. FINAL DX: none provided Records reveal patient experienced sore throat, rhinorrhea, irregular menses & on 8/13 BCP changed. RTC on 10/16/07 w/dizziness, HA, sore throat, left chest pain, wheezing, nonproductive cough, fever x 1 wk. Dx w/asthma, bronchitis & left lateral chest pain. Tx w/antibiotics.RTC next day w/increased left chest wall pain which increased w/inspiration. Dx w/bronchitis & pleurisy. Tx w/meds. Developed gastroenteritis. RTC 7/29/08 w/diffuse abdominal pain x 1 mo. Had gallbladder removed 3/2008 & been seen in ER for abdominal pain. Tx w/meds.

Other Meds: None

Lab Data: Increased LFT's LABS: 10/07 lymphs 69%(H). 12/07 & 1/08 ALT 37(H). CXR 10/07 WNL. CBC 7/08 showed lymphs 56%(H), monos 8.8(H), granulos 34%(L), absolute basos 0(L). Repeat CBC 7/29/08 WNL.

History: Asthma PMH: Irregular menses, acne, contraception. Asthma & allergies. Mononucleosis in childhood. Scoliosis.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321269-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	21-Jul-2008	21-Jul-2008	0	04-Aug-2008	12-Aug-2008	ID	ID08033	12-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0070X	0	Left arm	Unknown	
MNQ	SANOFI PASTEUR	42404AA	0	Left arm	Unknown	
TDAP	SANOFI PASTEUR	C2771AA	5	Right arm	Unknown	
VARCEL	MERCK & CO. INC.	0169X	0	Right arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB233AA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dyskinesia, Tension

Symptom Text: Vaccinations given with patient laughing, bright affect. After vaccinations completed patient got up and moved to another seat so a sister could be vaccinated. After setting vaccinations on table, I and nurse heard gurgling noises and turn to see patient body tense up and jerk. Pts eyes closed. This lasted approx. 10 seconds. Pt then relaxed body, opened eyes and said "I got dizzy". Had pt assessed by RN and referred to medical clinic.

Other Meds:

Lab Data:

History: NKA

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321270-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Jun-2008	19-Jun-2008	1	04-Aug-2008	12-Aug-2008	ID	ID08031	12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2561AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Headache, Pruritus generalised

Symptom Text: EMS called-unable to communicate with pt. language barrier. EMS ? H.A. Pt. with cough and itching all over-started tonight. Pt. on meds for TX x almost 3 months. cool mask applied

Other Meds: INH 300 mg

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321285-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		05-Aug-2008	06-Aug-2008	--	WAES0807USA04849	06-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Paralysis

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a third dose of GARDASIL. The physician reported that a lawyer friend of hers mentioned on 17-JUL-2008 that a girl getting paralyzed after her 3rd shot of GARDASIL. She is currently still in the hospital (duration unspecified). There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321286-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jul-2008	01-Jul-2008	0	05-Aug-2008	06-Aug-2008	--	WAES0807USA04601	06-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Blindness, Convulsion, Disorientation, Fatigue, Headache, Immediate post-injection reaction, Nausea, Pallor, Syncope

Symptom Text: Information has been received from an unspecified source ("someone who is not part of the clinic") concerning a 15 year old (reported by the source as a 16 year old) female who was vaccinated at the clinic with GARDASIL. The unspecified source told the Company representative that it was reported on television that the patient experienced "fainting and seizure like movements" after receiving GARDASIL. The unspecified source recounted the news report stating the patient was supervised in the office after the vaccine was given for about an hour and was released to home. The patient had "splitting headache" and "fatigue" that persisted for about one week after the fainting incident. According to the archived television program, the patient was a healthy, athletic 15 year old who in approximately July 2008 was taken to the clinic by her mother for a routine physical. As part of her exam, she was offered GARDASIL. When the mother asked about the side effects, she was told only about possible redness and soreness. Almost immediately after getting the vaccination, something went very wrong. The patient stood up and couldn't see anything. She fainted and began having seizure like motions. For several moments, the patient was thrashing on the examining room floor. When she woke up, the patient didn't know where and who she was. She was very pale. At first the clinic staff had her sit on the ground, and then eventually had her sit on the table. The patient then became nauseous. After more than two hours, the patient was sent home. Her parents were afraid to let her sleep. It took five days for the patient to get over the migraine-like headaches and debilitating loss of energy. The Company representative attempted to contact the clinic for follow up, but was unable to get anyone to verify the incident. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321287-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Sep-2007	12-Sep-2007	6	05-Aug-2008	06-Aug-2008	FR	WAES0807AUS00274	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0138U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Diplopia, Hypoaesthesia facial, Monoparesis, Myelitis transverse, Nausea, Vomiting

Symptom Text: Information was obtained on request by the Company from the agency concerning a 16 year old female who had received a total of 3 doses of GARDASIL (not all vaccination dates were reported). Her first 2 vaccinations included one given on 10-MAY-2007 (Lot No. 655742/0138U, Batch No. J0798, Expiry date 07-AUG-2009). On 06-SEP-2007, she was vaccinated with her third dose of GARDASIL (Lot No. 655742/0138U, Batch No. J0799, Expiry date 07-AUG-2009). On 12-SEP-2007 the patient experienced asthenia (described as left leg weakness), myelitis transverse (described as incomplete transverse myelitis), diplopia, hypoaesthesia facial (described as facial numbness), monoparesis, nausea and vomiting. At the time of reporting to the agency on 10-JUL-2007, the outcome of asthenia, myelitis transverse, diplopia, hypoaesthesia facial, monoparesis, nausea and vomiting was unknown. The agency considered that asthenia, myelitis transverse, diplopia, hypoaesthesia facial, monoparesis, nausea and vomiting were possibly related to therapy with GARDASIL. The original reporting source was not provided. The agency considered the events of asthenia, myelitis transverse, diplopia, hypoaesthesia facial, monoparesis, nausea and vomiting to be serious for the following reason: medically significant. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 321288-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	12-Jun-2008	19-Jun-2008	7	05-Aug-2008	06-Aug-2008	IA	WAES0807USA05139	04-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anxiety disorder, Condition aggravated, Hallucination, auditory, Headache, Nocturnal fear

Symptom Text: Information has been received from a licensed practical nurse as told to her by the patient's mother concerning a 12 year old female with no known drug allergies and a history of headaches, who on 12-JUN-2008 was vaccinated with the first dose of GARDASIL (lot # 654272/0073X), 0.5 mL, IM into her left deltoid. On approximately 19-JUN-2008, the patient developed the following behavioral symptoms: increase in the frequency of headaches, auditory hallucinations and fear of sleeping in the dark. The patient was hospitalized for an unspecified period of time and treated with unspecified medication. She continued taking medication to relieve the behavioral symptoms. No other symptoms or treatment reported. At the time of reporting, the patient was recovering. Additional information has been requested. 8/28/08-records received for DOS 7/17-7/19/08-DC DX:Anxiety disorder (NOS). Admitted with C/O having images in her head of people killing her. She was not seeing the them but they were images in her head. Tends to be a worrier. Strong family history of anxiety with panic attacks. Admitted for observation and participation in group therapy.

Other Meds: Unknown

Lab Data: Unknown

History: 8/28/08-records received-PMH-Attention-deficit hyperactivity disorder inattentive subtype.

Prex Illness: Headache

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321289-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		05-Aug-2008	06-Aug-2008	--	WAES0807USA05108	06-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paralysis

Symptom Text: Information has been received from a physician who reported that a parent of one of her patient's told her that on 21-JUL-2008 that she heard a news story on a television station geared toward Hispanics, that "about 90" girls were paralyzed on GARDASIL. Upon internal review, paralysis was considered an other important medical event. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321290-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Feb-2008	23-Jun-2008	143	05-Aug-2008	06-Aug-2008	PA	WAES0807USA05280	06-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abortion spontaneous, Blood test, Drug exposure during pregnancy, Ultrasound scan

Symptom Text: Information has been received from a consumer for the pregnancy registry for GARDASIL, concerning her 18 year old daughter who in February 2008, was vaccinated with the first dose of GARDASIL 0.5 ml for HPV prophylaxis. Concomitant therapy included nadolol. On an unspecified date, the physician was unaware the patient was pregnant and vaccinated her with the second dose of GARDASIL. The consumer reported that on approximately 23-JUN-2008, her daughter had a miscarriage after getting the second dose of GARDASIL; and had to stay in the hospital for 5 to 6 days. The patient was 4 and a half months pregnant. On an unspecified date, a blood work and ultrasound were done (results not provided). Her LMP was 15-FEB-2008 and EDD was 21-NOV-2008. The patient sought medical attention. Additional information has been requested.

Other Meds: nadolol

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 2/15/2008)

Prex Vax Illns:

Vaers Id: 321291-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Nov-2007	12-Apr-2008	156	05-Aug-2008	06-Aug-2008	FR	WAES0807USA05441	06-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Back pain, Blindness, Bone pain, Dizziness, Fall, Headache, Neurological examination normal, Optic neuritis, Physiotherapy, Vision blurred

Symptom Text: Information has been received from a gynecologist concerning a 16 year old female with a history of dizziness postural (2006), who on 05-SEP-2007 was vaccinated with the first dose of GARDASIL intramuscular (lot no. not reported) and on the same day was vaccinated with hepatitis B virus vaccine rHBsAg intramuscular. The second dose of GARDSASIL (lot no. not reported) was administered on 08-NOv-2007 and the third dose of GARDASIL (lot no. not reported) on 08-MAY-2008. Since 12-APR-2008 the patient complained of increasing blurred vision of the right eye. A few days later, on 17-APR-2008, she complained of complete loss of vision on her right eye, accompanied by intense headache. Outpatient neurological and ophthalmic exams showed no pathologies (no exact results reported), but high dose prednisone therapy (manufacturer unknown) 1000 mg, intravenous daily, was initiated (suspected diagnosis "optic neuritis"). Because of the side effects, nausea and dizziness, the mother refused this therapy after 3 days. The patient was hospitalized from 22-APR-2008 to 25-APR-2008. Cranial magnetic resonance imaging and cerebrospinal fluid showed normal results, as well as an electroencephalography performed on 24-APR-2008 and visual evoked potential performed on 25-APR-2008. On 05-MAY-2008, the patient fell on her back and had pain of the cervical spine with headache and dizziness. She went to see an orthopedist and also complained of pain in the lumbar spine since the lumbar punction performed on 22-APR-2008. The patient was treated with physiotherapy. On 17-JUL-2008, the patient again had an ophthalmologic check up, this time in a ophthalmologic department of a hospital. Fixation was good with both eyes and also Lang stereo test was completely positive (proof for intact stereoscopic vision). According to the ophthalmologist, "aggravation' of the symptoms must be considered; he evoked the diagnosis of "schoolgirl syndrome" and suggested psychotherapy. Other business partner numbers included: E2008-07071. Additional information ha

Other Meds: Unknown

Lab Data: ophthalmological, 17Apr08, Comment: definite good fixation and lang stereo test was completely positive; magnetic resonance imaging, 18Apr08, Comment: normal results; head and bone marrow; spinal tap, 18Apr08, Comment: normal results; elect

History: Dizziness postural

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321292-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Nov-2007	15-Mar-2008	134	05-Aug-2008	06-Aug-2008	FR	WAES0807USA05875	06-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0253U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraception, Meningitis viral, No reaction on previous exposure to drug

Symptom Text: Information has been received from a general practitioner concerning an 18 year old female who on 05-JUN-2007 was vaccinated with her first dose of GARDASIL which was well tolerated. On 02-NOV-2007 the patient was vaccinated with her second dose of GARDASIL, lot no. 0253U, into the upper arm. Concomitant medication included contraceptives. On 15-MAR-2008 the patient developed viral meningitis. The patient recovered completely within one week. The reporter considered the reaction unlikely related to the vaccine. Upon internal review, viral meningitis was considered to be an other important medical event. Other business partner numbers include E2008-06905. The case was closed.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321293-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Mar-2007	03-May-2007	36	05-Aug-2008	06-Aug-2008	FR	WAES0807USA05874	06-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Inflammation, Malaise

Symptom Text: The case is poorly documented and only partially confirmed by a physician. Information has been received from a consumer concerning her 18 year old daughter who on 28-MAR-2007 was vaccinated with her first dose of GARDASIL (lot no., route, injection site not reported). Since 03-MAY-2007 the patient "has been sick for several times". On 30-MAY-2007, the patient was vaccinated with a second dose of GARDASIL (lot no., route, injection site not reported). On 04-JUL-2007, the patient experienced sickness and abdominal pain and blood sample showed inflammation (no otherwise specified). On 12-SEP-2007, another blood sample was taken which was not normal (finds were not specified). On 14-SEP-2007, the patient was hospitalized until 21-SEP-2007. This information was confirmed by a physician. The outcome was not reported. Other business partner numbers include E2008-07120. Additional information is expected.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 04Jul07, signs of inflammation; diagnostic laboratory test, 12Sep07, not normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321294-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Jun-2008	22-Jun-2008	0	05-Aug-2008	06-Aug-2008	FR	WAES0807USA05896	06-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Gaze palsy, Immediate post-injection reaction, Loss of consciousness, Pallor

Symptom Text: Information has been received from a health care professional concerning her daughter a 17 year old female with no relevant medical history reported who on 22-JUN-2008 was vaccinated with the first dose of GARDASIL IM on the deltoid muscle. No concomitant administration with other medications or vaccines. Immediately after vaccine administration the patient experienced dizziness, then she sat resting her head backwards, she became pale and her eyes rolled back into her head, she lost consciousness presenting with convulsive movements in her arms (described by the reporter as not tonic-clonic movements, different from those of an epileptic seizure). The events lasted for approximately 15-20 seconds after which she recovered. No medication was used to treat adverse event. The events were considered medically relevant by the reporter and were considered to be other important events. Other business partner numbers included: E2008-07260. No further information is available. The case was closed.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321300-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Jul-2008	30-Jul-2008	0	05-Aug-2008	12-Aug-2008	IL		12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure, Cold sweat, Dizziness, Fall, Heart rate decreased, Pallor, Syncope

Symptom Text: After receiving HPV (#1) to L delt., pt walked to reception area & "felt dizzy" & fell to floor. Skin pale, clammy & cool. BP 70/40, P 48, faint. Assisted to supine position x20 mins until fully recovered.

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321305-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	28-Jun-2008	10-Jul-2008	12	05-Aug-2008	12-Aug-2008	MO		12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Pain, Pain in extremity

Symptom Text: Started with c/o bilat arm pain, shooting up about 2 wks after injection. Couldn't lift arms due to pain.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **321309-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	28-Jul-2008	28-Jul-2008	0	05-Aug-2008	13-Aug-2008	NY		13-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Fatigue, Headache, Muscular weakness, Vision blurred

Symptom Text: Pt developed HA that evening. Severe-went to sleep. Next day while exercising developed extreme fatigue, muscle weakness, SOB, blurred vision & dizziness. Symptoms are resolving today (7/30/08). Pt is a collegiate athlete.

Other Meds: ORTHO-NOVUM 1/35

Lab Data:

History: NKDA

Prex Illness: No

Prex Vax Illns:

Vaers Id: **321310-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Jul-2007	23-Sep-2007	68	05-Aug-2008	13-Aug-2008	GA		13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Echocardiogram normal, Electrocardiogram, Electrocardiogram ambulatory normal, Electroencephalogram normal, Headache, Hypophagia, Nuclear magnetic resonance imaging normal, Syncope

Symptom Text: The patient experienced syncope/seizures on two occasions. The first episode occurred on 9/23/07 in the P.M. after stepping out of the shower, resulting in an emergency room visit. An EKG was performed and the patient was released with no identifiable diagnosis. Two weeks later, the patient had another syncope/seizure episode. This episode also occurred in the P.M., while at a party. Because the patient is away from home in college, she was referred by the Medical Director to a local Neurologist. The neurologist ordered the following test: 1) MRI Scan, 2) EEG, 3) ECHO and 4) Holter monitor. All of the test results were benign. To date, no explainable cause has been identified for the seizures. 11/13/08-records received for DOS 9/23/07-ED visit with C/O possible seizure dy prior. Has been dieting times 1 week. Headache. At ED felt fine. Assessment:Evaluation of seizure.

Other Meds: ORTHO TRI-CYCLEN LO TAB

Lab Data: See Item 7

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **321329-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	31-Jul-2008	31-Jul-2008	0	05-Aug-2008	13-Aug-2008	AZ		13-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2658AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1758U	1	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB243AA	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper

Symptom Text: Pt. stated that the epigastric pain started after shots given. Epigastric pain continued after pt. ate lunch.

Other Meds: PRN albuterol

Lab Data: None. Returned for exam - no unusual findings.

History: Asthma

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321336-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	28-Jul-2008	29-Jul-2008	1	05-Aug-2008	13-Aug-2008	NE		13-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0541	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2580AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C2774AA	5	Right leg	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site warmth, Local reaction

Symptom Text: Local reaction - leg DTaP & 3 1/2" the left arm - GARDASIL area of redness and warmth. Rt arm both area VARIVAX & MENACTRA.

Other Meds:

Lab Data:

History: previous reaction flu shot 11/03 & fever 102 with tetra immuns 11/11/96

Prex Illness: tinea corpus under Rx

Prex Vax Illns: fever~Vaccine not specified (no brand name)~4~1~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321344-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	30-Jul-2008	30-Jul-2008	0	05-Aug-2008	13-Aug-2008	AZ		13-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2658AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Dizziness, Nausea

Symptom Text: Pt felt faint, no loss of consciousness. Pt felt nausea, no vomiting, no resp. problems. 1 min pt down, offered crackers, with PB, water, BP 90/60, increased to 100/70.

Other Meds:

Lab Data: Hgb, 12.5, ambulated ind without diff, skin warm and oxy.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321349-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Jul-2008	Unknown		05-Aug-2008	13-Aug-2008	OR		13-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2617AA	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Heart rate decreased, Oxygen saturation, Syncope

Symptom Text: Patient experienced syncope with drop in BP from initial 112/72 to 84/54, Pulse rate initially high 40's to 72 at discharge'; BP back to 102/66 at discharge. Oxygen 100% via pulse ox.

Other Meds:

Lab Data: Cap glucose

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321380-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Aug-2008	05-Aug-2008	0	05-Aug-2008	14-Aug-2008	FL		14-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	SANOFI PASTEUR	NULL	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Depressed level of consciousness, Dizziness, Fall, Hypoaesthesia, Malaise, Paraesthesia, Respiratory arrest, Syncope, Unresponsive to stimuli

Symptom Text: HPV vaccine given as a second administration, following Menactra administration. Patient verbalized feeling dizzy as the injection was complete and thereafter, fainted and collapsed non-responsively to the floor. No signs of breathing or alertness for approximately 15 seconds. Numbness and tingling to extremities for 10-15 minutes thereafter. Weakness and general malaise with upto 4 hours post admiinistration.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **321408-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Jul-2008	20-Jul-2008	4	06-Aug-2008	07-Aug-2008	--	WAES0808USA00052	12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse concerning a 15 year old female who on 16-JUL-2008 was vaccinated with the first dose of GARDASIL. Concomitant therapy included Tdap. The patient was also administered a TB test. On 20-JUL-2008 the patient experienced seizure. The patient was rushed to the Emergency Room. On an unspecified date, the patient recovered from seizure. No product quality was involved. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested. This was reported to VAERS by the healthcare facility on 23-JUL-2008.

Other Meds: tuberculin purified protein

Lab Data: tuberculin skin test, unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321409-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Jul-2008	23-Jul-2008	0	06-Aug-2008	07-Aug-2008	IN	WAES0807USA05580	07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness

Symptom Text: Information has been received from a physician concerning an 18 year old female with no known drug allergies and no pertinent medical history who on unspecified dates was vaccinated with the first and second doses of GARDASIL. On 23-JUL-2008, after receiving her third dose of GARDASIL the patient passed out and exhibited seizure like activity. The patient sought unspecified medical attention. No lab/diagnostic studies were performed. Fifteen minutes after the event, the patient improved. She recovered the same day. Upon internal review, seizure like activity was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321410-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.1	M	18-Jul-2008	Unknown		06-Aug-2008	07-Aug-2008	FR	WAES0807USA05879	07-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0588U		Unknown	Intramuscular	
	HEP	UNKNOWN MANUFACTURER	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Initial information received on 21-JUL-2008 from a health care professional regarding a 1-month-old male who on 18-JUL-2008 was inadvertently administered a dose of GARDASIL (Lot #0588U, batch # NG39260) on the thigh IM. According to the reporter, the infant was going to be vaccinated, according to schedule, with the second dose of hepatitis B virus vaccine, somehow the vaccines were mistaken and the infant was vaccinated with GARDASIL instead. Once the physician realized the mistake he administered, the same day, on 18-JUL-2008, the hepatitis B virus vaccine (manufacturer has not been reported) straight away but on a different site. As a precautionary measure, the patient remained in the hospital for observation. On 21-JUL-2008 the patient was again observed. The patient had no adverse event. Other business partner numbers include E008-06940. This case was closed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321419-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	04-Aug-2008	04-Aug-2008	0	06-Aug-2008	18-Aug-2008	MD		19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Dizziness, Hyperhidrosis, Pallor, Presyncope, Syncope

Symptom Text: 2 minutes after administering HPV 31, patient became pale, diaphoretic, dizzy, reaction complete syncope, anxious state x 1-2 minutes. Recovered in 15 minutes to discharge; Near fainting

Other Meds: None

Lab Data:

History: None

Prex Illness: none PE visit

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321425-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Feb-2007	Unknown		06-Aug-2008	11-Aug-2008	KS		08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0263U	2	Left arm	Unknown	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB319AA	2	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Anorexia, Arthralgia, Asthenia, Chest pain, Contraception, Conversion disorder, Cough, Depression, Dizziness, Dysmenorrhoea, Dyspepsia, Familial periodic paralysis, Fatigue, Hypersomnia, Hypoaesthesia, Hypotonia, Infectious mononucleosis, Intensive care, Lethargy, Malaise, Menstruation irregular, Migraine, Muscle spasms, Myalgia, Nausea, Neuralgia, Pain in extremity, Paraesthesia, Pharyngolaryngeal pain, Pyrexia, Rhinorrhoea, Viral infection

Symptom Text: 15 yo GO WF LMP October 2005 presents with her mother to discuss her infrequent menstrual cycles. The pt had her first menstrual cycle in August of 2005. She then had a cycle in September and then October 2005. She has not had a menstrual cycle since that time. She has never been sexually active. She has severe cramping with her menstrual cycles. She denies any weight changes, temperature instability or breast discharge. D/w pt and her mother issues regarding menarche and cycle irregularity. Also d/w the potential for PCOS. Explained to them the reason that cycle regulation is important long term. They agree to OBCP for cycle regulation. Plan to do some lab evaluation and induce menstrual flow w/ course of progestin. D/w pt information regarding HPV and hepatitis B vaccine. Entire patient history reviewed by MD. 9/23/08 Reviewed neuro 2nd opinion of 3/1/07 & subsequent visits. FINAL DX: periodic paralysis Records reveal patient experienced episodic limpness, constant HA. Tx w/meds. Developed numbness/tingling in fingers/toes & depression, severe heartburn, pinched nerve, leg/muscle pain & cramping on meds. 10/7/08 Reviewed hospital medical records of 2/14-2/15/2007. FINAL DX: conversion disorder Records reveal patient experienced 4 episodes of sudden unexplained paralysis within a 2 week period starting around 12/25/06 w/migraine HA. Then developed a cough & sore throat & dx w/mono. Had decreased energy & increased sleep. Divides time between parent's homes. Outpatient CT of head & EEG WNL. Had been transferred from outlying ER to PICU. Work up completely WNL. Parent refused psychiatric eval & referred instead for second neuro opinion at outpatient clinic where was seen 3/1/07. 8/26/08 Reviewed OB/GYN medical records for 10/3/2006-2/19/2007. FINAL DX: Records reveal patient experienced good health on 10/3/2006 date of 2nd vaccinations. Returned to clinic 2/5/2007 for f/u after d/cing contraception which she had been on for cycle regulation. Stopped due to severe HAs. HAs did not improve

Other Meds:

Lab Data: LABS: SGOT 88(H), SGPT 178(H), CPK 53(N). MRI WNL. CBC w/Hct 36.5(L), segs 31%(L), lymphs 47%(H), Mono test neg. Globulin 3.8(H), ALT 68(H). CBC WNL. ALT 73(H), AGR 1.1(L). CXR WNL. EKG abnormal. Flu A&B neg.

History: None PMH: migraines. Family hx epilepsy

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321429-1** **Related reports:** 321429-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Apr-2008	22-Apr-2008	0	06-Aug-2008	18-Aug-2008	ID		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2561AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2888AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Dizziness, Hypoaesthesia, Pallor, Paraesthesia, Pyrexia

Symptom Text: Arrived at clinic for HPV #2 on 7/22/08. Mom reports that patient had dizziness, paleness and fever (temp not taken) for 72 hours after first HPV on 4/22/08. Mom kept home from school on 4/23/08. Patient reported brief episode of right hand numbness/tingling at school on 4/24/08. HPV #2 deferred. Series suspended.

Other Meds: None

Lab Data: None

History: no

Prex Illness: no

Prex Vax Illns: No~ ()~~0~In Sibling|No~ ()~~0~In Patient

Vaers Id: **321429-2** **Related reports:** 321429-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Apr-2008	Unknown		17-Sep-2008	22-Oct-2008	ID	WAES0808USA01166	22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hypoaesthesia, Paraesthesia, Pyrexia

Symptom Text: Information has been received from a physician concerning a 12 year old female with no pertinent medical history and no drug reactions or allergies, who on 22-APR-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 659657/1487U). Concomitant therapy included meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA) and diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid. After vaccination on an unspecified date in 2008, the patient was sick for 72 hours with fever and dizziness. The patient's arm also became numb and was tingling. The patient sought unspecified medical attention. It was noted that when the patient went for her second dose of GARDASIL vaccine (yeast) on 22-JUL-2008, she told the physician about what happened after the first dose and then, the second dose was not given. The GARDASIL vaccine (yeast) series was discontinued. At time of reporting, the patient was recovered. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **321432-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	05-Aug-2008	05-Aug-2008	0	06-Aug-2008	18-Aug-2008	MI		18-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1446U	0	Right arm	Intramuscular	
HEPA	MERCK & CO. INC.	0018U	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2418AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Blood pressure decreased, Crying, Dizziness, Heart rate normal, Oxygen saturation normal, Pain in extremity, Pallor

Symptom Text: NP called into room at 2:50 pm after receiving Hep A and MCV4 in left arm. Patient felt lightheaded & crying that arms hurt. Alert & Ox3, appeared pale, HR-88, BP 116/62, pulse ox 98%. About 3pm pt sat up and Gardasil given in right arm. Had pt lie flat til 3:08pm. Verbalized feeling better & sat up. Pt felt dizzy again HR-96, BP 88/60. Had pt lie flat again & BP 98/56. At 3:20 pm pt felt better and sat up BP 110/70, HR-84. Had pt sit for a few minutes and then stand for a few minutes before walking. Steady on feet. Only complaint of arms sore.

Other Meds:

Lab Data: none

History: No allergies, hx of exercised induced asthma

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321436-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Aug-2008	05-Aug-2008	0	06-Aug-2008	18-Aug-2008	MO		18-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0608X	1	Right arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB239AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1740U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Heart rate normal, Nausea, Pallor, Respiratory rate

Symptom Text: Patient became lightheaded, pale and nauseated about 10 minutes after receiving the vaccines. She was lowered to the floor. She never blacked out. Pulse 70 Resp 20. Color slowly returned in about 10 minutes. Sat up, was given some apple juice. Patient left on her own power with mom 20 minutes after the incident occurred.

Other Meds: none

Lab Data: none

History: None

Prex Illness: none

Prex Vax Illns:

Vaers Id: **321439-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Jul-2008	15-Jul-2008	0	06-Aug-2008	18-Aug-2008	MI		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	MERCK & CO. INC.	0005U	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1446U	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B019AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Dizziness, Heart rate decreased, Hyperhidrosis, Oxygen saturation normal, Pallor

Symptom Text: 9:48 am Np called into room when pt c/o feeling dizzy & sweaty after Hep B #1, Tdap, and Gardasil #1 given. Appeared pale, BP 104/60, pulse 64, pulse ox 98%, pt moved to exam table and had lie flat. 9:51 am pt talking Bp 106/62, pulse 52, still lying down, feels alittle better. 10:02 am pt sat up on table BP 100/72 pulse 56. 10:10 am pt moved to chair, states feels OK, Bp 94/60, pulse 46, alert & oriented x3; gave apple to eat (no breakfast); 10:20 am BP 104/70, pulse 60, A & Ox3, steady on feet and ambulating. Verbaliezed feeling back to normal.

Other Meds: none

Lab Data: none

History: none

Prex Illness: no

Prex Vax Illns:

Vaers Id: **321443-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Apr-2008	03-Apr-2008	0	06-Aug-2008	18-Aug-2008	CA		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Hypersomnia, Immediate post-injection reaction, Pallor, Syncope

Symptom Text: RIGHT AFTER THE VACCINE SHE WAS PALE AND FAINTED, SHE BECAME VERY TIRED AND SLEPT FOR THE REST OF THE DAY.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **321470-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	06-Aug-2008	Unknown		06-Aug-2008	18-Aug-2008	MN		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: No adverse event noted at this time after 27 year old female received HPV.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **321472-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Aug-2008	06-Aug-2008	0	06-Aug-2008	18-Aug-2008	IL		18-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0843X	0	Right arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBV431BA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2618AA	0	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Fall, Syncope

Symptom Text: 15 minutes after immunization patient fainted in waiting room. She had been ambulating in exam room without difficulty and ambulated to waiting room by herself. Last meal greater than 12 hours prior to immunization. Complained of back pain as she fell back against the wall and slid to floor - Vitals checked. Ice applied, juice grape and crackers given. patient monitored x1 hr discharged to home with step mom.

Other Meds: none

Lab Data: Observation

History: NKDA

Prex Illness: none reported by patient or stepmom

Prex Vax Illns:

Vaers Id: 321501-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Mar-2008	28-Mar-2008	0	07-Aug-2008	08-Aug-2008	FR	WAES0807AUS00273	08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0900U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Malaise, Nausea, Rash, Urticaria, Vomiting

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Details form and concerning a 15 year old female who was vaccinated with GARDASIL (Lot No. 658278/0900U, Batch No. j5686, Expiry date 23-MAR-2010). On 28-MAR-2008, one hour post first dose of GARDASIL, the patient experienced nausea, arthralgia, malaise and vomiting. A rash developing on the chest and neck was noted and the patient was transported by ambulance to the hospital. She was admitted to the emergency department with mild urticaria noted to be fading. No other symptoms were noted at that time. The patient was given promethazine 10mg. The patient was observed and discharged. The patient felt unwell with joint pains over the weekend. At the time of reporting on 14-APR-2008, the patient recovered from nausea, arthralgia, malaise, rash, urticaria and vomiting. The agency considered that nausea, arthralgia, malaise, rash, urticaria and vomiting were possibly related to therapy with GARDASIL. The original reporting source was not provided. Information has been received from media monitors advising that the patient's experience was subsequently reported in an article, 18-JUN-2008, page 5. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321506-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	02-May-2007	10-Oct-2007	161	07-Aug-2008	08-Aug-2008	FR	WAES0807AUS00280	08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0138U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Athetosis, Central nervous system inflammation, Dizziness, Headache, Loss of control of legs, Memory impairment, Muscular weakness, Syncope

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form concerning a 16 year old female who on 02-MAY-2007 was vaccinated with the first dose of GARDASIL (Batch # J0798, Expiry date 07-AUG-2008, Lot # 655742/0138U). After vaccination with the first dose of GARDASIL, the patient experienced dizziness. On 13-JUN-2007 the patient was vaccinated with the second dose of GARDASIL (Batch # J0800, Expiry date 07-AUG-2009, Lot # 655742/0138U). After the second dose of GARDASIL, the patient developed headaches and was concerned about memory impairment. On 19-SEP-2007 the patient was vaccinated with the third dose of GARDASIL (Batch # J2300, Expiry date 12-FEB-2010, Lot # 657872/0583U). On 23-SEP-2007, a few days after the third dose of GARDASIL the patient got up during the night and lost control of her legs and collapsed. The next morning she had recovered. On approximately 10-OCT-2007, approximately 3 weeks after the third dose of GARDASIL, the patient developed right hand weakness and was referred to a neurologist. The patient was treated with methylprednisone to assist in recovery. On 30-JAN-2008 the patient was diagnosed with multifocal central nervous system (CNS) inflammatory disorder, presented with pseudoathetosis. It was advised that the patient recovered over 3 months. At the time of reporting to the agency on 10-JUL-2008 the patient had recovered from the athetosis, asthenia and central nervous system inflammation. The agency considered that athetosis, asthenia and central nervous system inflammation were possibly related to therapy with GARDASIL. The original reporting source was not provided. The agency considered the events of athetosis, asthenia and central nervous system inflammation to be serious for the following reason: medically significant. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321507-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	01-Jul-2008		07-Aug-2008	08-Aug-2008	IL	WAES0807USA05324	08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Injection site pain, Injection site swelling, Pain in extremity

Symptom Text: Information has been received from a physician concerning a female who received the three doses of GARDASIL. Recently in July 2008, the patient had soft tissue pain and swelling over the injection site which has persisted since the third injection. The patient complained of pain when raising her arm. The patient was referred to physical therapy. Soft tissue pain and swelling over the injection site and pain when raising her arm, were considered to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321508-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Jun-2008	06-Jun-2008	0	07-Aug-2008	08-Aug-2008	--	WAES0807USA05581	08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Haemorrhage

Symptom Text: Information has been received for the pregnancy registry for GARDASIL from a nurse practitioner concerning a 15 year old female patient who on 06-JUN-2008 was vaccinated with the first dose of GARDASIL IM. The day after receiving the first dose of GARDASIL, the patient found out she was pregnant (gestation or last menstrual period of "1 month"). On 11-JUN-2008 the patient started bleeding and went to the emergency room on 17-JUN-2008, where it was determined she had a miscarriage. Upon internal review, miscarriage was considered to be other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **321509-1 (S)** **Related reports:** 321509-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	24-Jul-2008	24-Jul-2008	0	07-Aug-2008	08-Aug-2008	IL	WAES0808USA00015	08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Immediate post-injection reaction, Myelitis transverse, Paralysis

Symptom Text: Information has been received from a physician concerning a female between 9 and 18 years of age who on approximately 24-JUL-2008 was vaccinated with a dose of GARDASIL. The patient developed paralysis immediately after the vaccination. She was taken to a hospital and diagnosed with transverse myelitis. She is still in the hospital. The patient's outcome was unknown. Transverse myelitis was considered disabling. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321509-2 (S)** **Related reports:** 321509-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		20-Aug-2008	21-Aug-2008	IL	WAES0808USA02760	21-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Myelitis transverse

Symptom Text: Information has been received from a nurse concerning a patient who was vaccinated with GARDASIL. Subsequently the patient experienced transverse myelitis and was hospitalized. The patient's outcome was unknown. It was unspecified if the patient sought medical attention. This is one of several reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 321510-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	01-Jun-2008	02-Jul-2008	31	07-Aug-2008	08-Aug-2008	FR	WAES0808USA00100	08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Deafness unilateral, Ear haemorrhage, Sudden hearing loss

Symptom Text: Information received from health authority (local number L200807-376, reference number RA-030-2008) concerning a 26 year old female in good health and with no risk factors for sudden deafness and no previous history of adverse reaction to other drugs, who in June 2008 was vaccinated with the first dose of GARDASIL via intramuscular route. On 02-JUL-2008 she suffered from sudden deafness of her left ear with haemorrhage of the left ear and C-reactive protein increased. On 04-Jul-2008, an audiogram was performed which confirmed neurosensory deafness of left ear with ear haemorrhage. There was a C-reactive protein elevation. The patient received corrective treatment with ibuprofen 400 mg three times a day during one week, deflazacort 30 mg during two days and buflomedil 600 mg once a day during one week. The patient recovered within an unspecified time frame. Sudden deafness was considered to be disabling. No further information is available. The case is closed. Other business partner number included: E2008-07313.

Other Meds: Unknown

Lab Data: audiogram, 04Jul08, neurosensory deafness of left ear with ear haemorrhage

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321511-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Jul-2007	01-Aug-2007	6	07-Aug-2008	08-Aug-2008	IL	WAES0808USA00236	12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL. Concomitant vaccinations included MENACTRA and DTaP (unspecified). But it was unknown at the time of report if the other vaccinations were administered at the same time. On an unspecified date, the patient developed multiple sclerosis (MS). Upon internal review, multiple sclerosis was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321512-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	25-Jul-2008	25-Jul-2008	0	07-Aug-2008	08-Aug-2008	--	WAES0808USA00255	08-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a 23 year old female with seizure disorder who on approximately 25-JUL-2008 was vaccinated intramuscularly with the first dose of GARDASIL. After vaccination on approximately 25-JUL-2008 the patient experienced a seizure. Medical attention was sought via calling ambulance. Subsequently, the patient recovered from seizure. No product quality complaint was involved. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Convulsion disorder

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321524-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Feb-2008	Unknown		07-Aug-2008	18-Aug-2008	VA		08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Acute sinusitis, Arthralgia, Back pain, Dysuria, Haematuria, Lymphadenopathy, Myalgia, Rash generalised, Rash pruritic, Rhinitis allergic, Sinus congestion, Sinus disorder, Urticaria

Symptom Text: C/O myalgias in joint. W/U by rheum/neuro. ANA-Neg, Lyme-Neg, B12-Normal, Sed rate-26. 9/23/08 Reviewed PCP medical records of 2/25-7/17/2008. FINAL DX: lymphadenopathy; allergic urticaria; acute sinusitis; allergic rhinitis Records reveal patient experienced tender lump on throat, sore throat & difficulty swallowing, frequent HA x 1 week on the day of vaccination. Exam revealed swollen turbinates, shotty tender cervical lymph nodes. RTC 6/14 w/itchy rash all over x 2 days. Had started Topamax 2 wks prior & was on accutane as well. Tx w/steroids. RTC 7/9 w/dysuria, hematuria & lower back pain x 4 days. Tx w/antibiotics. RTC 7/17 w/allergy s/s, sinus congestion. Reported having myalgias & athralgias s/p 1st HPV injection 2/21/08. Tx w/antibiotics & received Menactra that day. 10/3/08 Reviewed neuro medical records of 6/5-8/5/2008. FINAL DX: none provided Records reveal patient experienced multi neuro symptoms: sleep disturbance since childhood, mild sleep apnea, excessive fatigue x 1 year, chronic nausea, HA, tremor, joint & muscle pain, feeling out of it, depression, anxiety & mood disturbance. Stated contraception 1 year prior. Referred for MRI, EEG & labs. Responded to tx w/meds.

Other Meds:

Lab Data: LABS: EEG WNL. Brain MRI WNL except opacified right maxillary sinus. ESR 26(H). Alk phos 45(L).

History: PMH: stress fractures of shins. seasonal allergies. facial staph infection. acne. Family hx: anxiety, depression, arthritis, bipolar, DM2, cancer, HTN, kidney failure, migraines.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321530-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Jul-2008	31-Jul-2008	0	07-Aug-2008	18-Aug-2008	MI		18-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1968U	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB239AA	0	Left arm	Intramuscular	
HEP	MERCK & CO. INC.	0005U	0	Right arm	Unknown	
MNQ	SANOFI PASTEUR	U2619AA	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2844AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Confusional state, Fatigue, Feeling abnormal, Heart rate normal, Hypotonia, Muscle rigidity, Tremor

Symptom Text: P-60 B/P-120/64 Patient slumped down while in sitting position and I laid her down on exam table. Her eyes were closed and she began to tremor and all extremities became rigid. This lasted about 5 seconds then she relaxed & opened her eyes and asked what happened. She was confused she said & felt tired & not normal.

Other Meds: None

Lab Data: none

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 321538-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Mar-2008	03-Mar-2008	0	07-Aug-2008	18-Aug-2008	GA		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	0	Right arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHARB25AA	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	1179U	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2233CA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Acarodermatitis, Fatigue, Hypoaesthesia, Loss of consciousness, Paraesthesia, Rash erythematous, Rash generalised, Sensory loss

Symptom Text: Pt. passed out in office less than 5 minutes after vaccination. Approximately 1 month later started having paresthesia to left groin and right LE, which has not resolved. 8/15/08 Reviewed PCP medical records of 3/08-8//2008. FINAL DX: scabies; paresthesia left groin & right leg. Records reveal patient experienced fatigue since 10/2007 when began Depo for contraception, left scapula prominence & possible leg length discrepancy, mild clinical depression on 3/3/2008. Referred to ortho & GYN. Next office note is for 8/1/2008 for red bumpy rash all over body x 2 mo w/numbness of both legs starting 1 mo after HPV. Stopped contraception after numbness started with no improvement. Exam revealed red papules w/scabbing between fingers & toes, abdomen & lower arms; decreased sensation to left groin. Referred to neuro.

Other Meds: DEPO-PROVERA- pt stopped after symptoms

Lab Data: None

History: no birth defects

Prex Illness: Fatigue which has resolved

Prex Vax Illns:

Vaers Id: **321539-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	31-Jul-2008	31-Jul-2008	0	07-Aug-2008	18-Aug-2008	NY		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2561AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1063U	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B018CA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Hyperhidrosis, Pallor, Visual disturbance

Symptom Text: Client became pale, diaphoretic, and weak. Client states she was seeing "purple spots". Client was moved to supine position with feet elevated. Vital signs were monitored every 3-5 minutes. Symptoms resolved in 10 minutes from onset.

Other Meds: None reported

Lab Data: None

History: Denied

Prex Illness: Denied

Prex Vax Illns:

Vaers Id: 321541-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Aug-2008	06-Aug-2008	0	07-Aug-2008	18-Aug-2008	CA		18-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0538X	1	Left arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB284AA	1	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2583AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure normal, Dyspnoea, Hypoaesthesia, Paraesthesia, Reaction to previous exposure to any vaccine, Throat tightness, Tremor

Symptom Text: Received Hepatitis A, Menactra, Varivax, and Gardasil. Received Hepatitis A, Menactra, and Varivax first, and was fine. The nurse went to get a different needle for the Gardasil vaccine and was gone for 3-4 minutes. She returned and gave the shot. Within a few seconds, patient complained that her throat felt "like someone had [her] in a headlock". She also complained of pins and needles sensation on her face. She had short, quick breaths but did not initially have shaking or numbness of the hands. We had her lay down and put some ice behind her neck. We also had her blow into a paper bag. She still complained of the pins and needles sensation on her face. We also gave her some Gatorade. 10 minutes later she felt better but was then having shakineess and numbness of extremities. No headache, no vision changes, no syncope. Blood pressure was fine. 20 minutes later the pins and needles sensation was gone, she felt better, and went home. This same patient did have a reaction to a pertussis vaccine (Tetramune) in October 1994, but otherwise has not reacted to vaccines and has had all of them.

Other Meds: None

Lab Data: none

History:

Prex Illness:

Prex Vax Illns: Fever to 104, prolonged vomiting, crying for 2 hours~DTP + Hib (Tetramune)~3~1~In Patient

Vaers Id: **321546-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-Jun-2008	11-Jun-2008	0	07-Aug-2008	18-Aug-2008	NC		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	UNKNOWN ASK PED	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	UNKNOWN ASK PED	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise, Pain, Pyrexia

Symptom Text: malaise, pain, slight fever; reaction much worse than experienced with gardasil doses 1 & 2. think it may be due to menactra vaccine given on same day; treatment rest, ibuprofen

Other Meds:

Lab Data: n/a

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321547-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	07-Aug-2008	07-Aug-2008	0	07-Aug-2008	18-Aug-2008	IL		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2825AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Nausea

Symptom Text: Approximately 5-10 minutes after injections given, she felt faint, weak and nauseated. She did not faint, and recovered fully after approximately 10 minutes sitting in a chair and sipping water.

Other Meds: none

Lab Data: none

History: epilepsy, stroke with residual paralysis

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321562-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Aug-2008	07-Aug-2008	0	07-Aug-2008	18-Aug-2008	PA		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Pallor, Syncope

Symptom Text: Immediately after receiving GARDASIL - fainted - went pale - last less than one minute. Had her elevate feet and rest til no longer faint.

Other Meds: Vyvanase; Risperdal; Prozac

Lab Data: None

History: ADHD

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321563-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	07-Aug-2008	07-Aug-2008	0	07-Aug-2008	18-Aug-2008	PA		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB291BA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0229X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Dizziness, Headache, Heart rate normal, Malaise, Nausea, Vaccine positive rechallenge

Symptom Text: Patient complained of "feeling sick" about 15 min after injections c/o HA, nausea and dizziness. Vitals: BP 100/60, P 80 observed. Patient at office for about 30 minutes past injections. Vitals again: BP 100/60, P 88 patient also had similar episodes after GARDASIL 1 & 2 which were not reported to our office.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: ~HPV (Gardasil)~1~0~In Patient

Vaers Id: **321582-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-Aug-2008	07-Aug-2008	0	07-Aug-2008	18-Aug-2008	NV		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depressed level of consciousness, Dizziness, Feeling hot, Hyperhidrosis, Tremor

Symptom Text: When I walked everything started to fade slowly, and while my mom was filling out papers I got really dizzy and my hands were shaking. And when I sat down I started feeling hot and I started to sweat.

Other Meds:

Lab Data: none

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321583-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Aug-2008	04-Aug-2008	0	07-Aug-2008	18-Aug-2008	NY		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Left arm	Intramuscular	HEP MNQ TDAP

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaginal haemorrhage

Symptom Text: Pt reports that she had heavy vaginal bleeding for 3 days. The bleeding began about 2 hrs after receiving HPV vaccine.

Other Meds: None

Lab Data:

History: Seasonal allergies-Hx of heart murmur, Scoliosis

Prex Illness: None

Prex Vax Illns:

Vaers Id: **321620-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Jul-2007	Unknown		08-Aug-2008	11-Aug-2008	FR	WAES0808USA00912	11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Anaemia, Irritable bowel syndrome

Symptom Text: Information has been received from a health authority (ref # ADR 20289066) concerning a 13 year old female who on 13-JUL-2007 and 03-SEP-2007 was vaccinated with a dose of GARDASIL, (batch # not reported), intramuscularly (IM). On an unreported date, post vaccination, the experienced irritable bowel syndrome and subsequent anaemia. The patient outcome was unknown. It was reported that the patient's mother suspected a connection. The reporter considered the events to involve perisitent of significant disability or incapacilty. Other business partner numbers E2008-07404. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321621-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	31-Jul-2008	31-Jul-2008	0	08-Aug-2008	11-Aug-2008	MN	WAES0808USA00563	11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Dyspnoea, Local swelling, Rash erythematous, Salivary gland enlargement, Speech disorder, Swelling face

Symptom Text: Information has been received from a physician concerning a 26 year old female who on 31-JUL-2008 was vaccinated with the third 0.5 ml dose of GARDASIL. On 31-JUL-2008 the patient began to develop swelling of her face and her neck. The swelling caused the patient have difficulty with both breathing and talking. The patient also developed a red rash on her face and neck. The patient sought was hospitalized on 02-AUG-2008. A computed axial tomography (CT) scan showed enlarged salivary glands. Medical attention was sought via office visit. The patient had been treated with clindamycin and corticosteroids. After starting the clindamycin, the patient developed a rash on her chest. The patient was noted to be recovering. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: computed axial - showed enlarged salivary glands

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321622-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		08-Aug-2008	11-Aug-2008	FR	WAES0808USA00315	11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Head injury, Headache, Immediate post-injection reaction, Loss of consciousness, Malaise, Nausea, Pain, Wound

Symptom Text: Information has been received from a physician concerning a 14 year old female who on an unknown date was vaccinated with the second dose of GARDASIL (lot# and batch# not reported) via intramuscular route in the deltoid. She had concomitant medication with RUBOZINC. Immediately after injection, the patient experienced generalized pain. Three minutes later, she lost consciousness and experienced convulsions. Her malaise induced a wound of the superciliary arch and head trauma. She was seen at the emergency unit where she stayed one hour. No scan was performed. At the time of reporting the patient still had cephalgia and nausea. Generalized pain, lost consciousness, convulsions, head trauma, cephalgia and nausea were considered to be an other important medical event. Other business partner numbers included E2008-07300. No further information is available.

Other Meds: RUBOZINC, Unk - Unk

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321623-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Nov-2007	18-Jun-2008	204	08-Aug-2008	11-Aug-2008	FR	WAES0808USA00198	11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Hand deformity, Hyperreflexia, No reaction on previous exposure to drug, Pain

Symptom Text: Information has been received from a general practitioner concerning a 14 year old female who on 15-MAY-2007 was vaccinated with a first dose of GARDASIL and on 05-JUL-2007 was vaccinated with a second dose of GARDASIL and were well tolerated. On 27-NOV-2007, the patient was vaccinated with a third dose of GARDASIL. Suddenly, on 18-JUN-2008, at the age of 15 years, the patient experienced left-site hyperreflexia, loss of strength and claw hand with severe pain. The patient was hospitalised on an unknown date. Examinations did not reveal any pathological findings (electro-neurography normal, ANA/ANCA negative, rheuma screening normal, C peptides negative, Borrelia serology normal). Lumbar puncture results were pending. At the time of reporting the patient had not recovered. Other business partner numbers included: E2008-07216. No further information is available.

Other Meds: Unknown

Lab Data: spinal tap, results pending; electroneurography, normal; serum ANA, negative; serum ANCA, negative; serum B. burgdorferi Western blot IgG Ab, normal; serum rheumatoid factor, normal; serum C-peptide test, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321624-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Apr-2008	28-Apr-2008	0	08-Aug-2008	11-Aug-2008	FR	WAES0807AUS00269	11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Diarrhoea, Nausea, Rash generalised, Urticaria

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail form concerning a 15 year old female who on 28-APR-2008 was vaccinated with Gardasil vaccine. Subsequently, on 28-APR-2008 the patient experienced nausea, abdominal pain, diarrhoea and urticaria (also reported as the patient developed severe abdominal pain, nauseated, rash on the back of opposite arm, hive-live which spread all over body), and was hospitalized. At the time of reporting on 03-JUN-2008, the patient's nausea and abdominal pain and diarrhoea and urticaria persisted. The agency considered that nausea, abdominal pain, diarrhoea and urticaria were possibly related to therapy with Gardasil vaccine. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321625-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Mar-2008	Unknown		08-Aug-2008	11-Aug-2008	FR	WAES0808USA00316	11-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crohns disease

Symptom Text: Information has been received from a health care professional concerning an adolescent female who in March 2008 was vaccinated with GARDASIL (lot# and batch# not reported). On an unknown date, the patient developed Crohn's disease with an unknown latency after vaccination. At the moment of reporting she was treated with prednison (started on 30-JUL-2008, 30 mg daily dose) and IMURAN (azathioprine) (125 mg daily dose). Crohn's disease was considered an other important medical event. Other business partner numbers included E2008-07309. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321626-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Jul-2008	29-Jul-2008	0	08-Aug-2008	12-Aug-2008	FL		12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB238AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2663AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1967U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia

Symptom Text: "Tingling/numbness" (B) legs. Mostly in pinkie toe.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **321644-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Aug-2008	01-Aug-2008	0	08-Aug-2008	18-Aug-2008	MA		19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Immediate post-injection reaction

Symptom Text: Patient given vaccine at approximately 1130AM. Patient reported dizziness immediately following injection and was assisted to supine position. Patient then had witnessed seizure at approximately 1138 AM lasting approximately 30sec; No complaint of hypoxia during event. Patient recovered and was sent by ambulance to ER.

Other Meds: Microgestin 1.5/30 1 PO QD; Protonix 40mg 1 PO QD

Lab Data:

History: History of prior seizures of unknown etiology (last was 12/06); No allergies

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321664-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Apr-2008	06-Jun-2008	50	08-Aug-2008	12-Aug-2008	NY		17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Contusion, Grand mal convulsion, Loss of consciousness, Tonic clonic movements, Traumatic brain injury, Vomiting

Symptom Text: Patient had a grand mal seizure 2 mos. after receiving the Gardasil shot received at Dr's Office. The seizure last a full 5 minutes with tonic clonic episode and unconsciousness. The episode happened at the high school and taken to Hospital on June 6, 2008. 8/11/2008 MR received for ER visit 06/06/2008 with DX: Closed head injury, loss of consciousness <1 hour. Seizure, generalized. Pt presented to ER after witnessed tonic-clonic seizure at school. (+) vomiting. PE WNL except 2 cm L forehead contusion. D/c to f/u as out pt.

Other Meds: none

Lab Data: MRI/Brain, CaT SCAN, EEG done after the seizure. Labs and Diagnostics: Head CT (-). CBC, CMP unremarkable. Drug screen (-). Coags WNL>

History: NONE. PMH: none

Prex Illness: None - healthy 15 year old with NO HISTORY of seizure until after the Gardasil shot was given

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321672-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	06-Aug-2008	08-Aug-2008	2	08-Aug-2008	18-Aug-2008	VA		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TTOX	SANOFI PASTEUR	02019AB	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0072X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling, Rash macular

Symptom Text: GARDASIL GIVEN 8/6/08 IN RIGHT ARM. CAME IN ON 8/8/08 WITH SPECKLED RASH ON PLAM OF RIGHT HAND, SWOLLEN MILD UPPER RIGHT ARM WHERE SHOT WAS GIVEN. NOT PAINFUL, NO SIGNS OF INFECTION.

Other Meds: PCN

Lab Data: NONE

History: NONE

Prex Illness: STREP THROAT

Prex Vax Illns: NONE~ ()~NULL~~In Patient

Vaers Id: **321675-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		08-Aug-2008	18-Aug-2008	MA		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Chills, Dizziness, Loss of consciousness, Nausea, Syncope, Vomiting

Symptom Text: I is a few months After my daughter has rcieved the gardasil shot. On several occassions she has become sick out of the clear blue. She will get a wave of nausea, faintness and dizziness. After she vomits she will get the chills and a low grade temp. She is a otherwise healthy, athletic female. In the last three weeks this has occurred twice, however we have not kept track until recently, but there have been other episode of the same prior to the last few. After she recieved the first vaccination she passed out in the doctors office.

Other Meds: prosac 10

Lab Data:

History:

Prex Illness:

Prex Vax Illns: fainting, dizziness,vomiting~HPV (Gardasil)~3~23~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321683-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Aug-2008	07-Aug-2008	0	08-Aug-2008	13-Aug-2008	IA		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2938AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2665AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0070X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Activities of daily living impaired, Arthralgia, Dizziness, Immediate post-injection reaction, Immunisation reaction, Malaise, Nausea, Pain, Pain in extremity, Pyrexia, Vomiting

Symptom Text: Immunizations given at app. 3 pm, and immediately after administration of vaccines, patient c/o feeling light-headed. Had client lie down, ice pack to forehead & back of neck, feet elevated, and observed for about 30-45 minutes before she felt she was able to leave with her mother. Clt & mother had been given copies of VIS along with verbal& written info regarding possible side effects and action to take if side effects occured. Mother to call agency in am. Mother called on 8/8/08 to report that daughter still feeling dizzy, having abdominal cramps, that both hips were hurting, and that she felt feverish. Mother denied that client was nauseated, and that she had been able to eat this am. Instructed to continue to allow daughter to rest, push fluids, give Tylenol and observe, and if concerned, needs to see medical provider. Received call from ER about 11:30 am, and patient had been taken to ER by her mother. ER personnel reported that she had severe dizziness, bilateral leg pain, and nausea & vomitting, and was hospitalized for observation. 8/15/08 Reviewed ER records of 8/8/08. FINAL DX: immunization reaction Records reveal patient experienced dizziness, lightheadedness, felt faint immediately after receiveing vaccination. Recovered & went to work but recurred w/leg pain & had to leave work. Symptoms persisted next day & went to ER. In ER had nausea, anterior bilateral leg pain, left arm pain, upper abdominal pain, HA, felt sick & achy. Held for observation.

Other Meds: none

Lab Data: unknown LABS: platelets 125 (L). Neutrophils 82 (H), lymphocytes 12 (L). Total bilirubin 1.1 (H). Albumin 5.2 (H).

History: no known allergies PMH: innocent heart murmur.

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321688-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Jun-2008	08-Jul-2008	26	08-Aug-2008	18-Aug-2008	CA		18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pain, Swelling

Symptom Text: SWELLING AND REDNESS AND PAIN LASTING 6 WEEKS POST 3RD DOSE OF GARDASIL GIVEN ON LEFT DELTOID, IM

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 321693-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Nov-2006	02-Jan-2007	39	10-Aug-2008	13-Aug-2008	KY		20-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688	1	Left arm	Unknown	FLU UNK

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Amnesia, Arthralgia, Asthenia, Asthma, Back pain, Chills, Convulsion, Croup infectious, Dizziness, Drop attacks, Fatigue, Feeling of body temperature change, Fibromyalgia, Head injury, Headache, Hyperreflexia, Insomnia, Laceration, Loss of consciousness, Lymphadenopathy, Malaise, Musculoskeletal stiffness, Myalgia, Myositis, Nausea, Neck pain, Pain, Pain management, Pharyngitis, Pharyngolaryngeal pain, Psychotherapy, Sinus disorder, Syncope, Tooth fracture, Vomiting

Symptom Text: Had asthma. HPV shots (9/23/06, 11/24/06, 7/5/07). 1/07 tired, chills, dizzy, stomach ache, sick for one week saw doctor. Addtional appts for body ache, dizzy, vomitting, no energy through 2/07. 3/07 exhausted, sore throat, body aches, sinus. 5/07 chronic fatigue & referred to specialist. 7/26/07 specialist diagnosed fibromyalgia. 9/06 - 2/08 had 13 medical appts. 3/08 passed out in shower, possibly from medication, emergency room treatment. Through 7/08, multiple specialist appts for treatment and pain management. 08/21/2008 MR received from PCP. Seen 11/24/06 for HPV#2. Asymptomatic at that time. Frequent OVs beginning 2/9/07 with c/o feeling sick x 1 week-dizzy, H/A, belly pain, tired, chills-hot and cold, nausea, vomited x 2. PE (+) for exudate on tonsils, swollen lymph nodes in neck. Assessment: Fatigue. Seen again 2/15, 2/21, 2/27 for same sx. Assessment: Chronic Fatigue, Achiness. Myositis. OV 3/22/07 with c/o sore throat. Hyperreflexia noted on exam. Assessment: Healing myositis, r/o Guillain Barre. H/A, Tiredness. Pharyngitis. Seen 5/9 now dx CFS 2' to post-viral. R/O Fibromyalgia/COD. WCC 7/5/07 with HPV#3. Seen 3/18/08 in f/u to ER for passing out in shower with head trauma/chipped teeth. 4 episodes that day. Lacerations to chin, knee, head. Dx: Syncope. F/u 3/20/08 feeling exhausted, sore w/ H/A. 5/6/08 Dx: Croup, Pharyngitis. 7/3/08 WCC Dx: Fibromyalgia. 11/13/08 Consultant records received from Rheum. First seen in June 2007 and dx with fibromyalgia. OV 2/13/08 with report of worsening sx of malaise, fatigue, difficulty sleeping and H/A. PE (+) for joint pain, back pain, myalgias, neck pain, morning stiffness. Seeing Pain Mgmt and psych for CBT. Seen 4/17/08 in f/u for drop seizure, preceded by nausea and followed by amnesia of event, ?2' to Elavil. Reports muscle pain and daily occipitoparietal band-like H/A. OV 7/30/08 with improving sx.

Other Meds: amitriptyline, zyrtec, yaz 3-0, r-tanna, singulair, mucinex, sudafed, albuterol

Lab Data: Multiple performed from 2/07 through 3/08 by pediatrics and specialists. Labs and Diagnostics: Monospot (-). CBC WNL. EEG WNL. EKG WNL. Head CT WNL.

History: allegy to penicillins and sulfa antibiotics. No birth defects. Exercise induced asthma. PMH: PCOS, Acne, dysmenorrhea. Allergic to PCN, sulfa

Prex Illness:

Prex Vax Illns:

Vaers Id: **321696-1 (D)** **Related reports:** 321696-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	31-Mar-2008	03-Apr-2008	3	08-Aug-2008	11-Aug-2008	MO		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Left arm	Intramuscular	

Seriousness: DIED, HOSPITALIZED, SERIOUS

MedDRA PT Arrhythmia, Brain oedema, Cardiac arrest, Convulsion, Cough, Death, Dyspnoea, Fall, Haemorrhage, Headache, Hypotonia, Lobar pneumonia, Loss of consciousness, Organ donor, Respiratory tract congestion, Syncope, Tongue biting, Tremor, Upper respiratory tract congestion

Symptom Text: To Whom It May Concern: My daughter went to our nurse practitioner at Health Care Center on March 31, 2008 for a sore throat. She complained of her throat for about two days prior. Pt would get pharyngitis and strep about twice a year since she was 13. She received a shot of ROCEPHIN in the office on March 31st as well she was given a prescription for ZITHROMAX (Z-PAK) at the same time. I'm not sure exactly what time her appointment was it was around 11:00 am. that day. She dropped off her prescription at the pharmacy and I picked up on my way home. She took her first dose of ZITHROMAX on the 31st. She stayed home from school the next two days. She slept late both days which is not abnormal for her. In the evenings we played rummy, she was congested and coughing a little. She complained of a headache the next night and I gave her some ibuprofen. On Wednesday April 3rd she went to school, (school gets out at 3:05 p.m.) after school she went to tract practice. Her tract practice was a short one, I know she ran but I'm not sure how much. She stopped at a convenience store on the way home from school and got a Red Bull. She went home and changed clothes for work. She called me between 4:30 and 5:00 p.m. on her way to work to tell me about the road being blocked due to rain where we live. She parked her car and was walking the short distance into where she works she collapsed and started seizing. A lady in the drive through told the owner that she had fallen and he went out immediately. He said she was shaking, the employees inside called 911 and then me. The owner told me she stopped shaking and took a few strained breaths and then went limp. The police officer arrive within three minutes, he was a first responder. He did not check for a pulse or attempt CPR (I am in the process of getting a police report as well). Just as I got there an off duty paramedic arrived and started CPR. It took quite awhile before the ambulance arrived; she had been down too long. I later learned that they did not get her heart started unt

Other Meds: 3/31 ROCEPHIN; 3/31 ZITHROMAX

Lab Data: lab work, Cat scans, X-rays

History: Hx of pharyngitis; Bacterial Meningitis at 17 mons

Prex Illness: Sore throat

Prex Vax Illns:

Vaers Id: **321696-2 (D)** **Related reports:** 321696-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	31-Mar-2008	03-Apr-2008	3	06-Oct-2008	07-Oct-2008	--	WAES0809USA02791	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Left arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Cardiac arrest, Convulsion, Cough, Death, Dyspnoea, Fall, Headache, Hypotonia, Loss of consciousness, Respiratory tract congestion, Syncope, Tremor, Upper respiratory tract congestion

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. On 31-MAR-2008 a 16 year old female was vaccinated with the second dose of GARDASIL (lot no. 659657/1487U) IM in the left arm. Concomitant therapy included ROCEPHIN and ZITHROMAX on the same day. On 03-APR-2008, she experienced cardiac arrest, convulsion, cough, dyspnoea, fall, headache, hypotonia, loss of consciousness, respiratory tract congestion, syncope, tremor, upper respiratory tract congestion and death. The listing indicated that one or more of the events resulted in death. The report was as follows: "My daughter went to our nurse practitioner on 31-MAR-2008 for a sore throat. She complained of her throat for about two days prior. She would get pharyngitis and strep about twice a year since she was 13. She received a shot of ROCEPHIN in the office on 31-MAR-2008 as well she was given a prescription for ZITHROMAX (Z-PAK) at the same time. I'm not sure exactly what time her appointment was it was around 11:00 am that day. She dropped off her prescription at the pharmacy and I picked up on my way home. She took her first dose of ZITHROMAX on 31-MAR-2008. She stayed home from school the next two days. She slept late both days which is not abnormal for her. In the evenings we played rummy, she was congested and coughing a little. She complained of a headache the next night and I gave her some ibuprofen. On Wednesday 3-APR-2008 she went to school (school gets out at 3:05 p.m.). After school she went to track practice. Her track practice was a short one. I know she ran but I'm not sure how much. She stopped at a convenience store on the way home from school and got a Red Bull. She went home and changed clothes for work. She called me between 4:30 and 5:00 p.m. on her way to work to tell me about the road being blocked due to rain where we live. She parked her car and was walking the short distance into where she works she collapsed and started seizing. A la

Other Meds: ZITHROMAX, ROCEPHIN

Lab Data: computed axial, results not provided; X-ray, results not provided

History: Pharyngitis; Meningitis; Pharyngitis streptococcal

Prex Illness: Sore throat

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321698-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Aug-2008	06-Aug-2008	0	08-Aug-2008	19-Aug-2008	AZ		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2573AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1968U	1	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB284DA	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction, Loss of consciousness

Symptom Text: Patient passed out immediately following receiving the vaccine and then she had 2 30 second generalized seizure.

Other Meds: None

Lab Data:

History: Heart murmur (mitral valve regurgitation)

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321699-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Jul-2008	03-Jul-2008	0	08-Aug-2008	19-Aug-2008	MD		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	1	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2640AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyskinesia, Headache, Immediate post-injection reaction, Loss of consciousness, Pyrexia

Symptom Text: Received MENACTRA & GARDASIL - 5 mins later passed out & had jerking of arms & legs. Came to when lied down. Since then having headaches, dizziness & low grade fever.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: sister-same day~Vaccine not specified (no brand name)~UN~0~In Sibling

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321700-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Jul-2008	03-Jul-2008	0	08-Aug-2008	19-Aug-2008	MD		20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2640AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0279X	0	Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B19AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Loss of consciousness, Pyrexia, Tremor

Symptom Text: 5-7 mins after vaccination passed out and had shaking of arms and leg for few secs. Still having intermittent dizziness, headaches, low grade fever since then

Other Meds:

Lab Data: None

History: Re-current syncope

Prex Illness: None

Prex Vax Illns: sister- same day~Vaccine not specified (no brand name)~UN~0~In Sibling

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321703-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	30-Jul-2008	30-Jul-2008	0	08-Aug-2008	19-Aug-2008	NM		19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope episode after GARDASIL vacc.

Other Meds: None

Lab Data: None

History: Sulfa rash

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321704-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Feb-2007	Unknown		08-Aug-2008	19-Aug-2008	TN		19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2609AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0916F	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Pt had a genital wart on exam 2/20/07 that is again present on exam 8/8/8 and her mother feels that because warts come & go that the child "got some bad vaccine".

Other Meds:

Lab Data: Pap ASCUS, no HPV effect noted

History: none, except con. acuminatum 078,11 2/20/07

Prex Illness: none

Prex Vax Illns:

Vaers Id: **321721-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Dec-2007	24-Dec-2007	0	11-Aug-2008	12-Aug-2008	FR	WAES0808USA00913	12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Blood pressure immeasurable, Hypoventilation, Pallor, Syncope

Symptom Text: Information has been received from a health authority (ADR20205971) concerning a 15 year old female with no relevant medical history reported who on 24-DEC-2007 was vaccinated intramuscularly with a dose of GARDASIL. On 24-DEC-2007, the same day as vaccination, the patient experienced fainting, her blood pressure was unobtainable, and she was very pale with very shallow respiratory effort. On 24-DEC-2007, the patient recovered. Other business partner numbers included: E2008-07399. It was reported that the patient's experience was considered to be immediately life-threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **321724-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Apr-2008	21-Apr-2008	0	11-Aug-2008	12-Aug-2008	--	WAES0806USA07784	12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a physician concerning a 14 year old female who in February of 2008 was seen for an emergency contraceptive prevention. On 21-APR-2008 the patient was vaccinated with a first dose of GARDASIL (lot number) 0.5 ml by intramuscular injection (injection site not reported). Concomitant therapy included DEPO-PROVERA. Later the patient was found to be pregnant. At the time of this report the patient was in her 21st week of gestation. Unspecified medical attention was sought. Follow-up information was received from a nurse practitioner who reported that on 24-JUL-2008 the patient had a prenatal ultrasound performed, which revealed possible atrial septal defect of the fetus. Possible atrial septal defect was considered to be a congenital anomaly. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: ultrasound 7/24/08, possible atrial septal defect of the fetus; beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/25/2008)

Prex Vax Illns:

Vaers Id: 321725-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Apr-2007	22-Apr-2007	7	11-Aug-2008	12-Aug-2008	FR	WAES0808AUS00036	12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Asthenia, Blindness, Gait disturbance, Hypoaesthesia, Livedo reticularis, Multiple sclerosis, Oedema peripheral, Paraesthesia, Paresis, Visual disturbance

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form, concerning a 17 year old female with recurrent cough/cold and an allergy to egg whites (vomiting and getting a rash around her mouth after eating cooked egg). The patient was subsequently administered MMR vaccine (brand not specified) under observation in hospital, without any adverse event. She also has a history of an allergic reaction to erythromycin at the age of 3 years when her legs became very mottled and slightly swollen. On 15-APR-2007 the patient was vaccinated with GARDASIL, intramuscularly. One week prior to vaccination, the patient had been treated with penicillin (possibly amoxicillin) for her recurrent cough/cold. On approximately 22-APR-2007, one week after vaccination with GARDASIL , the patient developed multiple sclerosis included abasia, paraesthesia, vision loss and asthenia. It was described that the patient complained of numbness starting on torso from underarms down, which progressively increased over two weeks to include her legs and feet. She was unable to walk without assistance, and was hospitalised by her general physician. The patient was in hospital for three days and was treated with methotrexate. A Magnetic Resonance imaging (MRI) of the patient's brain and spine identified three spinal lesions. After discharge, she complained of flickering in the right eye, and over the next ten days she experienced progressively worsening vision and could only see grey. The patient was readmitted to hospital and was treated with methotrexate. Her sight gradually returned to normal and it took up to one year for her to regain her strength. At the time of reporting to the agency on 29-JUL-2008, the patient had recovered from multiple sclerosis and paresis. The agency considered that multiple sclerosis and paresis were possibly related to therapy with GARDASIL. The agency stated: "Note: disconnect between proposed diagnosis: MS". The original reporting source was not provided. Addition

Other Meds: Unknown

Lab Data: magnetic resonance imaging, brain and spine: three spinal lesions identified

History: Allergic reaction to antibiotics

Prex Illness: Cough; Egg allergy; Head cold

Prex Vax Illns:

Vaers Id: 321726-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Oct-2007	22-Oct-2007	0	11-Aug-2008	12-Aug-2008	FR	WAES0808AUS00032	12-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Complex regional pain syndrome, Facial paresis, Hemiparesis, Injection site pain, Pain in extremity, Paraesthesia, Paralysis, Psychiatric evaluation

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form. This case was also reported in a newspaper article. The patient was a 15 year old female who on 22-OCT-2007 was vaccinated with GARDASIL. The child had also received 2 other doses of GARDASIL (dates not reported). On 22-OCT-2007 the patient experienced pain in extremity, complex regional pain syndrome, hemiparesis, injection site pain, paraesthesia and paralysis. The patient was treated in the Accident/Emergency Department and was hospitalised. It was described that the child initially had pain in the whole left arm requiring emergency department presentation and then 3 days later, she experienced intermittent left arm paralysis and paraesthesia. Later she presented with left facial, arm and leg hemiparesis. The patient's symptoms were inconsistent with signs of brain MRI. The patient was placed on long term physiotherapy and hydrotherapy for left arm with ongoing psychiatric and counseling input as outpatient. At the time of reporting to the agency on 17-JAN-2008, the patient had recovered from pain in extremity, complex regional pain syndrome, hemiparesis, injection site pain, paraesthesia and paralysis. The agency considered that pain in extremity, complex regional pain syndrome, hemiparesis, injection site pain, paraesthesia and paralysis were probably related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, brain MRI

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321733-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	18-Jul-2008	19-Jul-2008	1	11-Aug-2008	18-Aug-2008	MA		20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	1	Right leg	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Grand mal convulsion, No reaction on previous exposure to drug, Sleep disorder, Stress

Symptom Text: Patient developed a grand mal seizure, new onset, the day after the HPV vaccine, dose #2. Did well with first dose. 8/19/08-records received for DOS 7/20/08-DC DX: Generalized tonic clonic seizure. Presented to ED with first time seizure. Had not eaten anything that day. Drank ETOH night before. Sleeping poorly due to stress.

Other Meds: ADDERALL XR 10mg

Lab Data: Witnessed seizure. 8/19/08-records received- EEG normal.

History: Hydrocephalus treated/Quiescent. 8/19/08-records received-PMH: aqueductal stenosis and hydrocephalus s/p 3rd ventriculostomy in 1998. Mastoiditis. Facial nerve palsy. ADHD.

Prex Illness: None

Prex Vax Illns:

Vaers Id: 321741-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	16-Jul-2008	18-Jul-2008	2	11-Aug-2008	20-Aug-2008	MO		28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Pain in extremity, Paraesthesia

Symptom Text: Left upper and lower arm tingling and pain and numbness intermittent starting 2-3 days post injection, has persisted for 20 days, without resolution. May have started earlier, but thought it was just due to recent injection. 8/19/08 Reviewed pcp office records of 12/19/07-7/16/08. FINAL DX: none provided. Records reveal patient experienced good health. HPV #1 given 5/13/08, lot 0152X, IM, LA; HPV#2 given 7/16/08, lot 0152X, IM, LA. No indications of complaints at either vaccine nursing visit.

Other Meds: MICROGESTIN 1/20

Lab Data: None

History: None PMH: contraception. Family hx: cancer, depression, DM, HTN, heart disease, kidney disease, osteoporosis, CVA, thyroid disease.

Prex Illness: None

Prex Vax Illns:

Vaers Id: 321754-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Jul-2008	27-Jul-2008	24	11-Aug-2008	20-Aug-2008	CA		20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0538X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2553AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister, Pruritus

Symptom Text: Received VARIVAX #2 7/3/08. Onset vesicle type blisters 7/27/08. Itchy, afebrile. Rx BENADRYL oral prn, calamine topical prn.

Other Meds: ADVAIR, ALLEGRA, SINGULAIR, albuterol

Lab Data: None

History: RAD and allergic rhinitis

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321759-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	08-Aug-2008	08-Aug-2008	0	11-Aug-2008	20-Aug-2008	NY		20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1854U	0	Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C2863AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2564AA	0	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ear congestion, Syncope

Symptom Text: Patient received Tdap, VVX, MCV4 and HPV vaccines. Fainted soon after vaccines were given.

Other Meds: None

Lab Data: Initial VS after fainting were BP 91/49 and P 60. Was given juice and crackers, layed down.

History: None

Prex Illness: Nasal and ear congestion.

Prex Vax Illns:

Vaers Id: **321760-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	06-Aug-2008	06-Aug-2008	0	11-Aug-2008	20-Aug-2008	PA		20-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0063X	0	Left arm	Intramuscular	
MMR	MERCK & CO. INC.	1029F	1	Right arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB284CA	0	Right arm	Intramuscular	
TD	SANOFI PASTEUR	U1993BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Loss of consciousness, Syncope, Syncope vasovagal

Symptom Text: Approximately ten minutes post injection patient experienced a vasovagel syncope episode. Hit head on floor. Lost consciousness for approximately 3 seconds. BP and heart rate monitored by nursing staff. Ambulance was called. Patient evaluated by EMS and released to mother. Will follow up with MD

Other Meds:

Lab Data: Sinus arrythmia EKG

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **321764-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	08-Apr-2008	01-Jun-2008	54	11-Aug-2008	20-Aug-2008	AZ		20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0930U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Hypoaesthesia, Panic attack, Paralysis

Symptom Text: SYMPTOMS STARTED WITH A STOMACH ACHE AND PROGRESSED TO HER LEGS AND ARMS FEELING NUMB AND PARALYZED. SHE PROCEED TO DEVELOP A PANIC ATTACK. FATHER PUT PATIENT IN THE CAR AND WAS EN ROUTE TO THE URGENT CARE WHEN PULLED OVER BY THE POLICE. WHILE DRIVING HER PANIC ESCALLATED. THE PARAMEDICS WERE CALLED, SHE WAS ATTENDED TO BY THEM AND SUBSEQUENTLY ADVISE TO RETURN HOME AS SHE HAD CALMED DOWN AND SYMPTOMS HAD SUBSIDED.

Other Meds:

Lab Data: NO DIAGNOSTIC TEST WERE PERFORMED AT THE TIME OF INDICENT

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321766-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-Aug-2008	08-Aug-2008	0	11-Aug-2008	21-Aug-2008	NY		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279C	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Dizziness, Flushing, Headache, Loss of consciousness, Pallor, Pyrexia, Syncope, Vomiting

Symptom Text: My daughter was scheduled for her 12yr-old well visit with Dr. on 8/8/08 at 10:15 am. She was examined and was in perfect health at the time of her scheduled appointment. The Gardasil vaccination was given to her by the nurse. As we were at the front scheduling the next series of shots, within minutes my daughter said she had a really bad headache and then she started to vomit and she blacked out and fainted. She was returned to the examining room where she was propped up on the table and her blood pressure was taken by the nurse. Soon after she started to come around and was given flat coke to drink by the nurse. Since the visit my daughter has experienced headaches and running fevers of 102F to 103F from 8/9/08 thru 8/11/08. 8/15/08 Reviewed PCP medical records of 8/3-8/11/08. FINAL DX: none provided Records reveal patient in good health on 8/3/08 day of vaccination. No records included of reaction. Next note is t/c to parent to check status of recovery on 8/11/08 when continued to have facial flushing & HA. Was afebrile at that time. Had seen another MD over the w/e due to fever with negative findings. Reaction noted to have been lightheadedness & pale.

Other Meds: NONE

Lab Data: None as of 8/11/08

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **321767-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	25-Jan-2008	27-Jan-2008	2	11-Aug-2008	18-Aug-2008	IL		24-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1210U	1	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal discomfort, Arthralgia, Blood test, Colonoscopy, Computerised tomogram, Culture stool, Endoscopy, Immediate post-injection reaction, Musculoskeletal pain, Pancreatitis, Pancreatitis acute, Stomach discomfort, Stool analysis

Symptom Text: She received the shot on Jan. 25,2008. Immediately after she started having an upset stomach. She then developed flu- like symptoms on April 18,2008. She was then hospitalized with pancreatitis on April 27, 2008 and was in the hospital with that till May 1, 2008 she had residual pain for 5-6 days and returned to school. Then on May 19, 2008 she started having abdominal. She has seen a pediatric gastroenteralogist every since with no explanation of her pain. She has had several blood test, CT scans, endoscopy, colonoscopy, and stool test. She has had little to no effect from the antispasm medication. She has been hospitalized on and off since several trips to the ED for pain management. She has also now for the last week had unexplained joint pain in her shoulders. I have given her Tylenol and Motrin for pain with little effect.10/20/08-records received for DOS 4/21-4/24/08-DC DX: Acute viral pancreatitis.Presented with C/O abdominal pain localized around epigastric and right upper quadrant began several days prior. GI type flu one week ago and suspected pancreatitis was probably due to enteroviral Coxsackie infection.

Other Meds:

Lab Data: 10/20/08-records received-Serum lipase 552.

History: None

Prex Illness: None 10/20/08-records received-GI type flu one week ago

Prex Vax Illns:

Vaers Id: 321771-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-May-2008	01-Jun-2008	23	11-Aug-2008	20-Aug-2008	CA		20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	MSD 1758U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: PAIN IN HANDS TO ELBOW AND LEFT THIGH,"STABBING" FEELING LASTING SECONDS. NO TREATMENT NEEDED. RESOLVES BY IT SELF AFTER SECONDS. NO PARALYSIS. NO NUMBNESS. FAMILY REPORTED PROBLEMS AFTER HPV VACCINE

Other Meds: NONE

Lab Data: NONE

History: PANIC ATTACKS/ANXIETY, MYOPIA

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 321775-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	20-May-2008	02-Jun-2008	13	11-Aug-2008	21-Aug-2008	PA		15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	19674	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal distension, Burning sensation, Chest discomfort, Decreased appetite, Diarrhoea, Fatigue, Irritable bowel syndrome, Limb discomfort, Paraesthesia

Symptom Text: intermittent burning/tingling in arms, fingers, upper chest, legs, and feet; burning pain and fatigue worsened as day progressed; symptoms the worst about 1-2 weeks following vaccine; these symptoms have lessened, but still occasionally get burning/tingling in extremities. 9/12/08 Reviewed PCP office vaccination records of 6/10/2008. FINAL DX: irritabile bowel syndrome Records reveal patient exprienced bloating, decreased appetite, loose stools, discomfort of chest & arms intermittently

Other Meds: none

Lab Data: all labs normal (full blood count), abdominal ultrasound and MRI normal LABS: pelvic US neg.

History: history of UTI's PMH: HPV infection tx w/colposcopy.

Prex Illness: tested positive for HPV (potential cervical cancer causing type) prior to vaccine (but OB-gyn recommended that I still get the v

Prex Vax Illns:

Vaers Id: **321778-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	05-Aug-2008	05-Aug-2008	0	11-Aug-2008	20-Aug-2008	AZ	AZ0811	20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	14466	5	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness

Symptom Text: Became dizzy,BP100/50--laid down, BP 112/60. Dizziness lasted about 15 minutes before sustained BP upon standing.

Other Meds: None

Lab Data: N/A

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 321779-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Apr-2008	18-Apr-2008	4	11-Aug-2008	18-Aug-2008	TX		20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Back pain, Blindness unilateral, Feeling abnormal, Gait disturbance, Headache, Hypoaesthesia, Hypoaesthesia facial, Malaise, Muscle twitching, Nerve injury, Pain, Radiculopathy, Sinusitis

Symptom Text: We have tract Ashleigh's symptoms back to early part of December. She complained on and off of achy joints and just not feeling right. In February one of her track coach's approched me with concern and asked if Ashleigh had told me about her knees hurting and the lower part of her legs going numb on several different occasions. The trainer had looked at her and suggested a knee brace. The sparactic numbness continued though. On 4-14-08 Ashleigh received the 3rd HPV vaccine. On 4-18-08 I received a phone call that Ashleigh had experience and ice pick type pain in the back of her head and could not see out of her right eye and was complaining that the right side of face and arm were completely numb. We went straight to Dr. Pai who sent us to Henderson Memorial for a cat scan and then to Trinity Mother Francis Emergency in Tyler for and MRI. Diagnosis: Sphrenoid Sinusitis. She was given a prescription for a Z-pack and Naprolan. Ashleigh's symptoms seem to improve but still complained of achy joints especially in her lower back and hips and now experiencing twitching on the right side of face and arm. On 5-7-08 we took Ashleigh to the emergency room again because her lower back, hips, knees and ankles were hurting and numb. She complained that the pain felt like it was coming from the inside of the bone. Diagnosis: Possible pinch nerve, ice and heat along with Advil were to be implemented 5-8-08 I called Dr. Pai because Ashleigh's symptoms had worsened overnight and now was having trouble walking. He called Dr. Karenpuza an nueroligist and set up for him to see her 5-9-08 the very next morning at 6:30a.m.. Dr. Karenpuza examined Ashleigh and told us he was admitting her into the hospital with the suspicions of MS. He treated her symptons as and MS patient. A spinal tap, MRI, and blood work was ordered along with and IV for a steroid treatment to be given every 6 hrs. for 30 mins each time. Ashleigh was discharged on 5-13-08 and to take Predizone for 5 days along with Aleeve. On 5-20 Dr. Karenpu

Other Meds:

Lab Data: Reflex test, Motor nerve conduction, Sense nerve conduction, muscle test, cat-scan, lumbar puncture, MRI with and without contrast, blood work: we were told that everything came back normal, eVoke potential 8/15/08-records received-MRI of

History: 8/15/08-records received-headache a few weeks ago.

Prex Illness: Sinus Infection

Prex Vax Illns:

Vaers Id: 321786-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	24-Jul-2008	27-Jul-2008	3	11-Aug-2008	20-Aug-2008	VT		20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2633AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1968U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gait disturbance, Headache, Myalgia, Pain, Pyrexia

Symptom Text: Fever 101-103 associated with headache & body aches. Intense muscle aches lower extrem > upper extrem to the point of difficulty walking, getting out of chair, etc. Duration 5-6d. Rx ibuprofen 600mg q 6 hr.

Other Meds: None

Lab Data: CK; Mono; BH: CBC; Lyme titer NL; ESR increased, 30; Parvo B19, c/w post infection

History: H/O peanut/nut allergy

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321790-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	22-Jan-2008	22-Jan-2008	0	11-Aug-2008	20-Aug-2008	MA		20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vision blurred

Symptom Text: Blurred vision in left eye unable to focus.

Other Meds:

Lab Data: none

History: no

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321792-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Aug-2008	05-Aug-2008	0	11-Aug-2008	20-Aug-2008	VT		20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2384BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope ~3 min - cold cloths to forehead, juice.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 321870-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Mar-2008	25-Jun-2008	111	12-Aug-2008	13-Aug-2008	CA	WAES0808USA01029	20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Convulsion, Gaze palsy, Loss of consciousness, Pyrexia, Syncope

Symptom Text: Information has been received from a nurse concerning her 16 year old daughter with questionable allergies to penicillin and a history of Bell's Palsy who in December 2007 or January 2008, was vaccinated with a first dose of GARDASIL (lot number, injection site and route not reported). In February 2008, the patient was vaccinated with a second dose of GARDASIL intramuscularly (injection site and lot number not reported). There was no concomitant medication. On 25-JUN-2008 or 26-JUN-2008, the patient had a relatively high fever of 101.9 F. She was put on ZITHROMAX from 26-JUN-2008 to 30-JUN-2008. On 02-JUL-2008 the patient had a seizure, her eyes rolled to the back of her head and she had a loss of memory. The patient was taken to the emergency room and the following tests were done: CT scan, EEG and MRI which were all normal. The ER did not find the cause of the seizure. Subsequently the patient recovered from the events. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested. 8/13/08-records received for DOS 7/2/08-presented to ED after loss of consciousness while eating lunch. Coherent and confused enroute to ED. In ED awake, alert oriented with no specific complaints. Unaware of any antecedent symptoms prior to episode. DX: Syncope, probably seizure. 8/15/08-records received-1st Gardasil received 12/26/07-2nd Gardasil received 3/6/08. On 7/10/08-Parent contacted PCP office concerned about seizure after 2nd vaccination. Seizure occurred 1 week ago. 8/13/08-experienced second seizure. Will continue to follow in office.

Other Meds: None

Lab Data: Computed axial, 07/02/08, normal; Electroencephalography, 07/02/08, normal; Magnetic resonance,07/02/08, normal. 8/13/08-records received-Ct scan brain negative. Metabolic panel, CBC normal. Pregnancy test negative. 8/15/08-records recei

History: Palsy 8/13/08-records received-PMH: Bell's palsy.

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **321871-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		12-Aug-2008	13-Aug-2008	TN	WAES0808USA01016	13-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a 15 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL (lot number, injection site and route not reported). There was no concomitant medication. Within 10 minutes after the vaccination, the patient developed a seizure. The patient stayed in the office and recovered prior to leaving the office. The duration of the seizure was unspecified. The physician reported that no hospitalization or laboratory work up was required for the patient. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321872-1** **Related reports:** 321872-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Feb-2008	04-Aug-2008	173	12-Aug-2008	13-Aug-2008	CA	WAES0808USA00773	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amnesia, Confusional state, Convulsion, Dizziness, Fall, Fatigue, Headache, Immediate post-injection reaction, Neck pain, Syncope, Syncope vasovagal, Tremor

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with GARDASIL. The physician reported that a patient experienced on 01-AUG-2008 after having at some point previously received a GARDASIL injection. Upon internal review seizure was considered an other important medical event. Additional information has been requested. 8/22/08 Reviewed PCP office records which included ER contact info, labs & vax records. FINAL DX: vasovagal syncope; possible idiopathic seizure Records reveal patient immediately after 1st HPV injection 2/13/08 felt dizzy fainted & had tremors lasting less than 30 second, awoke alert but tired. Recovered completely & d/c to home. Parent informed MD of fainting & tremors while vacationing out of state, woke up confused & had HA x 2 days. Seen in ER where CT scan & labs were WNL. 8/26/08 Reviewed ER medical records of 8/1/2008. FINAL DX: syncopal episode, probable vasovagal Records reveal patient experienced trip & fall into a few inches of water at beach. Got up & walked a few steps then fell forward & had seizure lasting 10-20 sec. Patient had no memory of event. Had HA & sore neck in ER.

Other Meds: Unknown

Lab Data: Unknown LABS: CBC WNL. Chemistry w/alk phos 75(L). CT of head WNL.

History: Unknown PMH:recurrent ear infections in childhood, wrist fracture Syncopal episode s/p HPV vaccine 2/08.

Prex Illness:

Prex Vax Illns:

Vaers Id: **321872-2** **Related reports:** 321872-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Feb-2008	13-Feb-2008	0	18-Aug-2008	25-Aug-2008	--		26-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446V		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion, Syncope

Symptom Text: Had fainting spell - short generalized seizure - tonic clonic tremors, lasted approximately 1 minute. Felt well after seizure. Has declined 2nd GARDASIL. 2nd idiopathic seizure today (8-1-08) while on the beach generalized lasted less than 1 minute.

Other Meds: None

Lab Data: patient being worked up for Recurrent seizures, scan, EEG lab, profile

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **321873-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	02-Jul-2007	16-Jul-2007	14	12-Aug-2008	13-Aug-2008	--	WAES0808USA00570	13-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal cardiac disorder

Symptom Text: Information has been received from a 21 year old female with no medical history or no drug allergies, for the Pregnancy Registry for GARDASIL, who on an unknown date was vaccinated with the first dose of GARDASIL, on 02-JUL-2007 was vaccinated with the second dose of GARDASIL and in October 2007, was vaccinated with the third dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified) and progesterone. In November 2007, the patient found out she was pregnant. The patient stated that she was given a pregnancy test each time and they came back negative, but it was assumed that the patient became pregnant around July 16, 2007. The patient reported that she had her baby on 11-APR-2008, and her son was born with heart defects. The patient stated that her son went to his physician every month too two months and had an electrocardiogram (EKG and ultrasound done), and he would have surgery when his heart gets bigger. The patient stated that her son's surgery around will be when he is a year old. No product quality complaint was involved. Upon internal review, heart defect was considered to be a congenital anomaly. Additional information has been requested.

Other Meds: Hormonal contraceptives; Progesterone

Lab Data: Beta-human chorionic, negative

History:

Prex Illness: Pregnancy NOS (LMP = 7/16/2007)

Prex Vax Illns:

Vaers Id: **321874-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Apr-2008	01-May-2008	2	12-Aug-2008	13-Aug-2008	FR	WAES0808USA00310	13-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	MEN	UNKNOWN MANUFACTURER	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Inflammation, Juvenile arthritis, Musculoskeletal stiffness, Pain in extremity

Symptom Text: Information has been received from a health authorities concerning a 14 year old female patient who on 17-JAN-2008 was vaccinated with the first dose of GARDASIL (batch number not reported) via intramuscular route. On 12-MAR-2008, the patient was vaccinated with the first dose of MENBVAC and on 29-APR-2008 was vaccinated with the second dose of MENBVAC. On 01-MAY-2008, she presented with metacarpal-phalangeal and interphalangeal proximal pain of second and third fingers of hands. She also had knee pain with markedly inflammatory rhythm, morning stiffness of 4 hours. Clinical examination defined arthritis. Biological analysis revealed erythrocyte sedimentation rate (ESR) at 20. Latex and Waaler-Rose tests were positive. Anti DNA antibodies were at 3.4 UI/ml. Anti CCP antibodies were expected. Radiology was normal, there was no signs of erosion. Diagnosis was juvenile rheumatoid arthritis. Methotrexate treatment was initiated. Thumb pain of right hand in Feb-2008 was reported in a traumatic context. At time of reporting the patient had not recovered. Upon internal review, juvenile rheumatoid arthritis was considered to be an other important medical event. Other business partner numbers include: E2008-07298. Additional information has been requested.

Other Meds:

Lab Data: diagnostic laboratory test, 3.4 UI/ml, Normal Range: - <20, Comment: anti DNA antibodies; diagnostic radiology, Comment: normal, no sign of erosion; diagnostic laboratory test, Comment: latex and waaler-rose tests: positive; serum rheumatoi

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321875-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Jul-2008	25-Jul-2008	0	12-Aug-2008	13-Aug-2008	FR	WAES0808USA00279	13-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Contusion, Fall, Head injury, Skin laceration, Syncope

Symptom Text: Information has been received from a paediatrician concerning a 15 year old female who on 25-JUL-2008 was vaccinated with GARDASIL (lot #, route and site not reported). Five hours p.v., (on 25-JUL-2008), the patient experienced syncope, she fell and experienced bruise of her head and laceration of chin (diameter about 0.8 cm length). She was hospitalized for monitoring from 25-JUL-2008 to 27-JUL-2008. Cranial CT on 25-JUL-2008 showed no intracranial bleeding, nor an increase in volume or an edema. A fresh ischemic lesion was not definable at the time of examination. Diagnosis of cranial contusion, fall of unclear cause and chin lesion were established. Routine laboratory: no pathological findings. At the time of the reporting the patient had recovered. Other business partner numbers include: E2008-07283. File is Closed. No additional information is expected.

Other Meds: Unknown

Lab Data: Head computed axial tomography, 25Jul2008, no intracranial bleeding and no increase in volume or an edema; Diagnostic laboratory test, routine laboratory: no pathological findings.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **321876-1 (S)** **Related reports:** 321876-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	31-Jul-2008	31-Jul-2008	0	12-Aug-2008	13-Aug-2008	--	WAES0808USA00272	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Dysphagia, Dysphonia, Dyspnoea, Ear, nose and throat examination, Eyelid oedema, Facial pain, Hypersensitivity, Joint range of motion decreased, Lip swelling, Local swelling, Lymphadenopathy, No reaction on previous exposure to drug, Pain, Parotid duct obstruction, Salivary gland enlargement, Sialoadenitis, Swelling face, Tenderness, Tonsillar hypertrophy

Symptom Text: Information has been received from a nurse practitioner concerning her daughter, a 26 year old female with depression, asthma exercise induced and allergy to nuts who on 31-JUL-2008 was vaccinated with a third dose of GARDASIL (route and administration site not reported). Concomitant therapy included EFFEXOR. On 01-AUG-2008, within 12 hours of the vaccination, the patient experienced facial swelling and puffy cheeks. The patient then had tenderness of her neck and enlarged lymph nodes. She was treated with BENADRYL, ZYRTEC and ice packs. It was mentioned that the patient had no adverse reaction after the first 2 doses of GARDASIL. The patient's facial swelling and tenderness of neck and enlarged lymph nodes persisted. She sought medical attention in the office. Follow-up information was received. The patient became progressively worse on 01-AUG-2008 and 02-AUG-2008 with continued facial swelling and enlargement of both lymph nodes and salivary glands, and difficulty swallowing. The patient underwent CT scan, ENT evaluation and was admitted to the hospital. IV steroids and pain medicine were given. An antibiotic was also given to which she had an allergic reaction. An infectious disease consult was called. At the report time, the swelling has just started to regress slightly, but the parotid glands were tense and obstructed. Additional information has been requested. 08/28/2008 MR received for DOS 8/2-5/2008 with D/C DX: Sialadenitis, likely 2' to allergic reaction. Depression. Pt presented with facial swelling and pain which began the pm of HPV4 shot. Pt developed lip, eyelid and neck swelling initially, then shooting pain with neck movement or touch. Pt then developed difficulty swallowing and eventually difficulty breathing. On PE in ER voice is hoarse, swelling of eyelids, face, lips and neck. Tender to touch. Tonsils enlarged, touching uvula. Decreased neck ROM 2' to pain. Started on abx and steroids with allergic rxn to Clindamycin. Continued steroid tx with clinical improvement. To f/u w

Other Meds: EFFEXOR

Lab Data: throat culture, 08/01/08, negative. Labs and Diagnostics: CT with patchy enhancement over the parotid and submandibular glans with edema in anterior SubQ, mucosal and deep tissues. CBC with WBC up to 16.5 with 91.0% neutro, 3.0% lymphs.

History: Anaphylaxis. PMH: Allergies to PCN, Compazine, Keflex, Clindamycin, nuts, red dye. Asthma. Depression. Pneumonia, Syncope, occ diarrhea

Prex Illness: Depression; Asthma exercise induced; Allergy to nuts

Prex Vax Illns:

Vaers Id: 321906-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	19-Jul-2007	12-Sep-2007	55	12-Aug-2008	18-Aug-2008	OH		03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Akinesia, Arthralgia, Arthritis, Crying, Decreased appetite, Erythema, Eye swelling, Fatigue, Gait disturbance, Inflammation, Joint effusion, Joint range of motion decreased, Joint stiffness, Joint swelling, Musculoskeletal stiffness, Myalgia, Nausea, Night sweats, Paraesthesia, Polyarthritis, Pyrexia, Rash maculo-papular, Rheumatoid arthritis, Sleep disorder, Synovitis, Temperature intolerance

Symptom Text: Had her second Gardasil vaccination at the end of August 2007, two weeks later suddenly developed pain in joints of hands, feet, knees and elbows. Pain got progressively worse and required emergency room visit when she could not bend her joints and was in extreme pain. Had multiple tests done and was given prednisone for the inflammation, pain medication and a referral to a Rhematologist. After 2 months of treatment with steroids and multiple blood tests for Lyme disease, Hepatitis and Lupus and others she was diagnosed with Rhematoid Arthritis. It came on out of the blue. She had never had any illness or symptoms prior to the sudden and unexplained onset. We went to the Clinic for a second opinion and they confirmed RA. She has been on Methetrexate and Enbrel which she will have to stay on for the rest of her life. She still has stiffness, pain and inflammation even with the drugs. This happened just after her second dose of Gardisal. I believe there is a connection, prior to that she was a strong healthy young woman with no history of any illness and never had joint pain. There is no history of autoimmune disease in either side of her family and it is extremely rare for RA to develop so suddenly and severely as it did in her case. 09/12/2008 MR received for ER visit 9/23/2007 with DX: arthralgias. Pt presented with c/o 1 week hx of joint pain, now worsening in legs, wrists and shoulder as well as low grade fevers and polymyalgia. Recently started on steroid taper by PCP however pain is now worse with lower extremity joint swelling. D/C on pain meds to f/u with rheumatologist. Rheumatology consult dated 9/28/07 with impression Inflammatory Arthritis in multiple joints. HPI as above now with morning stiffness > 1 hr, fatigue, night sweats, cold sensitivity, nausea and paresthesias in the hands and feet. PE (+) for limping gait, polysynovitis, shoulder, elbow and wrist tenderness with decreased ROM, PIP joints swollen and tender, effusions in both knees, ankles and forefeet tender. Started on prednison

Other Meds: Birth Contol (Yaz)

Lab Data: Multiple blood tests, CPR tests (very high),MRI of joints, Physical examination of joints. Tests were done. Labs and Diagnostics: X-ray bilateral hands (+) for soft tissue swelling of PIP joints which may be a manifestation of early synov

History: none. PMH: none. On oral contraceptives

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321909-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Jun-2008	27-Jun-2008	14	12-Aug-2008	21-Aug-2008	CA		22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Urticaria

Symptom Text: My daughter has become severely allergic to many foods, very suddenly. It all started about two weeks after her first shot. My daughter does have allergies, but never to these new items, (nuts, she was a big peanut butter fan), (and new strange items, like sweet tarts, just gave her a horrible reaction) and never with such a severe reaction as now. She gets terrible hives, and difficulty breathing. I just connected the Gardasil shot and the onset of her severe allergies, because she is due to receive her next shot tommorow and I started thinking about when all this started! * Another daughter age 16 received her first shot the same day and has had no side effects*

Other Meds: nonn

Lab Data: We have been given an epi pen in case of emergency. She is on Zrytec, and inhalers and of couse Bendryl creams. Next is a round of steroids.

History: yes allergies (not as severe) She did have a severe preexisting allergy to beans of all kinds

Prex Illness: none

Prex Vax Illns:

Vaers Id: 321921-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	12-Jun-2008	12-Jun-2008	0	13-Aug-2008	25-Aug-2008	IL		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Dizziness, Migraine, Mood swings, Myalgia, Nausea, Pain, Pyrexia, Tremor

Symptom Text: Severe nausea, migraines, aches, shakes, fever, muscle soreness, dizziness, diarrhea, mood swings

Other Meds: Yasmin

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321925-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-Aug-2008	12-Aug-2008	0	12-Aug-2008	22-Aug-2008	CA		22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2666AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0847X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Patient lost consciousness after GARDASIL vacc. Applied cold compress to back of neck and placed her on reclined chair. Regained consciousness in 20-30 seconds. Continue to observe for 30 minutes - offered cold water and glucose tablets - called patient's mother and they left pharmacy.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321970-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Apr-2007	23-Sep-2007	175	13-Aug-2008	14-Aug-2008	--	WAES0710USA06167	14-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Epidural anaesthesia, Foetal disorder, Heart rate increased, Labour induction, Pyrexia

Symptom Text: Initial and follow-up information has been received from a 23 year old female for the pregnancy registry for GARDASIL who in APR 2007 was vaccinated with the first dose of GARDASIL. No information was received concerning the second dose of GARDASIL. In OCT 2007 the patient was vaccinated intramuscularly with the third dose of GARDASIL. The patient states that she discovered she was pregnant about 1 week after receiving the third dose of GARDASIL (LMP=23-SEP-2007). The pregnancy was confirmed with a pregnancy test. No adverse events were reported. The patient sought unspecified medical attention. On 01-AUG-2008 the patient reported that her pregnancy was fine, no complications. Per the patient, she delivered an healthy and normal boy on 03-JUL-2008 at 40 weeks 5 days by cesarean section. The patient had an elective induction with pitocin and an epidural and progressed to 8cm dilation, at which time she had developed a fever - though she wasn't sure why as there was no infection and both she and the baby had elevated heart rates and the decision for a cesarean section was made at that time. Her son weighed 8 lbs, 3.3 oz. At that time of reporting, the infant was almost one month old and doing well. The patient, reported that she was recovering well - no problems at all. Upon internal review, the patient's fever and increased heart rate and the fetal increased heart rate were considered other important medical events as the events lead to the delivery via cesarean section. Additional information has been requested.

Other Meds: Unknown

Lab Data: beta-human chorionic - positive

History:

Prex Illness: Pregnancy NOS (LMP = 9/23/2007)

Prex Vax Illns:

Vaers Id: **321971-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	25-May-2007	25-May-2007	0	13-Aug-2008	14-Aug-2008	FR	WAES0808COL00001	15-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Leukaemia

Symptom Text: Information has been received from a physician concerning a 26 year old female with a history of loop electrosurgical excision procedure and cervical high grade squamous intraepithelial lesion who on 25-MAY-2007 was vaccinated with the first dose of GARDASIL. On 19-JUN-2008 was vaccinated with the second dose of GARDASIL. On 30-JUL-2008 was vaccinated with the third dose of GARDASIL. On 25-MAY-2007 the patient experienced inappropriate schedule of vaccine administration. In June 2008, the patient experienced symptoms of leukaemia and currently is being studied and treated to leukaemia. The patient's leukaemia persisted. The leukaemia was considered to be an other important medical event. The reporter felt that leukaemia was not related to therapy with GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Loop electrosurgical excision procedure; Cervical high grade squamous intraepithelial lesion

Prex Illness:

Prex Vax Illns:

Vaers Id: **321972-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		13-Aug-2008	14-Aug-2008	FR	WAES0808USA01050	14-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Pancreatitis, Pyrexia, Rash, Tenderness, Vomiting

Symptom Text: It was reported in a published article, titled as stated above that a 26 year old woman presented with 24 hours of severe constant epigastric pain and vomiting. She had no history of similar pains, alcohol consumption or gallstones. Four days before presentation she had received her first dose of GARDASIL. Two days after vaccination she developed a fever and self-limiting rash of 3 days' duration. Examination revealed marked epigastric tenderness and temperature of 40 centigrade. Other physical parameters were within normal limits. Biochemical investigations showed normal liver function, moderate leukocytosis, a serum amylase level of 1900U/L (reference range [RR], 23-85U/L) and lipase level of 3400 U/L (RR, 0-160U/L). An upper abdominal ultrasonography showed a non-dilated biliary tree and no evidence of gallstones. Computed tomography showed an oedematous pancreas with peripancreatic fat stranding and arterial enhancement of the pancreatic parenchyma, consistent with pancreatitis without necrosis (Box). Other investigations showed normal serum levels of calcium, triglycerides and parathyroid hormone. Serological tests were negative for acute infection with Coxsackie A9, Coxsackie B1-6, echo, mumps, herpes simplex, hepatitis and varicella zoster viruses. The patient was diagnosed with pancreatitis and treated conservatively with intravenous fluids and analgesia. Pain, symptoms and biochemical abnormalities settled after 10 days. She was discharged and remains well. Magnetic resonance cholangiopancreatography performed after discharge showed no pancreatic parenchymal or ductal abnormality. Acute pancreatitis is common, with an incidence of 5.4-80 per 100,000. Gallstones and alcohol use account for 70%-85% of cases; other causes include drugs, viral infections, tumours, hyperlipidaemia, hypercalcaemia, trauma, iatrogenic injury and pancreatic ductal anomalies. The cause is unidentified in up to 10% of cases. Viral pancreatitis is well recognized, with cytomegalovirus and mumps, Coxsackie, hepatit

Other Meds: Unknown

Lab Data: diagnostic laboratory test, other physical parameters were within normal limits; abdominal ultrasound, non-dilated biliary tree and no evidence of gallstones; computed axial tomography, oedematous pancreas with peripancreatic fat stranding;

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321973-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		13-Aug-2008	14-Aug-2008	FR	WAES0808USA01194	14-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	HEP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Epstein-Barr virus infection, Hepatitis, Skin discolouration

Symptom Text: Information has been received from a health professional concerning an 18 year old female who on an unknown date was vaccinated with the first dose of GARDASIL (lot# and batch# not reported). The patient had also received hepatitis B virus vaccine (unspecified) some time before. Subsequently the patient experienced severe asthenia and presented with a grayish skin color. Blood test were consequently performed and enabled to diagnosed Epstein-Barr virus infection. One week later, hepatitis was diagnosed. The reporter considered the case an other important medical event. At the time of the reporting, the patient had not recovered. Additional information has been requested.

Other Meds:

Lab Data: diagnostic laboratory test, EBV infection

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **321974-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	07-Jul-2008	09-Jul-2008	2	13-Aug-2008	14-Aug-2008	FR	WAES0808USA01336	14-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cardiac failure acute, Dyspnoea

Symptom Text: Information has been received from a general practitioner concerning a 14 year old female with a history of congenital transposition of great arteries and patent ductus arteriosus who on 07-JUL-2008 was vaccinated with the second dose of GARDASIL (lot No., injection site, route not reported). 36 hours post vaccination, the patient experienced dyspnoea due to acute cardiac insufficiency and was hospitalized in a children's cardiac unit. The patient recovered completely within an unspecified time. The patient's parents decided not to complete the vaccination series. The hospital report was not yet available. The hospital physician considered the event to be possibly related to therapy with GARDASIL. The first dose of GARDASIL was given on an unknown date, toleration not reported. Other business partner numbers included E2008-07448. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Transposition of the great vessels; Patent ductus arteriosus

Prex Illness:

Prex Vax Illns:

Vaers Id: 321979-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	20-Sep-2007	22-May-2008	245	13-Aug-2008	14-Aug-2008	FR	WAES0806USA01127	15-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Asthenia, Chills, Headache, Influenza like illness, Nausea, No reaction on previous exposure to drug, Pyrexia, Sinusitis, Somnolence, Tachycardia

Symptom Text: Initial and follow up information has been received from a general practitioner concerning a 22 year old female with no reported relevant medical history, who on 20-SEP-2007 was vaccinated with the first dose of GARDASIL, intramuscularly. On 20-NOV-2007, the patient was vaccinated with the second dose of GARDASIL, intramuscularly. These vaccinations were well tolerated. On 21-MAY-2008, the patient was given the third dose of GARDASIL, lot #, route of administration and site of injections were not reported. Exact onset not reported, the patient developed headaches, drowsiness, chills and tachycardia. She presented at the physicians office on 26-MAY-2008. At an unspecified time the patient recovered from chills and tachycardia, whereas drowsiness and headache were ongoing at the time of reporting. Follow-up information reported that "shortly" post vaccination, exact onset not reported, the patient developed additionally asthenia, fever, arthralgia, and nausea. Therapy was started with diclofenac and dexamethason. Examinations in the outpatient department of a hospital led to diagnosis of sinusitis. Electrocardiogram (ECG) was normal. It was recommended to carry out surgery. The reporter pointed out that most likely all symptoms were related to sinusitis than to vaccination. At the time of this report the patient had recovered (duration not reported) except for headache and drowsiness. Additional follow-up information reported that on 22-MAY-2008 the patient developed flu-like symptoms, headache drowsiness. On an unreported date at the end of May-2008 the patient was hospitalised. Maxillary sinusitis was diagnosed by x-ray of the paranasal sinuses. Cefuroxim and nasivin (OXYMETAZOLIN) were administered for therapy. Drug screening was negative. Peripheral vestibular disorder could be excluded. Schellong's test, electrocardiogram (ECG), cranial magnetic resonance imaging (MRI) and neurological examinations showed normal results. Electroencephalogram (EEG) showed unspecific "function disorder of the deeper brain struct

Other Meds: Unknown

Lab Data: Electrocardiogram, normal; Nasal sinus x-ray, maxillary sinusitis; Orthostatic hypotension measurement, normal; Electroencephalography, function disorder of the deeper brain structure; magnetic resonance imaging, cranial - normal; Urine dru

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321987-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	07-Aug-2008	07-Aug-2008	0	13-Aug-2008	22-Aug-2008	NY		22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024CA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1758U	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1764U	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Photopsia

Symptom Text: Within minutes of vaccination pt. c/o seeing bright lights. Staff observed pt. become pale. Pt. positioned lying down when c/o began - symptoms resolved in 15 minutes.

Other Meds: none

Lab Data: none

History: asthma

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321990-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	28-Jul-2008	28-Jul-2008	0	13-Aug-2008	22-Aug-2008	CA		22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bed rest, Dizziness, Migraine, Pain

Symptom Text: Migraine started after injection 7/28/08 & intensified. Unable to get out of bed for next few days, had body aches & dizziness x6 days. Went to urgent care informed "probable reaction".

Other Meds: YAZ

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **321995-1** **Related reports:** 321995-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Aug-2008	04-Aug-2008	0	13-Aug-2008	22-Aug-2008	OR		22-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB243AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0843X	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2774AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0524X	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Immediate post-injection reaction, Nausea, Syncope

Symptom Text: Patient fainted just after injections. Nauseated upon awakening - fanned, cool cloth applied to skin, BP checked. Left clinic with no dizziness or nausea within 15 min.

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **321995-2** **Related reports:** 321995-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Aug-2008	04-Aug-2008	0	17-Sep-2008	23-Oct-2008	--	WAES0808USA01185	23-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	NULL		Gluteous maxima	Unknown	
HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
TTOX	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Injection site pain, Musculoskeletal stiffness, Nausea, Pallor, Syncope

Symptom Text: Information has been received from a consumer concerning her 12 year old daughter who on 04-AUG-2008 was vaccinated with GARDASIL (yeast). VARIVAX (dose not reported), VAQTA (inactive) (manufacturer unknown) and tetanus toxoid (manufacturer unknown). On 04-AUG-2008, after being vaccinated with GARDASIL her daughter reported the vaccination stung. Then, she felt dizzy, developed a blank expression on her face, her arms tightened, her head dropped forward and she fainted. She was pale and felt nauseated and her blood pressure was 90/50. She sat at the doctor's office for 10-15 minutes. The arm that had the vaccination for tetanus toxoid also hurt. The patient had eaten very little before vaccination. The patient sought medical attention at the clinic. On 04-AUG-2008, the patient recovered from the events. Additional information is not expected.

Other Meds: Unknown

Lab Data: Blood pressure 08/04/08 90/50

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **321997-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		13-Aug-2008	22-Aug-2008	PA		22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1902U	1	Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Pallor

Symptom Text: Gave varicella & HPV at 1600. 1610 pt felt dizzy & fell to floor. Became pale. Gave Gatorade & sat for few minutes, pt admits not eating lunch prior to appt. Last ate at breakfast.

Other Meds:

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322023-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Jul-2008	19-Jul-2008	1	13-Aug-2008	25-Aug-2008	NY		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Rash pruritic

Symptom Text: Within 24 hours of first GARDASIL shot pt got rash all over her torso. She had raised bumps that are very itchy. Physician gave her steroid medpack w/o help. This continued for over 3 weeks. She still has itchy rash only on torso.

Other Meds: Multivitamin

Lab Data: None

History: allergic to amoxicillin, seasonal allergies (hay fever)

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322034-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Aug-2008	04-Aug-2008	0	13-Aug-2008	25-Aug-2008	FL		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	UNK	UNKNOWN MANUFACTURER	NULL	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Diarrhoea, Dizziness, Nausea, Tremor

Symptom Text: Patient received simultaneous Gardasil and Varivax vaccines and immediately felt faint, weak, shaky, nauseated and experienced subsequent diahrrea for 24 hours

Other Meds:

Lab Data:

History: gluten sensitivity

Prex Illness: none

Prex Vax Illns: none~ ()~NULL~~In Patient|none~ ()~NULL~~In Sibling1

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322038-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.8	F	12-Aug-2008	13-Aug-2008	1	13-Aug-2008	25-Aug-2008	MI		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2613AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2844AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1270U	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Nausea, Pain

Symptom Text: Body ache, head ache, dizzy, nausea

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **322053-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Jul-2008	29-Jul-2008	0	13-Aug-2008	25-Aug-2008	NC		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	2	Left arm	Intramuscular	
	HEPA	UNKNOWN MANUFACTURER	UNKNOWN	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness transient, Dizziness, Faecal incontinence, Immediate post-injection reaction, Visual disturbance

Symptom Text: Patient received her 3rd Gardasil vaccine in her left arm and then immediately following, her Hep A vaccine in her right arm. Within seconds following the vaccinations patient became lightheaded and dizzy, and said she could not see. She stated she thought she was blacking out. She did not lose consciousness. She had been standing up and was immediately assisted to the exam table to sit down. Upon sitting down her dizziness and blindness subsided. She was instructed to lie down. But, patient insisted she had to go to the bathroom right away. As she was escorted to the BR, she became dizzy again and was unable to see. She became incontinent of stool as well. She was assisted to the bathroom and after sitting on the toilet she said she felt better. She was cleaned up and sat in the bathroom for approx. 10 minutes. Upon trying to stand, she again became dizzy, so she sat back down. We stayed in the bathroom approx. 45 minutes until Megan felt able to walk with assistance to the car. During the walk to the car, she continued to feel lightheaded and dizzy, but did not lose consciousness or vision. Upon arriving home she layed on the sofa for 2-4 hours. There were no more adverse symptoms.

Other Meds: none

Lab Data: none done

History: Patient had a duodenal atresia at birth that was surgically repaired 1 day after she was born. No other medical conditions.

Prex Illness: no illness at time of vaccination

Prex Vax Illns:

Vaers Id: **322057-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Aug-2008	12-Aug-2008	0	13-Aug-2008	25-Aug-2008	MI		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Device leakage, Underdose

Symptom Text: While administering injection, a small amount of serum leaked out of the hub.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **322059-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Aug-2008	11-Aug-2008	0	13-Aug-2008	25-Aug-2008	OR		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Patient complained of headaches after receiving vaccine. Mild headache was still present the following morning when she was seen by me. Normal physical examination.

Other Meds:

Lab Data: none

History: no

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322093-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Jul-2008	08-Aug-2008	21	13-Aug-2008	25-Aug-2008	MI		25-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1968U	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0333X	1	Left arm	Subcutaneously	
TDAP	SANOFI PASTEUR	C2644AA	4	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB235BA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash generalised, Urticaria

Symptom Text: 8-8-08 AM woke up in AM with hives/rash on face which progressed to neck and arms. Pt went to an urgent care and got Rx for zyrtec which is not helping. F/U at medical center 8/12/08 now has "bumps on legs".

Other Meds: None

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322094-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
8.0	F	11-Aug-2008	Unknown		13-Aug-2008	25-Aug-2008	TX		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB233AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0522U	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2430AA	1	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B019AA	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: "None"

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322096-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	11-Aug-2008	12-Aug-2008	1	13-Aug-2008	25-Aug-2008	CO		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B015AA	5	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	00767X	2	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB284CA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Contusion, Erythema, Skin warm, Swelling, Urticaria

Symptom Text: T-100.5. 11.5x13.5cm rounded, raised, pink & warm area. Smaller 4x5cm bruised area on side reaction area. Hive like reaction below reaction yesterday.

Other Meds: None

Lab Data:

History: asthma-controlled, eczema

Prex Illness: None

Prex Vax Illns:

Vaers Id: **322110-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Jun-2008	18-Jun-2008	1	13-Aug-2008	25-Aug-2008	WA		25-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2688AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1585U	1	Left arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U2562AA	0	Right arm	Intramuscular	
MMR	MERCK & CO. INC.	14844	2	Right arm	Subcutaneously	
HPV4	MERCK & CO. INC.	1978U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Decreased appetite, Fatigue, Headache, Muscular weakness, Nausea, Paraesthesia

Symptom Text: Pt c/o fatigue, decreased appetite on the evening of 6/17/08. Woke up at 5:15am on 6/18/08 c/o headache, nausea, weakness in arms, "shocking" sensation on arms & trunk (from neck down to abdomen) - this sensation would come in "waves". T 98.3 axillary. All s/s resolved except fatigue.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **322112-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Aug-2008	07-Aug-2008	1	13-Aug-2008	25-Aug-2008	CA		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB291AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0279X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2658AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2996AA	4	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness, Pain, Pyrexia, Urticaria

Symptom Text: Flu like symptoms, low grade fever, body aches, hives in both arms and few hives on torso. Symptoms lasted for 4 days.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 322157-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	05-Aug-2008	05-Aug-2008	0	14-Aug-2008	15-Aug-2008	CA	WAES0808USA01344	23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0847X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Brachial plexopathy, Chills, Hypoaesthesia, Hyporeflexia, Muscular weakness, Neuralgia, Paraesthesia, Paralysis flaccid, Pyrexia, Radiculitis brachial, Sensation of heaviness, Steroid therapy

Symptom Text: Information has been received from a physician concerning a 25 year old female, with a weak immune system and respiratory tract infection, who is a medical assistant at the physician's office, on 03-JUN-2008 was vaccinated with the first dose of GARDASIL. On 05-AUG-2008 the patient went to the physician's office and received the second dose of GARDASIL in the deltoid. The physician reported that about 40 minutes after receiving the vaccination her arm became very numb and heavy, like something or someone was pulling on her arm, and her fingers were tingling. The physician reported that throughout the day her arm felt like a dead arm. The patient had her blood pressure taken that day which was fine. The physician reported that night the patient could not even move her arm; she had chills and a fever so she called the physician at 2:00 in the morning. The patient had then seen her primary care physician the next morning on 6-AUG-2008 who gave her an emergency referral to a neurologist. A CT scan, bloodwork and an X-ray were performed (results not provided). The patient was diagnosed with paralysis of the arm and was admitted to the hospital. The physician reported that the patient was still hospitalized on 07-AUG-2008 and still had the symptoms, but she was having more test done and had been given PROTONIX (manufacturer unspecified) and prednisone (manufacturer unspecified). Paralysis of the arm and chills and fever were considered to be disabling. Additional information has been requested. 9/5/08 Reviewed hospital medical records of 8/6-8/8/2008. FINAL DX: left acute brachial plexus neuritis; obesity Records reveal patient experienced flaccid paralysis of the LUE the day after the second HPV vaccination in LUE. Started w/numbness, tingling & weakness of LUE approx 15 min s/p vaccination & progressing to being unable to move her LUE. Exam revealed LUE 1-/5 strength diffusely. Neuro consult done. Tx w/prednisone & PT in hospital & to be continued as outpatient. 9/16/08 Reviewed neurologist med

Other Meds: Unknown

Lab Data: Unknown LABS: CT scan, MRI & CSF all WNL. ESR 23(H). CSF glucose 87(H). MRI c-spine, MRI brachial plexus, CXR, CT head, CBC, chemistry all WNL. CSF: WBC 0, RBC 5, protein 35 & c/s neg.

History: HPV #1, lot # 0073X, given right upper arm 6/3/2008 PMH: obesity. Family hx: DM, HTN, renal failure, MI.

Prex Illness: Immunosuppression; Respiratory tract infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322158-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	19-Mar-2008	26-Mar-2008	7	14-Aug-2008	15-Aug-2008	FR	WAES0808USA01394	15-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Sinus arrhythmia, Tachycardia paroxysmal

Symptom Text: Information has been received from an health authority (reference number PEI2008011501) concerning a 19 year old female with no relevant medical history reported who on 19-MAR-2008 was vaccinated with GARDASIL. On 26-MAR-2008 she developed paroxysmal tachycardia. Sinoatrial node dysfunction was diagnosed. On an unspecified date she was hospitalized. Myocarditis and hyperthyroidism (thyroid function test) were ruled out. Laboratory findings on cardiotropic viruses and Borrelia antibodies, (longterm) electrocardiogram (ECG), cardiologic magnetic resonance imaging (MRI) and echocardiography were carried out, and results were not reported. Since 25-APR-2008 she was treated with unspecified beta blocking agents and symptoms improved. On 02-APR-2008, she was vaccinated with hepatitis A and B vaccine (manufacturer unknown). Other business partner numbers included: E2008-07472. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, Laboratory findings on cardiotropic viruses were carried out, results not reported; electrocardiogram, results not reported; magnetic resonance imaging, results not reported; echocardiography, results not reporte

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322159-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	30-Oct-2007	30-Oct-2007	0	14-Aug-2008	15-Aug-2008	--	WAES0710USA07061	15-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received through the Merck pregnancy registry from a health professional concerning a 19 year old female patient with a history of allergic reaction to FLAGYL who on 30-OCT-2007 was vaccinated intramuscularly with the first dose of GARDASIL (Lot# 659437/1266U). An ultrasound performed on 30-OCT-2007, following vaccination with GARDASIL, confirmed that the patient was pregnant (LMP= end of September). No other symptoms were noted. The patient sought unspecified medical attention. This is a consolidation of reports regarding the same patient. Follow up information was received. The patient miscarried at the end of December 2007. Upon internal review, miscarriage was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, 10/30/07 - positive

History: Allergic reaction to antibiotics

Prex Illness:

Prex Vax Illns:

Vaers Id: **322160-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		14-Aug-2008	15-Aug-2008	MD	WAES0808USA01851	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Ectopic pregnancy, Uterine dilation and curettage

Symptom Text: Information has been received from a consumer, for the Pregnancy Registry of GARDASIL, concerning her 17 year old daughter who in February 2008 was vaccinated with the first dose of GARDASIL. The patient had ectopic pregnancy and dilation and evacuation in February 2008. Upon internal review ectopic pregnancy considered to be other important medical event. Subsequently the patient was pregnant while vaccinated with the second dose of GARDASIL (WAES 0808USA01038). Additional information has been requested.

Other Meds: Unknown

Lab Data: beta-human chorionic - positive

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 322161-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Jun-2007	01-Jul-2007	10	14-Aug-2008	19-Aug-2008	NC		29-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	0018U	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0186U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain lower, Anorexia, Aphthous stomatitis, Appendicectomy, Arthralgia, Congenital choroidal anomaly, Familial tremor, Fatigue, Feeling jittery, Headache, Hypersomnia, Joint swelling, Migraine, Pain, Sinusitis, Sports injury, Tremor, Visual disturbance

Symptom Text: On 7-1-07 mom picked up patient at volleyball practice with HA and tremors. Mom states since then patient has had severe HA right behind eyes, mouth sores, tremors on a daily basis. She has also had severe joint pain and swelling. Recently had appendix removed. 8/29/08 Reviewed neuro medical records of 7/9-8/4/2008. FINAL DX: migraine headaches; benign familial tremor. Records reveal patient experienced severe HA & shaking x 1 year, localized behing eyes & relieved only by sleep. Tx w/meds. 9/12/08 Reviewed PCP medical records of 6/21/07-7/31/2008. FINAL DX: none provided Records reveal patient experienced good health on day of vaccination. RTC 6/23 for HA which caused visual loss & jittery/shaking spells. Referred to Neuro. RTC 11/8 w/abdominal pain esp in RLT & anorexia. Admittd for Surgical consult & appendectomy done 11/8/2007. RTC 1/15/08 for HA x 3 wks, mouth blisters, tired, excessive sleeping, generalized aching. HA resolved w/antibiotics for sinus infection. RTC 7/31/08 for migraines being f/u w/neuro, canker sores & sports injuries of foot pain & swelling & knee pain.

Other Meds: None

Lab Data: None LABS: CT scan. EBV titers IgM 0.14(L), IgG 5.28(H), EBNA IgG 5.0(H). EEG abnormal w/marked asymmetry of amplitude w/sharp increased in left hemispher. MRI abnormal w/right choroidal fissure.

History: None PMH: acne. mood swings. Family hx epilepsy & cerebral palsy.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **322162-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Jul-2008	18-Jul-2008	2	14-Aug-2008	19-Aug-2008	AZ		29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	31264	0	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Activities of daily living impaired, Arthritis bacterial, Arthroscopic surgery, Bone marrow necrosis, Debridement, Endotracheal intubation, Extubation, Heart valve incompetence, Hypotension, Immediate post-injection reaction, Injected limb mobility decreased, Intensive care, Malaise, Mental status changes, Oedema peripheral, Oral herpes, Osteonecrosis, Pain, Pain in extremity, Pallor, Psychosis postoperative, Staphylococcal bacteraemia, Staphylococcal osteomyelitis, Surgery, Swelling, Tachycardia, Vaccination complication

Symptom Text: Right shoulder arthroscopic I & D with resection of necrotic bone performed 8/5/08. Hx: patient c/o pain and swelling since 48 hrs after injection. ER visit x 2. 9/26/08 Reviewed hospital medical records of 8/5-8/25/2008. FINAL DX: no d/c summary dictated yet. H&P & consults states septic arthritis/osteomyelitis right humerus, secondary to IM injection. Records reveal patient experienced septic osteomyelitis of right shoulder s/p arthroscopic I&D with debridement. Pain in right arm developed immediately s/p HPV vax 7/16. Seen by PCP & tx w/pain med. Pain persisted & developed low grade fever. Seen in ER on 7/23, x-ray neg & d/c to home on pain meds. Began to have swelling of right shoulder/arm, low grade fever, worsening pain & refusal to move arm. Was pale & ill-appearing, sent home from school & taken to ER. CT scan & x-ray revealed right humerus osteomyelitis. Taken to OR for I&D with debridement to remove necrotic bone. Tx w/IV antibiotics. Did well initially then developed tacycardia & hypotension. Tx w/fluid & transferrred to higher level of care ICU. ID, ortho, neuro consults done. Intubated until 8/15. Initially did well post extubation then had altered mental status thought to be ICU psychosis. Had repeat surgery x 2.

Other Meds: None

Lab Data: (+) Blood culture - gram (+) cocci; CT (R) shoulder - osteomyelitis LABS: blood c/s from outlying hospital (+) staph aureus. Echocardiogram abnormal w/tricuspid, pulmonary & mitral regurgitation.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **322165-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	07-Aug-2008	07-Aug-2008	0	14-Aug-2008	25-Aug-2008	CA		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB24AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0843X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Gaze palsy, Syncope

Symptom Text: Within seconds of receiving the shot father said patient collapsed onto table legs kicked and eyes rolled back. Lasted only a few seconds.

Other Meds: PPD skin test

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **322167-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Aug-2008	07-Aug-2008	0	14-Aug-2008	25-Aug-2008	TX		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB233AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0063X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted w/in a few minutes after receiving vaccine.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322180-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Jul-2008	24-Jul-2008	1	14-Aug-2008	25-Aug-2008	OR		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2639AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site warmth, Oedema peripheral

Symptom Text: Patient has swelling from shoulder to elbow for 3-4 days after injections were given skin at injection site hot to touch. Patient feels reaction from HPV - no MENACTRA.

Other Meds: none

Lab Data: None

History: ADHD

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322194-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	10-May-2007	12-May-2007	2	14-Aug-2008	25-Aug-2008	KS		05-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2278AA		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0243U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal distension, Abdominal pain lower, Abdominal pain upper, Eye swelling, Flatulence, Gastritis, Hypersensitivity, Hypoaesthesia, Lip swelling, Muscular weakness, Nausea, Oedema peripheral, Pain, Paraesthesia, Rash, Rash pruritic, Urticaria

Symptom Text: Clt. received the first 2 GARDASIL'S at Dr's office. 1st injection on 05/10/2007, the 2nd was given on 07/16/2007. Clt. states that she told the Dr. about her symptoms and was told that is was a normal reaction. Clt.noted numbness after the 1st gardasil. Her symptoms began approx. 2 days after the 1st injection. She C/O tingling and weakness in both arms, more weakness in the left arm/hand. The 3rd injection was given at county health dept. on 11/16/2007 along with recieving Menningococcol vaccine. Client did not mention any of her symptoms at that time. We became aware of her C/O until 08/06/2008. S/S continue. 10/31/08 Reviewed PCP medical records provided by CDC of 3/20/2007-4/17/2008. FINAL DX: allergic reaction Records reveal patient experienced good health on 5/10/07 for HPX #1, lot # 0011U. Seen 5/31 for school physical & all WNL. RTC 7/16/07 for HPV #2, lot # 0011U. RTC 8/15/07 for persistent epigastric, LLQ pain, bloating, gas, nauseous & pain getting up. Dx w/gastritis & tx w/meds. RTC 4/14 w/lips, eyes & hands swollen, rash on neck follwing tylenol, motrin & alka seltzer, Dx urticaria & tx w/steroids & antihistamine. RTC 4/17 for itchy body rash/hives. Dx w/allergic reaction & tx w/IM steroids & antihistamine. Sent home w/tapering steroids.

Other Meds: NONE

Lab Data: none LABS: strep test neg.

History: none reported. PMH: leg length discrepancy, LLQ pain, acid heartburn w/spicy or greasy foods. On 4/17/07 had sore throat, HA, fever, reddened right TM, red swollen tonsils, nausea. Dx w/URI & tx w/antibiotics. Family hx: uterine cancer.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322195-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	11-Aug-2008	11-Aug-2008	0	14-Aug-2008	25-Aug-2008	ND		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blindness, Feeling abnormal, Hypoaesthesia oral, Immediate post-injection reaction, Limb discomfort, Pallor, Posturing, Syncope

Symptom Text: Within seconds after vaccine was administered (2:20 pm) patient stated that her arm felt funny and that she couldn't see. Patient stated that she wasn't feeling right. Patient started to faint in the chair and was held up by nurse. Patient began to turn gray/blue until nurse stated her name and grabbed her shoulders. Color returned and with assistance from staff patient was laid on the floor. Color was pale. Patient was alert and talking. BP 92/54 P 84. Patient stated that her lips felt numb; Benedryl 25 mg po given at 2:27 pm. Patients hands were postured and she was unable to move them. Ambulance arrived at 2:35 pm. Oxygen was administered by paramedic and was taken to local emergency department.

Other Meds: BCP

Lab Data: UNKNOWN, ACCORDING TO PATIENT BLOOD WORK WAS DONE AT THE ED.

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **322204-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Aug-2008	12-Aug-2008	0	14-Aug-2008	25-Aug-2008	GA		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea, Dizziness, Fatigue, Headache, Vomiting

Symptom Text: PT WAS GIVEN HPV IN L-ARM ON 8/12/2008 PT THEN RETURNED TO OUR OFFICE ON 8/13/2008 C/O BEING DIZZY, VOMITING, HEADACHE, AND DIARRHEA. C/O FEELING TIRED SINCE THE SHOT. ADVISED PT TO MODIFY DIET AS TOLERATED AND TO CALL IF PT STARTS HAVING SEIZURES OR SEVERE WEAKNESS

Other Meds: NONE

Lab Data: NO LABS

History: ASTHMA

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **322205-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	04-Feb-2008	05-Feb-2008	1	14-Aug-2008	25-Aug-2008	VT		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Asthenia, Malaise, Pain

Symptom Text: 24 hours after gardisil feels unwell with abdominal pain, ackey, sore decresed energy lasting approx 1 to 2 days

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **322206-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-Apr-2008	08-Apr-2008	1	14-Aug-2008	25-Aug-2008	VT		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Asthenia, Influenza like illness, Malaise, Pain

Symptom Text: 24 hours after 2nd HPV injection patient became ill with flu like symtoms, body aches, abdomial pain, decreased energy, generlly feeling unwell.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **322207-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.2	F	11-Aug-2008	12-Aug-2008	1	14-Aug-2008	25-Aug-2008	VT		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Asthenia, Malaise, Pain

Symptom Text: 24 hours after injection patient again felt unwell with body aches,decreased energy, and abdominal pain.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **322209-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Aug-2008	08-Aug-2008	1	14-Aug-2008	25-Aug-2008	AZ		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Dizziness for several days, onset the day after the vaccine was given. No syncope.

Other Meds:

Lab Data:

History:

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322211-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	18-Jul-2008	18-Jul-2008	0	14-Aug-2008	25-Aug-2008	MD		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0847X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood glucose increased, Blood pressure orthostatic, Dizziness, Fall, Feeling hot, Gaze palsy, Headache, Nausea, Oxygen saturation normal, Oxygen supplementation

Symptom Text: Per Nurse Record: Nurse Stat called to front desk. When RN arrived, found pt flat on back on floor, verbal and responding to questions. Per other observers, pt was standing at the desk, her eyes rolled back, and she fell to the floor. This was about 5 minutes after receiving Gardasil injection at 330pm. Pt was immediately evaluated by MD and NP. BS 150; O2sat98%; Oxygen face mask was applied. RN called 911, but the pt declined these services and the call was not completed. MD advised pt that 911 should be called and she should be evaluated for r/o seizure and for the trauma to her head. She again declined 911 services and said her boyfriend would take her to the ER. She states she got her gardasil shot, felt fine, walked out of the room, states she became dizzy/nausea/hot, then she fell, when she came to she said it "felt like she was in a dream", then "flashes of images" orthostatics: 112/80; 80 lying 110/80; 82 sitting 110/80; 88 standing Now pt c/o pain to back of head, slightly nauseated. Pt's boyfriend arrived within 30 minutes and spoke to both NP and MD, who both advised that pt should be seen immediately in ED. Her boyfriend states he will take her now.

Other Meds: Ortho Tri Cyclen Lo

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322217-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Jun-2008	20-Jun-2008	1	14-Aug-2008	25-Aug-2008	AZ		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2622AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1904U	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Skin warm, Swelling

Symptom Text: L deltoid area very red swollen and warm to the touch 3 days after injection per her mother's phone call report.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **322230-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Feb-2008	04-Aug-2008	180	14-Aug-2008	19-Aug-2008	MI		28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	2	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2365AA	0	Right arm	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Rash, Skin lesion

Symptom Text: Left outer leg rash/lesion. Mother stated rash same appearance as seen on tv for rash reaction to immunization. 8/26/08 Reviewed PCP medical records of 8/4/2008. FINAL DX: vascular rash Records reveal patient experienced left outer leg & back rash x 1 week. Received Hep A & Varicella vaccines that day.

Other Meds: In 2/08 was on Concerta; not now.

Lab Data: LABS: CBC & ESR WNL.

History: NKDA; NSVD; ? Bipolar; NDKS

Prex Illness: None Rash x 1 week.

Prex Vax Illns:

Vaers Id: **322236-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Aug-2008	08-Aug-2008	3	14-Aug-2008	25-Aug-2008	MI		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abscess, Abscess drainage, Lymphadenopathy, Oedema peripheral

Symptom Text: Sterile abscess with drainage. Swollen supraclavicular lymph nodes. Swelling right arm (mild).

Other Meds: METADATE CD 20mg 3 PO qd

Lab Data: None

History: ADHD, Raynaud's Phenomenon

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322238-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Aug-2008	14-Aug-2008	0	14-Aug-2008	25-Aug-2008	NC		26-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Head injury, Musculoskeletal stiffness

Symptom Text: Within 5 minutes after HPV administration, patient was sitting up on bed, put her head in her lap then jerked backward suddenly. Hit head on wall and was stiff all over body for about 5 seconds. Immediately awake, alert. No other problems.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322250-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		15-Aug-2008	18-Aug-2008	--	WAES0808USA01968	18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a 22 year old female (a relative of another employee) who was vaccinated with a third dose of GARDASIL. Subsequently the patient died. The cause of death was unknown. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 322251-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	15-Dec-2007		15-Aug-2008	18-Aug-2008	--	WAES0808USA01694	18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Premature labour

Symptom Text: Information has been received from a consumer, for the Pregnancy Registry for GARDASIL, concerning her daughter, a 19 year old female with a history of respiratory syncytial virus infection who in approximately May or June 2007, was vaccinated with the first dose of GARDASIL, she subsequently had the second dose (date unknown); and on 02-JAN-2008, she had the third dose of GARDASIL. The patient had her LMP on 15-DEC-2007 and they later learned that she was pregnant at the time she had her third dose of GARDASIL. The patient went into pre-term labor at twenty-eight weeks and gave birth to a baby boy on 28-JUN-2008. The baby only survived two days. The death of the baby "was due to the delivery which caused a grade 4 hemorrhaging of the brain". The patient is presently doing well physically. The reporter said that her daughter, had consented to our contacting the nurse practitioner. The patient sought medical attention. Upon internal review, the baby born at 28 weeks was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic, positive

History: Respiratory syncytial virus infection

Prex Illness:

Prex Vax Illns:

Vaers Id: **322253-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		15-Aug-2008	18-Aug-2008	NJ	WAES0808USA01173	18-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cerebrovascular accident

Symptom Text: Information has been received from a physician concerning a 11 year old female patient who was vaccinated with GARDASIL. The lot number was not provided. The physician reported that a neurologist asked her if she had heard about a patient who had a stroke with GARDASIL. It was unspecified whether or not this patient was of the neurologist. Upon internal review, stroke was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 322254-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	18-Jan-2008	08-Feb-2008	21	15-Aug-2008	18-Aug-2008	NJ	WAES0808USA01711	29-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Contraception, Grand mal convulsion, Inappropriate schedule of drug administration, Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 27 year old female with no known drug allergies and no pertinent medical history reported, who on an unknown date was vaccinated with the first dose of GARDASIL. On approximately 18-JAN-2008, she was vaccinated with a second dose of GARDASIL. On approximately 17-JUN-2008, the patient was vaccinated with a third dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). About three weeks after the first dose, the patient had a syncopal episode. On 08-FEB-2008, about 3 weeks after the second dose, the patient experienced tonic-clonic seizure and was hospitalized overnight. The patient was hospitalized from 08-FEB-2008 to 09-FEB-2008. On 08-JUL-2008, about three weeks after the third dose, the patient experienced a second tonic-clonic seizure. An electroencephalography, a magnetic resonance imaging and blood work were done and showed normal results. She was started on an anticonvulsant medication. At the time of reporting, the patient had not recovered. Upon internal review severe tonic-clonic seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: electroencephalography, normal; magnetic resonance, normal; diagnostic laboratory, blood work-normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 322260-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Jul-2008	06-Aug-2008	13	15-Aug-2008	20-Aug-2008	NC		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB235BA	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2663AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0072X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Aphasia, Dizziness, Facial palsy, Facial paresis, Hypoaesthesia facial, Migraine with aura, Paraesthesia, Tongue paralysis, Transient ischaemic attack

Symptom Text: Expressive aphasia facial weakness unilateral 8/29/08 Reviewed hospital medical records of 8/6/2008. FINAL DX: Transient ischemic attack vs hemiplegic migraine Records reveal patient experienced sudden onset of expressive aphasia, left facial drooping, right facial weakness, numbness & tingling, lightheadedness, anxiety. Seen in outlying ER & had tongue deviation to the left & left facial weakness. Speech returned in approx 4 hours; left facial weakness/droop persisted. Symptoms resolved & all tests WNL. D/C to home same day w/referral to outpatient neuro for continued w/u.

Other Meds: PROZAC 10

Lab Data: MRI/MRA; blood work; Echocardiogram; Head CT LABS: CT of head, MRI/MRA, echocardiogram & EKG WNL.

History: depression PMH: Stong family hx of hemiplegic migraine, depression, anxiety & HTN.

Prex Illness: depression

Prex Vax Illns:

Vaers Id: **322267-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Jun-2008	Unknown		15-Aug-2008	26-Aug-2008	NE		26-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea, Weight decreased

Symptom Text: Menstrual cycle stopped, losing weight. (has not skipped since her first period-July 2006)

Other Meds: None

Lab Data:

History: Allergy to CECLOR

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322273-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	11-Aug-2008	11-Aug-2008	0	15-Aug-2008	26-Aug-2008	LA		26-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2613AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0063X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness

Symptom Text: 08/11/08 14:05, received GARDASIL and MENACTRA. Walked to door to waiting area, LOC < 1 minute. No vomiting or seizure. Suspect vasovagal reaction.

Other Meds: Mother

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322275-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	06-Aug-2008	07-Aug-2008	1	15-Aug-2008	26-Aug-2008	MO		26-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB235BA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	12660	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B020AA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	02620AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mass, Pain in extremity

Symptom Text: Pt felt a knot to her right arm on 08/07/08 around 9:00 pm. Pt felt a "knot" to her left arm around 8:00 am on 08/08/08. Pt states both left and right arm hurts only to touch.

Other Meds: None

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322286-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Aug-2008	13-Aug-2008	0	15-Aug-2008	26-Aug-2008	GA		26-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB245AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0331X	1	Right arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U2422AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1757U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Injection site erythema, Injection site warmth

Symptom Text: Within 2 hours of vaccine - numbness of pt hand, arm. On 8-15-08 by exam - glove numbness of rt hand, not of arm. Good color, movement of arm/hand. 3 cm warm redness of rt arm at vzv site.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322289-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	12-Aug-2008	14-Aug-2008	2	15-Aug-2008	26-Aug-2008	OH		26-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2759AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0229X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Rash

Symptom Text: Big red rash 2 1/2" X 1 1/2".

Other Meds: Albuterol, Multivitamin

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **322294-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	12-Jun-2008	12-Jun-2008	0	15-Aug-2008	25-Aug-2008	--		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U		Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	1857U		Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site urticaria, No reaction on previous exposure to drug, Urticaria

Symptom Text: MOM Came to our clinic on 8/12/08 for the second Gardisil shot. when asked if any problems after the first shot mom reported that after she got home and broke out in hives at the injection site and on her back mom gave benedryl. pt also recieved varicella at the same time but had no prvious reaction to varicella in the past per mom.

Other Meds:

Lab Data: n/a

History:

Prex Illness: none

Prex Vax Illns:

Vaers Id: **322296-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Aug-2008	14-Aug-2008	1	15-Aug-2008	25-Aug-2008	VT		25-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0334X	1	Right arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B027AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1740U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: Upper Right arm slightly swollen, hot to touch, pain with shoulder abduction. At site of varicella injection.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **322297-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Aug-2008	14-Aug-2008	0	15-Aug-2008	25-Aug-2008	OK		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Pt broke out in Hives approximately 3 hours after vaccine administered and had to go to the E.R. Pt was given Benadryl add Hydrocortisone injections. Hives cleared up shortly after E.R. visit. Denies local reaction to vaccine site. Pt is also taking medications that could have caused a similar reaction.

Other Meds: Prozac, Abilify, Synthroid, Lipitor, and Vistaril

Lab Data: None

History: Schitzophrenia, Anxiety Disorder, Hypothyroidism, High Cholestrol, Seasonal Allergies

Prex Illness: None Noted

Prex Vax Illns:

Vaers Id: **322302-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-Aug-2008	13-Aug-2008	0	15-Aug-2008	25-Aug-2008	CA		25-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	C2997AA		Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2583AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1968U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pruritus, Injection site swelling, Injection site warmth

Symptom Text: Immunes were given to the pt. Two days ago, immune site appears midly sollen, warm to touch, and per pt it itches, it was recomended to put warm compresses on the affected site and a Rx was given for Benadryl and Tylenol to treat the symptoms.

Other Meds: NONE

Lab Data: None

History: PT ALLERGIC TO BACTRIM

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **322310-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Aug-2008	06-Aug-2008	0	15-Aug-2008	25-Aug-2008	PA		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB239AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1740U	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2888AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2564AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea

Symptom Text: Mother reported to our office on 08/12/08 that patient had a headache and nausea since injections on 8/6/08. Her mother felt it was from the HPV vaccine, however Amanda received 3 other vaccines as well. No fever noted. She stated she would be seeing her doctor that evening for a physical and would call me the next day. 2 messages left for mother but she never returned my call to let me know the outcome of the visit.

Other Meds: None reported

Lab Data: Unknown

History: Unknown

Prex Illness: None reported

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322316-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	14-Aug-2008	14-Aug-2008	0	15-Aug-2008	25-Aug-2008	TX		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2774AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0072X	1	Right arm	Intramuscular	
	MMR	MERCK & CO. INC.	1672U		Left arm	Subcutaneously	
	VARCEL	MERCK & CO. INC.	0393X		Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Heart rate decreased, Hypotension, Syncope, Unresponsive to stimuli, Vomiting

Symptom Text: On 8/14/8 at ~0940 Pt had an adverse reaction to vaccines and/ or blood draw. Patient received Tdap Lot # C2774AA- left deltoid , MMR Lot # 1672U -left deltoid,ÿ Varicella lot # 0393X -Right deltoid,ÿÿ HPV Lot # 0072X -Right Deltoid .Patient also received blood draw of Standard tests Hepatitis A,B,C , HIV and RPR .Was not able to get CBCÿ due to patient fainted while obtaining blood specimen ~8 minutes after vaccines had been given. Vital signs obtained immediately after patient fainted were Blood pressure 60/40, RR = 18 Pulse = 60 . Was unable to arouse patient using tactile stimulation . after ~2 minutes. 911 initiated at 0942. Patient vomited stomach contents at ~0946.ÿ EMS workers arrived at ~0948. Patient care relinquished to EMS workers at that time.ÿ Patient was taken to Hospital by ambulance- ambulating on own, A&O x 3 VS at departure were BP 116/72, P=78, RR=18 .Patient had a child ageÿ 2years and 10 months old with her at time of incident. Patient child was unharmed and was cared for during incident. Patient child was also transported to hospital with patient. VAERS report completed . Please see attached

Other Meds: NONE

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **322319-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Apr-2008	03-May-2008	9	15-Aug-2008	25-Aug-2008	GA		08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1966U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Agitation, Anxiety, Arthralgia, Blister, Depression, Dermatitis, Ear pain, Emotional distress, Ephelides, Erythema, Fatigue, Hypersensitivity, Joint swelling, Keratosis pilaris, Melanocytic naevus, Mood swings, Oedema peripheral, Pharyngitis, Pharyngolaryngeal pain, Pruritus, Rash, Rash macular, Rash papular, Rash pruritic, Seborrhoea, Sinus headache, Skin irritation

Symptom Text: Mysterious rash began 9 days after receiving the initial injection with water blister type manifestion and systemic reaction like symptoms with agitation and anxiety (would come and go with no apparent provocation). Sore throat and ear pain. Swelling of right foot intermittent. Joint pain. Rash continued for months. Increasing fatigue, depression, mood swings, and emotional distress. Has seen general practitioner with no findings, dermatologist can not identify skin irritations and has prescribed lotions which have no effect. 9/26/08 Reviewed dermatologist medical records of 6/17/2008. FINAL DX: perioral dermatitis vs seborrheic dermatitis; nevi, freckling; keratosis pilaris, asymptomatic. Records reveal patient experienced rash on face, back & arms 2 days s/p initial HPV vaccine. Rash noted as recurrent water blisters & facial redness that would dry up w/minimal itching. Exam revealed rough patches over nose, cheeks, perioral area & chin area. No vesicles noted on exam. There was rough eczema appearing rash of antecubital & proximal aspects of bilateral forearms. Keratosis pilaris was noted on bilateral upper arms. Numerous macular freckles were noted on face & shoulders. Tx w/lotion/cream. Was to return should re-excerbation ocur. No further visits on record. 9/30/08 Reviewed urgent care medical records of 6/2004-6/17/2008. FINAL DX: none provided Records reveal patient exprienced pruitic rash of face & arms, sore throat, sinus HA, swollen feet on 5/8/08 dx w/allergic reaction/rash, pharyngitis. Tx w/antibiotics. RTC 5/21/08 w/intermittent pruitic rash & swollen hands/knees. Light pink papular itchy rash noted on cheek, scalp & upper arm but no joint swelling on exam. Tx w/antihistamine & steroids. Seen by dermatologist 6/17/08, records previously reviewed.

Other Meds:

Lab Data: LABS: ESR of 5/21/08 5 (N).

History: PMH: eczema, rashes PMH: URI, sinusitis, gastritis secondary to NSAID use, allergic rhinitis, pharyngitis, wrist sprain, viral syndrome, bronchitis, febrile illness, diarrhea, influenza, UTI, vaginitis, LBP. Family hx: HTN, hyperlipidemia. Recently had cousin dx w/RA. Allergic PCN.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322326-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Aug-2008	14-Aug-2008	3	17-Aug-2008	25-Aug-2008	CA		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthropod bite, Headache, Rash

Symptom Text: Headache rash on the legs - insect bites look like to MD though pt denies bug bites

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322332-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Aug-2008	14-Aug-2008	0	14-Aug-2008	26-Aug-2008	WA		26-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1908U	1	Left arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB235BA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2639AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Immediate post-injection reaction, Injection site erythema, Rash macular

Symptom Text: A 13 year old girl came in for immunization update, accompanied by her mother. The RN administered four vaccines, beginning with Hep A in the right deltoid. By the time the 4th vaccine was administered in the left arm, the patient's chest had developed red blotches, and it appeared to be spreading up her neck. Red blotches were noted over her right shoulder also. There was only minor erythema around the other vaccine sites. Patient denied itching, difficultly breathing, difficulty swallowing. The physician was called in to examine her and he prescribed Benadryl 50mg, po (the patient had expressed and exhibited extreme anxiety over "getting shots"). Benadryl 50 mg po was given at 11:00 am. The red blotches on her chest and neck resolved over the next 20 minutes. Blotchy erythema remained present, though diminished, surrounding the bandaid over the Hep A site. Patient's vital signs were WNL, and she was allowed to leave with her mother at 11:30 am. Her mother was given a prescription for Benadryl 25 mg to be given every 6 hours over the next 2 days, and advised to call 911 for any difficulty breathing or swallowing. Per phone call to the patient's mother three hours later, the redness had completely disappeared, and she reported the child was doing well.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322394-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	07-Jun-2008	07-Jul-2008	30	18-Aug-2008	19-Aug-2008	FR	WAES0807USA02907	19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0569U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Diarrhoea, Headache, Pain in extremity, Pharyngolaryngeal pain, Pyrexia

Symptom Text: Information has been received from a health professional, regarding her daughter, a 19 year old female who on 08-JUN-2008 was vaccinated with the first dose of GARDASIL (batch number not reported) on the deltoid by intramuscular route. On 07-JUL-2008, the patient started with pain in knees, ankles and thumbs. Different tests are being performed on the patient such as tests for rheum and blood smear tests. The patient has no medical history related with these events. Aspirine has been prescribed to treat the pain, the patient has been taking it since 10-JUL-2008. The patient's joint pain persisted. The case was considered by the physician as an other important medical event. Follow-up information was received which reported that the patient was vaccinated with a first dose of GARDASIL (lot# 0569U, batch# NG39330). According to this new information, the patient took Aspirine for 3 days, from the 10-JUL-2008 to 12-JUL-2008, with a frequency of 8 hours. Test results have been reported. C-reactive protein: 9 mg, Antistreptolysin 408, rheumatoid factor 20 units, PCR high sensitivity 1.2 mg/dl. Buccal swab test was positive for streptococcus piogeno. The patient was treated with Amoxicillin 750 mg every 8 hours; the treatment lasted from 15-JUL-2008 until 24-JUL-2008. On 22-JUL-2008 the patient presented cephalgia and fever. The patient recovered from cephalgia after two days, the fever lasted for one day, temperature not reported. It is also reported that the patient presented diarrhea from 24-JUL-2008 until 26-JUL-2008. On 4-AUG-2008 the patient started with headache and throat pain, on 6-AUG-2008 a new swab test and blood work is performed. The patient started on amoxicillin again. The reporter believes that the adverse event is due to the infection and not to the vaccine. The physician considered the patient's adverse events to be other important medical events. Other business partner numbers included E2008-06552. No further information is available.

Other Meds: Unknown

Lab Data: Serum C-reactive protein, 9 mg; Serum high sensitivity CRP, 1.2 mg/dl; Serum rheumatoid factor, 20 units; Serum antistreptolysin O antigen test, 408; Mouth culture, positive for streptococcus piogeno.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 322395-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Mar-2008	01-Mar-2008	0	18-Aug-2008	19-Aug-2008	FR	WAES0808USA01951	19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Aphthous stomatitis, Arthralgia, Condition aggravated, Crohns disease, Diarrhoea, General physical health deterioration, Inflammation, Uveitis, Weight decreased

Symptom Text: Information has been received from a health authority (reference number BX20080612) concerning a 21 year old female with a family history of Crohn's disease (paternal aunt) who in December 2007, was vaccinated with a dose of GARDASIL. In March 2008, the patient was vaccinated with a second or third dose of GARDASIL intramuscularly. In March 2008, the patient developed diarrhoea with 10 faeces per day (ie. day and night), deterioration of her general condition with a weight loss of 11 kgs in 4 months, colic-type abdominal pain, inflammatory-type arthralgia localised on the interphalangeal joint of the right thumb and both elbows. The patient was also found with oral aphthae and uveitis. In July 2008, she was hospitalised due to the initial flare of a severe Crohn's disease. The patient's condition improved after rehydration, corrective treatment with ofloxacine and budesonide, and enteral feeding. At the time of reporting, she had not recovered. Additional information has been requested. Other business partner numbers include E2008-07648.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **322396-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Jun-2008	09-Jun-2008	1	18-Aug-2008	19-Aug-2008	FR	WAES0808USA01948	19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from the Health Authorities agency concerning a 17 year old female patient, with history of suspect ovarian cyst (not confirmed) who in December 2007, was vaccinated with the first dose of GARDASIL (Lot No: 0311U; Batch No: NG14100) which was well tolerated. On 20-FEB-2008, the patient was vaccinated with the second dose of GARDASIL (Lot No: 0588U; Batch No: NG34100) and subsequently experienced fever and abdominal pain at the level of the left colonic frame. On 08-JUN-2008, the patient was vaccinated with the third dose of GARDASIL IM. On 09-JUN-2008, the day after vaccination, she was found with fever up to 40 C and abdominal pain in the left colonic frame inducing walking discomfort. The consults with a gynaecologist and a gastroenterologist, as well as abdominal ultrasound, were not contributory. At the time of reporting the patient had recovered. Health authorities considered that the event was medically significant (other important medical event) and led to several medically significant - several consultations and investigations. The case is closed. Other business partners included: E2008-07626. Additional information is not expected.

Other Meds: Unknown

Lab Data: abdominal ultrasound, not contributory;

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **322397-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Jan-2008	01-May-2008	121	18-Aug-2008	19-Aug-2008	FR	WAES0808USA01793	19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Inflammation, Lymphadenopathy, Lymphopenia, Neck pain, Pyrexia, Torticollis, Vomiting

Symptom Text: Information has been received from the patient's mother via a health authorities (reference number: MA20081362) concerning her 18 year old daughter who in January 2008, was vaccinated with the first dose of GARDASIL (batch number not reported), on an unspecified date received the second dose of GARDASIL and in July 2008 was vaccinated with the third dose GARDASIL IM. The patient's mother explained that her daughter had received 3 injections of GARDASIL, the latest of which was very recent. Exact dates of vaccination were not specified. In late May 2008, the patient was hospitalized in internal medicine due to a febrile episode with cephalgia. Meningeal syndrome was ruled out by normal CSF and spontaneous resolution of fever and torticollis. The patient was rapidly discharged due to high school exams. No aetiology was found. On 18-JUL-2008, she was hospitalized again due to the same symptoms: fever, cephalgia and vomiting with an onset on 15-JUL-2008, and also left-side cervicalgia with palpable lymph nodes. The patient did not present with skin eruption, adenopathy except left cervical adenopathy - nor hepatosplenomegaly. Signs of inflammation were found, with increased CRP at 245 mg/L on 19-JUL-2008. The same day, the patient also had lymphopenia at 0.88 g/L. It is noteworthy that she had already had lymphopenia at 1.14 g/L during her first hospitalization on 30-MAY-2008- Levels of hemoglobin and platelets were normal. Cervicalgia and fever resolved very rapidly. CRP level decreased at on 22-JUL-2008 and lymphopenia resolved on 22-JUL-2008 with lymphocytes at 2.54 g/L. Paraclinic work-up enabled to rule out many aetiologies: toxoplasmosis, viral serologies and rickettsiosis were negative. Investigations for antinuclear antibodies were negative. Assay for immunoglobulins was normal. Grisel's syndrome was ruled out. The patient was discharged from internal medicine unit after a six day hospitalization. At the time of reporting the patient had recovered. Health authorities considered that the ch

Other Meds: Unknown

Lab Data: spinal tap, ??May08, CSF: normal; diagnostic laboratory test, 22Jul08, viral serologies: negative; diagnostic laboratory test, 22Jul08, assay for immunoglobulins: normal; diagnostic laboratory test, 22Jul08, rickettsiosis: negative; lymphoc

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 322398-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-May-2008	23-Jul-2008	77	18-Aug-2008	19-Aug-2008	LA	WAES0808USA01180	19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	HEP	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Uterine dilation and curettage

Symptom Text: Information has been received for the pregnancy registry for GARDASIL from an 18 year old female patient, with no pertinent medical history and no drug reactions/allergies, who on 07-MAY-2008, was vaccinated with GARDASIL. Concomitant therapy included RECOMBIVAX HB the same day of the GARDASIL. The patient conceived on 03-MAY-2008. The mother reported that her daughter received GARDASIL and had a miscarriage two weeks ago. The mother reported that her daughter went to the hospital to have dilatation and curettage; however she did not stay in the hospital overnight. The patient sought unspecified medical attention. Upon internal review, miscarriage was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 4/11/2008)

Prex Vax Illns:

Vaers Id: **322399-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	04-Aug-2008	04-Aug-2008	0	18-Aug-2008	19-Aug-2008	TX	WAES0808USA02112	24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Feeling of body temperature change, Headache, Hypoaesthesia, No reaction on previous exposure to drug, Pain in extremity, Paraesthesia

Symptom Text: Information has been received from a medical assistant concerning an 18 year old female with no pertinent medical history and no allergies who on 19-JAN-2008 was vaccinated with the first dose of GARDASIL IM 0.5 ml (lot # 659439/1267U) well tolerated. On 29-MAR-2008 the patient was vaccinated with the second dose of GARDASIL IM 0.5 ml (lot # 655604/0052X) well tolerated. On 04-AUG-2008 the patient was vaccinated with the third dose of GARDASIL IM 0.5 ml (lot # 659184/0843X). There was no concomitant medication. On 04-AUG-2008 the patient experienced body chills and tingling in both legs several hours after receiving her third dose. The patient was examined in the local emergency room. The patient was rehydrated with an unspecified intravenous fluid and released to home. The patient's mother contacted the office by phone, on 05-AUG-2008, to relay the adverse event. The current status of the patient was unknown. The reporter considered the body chills and tingling in both legs to be other important events (IV hydration). This is one of several reports from the same source. Additional information has been requested. 9/23/08 Reviewed ER medical records of 8/4/08. FINAL DX: none provided Records reveal patient experienced numbness & pain in both legs, achy joints, pins & needles feeling in legs, temporal HA, felt feverish & chills. Tx w/IVF & pain meds. Improved & d/c to home.

Other Meds: None

Lab Data: None LABS: all WNL.

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322400-1 (S)** **Related reports:** 322400-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	05-Oct-2007	07-Nov-2007	33	18-Aug-2008	19-Aug-2008	--	WAES0808USA02128	26-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0742U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female with anxiety, depression and gastrointestinal issues, who on 07-NOV-2007 was vaccinated with a second 0.5 ml dose of GARDASIL intramuscularly (lot number and injection site not reported). On 07-NOV-2007 after the vaccination the patient began having seizure type episodes and was hospitalized for a week (dates unspecified). Therapy with human papillomavirus vaccine was discontinued. The outcome of the patient was unspecified. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Anxiety; Depression; Gastrointestinal disorder

Prex Vax Illns:

Vaers Id: **322400-2 (S)** **Related reports:** 322400-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	15-Oct-2007	18-Oct-2007	3	31-Dec-2008	05-Jan-2009	--		05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Adrenal disorder, Aphasia, Autism, Blindness transient, Condition aggravated, Confusional state, Congenital hearing disorder, Convulsion, Detoxification, Extremity contracture, Foaming at mouth, Gaze palsy, Hand deformity, Headache, Hepatic enzyme abnormal, Hormone level abnormal, Hypoaesthesia, Hypoglycaemia, Hypothyroidism, Loss of consciousness, Malaise, Migraine, Palpitations, Paraesthesia, Quality of life decreased, Regressive behaviour, Syncope, Vitamin D deficiency, Weight increased

Symptom Text: Where do I begin. My daughter is 23 years old. October of 2007 she received the 2nd GARDASIL vaccine and shortly after became very ill. She experienced migraines, saying her brain hurts, passing out -syncope-, numbness in hands and feet, tingling, limbs contracting, hands like claws, seizures, rolling eyes, foaming from mouth, confusion, heart palpitations. She has been hospitalized 9 times since January of 2008, 3 hospitals, 4 neurologists, she has had EEG's, TEE, lumbar puncture, MRI, MRA, CT, CTA, everything is normal. She also now goes into a regression. Sometimes unable to walk, speak, see, hear. She passes out every day since last year. She is on medical leave from college, no quality of life whatsoever. All the doctors told me that if it is not a medical issue, or a heart issue it was a medical issue. I did explore that route and needless to say, they were incorrect. I contacted a nutritionist and a biochemist and found out that due to her weak immune system the vaccine has traumatized her body and brain. She also is profound since last month in her right ear. She was born with a hearing loss but due to complexity of this illness it has affected her hearing and she has lost it in her right ear. Our nutritionist is putting her on a special diet because everything she is ingesting, all the foods with chemicals are affecting her brain and causing more reaction. They also will be detoxing her but right now she cannot be fully detoxed due to fact that she is do severely deficient. She has developed hypoglycemia, hypothyroidism, vitamin D deficient, her liver enzymes are shot, her adrenal glands are off as well as her hormones. She gained 40lbs from all the meds she was put on and the seizure medication has affected her brain. I was told that the vaccine had adhered to her tissues in her body and we have to remove it bit by bit. The biochemist is going to purchase the vaccine to break down cash component and give my daughter a natural supplement to repair her. Needless to say, we are devastated and heartbroken.

Other Meds:

Lab Data: MRI; MRA; CT; CTA TEE; EEG; Sonogram; Lumbar Puncture; Cerebral angiogram

History: acid reflux disease; duadinal ulcer; bilateral moderate to severe hearing loss pre-birth.

Prex Illness:

Prex Vax Illns:

Vaers Id: **322401-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	17-May-2007	Unknown		18-Aug-2008	19-Aug-2008	VA	WAES0808USA01292	19-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Breech presentation, Caesarean section, Contraception, Drug exposure during pregnancy, Live birth

Symptom Text: Information has been received from a 25 year old female with no known drug reactions/allergies who on an unknown date was vaccinated with the first dose of GARDASIL. This is part of a pregnancy registry. On 17-MAY-2007, the patient was vaccinated with a second dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). 3 months later, on approximately 17-AUG-2008, the patient returned for the third dose and a urine test was positive for pregnancy. On an unspecified date, the patient was hospitalized and delivered a female infant one month early on 19-APR-2008 via Cesarean section due to breech presentation. The infant is healthy. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: urine beta-human, 08/17?/07 - positive

History:

Prex Illness: Pregnancy NOS (LMP = 8/13/2007)

Prex Vax Illns:

Vaers Id: **322402-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Jul-2007	05-Jun-2008	340	18-Aug-2008	19-Aug-2008	NY	WAES0808USA01696	29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Blister, Diarrhoea, Incisional drainage, Leukopenia, Lymphadenopathy, Monocytosis, Neutropenia, Pain, Peritonsillar abscess, Pharyngitis, Pharyngolaryngeal pain, Pyrexia, Sepsis, Sinusitis, Skin lesion, Tachycardia, White blood cell count decreased

Symptom Text: Information has been received from a mother concerning her 20 year old female daughter, with unremarkable medical history and no known drug reactions/allergies, who in July 2007, was vaccinated with the third dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). The mother reported that her daughter had lab studies done early this year, and her WBC's were low. Her daughter was hospitalized for 4 days with a throat infection due to her low WBC count. The mother is concerned that GARDASIL is related to the low WBC. The physician cannot determine reason for low WBC count. At the time of the report the patient was recovering. Additional information has been requested. 8/1908 and 8/22/08 MR records received including heme/onc consult and some hospital records. Pt initially seen by PCP 6/5/2008 for c/o sinus sx. Tx with abx. Returned 6/9/08 still c/o being sick now with watery diarrhea. Blister like lesion on L upper thigh sent for bx and labs. Labs showed leukopenia/neutropenia. Refered to heme/onc. Heme/onc consults beginning 6/16/08 for eval of low white count. Assessment: profound neutropenia with a relative monocytosis suggests likely autoimmune disease or drug reaction. To stop BCP. DX: Neutropenia/leukopenia. F/U 6/19/08 with 1 cm supraclavicular node noted on PE. Seen 7/01/08 with sore throat, aches and fever. PE (+) for red tonsils. Tx with abx. WBCs and Neutrophils remain low. Tx with Neupogen. D/C Summary received for DOS 7/2-8/2008 with D/C DX Neutropenia. Light pharyngitis/early peritonsillar abscess, s/p incision and drainage (sepsis and fever resolved). Pt presented with fever of 102' and worsening pharyngitis. WBCs 2.2 on admission. Tachycardic at 123. (+) lymphadenopathy and exudate on tonsils. Pt had I&D of tonsillar abscess (+) for normal respiratory flora. Tx with IV abx and neupogen. WBCs up to 4.2 by d/c.

Other Meds: Hormonal contraceptives

Lab Data: complete blood cell, ?/?/08 - COUNT WAS LOW. Labs and Diagnostics: 6/16/08 WBC 2.8. Neutros 0.15. Admitted to hospital. Lymphoma/leukemia eval (-). Flow cytometry WNL. Bone marrow aspirate with normal karyotype, (-) for leukemia. RF (-

History: None. PMH: none. Recent respiratory sx past 6 months. NKDA

Prex Illness:

Prex Vax Illns:

Vaers Id: 322403-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	16-Jun-2008	23-Jun-2008	7	18-Aug-2008	19-Aug-2008	KS	WAES0808USA01846	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Amnesia, Anticoagulant therapy, Antinuclear antibody positive, Antiphospholipid syndrome, Arthralgia, Asthenia, Cerebrovascular accident, Contusion, Fatigue, Gait disturbance, Hyperreflexia, Ischaemic stroke, Joint swelling, Memory impairment, Myalgia, Night sweats, Nystagmus, Oedema peripheral, Oral contraception, Pain in extremity, Personality change, Pituitary tumour benign, Pyrexia, Speech disorder, Strabismus, Systemic lupus erythematosus, Tonsillar hypertrophy, Transaminases increased, Vision blurred, Visual disturbance, Visual field defect, Weight decreased

Symptom Text: Information has been received from a physician concerning a 13 year old female with attention deficit disorder and no history of drug reactions or allergies who on 11-APR-2008 was vaccinated with the first dose of GARDASIL (LOT#: 659962/1740U) and on 16-JUN-2008 was vaccinated with the second dose of GARDASIL (LOT#: 660389/1968U). Concomitant therapy included oral birth control and ADDERALL. One week after the second vaccine (on approximately 23-JUN-2008) the patient developed joint pain that continued to get worse. She was not able to bath herself. She developed short term memory loss and blurred vision. The patient saw her primary physician and the physician ordered a magnetic resonance imaging (MRI) that revealed a cerebral vascular accident (CVA). The patient was hospitalized. Further diagnosis revealed the patient had lupus and antiphospholipid syndrome. As of 11-AUG-2008 the patient was recovering. Additional information has been requested. 08/25/2008 MR received from PCP from 6/13/08 to 8/7/08. Pt presented 6/13/08 for well check with normal exam and no c/o. Some recent weight loss due to increased activity while training for an athletic event. Seen again 7/1/08 with c/o 3 wk hx of arthalgias, myalgias, weight loss and fatigue. Pt reports poor memory. Subjective fever past weekend as well as swelling of R ankle. Recent ?tick bite. Seen again 7/10/08 with persistant arthralgias, fatigue, muscle aches and loss of vigor. Currently with night sweats and increased transaminases. Rheumatology consult 8/7/08 with DX: SLE characterized by a midbrain stroke and positive labs. On anticoagulants for the CVA. MD reports sx started after 2nd Gardasil dose. PE (+) for several areas of bruising, otherwise WNL. 9/10/2008 MR received for DOS 7/29-8/01/2008 with D/C DX: Antiphospholipid syndrome. Positive ANA, questionable reactive vs true Systemic Lupus Erythematosus. Ischemic stroke. Pituitary adenoma as an incidental finding on MRI. Pt presented with 5 week hx of myalgias, one week hx of vision changes as

Other Meds: ADDERALL TABLETS; hormonal contraceptives

Lab Data: magnetic resonance, 06/??/08 - revealed CVA. Labs and Diagnostics: Alk Phos 133, AST 57. ALT 75. Sed rate 46. ANA (-) on 7/1/08 reported as (+) by rheum. Lyme IgG, IgM (-). Ehrlichia (-). Hepatitis panel (-). Labs and Diagnostics: AP

History: PMH: ADHD, Acne. Oral contraceptives. NKDA.

Prex Illness: Attention deficit disorder

Prex Vax Illns:

Vaers Id: **322451-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	11-Aug-2008	Unknown		18-Aug-2008	27-Aug-2008	NV		27-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB264AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0843X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2658AA	0	Left arm	Intramuscular	
TD	SANOFI PASTEUR	U2077BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Blood pressure, Heart rate normal, Pallor

Symptom Text: After shots, walked to check out area. Became pale and weak. Sat in chair. With help, walked back to room. Laid down, AP 60+, BP 102/72, went home, nap, fine next day.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322454-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Aug-2008	12-Aug-2008	0	18-Aug-2008	27-Aug-2008	PA		29-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Chills

Symptom Text: Patient developed abdominal pain after vaccine (ten hours after); pelvis ultrasound ordered to rule out cyst; GARDASIL 8/20/08-records received for DOS 8/13/08-C/O LLQ abdominal pain with onset 10 hours prior to visit. Afebrile. Chills. Cold. R/O ovarian cyst.

Other Meds:

Lab Data: Ultrasound of pelvic 8/20/08-UA negative.

History: N. Sulfa

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322456-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Aug-2008	11-Aug-2008	0	18-Aug-2008	27-Aug-2008	WI		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0270X	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2580AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Post immunization syncopal episode.

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **322459-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Aug-2008	11-Aug-2008	6	18-Aug-2008	27-Aug-2008	NC		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Left arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHAVB292AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Dysuria, Pharyngolaryngeal pain

Symptom Text: Sore throat, lower back pain, urination with burning.

Other Meds:

Lab Data: awaiting labs for coxsackievirus

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **322460-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	05-Aug-2008	11-Aug-2008	6	18-Aug-2008	27-Aug-2008	NC		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB292MA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1740U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Dysuria, Pharyngolaryngeal pain

Symptom Text: Sore throat, lower back pain, urinating with burning.

Other Meds:

Lab Data: Awaiting labs for corsascievirus.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **322466-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	29-Jul-2008	Unknown		18-Aug-2008	27-Aug-2008	CT		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Rash

Symptom Text: Mom reported the child complained of joint pain and rash after receiving GARDASIL. Lasted a few days then went away.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **322471-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	29-Jul-2008	15-Aug-2008	17	18-Aug-2008	25-Aug-2008	FL		25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea, Dizziness, Migraine, Pyrexia, Vomiting

Symptom Text: Bad vomiting, ever 20-30 minutes, diarrhea every two hours, fever 101 degree , dizzyness 12-24 hrs, migraine (no hx). Onset 08/15/2008. Went to Medical Center received medicine for vomiting. No antibiotics if virus. Symptoms diminishing by 08/17/2008. ER suggest flu but mother disagreed as daughter had similar reaction in 2006 after taking Menactra Vaccine. Vaccine received on 07/29/2008 was HPV Vaccine.

Other Meds:

Lab Data: Drew blood. Tests unknow.

History: Bronchitis - albuterol inhaler as needed.

Prex Illness: No illness.

Prex Vax Illns: Same reaction~Meningococcal (no brand name)~~15~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322485-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	18-Aug-2008	18-Aug-2008	0	18-Aug-2008	27-Aug-2008	CA		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	1	Right leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Syncope

Symptom Text: Fainted and hit head on floor after injection.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **322486-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	05-Sep-2007	05-Sep-2007	0	18-Aug-2008	25-Aug-2008	--		28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0802U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abscess limb, Arthralgia, Arthropod bite, Asthma, Cellulitis, Eyelid oedema, Fatigue, Headache, Herpes simplex, Hypersensitivity, Hypothyroidism, Incisional drainage, Insomnia, Lip swelling, Menstruation irregular, Nausea, Obesity, Pruritus generalised, Rash generalised, Swelling, Weight decreased

Symptom Text: swelling all over rash that doesnt go away aches in joints and a lot of headaches tired a lot cant sleep but to tired to do much her period is all messed up goes weeks at a time. 8/25/08-records received-office notes. 3/7/07-C/O shortness of breath, fever, chills times 2 days with cough today. Assessment URI, herpes simplex, asthma. C/O fatigue, weight loss. received HPV4 and meningococcal vaccines. Assessment: hypothyroidism. 8/27/07-see in office for follow-up after ED visit for spider bite on left thigh. Assessment: abscess and cellulitis. Followed by visit 8/29/07-for incision and drainage of abscess. 9/5/07 second HPV 4 vaccine given. On 12/10/07-C/O rash for 2 months, itching all over body. 12/14/07-rash continues, asthma acting up, nausea. 12/21/07 rash all over, eyes swollen. Treated with steroids. Allergic reaction. 1/30/08 lips swollen times 2 days. 3/26/08-menstral cycle every 2 weeks. 8/6/08-rash continues but not as severe, occurs on walking and diminishes through the day.

Other Meds: synthroid

Lab Data: allergies, thryroid ,blood work ? 8/25/08-records received-TSH 5.59, TSH on 8/14/08 7.25. Antigliadin ABS IGA elevated at 6.

History: thyroid problems that is all

Prex Illness: none

Prex Vax Illns: rash ,swelling ,hurting all over , tired alot~HPV (Gardasil)~3~16~In Patient

Vaers Id: **322494-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Aug-2008	08-Aug-2008	1	18-Aug-2008	27-Aug-2008	WA		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB235BA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1486U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Tenderness

Symptom Text: Right arm swelling and tenderness

Other Meds:

Lab Data: None

History:

Prex Illness: Depression/ADHD

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322497-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Sep-2007	27-Sep-2007	0	18-Aug-2008	27-Aug-2008	TX		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hot flush, Hyperhidrosis, Malaise

Symptom Text: Pt states, after being notified of ad on TV, that she has had the symptoms hot flashes, malaise and increased sweating under arms since first shot of GARDASIL given 9-27-07. Second shot 11-29-07, 3rd shot 4-29-08. No symptoms or reactions told to nurse at any visit.

Other Meds: None

Lab Data: 8-12-08, CBC, sed rate, CMP, TSH, prolactin

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322499-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	24-Mar-2008	24-Jun-2008	92	18-Aug-2008	27-Aug-2008	AR		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: Vomiting X 2-3 days.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322550-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	10-Jun-2008	10-Jun-2008	0	19-Aug-2008	20-Aug-2008	NJ	WAES0807USA00801	20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion missed, Abortion spontaneous, Drug exposure during pregnancy, Pain

Symptom Text: Initial and follow-up information has been received from a nurse, for the Pregnancy Registry for GARDASIL, concerning a 25 year old female with allergy to TORADOL who on 10-JUN-2008 was vaccinated intramuscularly with the first and only 0.5 ml dose of GARDASIL (lot no. 659962/1740U). There was no concomitant medication. The physician reported that on 27-MAY-2008 the patient had an ultrasound due to complaints of "pain" and the result was negative. The patient had a history of "negative menses". On 12-JUL-2008 the patient had a spontaneous abortion when she was eight weeks pregnant. On the same day, the patient had an evaluation due to a (+) serum beta-human chorionic gonadotropin (missed abortion). The patient saw the physician to seek unspecified medical attention. Upon internal review spontaneous abortion was considered to be an other important medical event. Additional information is not expected.

Other Meds: None

Lab Data: ultrasound, 05/27/08, negative; serum beta-human, positive

History:

Prex Illness: Pregnancy (LMP = 4/16/2008); Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **322551-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Jan-2008	21-Jan-2008	3	19-Aug-2008	20-Aug-2008	FR	WAES0808USA01976	20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0510U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Muscular weakness, Paralysis, Presyncope, Vaccine positive rechallenge

Symptom Text: Information has been received from general physician who is specialized in homeopathic medicine via health authorities (HA reference no. PEI2008009659) concerning a 16 year old female who on 18-JAN-2008 was vaccinated with the first dose of GARDASIL (Lot No. 0510U; Batch No: NG20180). On 21-JAN-2008, patient experienced ongoing muscle weakness and presyncopes. On 18-MAR-2008 the patient was vaccinated with the second dose of GARDASIL (Lot No. 1113U; Batch No. NH04240). One week p.v (approximately on 25-MAR-2008), the patient experienced with aggravated postvaccinal paralytic weakness attacks (no symptoms specified) and aggravated presyncopes. Electrocardiogram, electroencephalography, computed axial tomography and magnetic resonance imaging showed normal results. The patient was hospitalized twice on an unknown dates. At the time of report to health authority (on 30-JUL-2008) the patient had not yet recovered. Other business partner numbers included: E2008-07559. Additional information has been requested.

Other Meds: Unknown

Lab Data: electrocardiogram, normal; electroencephalography, normal; computed axial tomography, normal; magnetic resonance imaging, normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 322552-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Jan-2008	12-May-2008	103	19-Aug-2008	20-Aug-2008	FR	WAES0808USA01991	20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	027U	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Erythema migrans, Fatigue, Headache, Hemiparesis

Symptom Text: Information has been received from health authority (HA reference no PEI2008011443) through SPMSD concerning a 14 year old female who on 24-MAY-2007 was vaccinated with the first dose of GARDASIL (Lot No. 1466F; Batch No: NF15720) and on 14-AUG-2007 was vaccinated with the second dose of GARDASIL (Lot no. 1339F; Batch No: NF23310), both doses were well tolerated. On 30-JAN-2008, the patient received the third dose of GARDASIL (Lot No 0227U; Batch No: NG0020) into the left arm. On 12-MAY-2008 the patient developed hemiparesis right, cephalgia and asthenia. On 19-MAY-2008, the patient presented with erythema migrans. The patient was hospitalized on an unknown date. Cervical spinal fluid, serology (not specified), magnetic resonance imaging and electromyography showed normal results. Borrelia antibody titer was negative. Neuroborrelosis and myasthenia were ruled out. It was reported that erythema migrans resolved on 06-JUN-2008, hemiparesis right, cephalgia and fatigue on 17-JUL-2008. Nevertheless outcome was reported to be not recovered at the time of reporting to Health Authority. Other business partner numbers included: E2008-07558. Additional information has been requested.

Other Meds:

Lab Data: spinal tap, normal; diagnostic laboratory test, serology (not specified): normal; magnetic resonance imaging, normal; electromyography, normal; diagnostic laboratory test, Borrelia antibody titer: negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **322553-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	05-Apr-2008	Unknown		19-Aug-2008	20-Aug-2008	--	WAES0808USA02152	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Headache, Neurological examination normal, Poor quality sleep, Sleep disorder, Sleep paralysis

Symptom Text: Information has been received from a nurse practitioner concerning a female who an unspecified dates was vaccinated with the first and second doses of GARDASIL. After the second dose the patient developed "sleep paralysis" who was diagnosed after a patient was seen at sleep lab. The patient will not receive the third dose of GARDASIL. Upon internal review, sleep paralysis was determined to be an other important medical event. Additional information is not expected as the nurse practitioner requested not to be contacted. 8/29/08 Reviewed neuro medical records of 5/22/2008. FINAL DX: isolated sleep paralysis Records reveal patient experienced HA 2 years prior after 2 concussions 1 month apart from sports injuries w/resultant diagnosis of postconcussion syndrome & migraines. Tx w/Keppra & Topamax, Elavil, Imitrex among other medications. Currently gets HA once every 2 weeks that are less severe & respond to Advil. Was having spells of sleep paralysis for over 1 year w/waking & unable to move arms or legs & unable to speak which last for about 1 minute about once a month. Has abnormal & restless sleep, tired during the day. Neuro exam was WNL on 5/22/2008.

Other Meds: Unknown

Lab Data: sleep study, sleep paralysis LABS: EEG WNL.

History: Unknown HPV #1 received 8/28/2007, Lot # 0742U PMH: concussions x 2, syncopal spells in the fall, 2007. Smoker.

Prex Illness:

Prex Vax Illns:

Vaers Id: **322554-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		19-Aug-2008	20-Aug-2008	CA	WAES0808USA02164	20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Hemiplegia, Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 19 year old female who was vaccinated with the first dose of GARDASIL 0.5 mL. The physician reported that the patient experienced tingling and numbness in her arm which progressed into paralysis of an entire one side of her body after receiving the vaccination. The patient sought medical attention and was seen by the physician. At the time of reporting, the patient had not recovered. The physician considered tingling and numbness in her arm and paralysis of an entire one side of her body to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322555-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		19-Aug-2008	20-Aug-2008	FR	WAES0808USA02334	20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Fatigue, Malaise, Pyrexia

Symptom Text: Information has been received from a general practitioner, as part of a business agreement with Sanofi Pasteur MSD (manufacturer control # E2008-07575), concerning a 12 year old female with no reported relevant history who on an unspecified date in 2008 was vaccinated with the second dose of GARDASIL. Several days later the patient developed fever and pain in all large joints. Additionally she complained of tiredness and malaise. The patient was admitted in a hospital and was hospitalized (date and duration not reported). Significantly increased antinuclear antibodies (1:640) and decreased hemoglobin values were found. Rheumatoid factor was negative, inflammatory parameters were not elevated. It was evoked that the vaccination could have triggered a rheumatic disease. The patient was not able to go to school for 3 weeks. Subsequently, the patient was recovered from fever, joint pain, tiredness and malaise at the time of reporting. Lab parameters were not yet controlled. The causality of fever, tiredness, malaise, significantly increased antinuclear antibodies and decreased hemoglobin was not provided. Other business partner numbers include E2008-07575. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, inflammatory signs were not detected; hemoglobin, decreased; serum ANA, 1:640; serum rheumatoid factor, negative

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322556-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	12-Aug-2008	12-Aug-2008	0	19-Aug-2008	20-Aug-2008	IL	WAES0808USA02422	20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	NULL		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1060U	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Petit mal epilepsy

Symptom Text: Information has been received from a registered nurse concerning a 11 year old female with a history of hospitalization in 2005 due to convulsion who on 12-AUG-2008 was vaccinated at 16:30 with a first dose of GARDASIL (lot # 658556/1060U), 0.5 mL, IM, into the left deltoid. At the same visit, the patient also received ADACEL and MENACTRA into the right deltoid. On 12-AUG-2008, after getting her first dose of GARDASIL, the patient experienced a petit mal seizure lasted for about 15 seconds. No lab tests were performed. The patient recovered at the office and was released. Upon internal review, petit mal seizure was determined to be an other medical event. Additional information has been requested.

Other Meds:

Lab Data: None

History: Convulsion; Hospitalisation

Prex Illness:

Prex Vax Illns:

Vaers Id: **322557-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	20-May-2008	Unknown		19-Aug-2008	20-Aug-2008	--	WAES0808USA02460	20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Ketoacidosis, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse practitioner (N.P.) concerning a 23 year old female with diabetes mellitus who on 20-MAY-2008 was vaccinated with the first dose of GARDASIL (lot # 0152X) and on 21-JUL-2008 was vaccinated with the second dose of GARDASIL (lot # 0250X). Concomitant therapy included ORTHO-CYCLEN, LANTUS, NOVOLOG, montelukast sodium (MSD), finasteride (manufacturer unknown), SIMVASTATIN (manufacturer unknown), XYZAL and minoxidil. The patient experienced dizziness after receiving the first dose (recovered) and also the second dose. The patient was recently hospitalized for ketoacidosis. Medical attention was sought via calling the nurse. At the time of this report, the outcome was unknown for the second episode of dizziness and ketoacidosis. No product quality complaint was involved. The temporal relationship to GARDASIL was unspecified by the N.P.. Additional information has been requested.

Other Meds: ORTHO-CYCLEN; finasteride; NOVOLOG; LANTUS; XYZAL; minoxidil; SINGULAIR; simvastatin

Lab Data: Unknown

History:

Prex Illness: Diabetes mellitus

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322558-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	05-Nov-2007	05-Nov-2007	0	19-Aug-2008	20-Aug-2008	--	WAES0808USA02488	20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Right arm	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Fall, Fracture, Loss of consciousness, Skin laceration, Surgery

Symptom Text: Information has been received from a registered nurse (R.N.) concerning an 18 year old female with no pertinent medical history, drug reactions or allergies who on 05-NOV-2007 was vaccinated in the right arm with a dose of GARDASIL. On the same day the patient also received concomitant therapy Flu vaccine (unspecified). On 05-NOV-2007, 10 minutes after receiving GARDASIL, the patient passed out, and fell on her face. She had a laceration over her left eye and fractured her cheek bone. It was reported that the patient was hospitalized and had several surgeries. The outcome of the patient was not reported. The reporter considered passed out, a laceration over her left eye and fractured her cheek bone to be disabling. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 322559-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Jun-2008	18-Jun-2008	17	19-Aug-2008	20-Aug-2008	FR	WAES0808USA02518	20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427U	2	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Condition aggravated, Crohns disease, Diarrhoea, Erythema nodosum, Headache, IIIrd nerve disorder, Mobility decreased, Muscular weakness, Nausea, No reaction on previous exposure to drug, Oral intake reduced, Vision blurred, Vomiting

Symptom Text: Information was received on 08-AUG-2008 from a health authority concerning a 21-year-old female with a medical history of Crohn's disease (known since May 2005 and epilepsy (known since May 1997, who in June 2008 was vaccinated with a third dose of GARDASIL (lot # 1427U, batch # NG15200) into her left deltoid muscle via intramuscular route. In one document (hospital report) it was mentioned that the vaccine was given on 12-Jul-2008, but this was a holiday. On another reporting form the date was 19-Jun-2008. The two previous doses of GARDASIL, P1 (lot # 0482U, batch # NG09920) on 11-Dec-2007 and P2 (lot # 0510U, batch # NG20180) on 11-Feb-2008 given to her both in left deltoid via intramuscular route, were well tolerated. On 18-Jun-2008, the patient developed headache, nausea and vomiting. Also, she complained of blurred vision (the patient was experiencing episodes of blurred vision since years lasting a couple of days). On 26-Jun-2008 the patient complained of increasing weakness, especially in the legs (intermittent paralysis?). On 27-Jun-2008, she also complained watery diarrhoea up to 12 times per day, but no abdominal pain. She was hospitalized. On admission, the patient had subfebrile temperature, the clinical examination showed no paresis but erythema nodosum on both lower legs. The following exams showed no pathologies: abdominal sonography, cranial CT and cranial MRI on 26-JUN-2008; ECG and CSF (infectious parameters in the CSF- tick borne virus, CMV, HSV, VZV, EBV-were negative) on 27-Jun-2008. A wide range of lab test was performed, all normal except increased CRP (90 mg/L) and blood sedimentation rate (47/1h), no leucocytosis. In the urine, only 100 germs/mL were detected, nevertheless antibiotic treatment was given. The neurologist could rule out meningitis but stated an oculomotor nerve disturbance probably due to valproic acid overdose following reduced food intake. The dose of valproic acid was reduced. The ophthalmologic exam showed no pathologies. As the leading diagnosis was acute episode of Cr

Other Meds: None

Lab Data: abdominal ultrasound, 26Jun08, normal; head computed axial tomography, 26Jun08, normal; electrocardiogram, 27Jun08, normal; colonoscopy, 04Jul08, showed an acute episode of Crohn's disease; laboratory test, 27Jun08, negative, infectious par

History:

Prex Illness: Crohn's disease; Epilepsy; Vision blurred

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322563-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Aug-2008	01-Aug-2008	0	19-Aug-2008	20-Aug-2008	FR	WAES0808USA02533	20-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1147U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Clonic convulsion, Syncope

Symptom Text: Information has been received from a Health Authority concerning a 16 year old female who on 01-AUG-2008 was vaccinated with the first dose of GARDASIL (lot number 1147U, batch number NH17630) into the left upper arm (route not reported). Approximately 20 seconds P.V., the patient experienced a syncope with clonic convulsion lasting for 10 seconds. The patient has no history of epilepsy or syncope. A recent cardiological check-up (done before this event) did not show any pathologies. Subsequently, the patient recovered from syncope and clonic convulsion completely. She was not hospitalized. Other business partner numbers included: E2008-07643. No further information is available. The case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **322565-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Jun-2007	12-Jun-2007	0	19-Aug-2008	25-Aug-2008	LA		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Anorexia, Chills, Gastrointestinal tube insertion, Haemorrhoids, Ileus, Laparoscopy, Menstruation irregular, Nausea, Oral intake reduced, Pain, Pyrexia, Syncope, Vomiting, Weight decreased

Symptom Text: Fainted after first shot (10 mins after), fever, chills, pain 3 days after. Then had stomach problems for month after. Vomiting, stomach pains, was hospitalized, and found nothing. In ICU for 2 days. Still has no need to eat. Nausea, no menstrual cycle for month, no period for 3-4 months at a time. Lost a lot of weight. Sick in stomach. 8/22/08-records received for DOS 8/7/08 and 8/9/08-Diagnostic laparoscopy. Normal pelvic findings. C/O abdominal pain. One month prior began having vague abdominal pain mostly in lower abdomen on right side. Impression: post op ileus. Ten days prior flexible sigmoidoscopy normal with internal hemorrhoids. Returned after laparoscopy with C/O abdominal pain with nausea. NG tube placement.

Other Meds:

Lab Data: 8/22/08-records received-Labs:segs percentage elevated 74.5, lymphocyte percentage decreased 17.1. Amylase normal 56 and lipase low at 19 and albumin low 2.9.

History: None8/22/08-records received-PMH:intermittent constipation.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322573-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	12-Jun-2008	12-Jun-2008	0	19-Aug-2008	27-Aug-2008	MO		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Malaise, Pyrexia

Symptom Text: Per pt report she developed a fever of 103, had a headache and general malaise approx one hour after being given the injection. She also reports taking Ibuprofen 400 mg. No other treatment received.

Other Meds: Keflex 500 mg PO started one hour after injection

Lab Data: None

History: Allergy to Imitrex and Clindamycin/denies

Prex Illness: Urinary tract infection

Prex Vax Illns:

Vaers Id: **322587-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Aug-2008	14-Aug-2008	0	19-Aug-2008	27-Aug-2008	IL		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0847X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Loss of consciousness, Syncope, Tremor

Symptom Text: Patient fainted and fell to ground from standing position approximately 5-8 minutes after vaccination with GARDASIL (HPV) vaccine. Patient was unconscious for less than one minute. She shook briefly and yelled out prior to awakening. Patient had hit front of head on stool when fell. (Patient was sitting on chair when received vaccine).

Other Meds: fexofenadine 180mg daily

Lab Data:

History: Recurrent urinary tract infections

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322589-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-Aug-2008	12-Aug-2008	1	19-Aug-2008	27-Aug-2008	OR		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Nausea, Pyrexia

Symptom Text: Fever 102.9, Dizzy, lightheaded, nausea, HA treated with Tylenol/ibuprofen. Symptoms lasted approx 24 hours

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **322598-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Aug-2008	Unknown		19-Aug-2008	27-Aug-2008	MN		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise, Syncope

Symptom Text: Administered HPV vaccine, had patient wait for a little while afterwards in chair. Parent said she didn't feel well and then she fainted.

Other Meds:

Lab Data:

History:

Prex Illness: None known

Prex Vax Illns:

Vaers Id: **322599-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	12-Aug-2008	12-Aug-2008	0	19-Aug-2008	27-Aug-2008	IL		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2406AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C2767AA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1060U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Neurological examination normal, Somnolence, Syncope, Tonic clonic movements

Symptom Text: Immediately after receiving HPV, pt fainted, closed eyes, laid on table. Then for 12-15 sec had tonic/clonic movements of her hands. Next, woke up groggy but responding. Normal neuro exam 10 min. later. Pt had 1 nonfebrile seizure 3 years ago - no meds.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322606-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Jul-2008	18-Jul-2008	0	19-Aug-2008	27-Aug-2008	TN		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Emotional distress, Hypotonia

Symptom Text: Gave pt vaccine. As I was pulling needle out of deltoid muscle pt looked at me and stated she felt like she was going to pass out. As she said that pt dropped her head and went limp in chair. Put pt in Trendleberg position and paged doctor. Stat overheard and got cold rag. Mom was by patient side entire time. Pt then woke up emotional and fine and stated she had not eaten that morning. Pt hung around office. Color came back in face and pt was able to walk out of office with mother. Pt called next day to doctor and they said she was fine.

Other Meds:

Lab Data:

History:

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322608-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Jul-2008	17-Jul-2008	0	19-Aug-2008	27-Aug-2008	OR	OR200818	27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2862AA	6	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2540AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1968U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Convulsion, Hyperhidrosis, Loss of consciousness, Syncope, Urinary incontinence

Symptom Text: Within 5 minutes after injections the patient fainted and had mild seizure-like activity. Pt was diaphoretic and incontinent of urine. The patient regained consciousness and walked to exam table to lie down with RN assistance. Blood pressures taken twice 15 minutes apart, patient monitored for 30 minutes then released to mother's care. Patient walked out of clinic. Patient referred to PCP for follow up care. Mom states pt had anxiety related to medical treatment and the use of needles.

Other Meds: ALLEGRA, minocycline

Lab Data: Referred to Primary Care Physician for follow up

History: seasonal allergies

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322617-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Jul-2008	30-Jul-2008	1	19-Aug-2008	27-Aug-2008	AZ	AZ0811	27-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B016BA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2659AA	4	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0070X	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB268EA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Burning sensation, Oedema peripheral, Pruritus, Speech disorder, Swelling face, Swollen tongue

Symptom Text: Client's mother called cliinic 7/30/08 reporting bilateral swelling of deltoids, arms, hands, feet & face of client. Client's "face feels fat". Hand & feet itchy & burning; client's tongue swollen & client having difficulty talking. RN counsel to call 911 or take to emergency care immediately; give Benadryl. 7/31/08 mother reports that client was given shots in hospital & kept for observation but released same day. Also given RX for medication (unknown). All SxS gone.

Other Meds: none known

Lab Data: unknown

History: none reported

Prex Illness: none reported

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322642-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Aug-2008	13-Aug-2008	1	19-Aug-2008	27-Aug-2008	NY		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1904U	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1487U	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2565AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Shots given 8-12-08, Gardasil, Menactra, Varicella.

Other Meds:

Lab Data:

History: H/O dizziness 6 months ago

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322645-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	29-Jul-2008	17-Aug-2008	19	19-Aug-2008	27-Aug-2008	MO		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nodule, Skin discolouration, Skin warm, Tenderness

Symptom Text: Received 3rd dose of GARDASIL 7/29/08. Contacted office 8/19/08 with c/o dime sized "knot" that had increased in size within past 2 days. Area slightly tender to touch, skin slightly discolored - pinkish red. Very slight warm to touch. Stated has had "knot" since date of injection.

Other Meds: Oral contraceptives

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322646-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-May-2008	06-Jun-2008	7	19-Aug-2008	27-Aug-2008	IN		28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	14864	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Began losing hair - about the size of golf ball each time she would shower. I have some in baggies. Multiple blood tests were complete. Tests were fine.

Other Meds: None

Lab Data: Lab tests included - all fine.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **322682-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Sep-2007	25-Sep-2007	0	20-Aug-2008	21-Aug-2008	KY	WAES0710USA03546	21-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Malaise, Premature labour

Symptom Text: Information has been received from a consumer and a physician for the pregnancy registry for GARDASIL concerning a 15 year old female with a history of appendicectomy (December 2006) who on 25-SEP-2007 was vaccinated with the first dose of GARDASIL (658100/0525U). The patient also received her last dose of MENACTRA (lot# not reported) on 25-SEP-2007. On 03-OCT-2007, the patient was confirmed to be pregnant by a urine pregnancy test (LMP = 20-AUG-2007). Per the patient's mother, the patient did not have any adverse reaction with the vaccination, but is just feeling sick because of the pregnancy. Follow-up information received from the physician indicated that GARDASIL was not received in their office but the patient sought unspecified medical attention in the physician's office. On 27-MAR-2008, the patient gave birth to a normal, healthy male infant weighing 4 lbs 14 oz. The baby's length was 44 cm, head circumference was 34 cm and the Apgar score was 8/9. The patient was 31 weeks from her last menstrual period. There were no complications or abnormalities. At the time of this report, the patient's outcome was unknown. Upon internal review, birth 31 weeks from LMP was considered to be an other important medical event. Additional information is not expected.

Other Meds:

Lab Data: Urine beta-human, 10/03/07, positive; Apgar score, 03/27/08, 8/9

History: Appendicectomy

Prex Illness:

Prex Vax Illns:

Vaers Id: **322687-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Feb-2008	22-Feb-2008	0	20-Aug-2008	21-Aug-2008	FR	WAES0808AUS00136	21-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0583U		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Depressed level of consciousness, Dizziness, Fatigue, Gait disturbance, Immediate post-injection reaction, Nausea, Paraesthesia, Somnolence

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing and Public Case Detail form concerning a 15 year old female patient who on 22-FEB-2008 was vaccinated with GARDASIL (Lot No 657872/0583U, Batch No J2896, Expiry Date 12-FEB-2010). On 22-FEB-2008, immediately following vaccination, the patient experienced fatigue, depressed level of consciousness, dizziness, gait disturbance, nausea, paraesthesia and somnolence and was hospitalized. The patients experience was also reported as immediately following vaccination, the student felt tired, dizzy and nauseated. 5 minutes later she developed pins and needles in her hands and felt drowsy. An attempt was made to walk the patient to the sick bay, but she could not walk. The patient's condition worsened. She became more drowsy and needed waking to communicate. The patient's vital signs were satisfactory. The student was transferred to hospital as she was still unable to walk. The patient was discharged from hospital that afternoon. Subsequently, the patient recovered from fatigue, depressed level of consciousness, dizziness, gait disturbance, nausea, paraesthesia and somnolence. The agency considered that fatigue, depressed level of consciousness, dizziness, gait disturbance, nausea, paraesthesia and somnolence were certainly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322688-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	11-Mar-2008	11-Mar-2008	0	20-Aug-2008	21-Aug-2008	FR	WAES0808AUS00139	21-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	J5171		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Dyspnoea, Nausea, Paraesthesia oral, Pleuritic pain

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing and Public Case Detail form concerning a 19 year old female who on 11-MAR-2008 was vaccinated with GARDASIL (Batch No. J5171, Expiry date 22-MAR-2010). On 11-MAR-2008, after vaccination, the patient experienced dyspnoea, nausea, paraesthesia oral and pleuritic pain. The patient's experience was also reported as being short of breath, pleurtic like chest pain, lip tingling and nausea. The patient was treated with anti histamine and was off work as a result of 2 days. Subsequently, the patient recovered from dyspnoea, nausea, paraesthesia oral and pleuritic pain were possibly related to therapy with GARDASIL. The original reporting source was not provided. Dyspnoea, nausea, paraesthesia oral and pleuritic pain were considered to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **322689-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Aug-2008	01-Aug-2008	0	20-Aug-2008	21-Aug-2008	IL	WAES0808USA02463	21-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0802U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a licensed practical nurse (L.P.N.) concerning a 22 year old female with no pertinent medical history and no known drug allergies who on 20-MAY-2008 and 01-AUG-2008, was vaccinated intramuscularly with her first and second 0.5 ml doses, respectively, of GARDASIL (Lot # of the two doses 658490/0802U). There was no concomitant medication. On 01-AUG-2008, after receiving her second dose of GARDASIL, the patient fainted and experienced two small seizures. The patient's symptoms resolved in 20 minutes. The patient had a full meal prior to administration of GARDASIL. The adverse events happened during office visit. Follow-up information was received on 15-AUG-2008 from the L.P.N. via phone call. The nurse refused to provide the patient's name. It was reported that the patient only had fruit prior to receiving the second dose of GARDASIL. The nurse stated that when the patient "came to" she was fine. It was reported that the patient was scheduled for her third dose of GARDASIL in October 2008. Upon internal review, seizures were determined to be an other important medical event. This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322715-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Jun-2008	29-Jun-2008	4	20-Aug-2008	28-Aug-2008	NY		29-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Chills, Decreased appetite, Dizziness, Hyperhidrosis, Joint swelling, Juvenile arthritis, Pain, Pyrexia, Rash, Rash macular, Tremor, Weight decreased

Symptom Text: Received GARDASIL #1 6/25/08; Developed body aches and fever, joint pain 4 days after receiving vaccine. Seen by a rheumatologist - Diagnosed with systemic onset juvenile inflammatory arthritis requiring Kineret injections. 8/22/08-records received for DOS 7/16/08-presented to rheumatology clinic with C/O fever and arthritis which began 17 days ago with pain in right hip then pain all over. Fevers are down during day but up at night. Shaking chills and then defervesces with drenching sweats. Rash began on 2nd or 3rd day with red blotchy areas on extremities. Appetite poor and lost 6 pound in past week. Pain seems to be in joint with joint swelling. Dizziness. Office visit 8/11/08-Joint pain improved except shoulders are not strong. Tapering prednisone. Assessment:Systemic onset juvenile inflammatory arthritis on kineret. Possible adverse reaction to Gardasil.

Other Meds: None

Lab Data: Blood work, followed by rheumatologist 8/27/08-records received-WBC 20,000, sedimentation rate elevated at 105 and C-reactive protein over 250. Ferritin elevated. ANA and ANCA negative. Complements normal. Serology for strep, EB virus and

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **322743-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	18-Aug-2008	18-Aug-2008	0	20-Aug-2008	28-Aug-2008	IL		28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Disorientation, Dizziness, Feeling abnormal, Hypotonia, Postictal state, Urinary incontinence

Symptom Text: Pt was administered GARDASIL injection-tolerated well. Less than five minutes later, while checking out, pt stated she was feeling funny, light headed, was taken into an exam room and sat on the table. Pt became limp, closed her eyes and made a few strange noises, and began to seize, made sounds 3 more times and urinated on herself. Dr came in and checked her breathing and took her blood pressure. Pt regained consciousness after approximately 2 minutes, but remained disoriented for another several minutes. During this post-ictal period, Dr. arrived. Pt states she felt like everything was a dream. Transport was called to take the patient to the emergency department.

Other Meds: IMPLANON

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322745-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Aug-2008	15-Aug-2008	1	20-Aug-2008	28-Aug-2008	MN		28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0329X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site warmth

Symptom Text: Quarter size red ring around injection site warm to touch no treatment done.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: ~HPV (Gardasil)~2~15~In Sibling

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322746-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Aug-2008	15-Aug-2008	1	20-Aug-2008	28-Aug-2008	MN		28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0329X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1978U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site warmth

Symptom Text: Quarter size red ring around injection site. Warm to touch. No treatment.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: ~Varicella (no brand name)~2~13~In Sibling

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322758-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-Aug-2008	20-Aug-2008	1	20-Aug-2008	27-Aug-2008	MI		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2997AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2686AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Hypoaesthesia, Malaise, Nausea, Pain in extremity, Pyrexia, Sensation of heaviness

Symptom Text: At 2am on 8/20/08 client woke up with a fever(temp not taken),nausea,arms and legs felt heavy,both arms very sore, left arm felt numb.Client took a Motrin. At 10am on 8/20/08 client no longer complained of fever but still had nause, HA and generally did not feel well.

Other Meds:

Lab Data: None

History: allergic to Bactrim

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322760-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Aug-2008	20-Aug-2008	0	20-Aug-2008	27-Aug-2008	TX		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling hot, Headache

Symptom Text: Pt c/o dizziness, warm feeling to face, headache 10 min. after recieving vaccine. Pt observed rechecked BP. Crackers, Gatorade and Tylenol given to pt. Pt examined by MD prior to D/C. Pt observed by RN gait assesed pain reassesed pt d/c'd home with mom 1 hour after vaccine administered ER warnings given.

Other Meds: Albuterol PRN DepoProvera

Lab Data:

History: Asthma

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322762-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Aug-2008	20-Aug-2008	0	20-Aug-2008	27-Aug-2008	WI		27-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0843X	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2580AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52BO24BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness, Hypotonia, Syncope

Symptom Text: Pt experienced syncopal episode about 10 minutes after her injections on her way out of the clinic. She had loss of muscle tone and vision. Pt was monitered for 20 minutes following. Vital were stable, pt. felt fine, and pt. was discharged home.

Other Meds: None

Lab Data: None.

History: None.

Prex Illness: No.

Prex Vax Illns:

Vaers Id: **322765-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Aug-2008	15-Aug-2008	1	20-Aug-2008	27-Aug-2008	IN		27-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2631AA	5	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2643AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0243U	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB291CA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0100X	0	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Erythema, Injection site pruritus, Nausea, Swelling, Tenderness

Symptom Text: RECIEVED VACCINATIONS ON 8-14-08, ON 8-18-08 CAME TO OFFICE WITH C/O BEING NAUSEATED, DIZZY, ITCHING AT INJECTION SITES. R>L BIL DELTOID SWELLING, REDNESS, TENDER FROM SHOULDER TO ELBOW. REDNESS AND SWELLING, SIZE OF SOFTBALL, 5" DIAMETER. INSTRUCTED MOM TO GIVE OTC TYLENOL/MOTRIN, BENADRYL ON 8-15-08. ON 8-18-08 WAS GIVEN MEDROL DOSE PAK AND LORATIDINE 10MG DLY.

Other Meds: OTHER

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322771-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	20-Aug-2008	Unknown		20-Aug-2008	29-Aug-2008	WA		29-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope, Tremor

Symptom Text: Fainting/violent shaking

Other Meds: NOne

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322783-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-Jun-2008	12-Jun-2008	0	20-Aug-2008	28-Aug-2008	OK		28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Treatment none - Patient complained of "a little dizziness for less than 2 hours" after receiving vaccine

Other Meds: Yasmin BCP

Lab Data: None

History: Healthy, normal 18 year old

Prex Illness: None

Prex Vax Illns: none~ ()~~0~In Patient|none~ ()~~0~In Sibling

Vaers Id: **322784-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Aug-2008	18-Aug-2008	0	20-Aug-2008	28-Aug-2008	MI		28-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB213AA	0	Unknown	Intramuscular	
MNQ	SANOFI PASTEUR	U2365AA	0	Unknown	Intramuscular	
VARCEL	MERCK & CO. INC.	1902U	1	Unknown	Subcutaneously	
HPV4	MERCK & CO. INC.	1446U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site swelling, Injection site warmth, Tenderness

Symptom Text: R arm at injection site very warm to the touch; approx. 3 inch red, raised area around site; palm sized area very tender + slightly hard.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322806-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	14-Jan-2008	14-Jan-2008	0	21-Aug-2008	22-Aug-2008	FR	WAES0808AUS00140	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Headache, Injection site pain, Lethargy, Nausea, Pain, Pyrexia

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Details Form and a Case Line Listing, concerning a 25 year old female who on 14-JAN-2008 was vaccinated with her second dose of GARDASIL, intramuscularly, as prophylactic vaccination. Subsequently the patient experienced lethargy, headache, injection site pain, nausea, pain and pyrexia, which were considered to be disabling by the reporter. It was described that the patient was vaccinated between 10:00 am and 10:30 am on 14-JAN-2008. She felt very well that morning, then experienced onset of lethargy and feeling run-down by mid-afternoon. On 15-JAN-2008 the patient's tiredness continued and she experienced a severe headache which developed around midday around her face and forehead. The patient's headache worsened and she experienced aches (described as body aches) near injection site which spread through muscles in her back and were painful enough that she took pain killers. On 15-JAN-2008 she also experienced nausea. On 16-JAN-2008 the patient developed a fever of 38 degrees Celsius, her normal temperature being 37.5 degrees Celsius. Her headache continued. At the time of reporting to the agency on 16-JAN-2008, the patient stated that lethargy, headache, injection site pain, nausea, pain (body aches), and pyrexia persisted but body aches and nausea were greatly lessened. The agency considered that lethargy, headache, injection site pain, nausea, pain and pyrexia were possibly related to therapy with GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: temperature measurement, 16Jan08, 38 degrees celsius, fever

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 322807-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
35.0	F	08-Jun-2007	26-Apr-2007	-43	21-Aug-2008	22-Aug-2008	FR	WAES0808USA02517	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0902F	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Hypoaesthesia, Inappropriate schedule of drug administration, Paraesthesia

Symptom Text: Information was received from a health authority (local reference # PEI2008011648) concerning a 35-year-old female with a medical history of intermittent right sided foot extensor paresis, who on 08-Jun-2007 was vaccinated with a first dose of GARDASIL (lot # 654884/0902F, batch # NE24240, route and injection site not reported). Beforehand, on 18-Jan-2007 and 26-Apr-2007 the patient had been vaccinated with tick-borne encephalitis virus vaccine (ENCEPUR, lot # 070021A) (reported as "ENCEPUR ERWACHSENE", encephalitis spring-summer virus vaccine). On 26-APR-2007 she was also vaccinated with a first dose of REPEVAX, lot # Z0869-1 in the left upper arm (route not reported). Since spring/summer 2007, the patient had suffered from generalized weakness. On 20-Aug-2007 the patient was vaccinated with a second dose of GARDASIL (lot # 1339F, batch # NF23310, route and injection site not reported). On 27-OCT-2007, the patient was vaccinated with a third dose of GARDASIL (lot # 1536F, batch # NG08000, route not reported) into her right upper arm. Simultaneously she was vaccinated with an BEGRIVAC, lot # 157041A) into the left upper arm. Generalized weakness had been ongoing when in Nov-2007, the patient developed numbness of foot and hand, and paresthesia of upper limb. Cranial MRT revealed signal enhancement of inferior horns of lateral ventricles. Lumbar MRT showed no pathology of intervertebral disk. The patient was hospitalized on 27-Nov-2007 in order to undergo MRT of cervical and thoracic spine and lumbar puncture. MRT of cervical and thoracic spine revealed no pathological findings. The results of lumbar puncture were normal, whereas results of the oligoclonal antibodies were pending at the time of discharge. Physical examination showed no pathological findings. Microbiological examinations revealed no signs of borreliosis. With all findings considered, numbness, paresthesia and MRT signal changes were of unspecific genesis. The patient was discharged on 29-Nov-2007 with ongoing symptoms. Multiple scl

Other Meds: Unknown

Lab Data: serum HDL-C, 60 mg/dl; serum LDL-C, 123 mg/dl; serum cholesterol, 201 mg/dl

History:

Prex Illness: Paresis

Prex Vax Illns:

Vaers Id: **322808-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Jul-2008	16-Jul-2008	0	21-Aug-2008	22-Aug-2008	AZ	WAES0808USA02158	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Osteomyelitis

Symptom Text: Information has been received from a registered nurse, concerning a 12 year old female patient who on 16-JUL-2008 was vaccinated with the first dose of GARDASIL in her right arm. The patient subsequently, had "complications involving her left arm". The patient had to be hospitalized and was diagnosed with osteomyelitis. The patient was still in the hospital at the time of this report. No other details were provided. The patient's osteomyelitis persisted. The patient did seek medical attention. There was no product quality complaint. The patient's experience was considered an other important medical event by the reporter. Additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 322809-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Mar-2008	13-Mar-2008	0	21-Aug-2008	22-Aug-2008	FR	WAES0808AUS00148	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0617U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Feeling hot, Nausea, Somnolence, Syncope

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and Case Line Listing, concerning a 13 year old female who on 13-MAR-2008 was vaccinated with her first dose of GARDASIL, intramuscularly, as prophylactic vaccination (Lot No. 658219/0817U, Expiry Date 16-MAR-2010, Batch No. J6137). Subsequently, the patient experienced syncope, dizziness, feeling hot, nausea and somnolence and was hospitalised. It was described that approximately one hour post vaccination with her first dose of GARDASIL, the patient complained of dizziness, sleepiness, nausea and feeling hot. The patient (a school student) fainted and the nurses noted that she was slow to recover from the faint. The following day the patient's mother took her to the hospital where she was observed. By the afternoon of day 1 post vaccination, the patient had recovered from syncope, dizziness, feeling hot, nausea and somnolence. Subsequently, the patient was vaccinated with her second dose of GARDASIL (date not reported) and experienced nausea (with associated vomiting). The agency considered that syncope, dizziness, feeling hot, nausea (and associated vomiting) and somnolence were certainly related to vaccination with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322810-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-May-2008	29-May-2008	1	21-Aug-2008	22-Aug-2008	FR	WAES0808AUS00134	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1949U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Ocular hyperaemia, Pharyngeal oedema, Rash generalised, Rash pruritic, Swelling face

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 15 year old female who on 28-MAY-2008 was vaccinated with the first dose of GARDASIL (Lot # 659053/1949U, Batch # K0626, Expiry date 12/06/10). On 29-MAY-2008 the patient experienced rash generalised, ocular hyperaemia, pharyngeal oedema and swelling face. It was described that 19 hours following receiving GARDASIL the student developed itchy rash over her whole body. Also reported swelling to face and throat with red eyes and no difficulty in breathing. The patient attended a hospital for treatment and was provided with cream, eye drops and antihistamines. At the time of reporting to the agency on 08-AUG-2008, the patient had recovered from rash generalised, ocular hyperaemia, pharyngeal oedema and swelling face. The agency considered that rash generalised, ocular hyperaemia, pharyngeal oedema and swelling face were possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **322811-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Apr-2007	Unknown		21-Aug-2008	22-Aug-2008	FR	WAES0808AUS00133	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blindness transient, Visual disturbance

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 17 year old female who on 15-APR-2007 was vaccinated with GARDASIL. Subsequently the patient experienced blindness and visual disturbance and was hospitalised. It was described that the patient complained of flickering vision in the right eye and progressively lost sight over next 8-10 days until all she could see was grey. The patient was treated with methotrexate. At the time of reporting to the agency on 29-JUL-2008, the patient had recovered from blindness and visual disturbance. The patient is undergoing further lumbar, brain and spinal testing. The agency considered that blindness and visual disturbance were possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: spinal tap, lumbar and spinal test; head computed axial tomography, brain test

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **322817-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Apr-2008	23-Apr-2008	0	21-Aug-2008	22-Aug-2008	FR	WAES0808AUS00146	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1949U	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Chest pain

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing and a Public Case Detail Form concerning a 15 year old female who on 23-APR-2008 was vaccinated with the first dose of GARDASIL (Batch # K0532, Expiry date 12-JUN-2010, Lot # 659053/1949U). On 23-APR-2008, 6 hours after vaccination with GARDASIL, the patient experienced chest pain. It was described as thoracic pain that has failed to settle to date. At the time of reporting to the agency on 14-MAY-2008 the patient had not yet recovered from the chest pain. The agency considered that chest pain was possibly related to therapy with GARDASIL. The original reporting source was not provided. Chest pain was considered to be disabling by the reporting agency. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

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Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322818-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	30-Jan-2008	30-Jan-2008	0	21-Aug-2008	22-Aug-2008	FR	WAES0808AUS00129	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthma, Dyspnoea

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 21 year old female who on 30-JAN-2008 was vaccinated with the second dose of GARDASIL. On 30-JAN-2008, 30 minutes after vaccination, the patient experienced asthma and dyspnoea and was hospitalised. The patient was treated with VENTOLIN, ATROVENT, PULMICORT (in nebuliser), 0.3 ml s/c of adrenaline and oxygen. At the time of reporting to the agency on 27-FEB-2008, the patient had recovered from asthma and dyspnoea. The agency considered that asthma and dyspnoea were possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **322819-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	29-Dec-2007	29-Dec-2007	0	21-Aug-2008	22-Aug-2008	FR	WAES0808AUS00131	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0582U		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hypotension, Loss of consciousness, Pallor, Syncope

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 25 year old female who on 29-DEC-2007 was vaccinated with GARDASIL (Lot No. 657874/0582U, Batch No. J2299, Expiry date 26-FEB-2010). On 29-DEC-2007, 10 to 15 minutes after vaccination, the patient experienced syncope, hypotension, loss of consciousness and pallor. It was described that the patient collapsed and was unconscious. The patient was treated in Accident/Emergency Department and was hospitalised. The patient was given adrenaline, oxygen and IV steroids. The patient was informed by the emergency department physician that the reaction was not anaphylaxis. The patient recovered from syncope, hypotension, loss of consciousness and pallor later that day. The agency considered that syncope, hypotension, loss of consciousness and pallor were possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **322820-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	12-Feb-2008	12-Feb-2008	0	21-Aug-2008	22-Aug-2008	FR	WAES0808AUS00127	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Chest pain, Hyperventilation, Tachycardia

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 14 year old female who on 12-FEB-2008 was vaccinated with GARDASIL. On 12-FEB-2008, 1 hour and 10 minutes post vaccination, the patient experienced hyperventilation, abdominal pain, chest pain and tachycardia and was hospitalised. At the time of reporting to the agency on 12-MAR-2008, the outcome of hyperventilation, abdominal pain, chest pain and tachycardia was unknown. The agency considered that hyperventilation, abdominal pain, chest pain and tachycardia were possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322831-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		21-Aug-2008	22-Aug-2008	FR	WAES0808USA02879	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Asthma, Dyspnoea, Raynauds phenomenon

Symptom Text: Information has been received from an agency concerning a female patient who was vaccinated with the first dose of GARDASIL in May 2007, toleration was not reported. The second dose of GARDASIL (Lot #, route, injection site not reported) was given in June 2007. The patient's mother reported that, since October 2007, the patient developed severe pain in the joints (feet, hands, knees). For exploration, the patient was hospitalized (duration and results of examinations not reported). The physicians evoked different differential diagnoses, such as thrombosis, rheumatism and growth disorder. The patient also had Raynaud's syndrome and was treated with NORVAC tablets, but hardly showed any improvement. Despite the symptoms, the patient was vaccinated with her third dose of GARDASIL in November 2007. The mother also reported that since that 3 months the patient developed asthma and difficulty in breathing. At the time of reporting, from time to time, the patient is still suffering from pain lasting several days. Current treatment consist in "vaccine detoxication", performed by an alternative practitioner. The patient has not yet recovered. Other business partner numbers included: E2008-07588. The case is closed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322832-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	05-Aug-2008	05-Aug-2008	0	21-Aug-2008	22-Aug-2008	NJ	WAES0808USA02565	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bruxism, Catatonia, Hyperhidrosis, Immediate post-injection reaction, Incontinence, Loss of consciousness, Pallor, Syncope

Symptom Text: Information has been received from a physician concerning a 19 year old female who on 05-AUG-2008 at 1:45 PM was vaccinated intramuscularly with a third dose of GARDASIL (lot #660620/0571X) in her left arm. There was no illness at time of vaccination. On 05-AUG-2008 at 1:46 PM, one minute after vaccination, the patient fainted, turned pale, had a catatonic reaction and her teeth clenched. The patient was diaphoresis, "blacked out" and needed Oxygen for about 7 minutes. 911 was called. The patient had incontinence. No laboratory diagnostics studies were performed. On 05-AUG-2008, the patient recovered. The physician considered the patient's events to be other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **322833-1 (S)** **Related reports:** 322833-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Dec-2007	01-Feb-2008	62	21-Aug-2008	22-Aug-2008	--	WAES0808USA02075	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anaemia of chronic disease, Arthralgia, Autoimmune disorder, Cervical dysplasia, Cutaneous lupus erythematosus, Dysstasia, Fatigue, Gait disturbance, Gonorrhoea, Lymphadenopathy, Mixed connective tissue disease, Myalgia, Nail discolouration, Ophthalmological examination normal, Pain, Pain in extremity, Papilloma viral infection, Proteinuria, Pruritus, Rash, Scar, Sexually active, Skin hyperpigmentation, Skin nodule, Skin plaque, Swelling, Swelling face, Systemic lupus erythematosus, Thrombocytopenia, Vasculitic rash

Symptom Text: Information has been received from a consumer on a news station reporting that her teenage daughter (age not reported) was vaccinated with GARDASIL in December 2007. Subsequently in February 2008, 2 months after receiving GARDASIL the patient developed an "autoimmune disease". The patient developed a rash on her face and arms, leaving scars. She had swelling all over, pain in her joints and poor circulation in her fingertips. Her doctor says "she now suffers from an autoimmune disease and says it is possible the GARDASIL triggered her illness". The mother stated that her daughter had no prior illness or hospitalization. At the time of reporting the patient had not recovered. Upon internal review autoimmune disease was an other medical event. The reporter felt that the autoimmune disease was disabling. Additional information is not expected. 11/21/08 Reviewed PCP medical records o 12/12/07-10/01/2008. FINAL DX: SLE, mixed connective tissue disorder, anemia of chronic disease Records reveal patient in good general health 12/2007, sexually active but urine protein 300+ (H). Started on Bactrim. RTC 1/3/08 w/fatigue. RTC 2/08 w/symetric nodular rash on arms & face x 1 wk w/mild itching & aches/pains x 6 mo. Dermatology, Rheumatology, Nephro & GYN consult done & dx w/SLE (ANA+, rash & proteinuria). Tx w/steroids & plaquenil. 10/24/08 Reviewed rheumatology clinic records of 4/1/08 & hospital medical records of 7/23-7/25/2008. No other records available. FINAL DX: mixed connective tissue disorder w/SLE Records reveal patient had initially been seen in rheumatology clinic on 3/18/08 & dx w/SLE. Tx w/steroids, plaquemil & ASA for rash & (+)ANA. Improved by 4/1 visit w/only minimal pain in distal fingertips. Had been seen by ophthalmology 3/22/08 & exam WNL. Exam on 4/1 revealed slightly enlarged but nontender inguinal lymph nodes, hyperpigmented plaques on face, upper arms, axillae, vasculitic rash on palms, plinter hemorrhages in distal fingermails. Dx at that time: SLE w/discoid rash, elevated muscl

Other Meds: Unknown

Lab Data: LABS: Urine protein >300(H). ANA 1.2360(+). ESR 23(H). PAP abnormal w/PCR (+) for gonorrhea & HPV/CIN I. CRP 0.11, AST 69(H), serum albumin 3.4(L), complement 3-38(L), complement 4-3(L). Plts 584K(H), AST 320(H), ALT 475(H), cardiolipin

History: Unknown PMH: autoimmune thyroid disorder. Family hx: renal failure, HTN.

Prex Illness:

Prex Vax Illns:

Vaers Id: **322834-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		21-Aug-2008	22-Aug-2008	FR	WAES0808AUS00141	22-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Retinitis viral

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a female who was vaccinated with GARDASIL. Subsequently after vaccination the patient experienced retinitis viral (described as de novo viral retinitis) which required an ophthalmologist consultation. At the time of reporting to the agency on 06-MAY-2008, the outcome of retinitis viral was unknown. The agency considered that retinitis viral was possibly related to therapy with GARDASIL. The original reporting source was not provided. The agency considered the event of retinitis viral to be serious for the following reason: medically significant. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322852-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Aug-2008	12-Aug-2008	0	21-Aug-2008	28-Aug-2008	WI		12-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2567AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral

Symptom Text: Dr. saw patient on 8-14-08 due to red swollen left arm. Swelling extended from shoulder to elbow. No fever. No drainage. Patient placed on AUGMENTIN. Dr. saw patient on 8-15-08 for follow-up. Arm no longer red. Swelling down a bit.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322889-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Aug-2008	18-Aug-2008	0	21-Aug-2008	27-Aug-2008	KS		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash erythematous, Rash generalised

Symptom Text: BROKE OUT IN FINE RED RASH,ALL OVER BODY, INCLUDING FACE. RASH NOT NECESSARILY HEAVIER AROUND INJECTION SITE. RASH STARTED ALITTLE LATER THE SAME DAY AS VACCINATION --- CONTINUED FOR NEXT 36 TO 48 HRS. NO DIFFICULTY BREATHING OR ANY OTHER S/S. SG

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **322892-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	21-Aug-2008	21-Aug-2008	0	21-Aug-2008	27-Aug-2008	WA		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	1	Right arm	Intramuscular	
	TTOX	SANOFI PASTEUR	U1993CA	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Urticaria

Symptom Text: Patient developed urticaria on her legs and torso within 1 hour of administration/ It should be noted that she had urticaria, although less severe, off and on for the week prior, on her arms only. Patient had no angioedema, dyspnea, dysphonia, or other evidence of more serious allergic reaction.

Other Meds: Ortho TriCyclen

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322899-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	12-Feb-2008	30-Apr-2008	78	21-Aug-2008	29-Aug-2008	VA		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Burning sensation, Dizziness, Dysphagia, Extrasystoles, Fatigue, Fluid intake reduced, Gastroenteritis viral, Headache, Inflammation, Joint stiffness, Joint swelling, Lymphadenopathy, Muscle tightness, Muscular weakness, Myalgia, Nausea, Oedema peripheral, Paraesthesia, Pharyngeal erythema, Pharyngolaryngeal pain, Polyarthritis, Pyrexia, Rash, Sleep disorder, Synovitis, Thoracic outlet syndrome, Tonsillar hypertrophy, Tonsillitis, Vision blurred

Symptom Text: Headache, nausea, low fever, slight rash behind legs, very very very bad muscle and joint paints. Couldn't move from bed. Painful to bend or even put feet on floor. Pain was unbearable. Went to doctor and was prescribed IBU 800mg 3 times daily to help keep inflammation down. Sent to a rheumatologist. Tested twice for rheumatoid arthritis, both times negative. All other tests were negative as well. Slowly developed a sore throat and swollen glands. Unable to swallow or drink, everything burned and felt as if tearing at the throat. Went to doctor, tested for mono and strep, again, both negative. Was given antibiotics (doxycycline). They helped clear the infection but still the swollen glands and soreness remain, mostly sore in the morning, and minimizes slightly after taking the first IBU 800mg. Appointments are made for another rheumatologist for joint pain and for primary care physician for swollen glands. 9/04/2008 PCP records rec'd which include 2 rheum consults. Pt presented 5/8/08 with c/o joint pain x 1 week, morning stiffness and swollen joints. DX: arthalgia. Refered to rheum for (+) ANA. Reporting skipped heartbeats 5/29/08. Instructed to eliminate caffeine/choc/ETOH. Seen 5/20/08 with recent viral gastroenteritis. Reporting paresthesias of the hands, stiffness of feet. DX: arthralgia, thoracic outlet syndrome. Seen 6/10/08 with throat pain. Rheum consult 6/18/08. As above, now with muscle weakness and fatigue. PE(+) for trapezius tightness, synovitis in MCP joints. DX: Polyarthralgia. Inflammatory Polyarthritis. Positive ANA. F/U 7/2/08 with increased muscle pain in legs. PE (+) for hand swelling and hallux valgus deformity. PCP OV 7/21/08 No resolution of throat pain- throat red, with enlarged tonsils, yellow exudate, increased cervical nodes. DX: Tonsillitis. Adenopathy. OV 8/29/08 New onset blurry vision, dizziness, poor sleep. To see another rheum in 11/2008.

Other Meds:

Lab Data: mono, strep, thyroids, rheumatoid all negative. Labs and Diagnostics: ANA 1:1280. Lyme (-). DSDNA equivocal. Strep and mono (-). Throat cx (-)

History: no allergies, brachymetatarsia. PMH: Excema, back pain, HPV. NKDA

Prex Illness:

Prex Vax Illns: severe muscle and joint paints, headaches~HPV (Gardasil)~2~24~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322900-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Aug-2008	11-Aug-2008	0	21-Aug-2008	29-Aug-2008	CA		29-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site desquamation, Injection site discolouration, Injection site erythema, Injection site nodule, Injection site pain, Injection site swelling

Symptom Text: Date of HPV vaccine #2,8/11/08 developed pain, swelling and erythema at injection site of left arm. Next two days at injection site sloughing of epidermal layer and development of a sore at injection site. Now healing over but with residual hyperpigmented scar involving ares of injection and sore. Date of initial HPV vaccine 6/11/08.

Other Meds: None

Lab Data: None

History: Penicillin Allergy

Prex Illness: None

Prex Vax Illns:

Vaers Id: **322903-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Aug-2008	20-Aug-2008	1	21-Aug-2008	27-Aug-2008	CA		27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0272X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0070X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Pain in extremity, Pruritus, Skin warm

Symptom Text: 8/20/08- PT TOLD HER MOM THAT HER LT ARM WAS ITCHING AND HAVING PAIN. SHE CAME INTO THE OFFICE AND HER LT ARM SUB CUT WAS WARM TO THE TOUCH AND HAD SOME SWELLING (3 1/2 x 5 cm in length) PARENT AND PT. WAS ADVISED TO TAKE SOME BENADRYL, USE COOL COMPRESSES, TAKE ADVIL FOR ANY PAIN -PER RANI KOKATNUR NP. ADVISED TO RETURN TO OPFFICE IN NO IMPROVEMENT.

Other Meds:

Lab Data:

History: NKDA

Prex Illness:

Prex Vax Illns:

Vaers Id: **322910-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	20-Aug-2008	20-Aug-2008	0	21-Aug-2008	29-Aug-2008	NJ		01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	C2908AA	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0863X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Muscle spasms, Pain in jaw, Trismus

Symptom Text: Patient received GARDASIL #1 around 2 am. At 2:20 pm, patient developed dizziness and right leg cramp followed by locked jaw C-1. Patient remained alert. Sent to ER - patient received IV turodol and recovered in 5-10 minutes and discharged from ER. Phone patient at 2 am 8/20 - patient ok. 8/22/2008 ER record received for DOS 8/20/2008 with DX: Trismus-resolved. Pt presented to ER from PCP office after receiving 1st Gardasil. Following shot, pt's jaw locked and couldn't open mouth. Pt c/o 8/10 jaw pain. Toradol given IV. Full ROM of jaw 40 minutes later. D/c home

Other Meds:

Lab Data:

History: Episode of lock jaw 1/08

Prex Illness: None

Prex Vax Illns:

Vaers Id: 322913-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	18-Aug-2008	18-Aug-2008	0	21-Aug-2008	29-Aug-2008	FL		29-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0088X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0070X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Lymphadenopathy, Malaise, Nausea, Pain, Pyrexia, Vomiting

Symptom Text: 2 hrs after getting GARDASIL #3 and VARIVAX #2, patient had body aches, headache. Later that evening, had fever to 102. Woke 4AM with nausea, vomiting x 2-3. Nausea, malaise persisted. Seen in office for evaluation 8/19, was afebrile, mild cervical and inguinal adenopathy.

Other Meds: None

Lab Data: Urine - trace WBCs, mod blood, about to start mensed. CBC, WBC 5.5 with 75% segs, 12% monos, CMP normal.

History: Mild acne

Prex Illness: None

Prex Vax Illns:

Vaers Id: **322915-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-Aug-2008	20-Aug-2008	1	21-Aug-2008	29-Aug-2008	IL		29-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature, Dizziness, Hypoaesthesia, Nausea, Nervousness, Paraesthesia, Rash

Symptom Text: Complained of forearm that - PM both left and right; Next day numbness and tingling, shaking and light headedness lasting 3-4 hours. Nausea 48 hours; Temp normal 2D post.

Other Meds: Yasmin, Allegra D, Albuterol Inhaler.

Lab Data:

History:

Prex Illness: None.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **322916-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	20-Aug-2008	20-Aug-2008	0	21-Aug-2008	29-Aug-2008	AZ		29-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B020AA		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2665AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0570X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyskinesia, Fall, Haematoma, Head injury, Immediate post-injection reaction, Loss of consciousness

Symptom Text: As soon as HPV vaccine was given pt's body "jerked out of chair" & fell on floor on L side hitting L supraorbital area. Hematoma 5cm. Pt stated she felt dizzy & lost consciousness for a second or two.

Other Meds:

Lab Data: Pt had H/A & nausea taken to hospital, CT scan normal

History: Allergic to BACTRIM, asthma, depression, MIRENA IUD

Prex Illness:

Prex Vax Illns:

Vaers Id: **322918-2** **Related reports:** 322918-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Jun-2008	19-Jun-2008	1	18-Aug-2008	30-Sep-2008	VA	WAES0807USA00841	30-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blister, Swelling face

Symptom Text: Information has been received from a licensed practical nurse concerning a 16 year old female with no pertinent medical history and sulfa allergy, CECLOR allergy and seafood allergy who on 18-JUN-2008 was vaccinated intramuscularly with a 0.5 mL first dose of GARDASIL vaccine (LOT# 660391/0063X). On the same day, the patient was also vaccinated with a dose of ADACEL, MENACTRA and HAVRIX. There was no concomitant medication. On 19-JUN-2008, the patient developed blisters that varied in size from a pin point to an eraser. The blisters first appeared under one arm (which arm was unspecified) and then spread over entire body. Her face was swollen and covered with blisters. The patient was examined by her physician on 21-JUN-2008 and an allergist on 23-JUN-2008. The allergist prescribed prednisone. The patient was recovering. Additional information has been requested.

Other Meds:

Lab Data: None

History:

Prex Illness: Sulfonamide allergy; Allergic reaction to antibiotics; Seafood allergy

Prex Vax Illns:

Vaers Id: **323024-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Aug-2007	30-Aug-2007	14	22-Aug-2008	25-Aug-2008	FR	WAES0808USA02862	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1339F	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Myoclonic epilepsy

Symptom Text: Information has been received from a health authority (HA ref No PEI2008008366) concerning a 14 year old female who on 16-AUG-2007, was vaccinated with the first dose of GARDASIL (lot # 1339F batch# NF 23310) i.m. Since 30-AUG-2007, the patient experienced persisting juvenile myoclonic epilepsy. The patient was hospitalized on an unknown date. The treating physician considered the causal relationship as very unlikely. The patient's mother insisted on notification of this case after she had seen an emission on TV. On 11-OCT-2007, was vaccinated with the second dose of GARDASIL (lot # 1340F batch# NF14740) i.m. and on 21-FEB-2008, was vaccinated with the third dose of GARDASIL (lot # 1536F batch # NG1520) i.m. Other business partner numbers included E2008-07675. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323025-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-Aug-2008	04-Aug-2008	0	22-Aug-2008	25-Aug-2008	--	WAES0808USA02481	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Unknown	
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness, Mydriasis, Respiratory arrest, Skin disorder

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a 17 year old female with no pertinent medical history, drug reactions or allergies who on 04-AUG-2008 was vaccinated with a dose of GARDASIL (Lot #660389/1968U). Concomitant therapy included Hep A (unspecified). On 04-AUG-2008, after receiving GARDASIL, the patient stood up, passed out with eyes open and hit the ground. She did not breathe for 30 seconds, eyes were dilated and still open and skin was terrible. The patient looked like a corpse. The nurse called the patient the next day (05-AUG-2008) and the patient said she was fine. Unspecified medical attention was sought. Upon internal review, "did not breathe for 30 seconds" was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 323026-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	02-Apr-2008	17-Apr-2008	15	22-Aug-2008	25-Aug-2008	FR	WAES0808AUS00145	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0817U		Unknown	Intramuscular	
	HEP	UNKNOWN MANUFACTURER	JB148		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Contusion, Epistaxis, Idiopathic thrombocytopenic purpura, Petechiae, Urticaria

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing a 12 year old female who on 02-APR-2008 was vaccinated with GARDASIL (Lot 3 658219/0817U, Batch # J6137, Expiry date 16-MAR-2010). Other suspect therapy hepatitis B virus vaccine (unspecified) (Batch # JB148). On 17-APR-2008 the patient experienced petechiae, contusion and idiopathic thrombocytopenia purpura and was hospitalised. It was described that approximately 2 weeks following vaccination, the patient developed hives and petechial rash and by the following week she had extensive bruising over her body. On approximately 05-MAY-2008, she was diagnosed with severe idiopathic thrombocytopenic purpura (ITP) and was admitted to hospital. On 16-MAY-2008, haemoglobin was found to be 119 (units not specified) (normal range 120-150) ; platelets were found to be 4 x10^9/L (normal range 150-400 x10^9/L) ; haematology (PCV) was found to be 0.33 (units not specified) (normal range 0.36-0.46) and haemtology (MCHC) was found to be 360 (units not specified) (normal range 315-355). On 17-MAY-2008, platelets were found to be 4 x10^9/L (normal range 150-400 x10^9/L) and haematology (PCV) was found to be 0.35 (units not specified) (normal range 0.36-0.46). The patient is being followed up by physician and is still symptomatic (nose bleeds and excessive bruising). At the time of reporting to the agency on 01-AUG-2008, the patient's petechiae and contusion and idiopathic thrombocytopenic purpura persisted. The agency considered that petechiae, contusion and idiopathic thrombocytopenic purpura were possibly related to therapy with GARDASIL and hepatitis B virus vaccine (unspecified). The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: hematology, 16May08, 0.33, 0.36 - 0.46, PCV; hematology, 16May08, 360, 315 - 355, MCHC; hemoglobin, 16May08, 119, 120 - 150; platelet count, 16May08, 4 x10^9L, 150 - 400; hematology, 17May08, 0.35, 0.36 - 0.46, PCV; platelet count, 17May08,

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 323027-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	19-Feb-2008	21-Feb-2008	2	22-Aug-2008	25-Aug-2008	FR	WAES0808AUS00144	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0582U	2	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site nodule, Injection site reaction, Pain, Skin inflammation, Urticaria

Symptom Text: Information was obtained on request by the Company from the agency, via a Public Case Detail Form and Case Line Listing, concerning a 23 year old female who on 19-FEB-2008 was vaccinated with her third dose of GARDASIL (Lot No. 657874/0582U, Expiry Date 26-FEB-2010, Batch No. J2299), intramuscularly, as prophylactic vaccination. On 21-FEB-2008 the patient developed injection site nodule and injection site reaction. It was described that the patient developed a "hard nodule two days after her third vaccination with GARDASIL. Subsequently, one month later, on 18-MAR-2008, the lump increased in size and sensitivity. It appeared like a misshapen, circular wheal, approximately 3x4 cm round. The patient has dark skin but area appeared inflamed and pinkish in colour and was painful to touch (4/10). It intermittently restricted upward movement of arm due to moderate discomfort." The patient applied cold packs without relief and antibiotic therapy prescribed by her physician was commenced. The patient was advised to observe area and inform clinic of changes and/or when it dissipated. At the time of reporting to the agency on 19-MAR-2008, the patient's injection site nodule and injection site reaction persisted. The agency considered that injection site nodule and injection site reaction were certainly related to therapy with GARDASIL. The original reporting source was not provided. The reporter considered that injection site nodule and injection site reaction were disabling. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 323028-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Jul-2008	02-Jul-2008	0	22-Aug-2008	25-Aug-2008	FR	WAES0808AUS00143	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0817U	2	Unknown	Intramuscular	
	HEP	UNKNOWN MANUFACTURER	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Dysphagia, Dyspnoea, Nausea, Panic attack, Throat tightness

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 13 year old female who on 02-JUL-2008 was vaccinated with the third dose of GARDASIL (Lot # 658219/0817U, Batch # J6137, Expiry date 16-MAR-2010). Other suspect therapy included hepatitis B virus vaccine (unspecified). On 02-JUL-2008 the patient experienced panic attack, dizziness and nausea and was hospitalised. It was described that 20 minutes post vaccination with the third dose of GARDASIL, the student felt faint and nauseous. The student reported that her throat felt tight and she was unable to breathe. She was given adrenaline 0.5 mg and was repeated as the student had difficulty swallowing. The patient was transported to hospital for observation. The ED records and the physician indicate that episode was a panic attack. On 02-JUL-2008, the patient recovered from panic attack, dizziness and nausea. The agency considered that panic attack, dizziness and nausea were possibly related to therapy with GARDASIL and hepatitis B virus vaccine (unspecified). The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 323029-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	06-May-2008	06-May-2008	0	22-Aug-2008	25-Aug-2008	FR	WAES0808AUS00137	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	UNKNOWN MANUFACTURER	NULL		Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Dyskinesia, Headache, Hypoaesthesia, Muscle twitching, Somnolence, Vomiting

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 12 year old female who on 06-MAY-2008 was vaccinated with GARDASIL. Other suspect therapy included varicella (unspecified). On 06-MAY-2008 after vaccination with GARDASIL and varicella (unspecified), the patient experienced dizziness, headache, dyskinesia, hypoaesthesia, muscle twitching, somnolence and vomiting and was hospitalised. It was described that the patient experienced headache, vomiting, dizziness, numbness in legs and became floppy and drowsy, was twitching, had jerking limbs and body. At the time of reporting to the agency on 28-MAY-2008, the outcome of dizziness, headache, dyskinesia, hypoaesthesia, muscle twitching, somnolence and vomiting was unknown. The agency considered that dizziness, headache, dyskinesia, hypoaesthesia, muscle twitching, somnolence and vomiting were possibly related to therapy with GARDASIL and varicella (unspecified). The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323030-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	28-May-2008	28-May-2008	0	22-Aug-2008	25-Aug-2008	TN	WAES0807USA03787	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a medical assistant for the pregnancy registry for GARDASIL, concerning a 22 year old female with no known pertinent medical history or drug reactions/allergies who on 28-MAY-2008 was vaccinated with a first dose of GARDASIL 0.5 ml IM. Concomitant therapy included ALESSE, LEXAPRO, ZOMIG and phentermine. On 01-JUL-2008 the patient had a blood test that showed she was 5 to 8 weeks gestation. Her last menstrual period was approximately 27-MAY-2008 and her estimated due date is approximately 03-MAR-2009. The patient sought medical attention in the office. Follow-up information was received. On 10-JUL-2008 the patient underwent elective termination. Upon internal review the patient's elective termination was considered to be an other important medical event. Additional information is not expected.

Other Meds: LEXAPRO; ALESSE; phentermine; ZOMIG

Lab Data: serum beta-human, 07/01/08, 5-8 weeks pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 5/27/2008)

Prex Vax Illns:

Vaers Id: **323031-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	07-Apr-2008	07-Apr-2008	0	22-Aug-2008	25-Aug-2008	FR	WAES0808USA02866	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0466U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chills, Contraception, No reaction on previous exposure to drug, Pyrexia

Symptom Text: Information has been received via Health Authority (HA ref. No. PEI2008011493), concerning a 26 year old female patient with allergy against paracetamol and no previous medical history reported, who on 07-APR-2008 was vaccinated with a third dose of GARDASIL (Lot # 0466U and Batch # NG34890), I.M., on a deltoid muscle. Concomitant medication included unspecified hormonal contraceptives. The same day, the patient developed chills and fever. The patient was hospitalized on an unknown date, length of stay was not reported, no hospital report or findings were provided. The patient received symptomatic treatment (no details reported) and recovered within approximately 24 hours. The previous doses of GARDASIL were well tolerated. The case is closed. Other business partner numbers included: E2008-07640. No further information is available.

Other Meds: hormonal contraceptives (unspecified), Unk - Unk

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323032-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Apr-2008	28-Apr-2008	0	22-Aug-2008	25-Aug-2008	FR	WAES0808AUS00147	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Rash, Rash papular

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing and a Public Case Detail Form concerning a 15 year old female who on 28-APR-2008 was vaccinated with GARDASIL. On 28-APR-2008 the patient developed a rash and papular rash which was described as papules on elbows, thighs and chest with sharp severe abdominal pain. The patient was hospitalised and treated with pethidine. At the time of reporting to the agency on 27-MAY-2008 the patient had not yet recovered from the rash and papular rash. The agency considered that rash and papular rash were possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323033-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	09-May-2008	16-May-2008	7	22-Aug-2008	25-Aug-2008	FR	WAES0808AUS00138	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anger, Dizziness, Malaise, Myalgia, Neck pain, Pain in extremity, Palpitations, Syncope

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 26 year old female who on 09-MAY-2008 was vaccinated with GARDASIL. On 16-MAY-2008 the patient experienced dizziness, malaise, myalgia, neck pain, pain in extremity, palpitations and syncope which required a visit to the physician and the patient was hospitalised. It was described that the patient felt faint, dizziness, heart palpitations, sore arm and hands, feeling unwell with sore aching muscles and neck and very angry and upset about this as it has made life horrible. At the time of reporting to the agency on 31-JUL-2008, the patient's dizziness and malaise and myalgia and neck pain and pain in extremity and palpitations and syncope persisted. The agency considered that dizziness, malaise, myalgia, neck pain, pain in extremity, palpitations and syncope were possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323034-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	29-Jul-2008		22-Aug-2008	25-Aug-2008	FR	WAES0808AUS00135	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Headache, Injection site pain, Injection site reaction, Lethargy, Visual disturbance

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 20 year old female who was vaccinated with GARDASIL. On 29-JUL-2008 the patient experienced visual disturbance, abdominal pain, headache, injection site reaction (described as local tenderness) and lethargy. The patient was treated with simple analgesia and fluids with rest. At the time of reporting to the agency on 30-JUL-2008, the outcome of visual disturbance, abdominal pain, headache, injection site reaction and lethargy was unknown. The agency considered that visual disturbance, abdominal pain, headache, injection site reaction and lethargy were possibly related to therapy with GARDASIL. Visual disturbance, abdominal pain, headache, injection site reaction and lethargy were considered to be disabling by the agency. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323035-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	31-Aug-2007	02-Sep-2007	2	22-Aug-2008	25-Aug-2008	FR	WAES0808AUS00128	25-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Appendicectomy, Back pain, Dyspnoea, Muscular weakness, Paraesthesia

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 14 year old female who on 31-AUG-2007 was vaccinated with GARDASIL. On 02-SEP-2007 ("2 days later") the patient experienced muscular weakness, abdominal pain, back pain, dyspnoea and paraesthesia which required an ambulance treatment and the patient was admitted to hospital. It was described that the patient developed lower right abdominal pain, leg weakness and tingling with back pain. The patient still has episodes with some days worse than others. Patient also experienced difficulty breathing. An appendectomy was required. At the time of reporting to the agency on 28-FEB-2008, the patient's muscular weakness and abdominal pain and back pain and dyspnoea and paraesthesia persisted. The agency considered that muscular weakness, abdominal pain, back pain, dyspnoea and paraesthesia were possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323041-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	12-Jun-2008	12-Jun-2008	0	22-Aug-2008	29-Aug-2008	NH		29-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza, Pain in extremity, Pyrexia

Symptom Text: Patient developed flu symptoms (mild) x 3d with fever and some soreness in arm after receiving #1 GARDASIL on June 12, 2008. Patient reported this on visit when getting #2 GARDASIL 8/14/2008.

Other Meds: Yasmin; Lorozepam

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323073-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-Aug-2008	20-Aug-2008	0	22-Aug-2008	29-Aug-2008	TN		29-Aug-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2656AA	1	Left leg	Intramuscular	
HPV4	MERCK & CO. INC.	0843X	0	Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Gaze palsy, Hypotension, Loss of consciousness, Mydriasis, Pallor, Syncope

Symptom Text: Patient received Gardasil and Menactra. Remained seated for approximately 5 - 10 minutes and was discharged. Became clammy and faint when walking to check out of office. Mother noticed she was very pale and asked if she was all right - the child said not. Mother lowered her to the floor. At that time the child's eyes rolled back and her lips and mouth were drawn back. She lost consciousness for a few seconds and then came to on her own. She was examined by a physician who came immediately. Her pupils were slightly dilated, her B/P was slightly lower than normal. When asked if she knew where she was she responded + and she also remembered what had gone on before her syncopal episode. The patient left the office on her own without further difficulty.

Other Meds:

Lab Data: None

History: None

Prex Illness: None - in for well child check-up

Prex Vax Illns:

Vaers Id: 323085-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Jul-2007	25-Aug-2007	45	22-Aug-2008	29-Aug-2008	TX		10-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	MERCK & CO. INC.	0649U	1	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2336AA	0	Left leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Arthralgia, Arthritis reactive, Behcets syndrome, Blister, Contusion, Erythema nodosum, Fatigue, Genital lesion, Headache, Infectious mononucleosis, Inflammation, Joint swelling, Lymphadenopathy, Nausea, Oedema peripheral, Pain, Pharyngolaryngeal pain, Phonophobia, Photophobia, Polyarthritis, Pyrexia, Rash, Skin lesion, Steroid therapy, Stomatitis, Tonsillitis, Upper respiratory tract congestion, Viral infection

Symptom Text: On July, 2007 Patient received the HPV and mennicoccal vacines in preparation for college enrollment. 3 weeks after school began for Fall 2007 she started to expereice extreme fatigue and swollen glands. 4 strep tests over the next 2 months at the campus clinic all came back negative. She continued to have some good days mixed with some bad where she could not get out of bed to attend class. Sometime around late October she started having swelling in her ankles and feet (could not put shoes on) and pain in her elbows and wrists. This was followed by sores and bruising on her lower legs. A week or so later she developed sores inside her mouth and in her genital area. During all of this time, several trips were made to the school clinic, the regional ER and trips back home to see her own doctor. By the time she came home for Christmas in early December she could barely walk due to the blisters and swelling/bruising of her legs and feet. Another trip to her doctor, who recommended she see an infectious disease doctor who once he saw her referred her to another specialist. She was diagnosed with Behcet's Disease - an auto-immune disease. She was immediately put on steriods and another medication to keep the immune system in check. After 7 months she is now off of the steriod but will probably have to take the other medication for the rest of her life. I strongly believe that the vaccines she received in July attacked her immune system. 8/29/08 Reviewed PCP office records. Patient received only one HPV vaccine & it was from one of these lots: 0244U, 0389U or 0524U. FINAL DX: Behcet's disease, anemia Records reveal patient experienced Office note of 9/28 indicates patient had fatigue, sore throat, congestion, aching & low grade fever x 3 wks & had been on oral antibiotics x 1 week w/o improvement. Exam remealed exudate on tonsils & dx w/viral tonsillitis & anemia. Received t/c from patient 11/1/07 following sore throat x 5 days w/temp 104. Again on antibiotics w/o improvement. T/C to office 12/2

Other Meds:

Lab Data: MRI, CAT scans of hands and feet LABS: EBV IgG1937(H) & EBV antibody 305(H). WBC 19.9(H), H/H 9.7/30.2(L), neutros 81%(H), lymphs 12%(L). CRP 9.8(H). ESR increased. MRI WNL. CXR WNL. Herpes 1&2(-).

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: 323095-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	17-Oct-2006	26-Nov-2006	40	23-Aug-2008	25-Aug-2008	MO		12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Anxiety, Balance disorder, Borderline personality disorder, Cognitive disorder, Complex partial seizures, Condition aggravated, Confusional state, Depression, Dizziness, Dysgeusia, Dyspnoea, Epilepsy, Fatigue, Feeling hot, Headache, Hyperventilation, Incontinence, Loop electrosurgical excision procedure, Muscle twitching, Musculoskeletal stiffness, Nausea, Panic disorder, Partial seizures, Postictal state, Posturing, Somnolence, Speech disorder, Stress, Tension, Tongue biting, Vision blurred

Symptom Text: On October 17, 2006 I recieved my first dose of the Vaccine. I felt fine afterwards other than being a little dizzy. I was a normal 19 year old college student, working, and doing sports. A month and a week after my first dose of the vaccine I was hospitalized with seizures. I had many tests done and continued to have seizures. They said there was no apparent cause for my seizures. I am now 21 years old and am living with epilepsy. It has changed every aspect of my life. I just recently heard a talk show on CNN talking about people who have recieved gardasil and have had adverse side effects including seizures. Now I am on two different seizure drugs and am struggling through school and I can no longer hold a steady job due to driving restrictions, fatique,etc. 10/21/08 Reviewed multiple hospital admission & ER records of 6/27-12/30/2006. FINAL DX: focal to secondary generalized seizure disorder; panic disorder. 11/25-11/27/2006 Hospital admission s/p 3 new witnessed generalized motor seizures while sleeping & bit her tongue; followed by HA, stiffness & confusion. Tx w/dilantin & folic acid. 12/2/06 Seen in ER for possible family witnessed seizures x 2, patient found to be incontinent, postictal, HA, blurred vision, nausea, anxiety. Found w/muscle tension & hyperventilation. Labs revealed toxic dilantin level, 26.2. Meds adjusted & d/c to home w/o further seizure activity. 12/26-12/30/2006 FINAL DX: multiple spells, seizure vs pseudoseizure; borderline personality disorder w/somatoform features; hx of panic disorder. Admission for video EEG after having increased frequency of seizure activity at home despite therapeutic levels of meds. Neuropsych consult done & referred to outpatient psych. D/C to home w/o antiseizure meds. 10/31/08 Reviewed OB/GYN clinic records of 10/06-9/2008. FINAL DX:none provided Records reveal patient had LEEP done 5/23/08. Had been on Yaz & changed to other BCP. 11/11/08 Reviewed neuro clinic records of 11/28/2006-9/19/2008. FINAL DX: epilepsy

Other Meds: birth control, zoloft

Lab Data: LABS: EEG abnormal w/paroxysmal dysfunction but no frank epileptiform activity. CT & MRI brain WNL. CBC, chemistry, CPK 357(H), UA abnormal, tox screen (+) cannabis, EKG.

History: Anxiety PMH: atypical panic disorder on high dose zoloft. Allergy: latex. Contraception. UTI. Night sweats.

Prex Illness: None!

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323097-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	08-Apr-2008	Unknown		23-Aug-2008	29-Aug-2008	PA		29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	3	Gluteous maxima	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Carpal tunnel syndrome, Dizziness, Immediate post-injection reaction, Joint swelling, Myalgia, Polyarthritis, Tenosynovitis

Symptom Text: Right after my first vaccine I immediatly fainted, since that day and throughout the last two vaccines i have had strange symptoms. Feeling dizzy occurs all of the time and i have had extreme joint problems including swelling and horrible pain. The dizzyness is continuous, but the joint pain comes and goes. The joint pain and swelling mostly occurs where i had been given the vaccines(arm and thigh). 10/10/08 Reviewed rheumatology records of 1/24-3/11/08. FINAL DX: inflammatory polyarthralgia NOS Records reveal patient experienced intermittent right hip, left shoulder & right wrist pain x 3 mos along with myalgia of LEs, dizziness & lightheadedness s/p HPV vaccines 10/07 & 12/07. Tx w/pain meds initially but no improvement. 3/08 tx w/steroid tx for possible seronegative RA. No further records available. 10/3/08 Reviewed GYN medical records of 2/28/07-4/25/2008. FINAL DX: none provided Records reveal patient in usual state of good health on day of vaccination w/sexual dysfunction. Joint pain reported on 4/25/08 & was being seen by rheumatologist. 10/24/08 Reviewed PCP medical records of 10/11/07-1/22/2008. FINAL DX: Records reveal patient experienced right wrist pain 10/11/07 w/x-ray normal. 12/12/07 c/o of dizziness, lightheadedness, feeling faint x 2-3 weeks. Had fainted w/HPV #1. Right wrist pain persisted & referred to ortho. 1/16/2008 c/o continued left shoulder joint pain, right wrist pain & right hip pain. Referred to rheum.

Other Meds: none

Lab Data: I still to this day see a rheumatologist along with my primary doctor. I had been tested numerous times for all kinds of joint associated problems and all came back normal. LABS: CBC, chemistry WNL. Sed rate 45(H). CRP 4.73(N). ANA

History: No

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323110-1** **Related reports:** 323110-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	05-Aug-2008	06-Aug-2008	1	22-Aug-2008	29-Aug-2008	--		29-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0027	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Genital cyst

Symptom Text: Mother claims that a cyst developed on her genital area the day after 2nd GARDASIL shot was given. All summer long - been tired.

Other Meds: None

Lab Data: Sent for CBC, CRP, Mono test, CMP

History: Seasonal allergies - on Claritin as needed

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323110-2** **Related reports:** 323110-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	05-Aug-2008	06-Aug-2008	1	17-Sep-2008	29-Dec-2008	MA	WAES0808USA04938	08-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Genital rash

Symptom Text: Information has been received from a physician concerning an 11 year old female with no medical history who on an unspecified date was vaccinated with the first dose of GARDASIL and on 05-AUG-2008 was vaccinated with the second dose of GARDASIL IM. There was no illness at the time of vaccination. On 06-AUG-2008 the patient experienced rash on genital area and was noted to be tired all summer long. At the time of reporting, the outcome of the patient was unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: WBC count, 08/22/08, 3.8 X10*3;

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **323122-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Aug-2008	15-Aug-2008	10	22-Aug-2008	29-Aug-2008	WI		01-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0847X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased

Symptom Text: Temp 102 8/15 & 8/16/08.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323140-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	24-Oct-2007	24-Oct-2007	0	25-Aug-2008	26-Aug-2008	AZ	WAES0711USA03915	26-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1264U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received for the Merck Pregnancy Registry for GARDASIL from a health professional concerning a 20 year old white female with no pertinent medical history, drug reactions/allergies. On 24-OCT-2007 the patient was vaccinated with a first dose of GARDASIL (lot# 658488/1264U) 0.5 mL IM. There was no concomitant therapy used. On 24-OCT-2007 the patient tested positive on a home pregnancy test after receiving the first and only dose of GARDASIL. Medical attention was sought. The patient called the office. No further information was available. The date of the last menstrual period was 26-SEP-2007 and the estimated date of delivery is 02-JUL-2008. Follow up information was received which reported that in February 2008 the patient had an elective termination at approximately 19 weeks of pregnancy. Additional information is not expected.

Other Meds: None

Lab Data: beta-human chorionic - home

History:

Prex Illness: Pregnancy NOS (LMP = 9/26/2007)

Prex Vax Illns:

Vaers Id: 323141-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-Jul-2008	07-Jul-2008	0	25-Aug-2008	26-Aug-2008	--	WAES0807USA05053	26-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner for the pregnancy registry for GARDASIL concerning a 17 years old female who on 07-JUL-2008 was vaccinated with the first dose of GARDASIL. Concomitant therapy included PROZAC, XANAX, trazodone HCl and albuterol. The nurse practitioner reported that the patient may have been pregnant when the first dose of GARDASIL. No adverse reactions reported. The last menstrual period was 18-JUN-2008. Her due date is 25-MAR-2009. The patient sought medical attention, she was seen by nurse practitioner. There was no product quality complaint. Additional information has been requested. Follow up information has been received from a nurse practitioner that reported that the patient had an elective termination of her pregnancy last week at approximately 8 weeks estimated gestational age (EGA) (approximately 08-AUG-2008). The nurse practitioner reported that she saw the patient on 13-AUG-2008 and she seemed to be doing well, following the termination of her pregnancy last week at approximately 8 weeks EGA. The nurse practitioner stated that the decision to have the termination was not due to the GARDASIL. The patient was also being treated with PROZAC, XANAX and trazodone HCl, and had concerns related to these medication as well as other concerns. Upon internal review termination of her pregnancy was determined to be an other important medical event. Additional information is not expected.

Other Meds: albuterol; XANAX; PROZAC; trazodone hydrochloride

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 6/18/2008)

Prex Vax Illns:

Vaers Id: **323142-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Mar-2008	05-Mar-2008	0	25-Aug-2008	26-Aug-2008	FR	WAES0808AUS00152	26-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0784U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chest pain

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Details Form and Case Line Listing, concerning a 14 year old female, who was born prematurely. She has asthma, mild-to-moderate hearing loss and intellectual delay. On 05-MAR-2008 the patient was vaccinated with GARDASIL (Lot No. 658275/0784U, Expiry date 22-MAR-2010, Batch No. J3206), intramuscularly. Subsequently, on 05-MAR-2008, the patient developed chest pain and was hospitalized. At the time of reporting to the agency on 31-MAR-2008, the patient had recovered from chest pain. The agency considered that the patient's chest pain was possibly related to therapy with GARDASIL. The original reporting source was not provided by the agency. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Premature birth

Prex Illness: Asthma; Partial hearing loss; Intellect impaired

Prex Vax Illns:

Vaers Id: 323143-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	21-Nov-2007	23-Nov-2007	2	25-Aug-2008	26-Aug-2008	FR	WAES0808AUS00153	26-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0582U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Chest pain, Dyspnoea, Nausea, Paraesthesia, Pyrexia, Vaginal haemorrhage

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing and a Public Case Detail Form concerning a 19 year old female who on 21-SEP-2007 was vaccinated with the first dose of GARDASIL (Batch # J1599, Expiry date 11-FEB-2010, Lot No. 657870/0491U). On 21-NOV-2007 the patient was vaccinated with the second dose of GARDASIL (Batch No. J2299, Expiry date 26-FEB-2010, Lot No. 657874/0582U). On 23-NOV-2007 the patient experienced nausea, abdominal pain, chest pain, dyspnoea, genital haemorrhage, paresthesia and pyrexia. It was reported that the patient developed nausea, shortness of breath, abdominal pain, chest pain which was described as sharp stabbing to back, per vaginal bleeding three days later (? period) and tingling fingers. The patient was hospitalised and the following tests were done: chest - x-ray, ECG, blood tests and stress test (results not specified). At the time of reporting to the agency on 22-JUL-2008 it was not known if the patient had recovered from the nausea, abdominal pain, chest pain, dyspnoea, genital haemorrhage, paresthesia and pyrexia. The agency considered that nausea, abdominal pain, chest pain, dyspnoea, genital haemorrhage, paresthesia and pyrexia were related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Chest X-ray, ??Nov07; Electrocardiogram, ??Nov07; Diagnostic laboratory test, ??Nov07; Cardiac exercise tolerance test, ??Nov07

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323144-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		25-Aug-2008	26-Aug-2008	MO	WAES0808USA02819	26-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Monoplegia

Symptom Text: Information has been received from a nurse concerning a female patient who on an unspecified date was vaccinated with the first dose of GARDASIL. Subsequently, the patient developed paralysis in the arm. It was unknown if the paralysis occurred in the injection site arm. The patient recovered on an unknown date. There was no product quality complaint. Upon internal review, the patient's paralysis in the arm was considered an other important medical event. Additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 323145-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Mar-2008	14-Mar-2008	1	25-Aug-2008	26-Aug-2008	FR	WAES0808USA03453	26-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Peripheral vascular disorder

Symptom Text: Information has been received from a health authority (reference no. PEI2008011259) concerning a 15 year old female who on 13-MAR-2008 was vaccinated with a first dose of GARDASIL. The next day, the patient developed dizziness and peripheral circulatory disorder. She was hospitalized. Ophthalmological examinations, electroencephalography, electrocardiogram and Schellong test showed normal results. Although she had not completely recovered from the symptoms, on 24-JUL-2008, she was administered the second dose of GARDASIL. The final outcome was not reported. No further information is available. The case is closed. Other business numbers included E2008-7642.

Other Meds: Unknown

Lab Data: ophthalmological exam, normal; electroencephalography, normal; electrocardiogram, normal; orthostatic hypotension measurement, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323146-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-May-2008	29-May-2008	22	25-Aug-2008	26-Aug-2008	FR	WAES0808USA03621	26-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1049U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Ageusia, Facial palsy, Facial paresis, Hypoaesthesia oral

Symptom Text: Information was received from a physician via health authority concerning an 18-year-old female, who on 07-MAY-2008 was vaccinated with a first dose of GARDASIL (lot # 1049U, batch # NG46500, injection site not reported) via intramuscular route. On 29-MAY-2008 the patient present to her general practitioner with numbness of the tongue and loss of taste. Her tongue and facial muscles were normal. Fungal infection was suspected and AMPHO-MORONAL was given for symptomatic treatment. The treatment was not successful. On 01-JUN-2008 the patient experienced drooping of the left corner of the mouth and eyelid paresis, which was diagnosed as left idiopathic facial paresis in the neurology unit. "MRT" and lumbar puncture revealed no pathological findings. At the time of reporting, the patient was recovering. The events were considered to be serious because of the patient's hospitalization (date not specified). Follow-up information was received which reported that on 01-JUN-2008 the patient experienced drooping of the left corner of the mouth and eyelid paresis. The patient was admitted to the neurological hospital where the diagnosis of the left idiopathic facial paresis was established. "MRI" and lumbar puncture revealed no pathological findings. At the time of reporting, the patient was recovering. Other business partner numbers included: E200807755. No further information is available.

Other Meds: Unknown

Lab Data: spinal tap, no pathological findings; magnetic resonance imaging, No pathological findings

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323147-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Apr-2008	26-May-2008	55	25-Aug-2008	26-Aug-2008	FR	WAES0808USA03639	26-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Central nervous system lesion, No reaction on previous exposure to drug

Symptom Text: Information was received from a health authority (local reference # PEI2008008421) concerning a 17-year-old female with complaints about preexisting headache for 5 months, who in APR-2008 was vaccinated with a third dose of GARDASIL (lot number, route and injection site not reported). No adverse effect was reported after the patient's previous vaccination with GARDASIL (P1 in NOV-2007 and P2 in DEC-2007, lot numbers not reported). On an unknown date the patient was hospitalized. MRI of brain on 26-MAY-2008 revealed a left-sided frontal lesion. It was not possible to differentiate whether it was a brain tumor or an encephalitis. A short-term control was recommended. On 29-MAY-2008, CSF test to herpes virus DNA was negative and serology of Borrelia burgdorferi (CSF and serum) for IgG and IgM was negative. Additionally, EEG, cranial MRI, OCT and methionine PET were performed. Detailed results were not reported. Demyelinating disease was excluded. The patient's outcome was unknown. Other business partner numbers included: E200807658. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 26May08, MRI of brain revealed a left-sided frontal lesion; diagnostic laboratory test, 29May08, negative, CSF test to herpes virus DNA; diagnostic laboratory test, 29May08, negative, Serology of Borrelia burgdor

History:

Prex Illness: Headache

Prex Vax Illns:

Vaers Id: **323164-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	02-Jun-2008	21-Jun-2008	19	25-Aug-2008	02-Sep-2008	MA		10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Dizziness, Erythema nodosum, Headache, Migraine, Musculoskeletal stiffness, Rash

Symptom Text: Patient received her 3rd GARDASIL/HPV vaccination on 6/02/08. She was seen in the ER on 6/21/08 with diagnosis of Erythema Nodosum. ? related to vaccination. 9/10/08-records received for DOS 6/21/08-presentd to ED with C/O migraine and rash. DX:erythema nodosum. Physical exam on 11/27/07 C/O right anterior knee pain. 7/23/08 persistent knee pain waxing and waning lower leg rash/lumps with sensitivity. After third dose of HPV C/O stiff neck on right side, severe headache, nausea and dizziness which lasted for about 3 days.

Other Meds: Zovia 1/35 QD

Lab Data: Labs from 6-21-08 included

History: Benadryl - Hives

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323165-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Aug-2008	19-Aug-2008	0	25-Aug-2008	02-Sep-2008	OH		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Nausea, Pallor

Symptom Text: Immediately after vaccine was given, patient became pale and nauseous. Also, felt dizzy and light-headed. Feeling passed after laying down x few minutes.

Other Meds: Thyroid, Prevacid, Zoloft, Yaz, Ducolax, clonazepam

Lab Data:

History: NKDA, irritable bowel syndrome, scoliosis

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323168-1** **Related reports:** 323168-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Aug-2008	14-Aug-2008	0	25-Aug-2008	02-Sep-2008	CO		02-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	C2937AA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2666AA	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	0072X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Disorientation, Dizziness, Hypoventilation, Immediate post-injection reaction, Pallor, Paraesthesia

Symptom Text: Client was sitting in chair and became pale, faint and disoriented just after receiving 3 vaccines. She responded to touch, questions and commands. Several minutes later she became faint again, was placed supine and given Od. She was pale with shallow respiration's but took deep breaths when asked. She c/o her arm tingling. Because she remained pale and disoriented, 911 was called and she was taken to the ER.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323168-2** **Related reports:** 323168-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jan-2009	01-Jan-2009	0	24-Feb-2009	25-Feb-2009	--	WAES0902USA02758	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Malaise, Pallor, Respiratory arrest, Sensation of heaviness

Symptom Text: Information was viewed in an internet article concerning an adolescent female. " A few weeks ago", in approximately January 2009, the patient was vaccinated with a first dose of GARDASIL, along with a few other booster shots of unspecified vaccines. Moments after getting the injection, the patient felt like "a lead weight was in her veins", all of sudden, "the room started getting dizzy", she complained that she didn't "feel good" and then she went out. The patient passed out. Her mother noticed that "she wasn't breathing and her face was very white, her mouth was white". Paramedics rushed the patient to the emergency room. The patient stayed there for hours as doctors worked to keep her blood pressure up. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323170-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	20-Aug-2008	20-Aug-2008	0	25-Aug-2008	02-Sep-2008	NJ		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0863X		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Muscle spasms, Trismus

Symptom Text: Patient received GARDASIL #1 around 2 pm along with MANTOUX. At 2:20 pm patient developed transient dizziness, & R leg cramp followed by locked jaw (-) syncope (-) respiratory distress. Patient remained alert. Sent to ER. Patient received IV TORADOL & VALIUM. Recovered in 5-10 mins. & discharged from ER. Phone f/u x2 on 8/20 - patient OK.

Other Meds: Mantoux, Sanofi, C2908AA, intradermal

Lab Data:

History: Pers. transient episode of locked jaw 1/08

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323176-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	13-Aug-2008	Unknown		25-Aug-2008	02-Sep-2008	NY		02-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0072X	0	Left arm	Unknown	
PPV	MERCK & CO. INC.	024841059		Right arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B27AH		Right arm	Unknown	
MNQ	SANOFI PASTEUR	U2649AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain, Pyrexia, Swelling

Symptom Text: Swelling and pain and fever 38 deg C.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323178-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	05-Aug-2008	07-Aug-2008	2	25-Aug-2008	02-Sep-2008	CA		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lip swelling

Symptom Text: Lip swelling bottom > top lip began evening after receiving HPV vaccine. No lip swelling. No resp breathing difficulty. Patient presented to MD office 2nd day - exam showing mild swelling lower lip only. No wheeze/resp distress.

Other Meds: PPD Skin test

Lab Data: None

History: None unknown

Prex Illness: Physical

Prex Vax Illns:

Vaers Id: **323180-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	24-Mar-2008	24-Mar-2008	0	25-Aug-2008	02-Sep-2008	OK		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site urticaria, Pyrexia, Vomiting

Symptom Text: Hives around injection site. Fever, vomiting day of injection.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323181-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	19-Aug-2008	19-Aug-2008	0	25-Aug-2008	02-Sep-2008	MO		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Urticaria

Symptom Text: Rash with hives. Given Benadryl and topical creme. Using Claritin OTC. No Breathing difficulties.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323184-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Jul-2008	19-Aug-2008	26	25-Aug-2008	02-Sep-2008	OH		09-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBV409AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1263U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Furuncle, Rash erythematous, Rash papular, Tenderness

Symptom Text: 2 wks after immunizations - client c/o abdominal cramping. Today client reports 1 boil on her (R) knee and approx 5 smaller boils on her abd - around her panty-line. Red, raised ,hard bumps that are tender. 11/14/08 Reviewed PCP medical record of 8/21/2008. FINAL DX: boils Record reveals that patient started developing boils all over after started DepoProvera for birth control. Tx w/antibiotic. Plan to refer to dermatology if treatment not successful.

Other Meds: None

Lab Data: Client was referred to her family MD.

History: None - allergy to PCN

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323205-2** **Related reports:** 323205-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	U	11-Jul-2008	25-Aug-2008	45	09-Sep-2008	09-Oct-2008	IL	200802711	09-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	NULL	0	Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
MNQ	SANOFI PASTEUR	U2621A	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Pain in extremity

Symptom Text: Initial information was received on 25 August 2008 from a health care professional. An 11 year old patient received an injection of MENACTRA (U2621AA) and BOOSTRIX (manufacturer GSK, lot number not reported) on 11 July 2008. On 19 August 2008 the patient received an injection of GARDASIL (manufacturer Merck, lot number not reported). On 25 August 2008 the patient reported symptoms of "legs numb and hurting". The patient was unaware when the symptoms began. The recovery status was unknown. No further information was provided.

Other Meds:

Lab Data: None reported.

History: No past medical history was reported.

Prex Illness:

Prex Vax Illns:

Vaers Id: **323206-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	21-Aug-2008	21-Aug-2008	0	25-Aug-2008	01-Sep-2008	CO		02-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1757U	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B020AA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0270X	1	Right arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U2546AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncopal event within 5 minutes after 4 vaccines administered. Recovered from syncopal event within 15 minutes. Other than observation for 30 minutes no further treatment given.

Other Meds: none

Lab Data: none

History:

Prex Illness: None other than anxiety around stressors in life.

Prex Vax Illns:

Vaers Id: **323218-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Aug-2008	25-Aug-2008	0	25-Aug-2008	01-Sep-2008	NC		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAPHE	GLAXOSMITHKLINE BIOLOGICALS	AC21B160BA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0571X		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: WRONG IMMUNIZATION GIVEN GAVE PEDIARIX AND SHOULD HAVE BEEN HEP A

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **323219-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	22-Aug-2008	22-Aug-2008	0	25-Aug-2008	01-Sep-2008	CA		02-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	MERCK & CO. INC.	1442U	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2605AA	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2995BA	5	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0229X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Feeling abnormal, Loss of consciousness, Syncope

Symptom Text: felt funny when left clinic, fainted and lost consciousness on ride down on elavator from pedi clinic. IZ given at 1215pm and had not eaten since the night before. Juice and crackers given, monitored vitals

Other Meds: ppd skin test RFA

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **323222-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Aug-2008	22-Aug-2008	1	25-Aug-2008	01-Sep-2008	OR		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB239AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1757U	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0319X	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: LARGE RED SWOLLEN AREA WITH PAIN, WARM TO TOUCH THE DAY AFTER THE INJECTION. CLIENT'S CAREGIVER REPORTED TO THE CLINIC. WAS INSTRUCTED TO USE ICE, BENADRYL, IBUPROFEN

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323231-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	07-Jul-2008	29-Jul-2008	22	25-Aug-2008	02-Sep-2008	NJ		18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0053X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contraception, Injury, Oedema peripheral, Pain in extremity, Thrombosis

Symptom Text: Was in ER on 07/29/08 - told had blood clot in upper left arm, that traveled to lung - on Coumadin x 3-6 months *Pulmonary Embolism 8/29/08-records received phone call to office by pt 8/25/08-seen in ER due to pulmonary embolism on 7/29/08-notes from 8/25/08-indicated patient hospitalized and followed by hematologist who indicated condition was secondrry to trauma with surf board. Pt returned to work and doing well. 9/18/08-records received for DOS 7/29/08-Impression:thrombosis of axillary vein after several days after surfing for first time. Use arms extensively and did have compression of axillary vein at that time. Comorbid problem use of estrogen ring NuvoRing. Thrombosis due to trauma of surfing. Presented to ED with C/O aching in left arm and axilla and increasing swelling.

Other Meds: Nuva Ring

Lab Data: requires follow up with Hematologist 9/18/08-records received-Labs WNL, antithrombin III activity low at 77.Duplex scan of left upper extremity venous system occlusive venous thrombosis involving left axillary and left brachial veins with

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323234-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	22-Aug-2008	22-Aug-2008	0	25-Aug-2008	02-Sep-2008	MO		22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Fatigue, Headache, Malaise, Nausea, Oedema peripheral, Paraesthesia, Pyrexia

Symptom Text: Generalized weakness in arms and legs, Tingling in feet; Fever, Nausea 10/17/08-records received-office note for 8/25/08-C/O dizzy, headache weakness and tired, feeling acutely ill, arm swelled. Saw physician stated it was reaction to vaccine.Still feeling tired but able to go to school.

Other Meds: Unknown

Lab Data: EKG; urinalysis; CBC; Chem 12; TSH

History: depression

Prex Illness: None

Prex Vax Illns:

Vaers Id: 323236-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	13-Jun-2008	18-Jun-2008	5	25-Aug-2008	02-Sep-2008	IL		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Dizziness, Dyspnoea

Symptom Text: 5 days after receiving the vaccine-woke up, felt faint and had difficulty breathing, tightening of the chest-went to ER.

Other Meds: XOPENEX inhaler; SINGULAIR; PHENTERMINE; ZYRTEC; MACROBID

Lab Data:

History: hx of asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323237-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Aug-2008	21-Aug-2008	1	25-Aug-2008	02-Sep-2008	PA		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Local reaction, Pruritus, Swelling

Symptom Text: Local reaction to MENACTRA; red, a little swollen, itchy - about size of a golf ball. CRNP - told her it was localized, and use ice and TYLENOL. Warm to touch.

Other Meds: None

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **323241-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Aug-2008	Unknown		25-Aug-2008	02-Sep-2008	MI		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB213AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1446U	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2365AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Local reaction, Oedema peripheral, Pain in extremity, Tenderness

Symptom Text: Dizziness, weakness, arms very sore. Left arm tender, mild swelling - local reaction. Rx Benadryl 25 mg QID, cold compresses. RTO if symptoms get worse or if new concerns.

Other Meds: None

Lab Data: N/A

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 323263-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Nov-2007	18-Aug-2008	286	26-Aug-2008	27-Aug-2008	MO	WAES0808USA03971	02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Activities of daily living impaired, Arthralgia, Back pain, Depression, Dizziness, Gastritis, Headache, Insomnia, Myalgia, Oedema peripheral, Pain, Pain in extremity, Tremor, Vitamin D deficiency

Symptom Text: Information has been received from a medical assistant concerning a 15 year old female with allergy to CEFZIL and no relevant medical history who on an unspecified date was vaccinated with a dose of GARDASIL (lot number, injection site and route not reported). In November 2007, the patient experienced headaches, stomach ache, dizziness, shakiness, dull and sharp aches all over. The patient also experienced joint pain all over, swelling of the right thumb, depression and insomnia. The patient had been set up with an appointment with a rheumatologist. Laboratory tests (included unspecified lab work, MRI of brain and X-ray of right hand (results unspecified). At time of this report, the patient's events persisted. According to the reporter, the patient's events prevented her from school schedule and were considered to be disabling. Additional information has been requested. 10/22/08-records received-presented on 8/8/08 with C/O headache,stomach ache, dizzy and shaking on and off for a while. Generalized pain. Abdominal pain. DX gastritis. Dizziness. 8/18/08 continues with C/O headaches and body aches. DX: arthrlagias, polymyalgias. Swelling of right thumb. Cephalgia. Dep ression. Insomnia. 9/3/08 continues with cephalgia, myalgias and depression.10/1/08-C/O abdominal pain. 12/31/08-records received for DOS 11/10/08-C/O arthralgia/back pain left limb pain. Vitamin D deficiency.

Other Meds: Unknown

Lab Data: magnetic resonance - brain; upper extremity X-ray; laboratory test 10/22/08-records received-CBC and chemistry WNL. 12/31/08-records received-Complement C3, C4, CK, metabolic panel , CBC, sed rate, C-reactive protein normal, rheumatoid f

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **323264-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Aug-2008	01-Aug-2008	0	26-Aug-2008	27-Aug-2008	--	WAES0808USA03716	09-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Urinary incontinence

Symptom Text: Information has been received from a licensed visiting nurse concerning a 13 year old female with a history of seizure during childhood and no history of drug reactions or allergies who 2 to 3 weeks ago (on approximately 01-AUG-2008) was vaccinated with the first dose of GARDASIL 0.5ml IM, the second dose of VARIVAX (Oka/Merck), MENACTRA and Tdap. Subsequently, the patient went home, sat down and had a drink of water. She then dropped her glass of water; she had a quick seizure and urinated on herself. She recovered soon after. The patient did not have any breakfast that day and the weather that day was very hot. The patient recovered on the same day. The patient was contacted by the nurse. Upon internal review, quick seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: None

History: Convulsion in childhood

Prex Illness:

Prex Vax Illns:

Vaers Id: **323265-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	18-Aug-2008	18-Aug-2008	0	26-Aug-2008	27-Aug-2008	--	WAES0808USA03624	27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Right arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abnormal behaviour, Convulsion, Disorientation, Dizziness, Hypotonia, Loss of consciousness, Urinary incontinence

Symptom Text: Information has been received from a physician office manager concerning a 24 year old female who on 18-AUG-2008 was vaccinated with GARDASIL IM into the right arm. Five minutes after the vaccination, the patient became "woozy" and laid down in an exam room. Her body then went limp. She closed her eyes, made strange noises, and appeared unconscious for 2 minutes. She urinated on herself and then started to seize. After 2 minutes, she returned to consciousness and was disoriented. The patient was attended to by several doctors and was taken to the emergency room. The reporter considered seizure to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323266-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	13-Aug-2008	13-Aug-2008	0	26-Aug-2008	27-Aug-2008	NY	WAES0808USA04009	27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain

Symptom Text: Information has been received from a physician concerning a 10 year old female with penicillin allergy and a history of Helicobacter pylori infection who on 13-AUG-2008 was vaccinated with the first dose of GARDASIL. Suspect therapy included VARIVAX at the same time (unspecified if this was the first dose). On 13-AUG-2008 the patient experienced abdominal pain the evening that she was given the vaccines. The patient went to the emergency room on 15-AUG-2008 and was admitted to hospital. Subsequently, the patient recovered from abdominal pain. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Helicobacter pylori infection

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: 323267-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	18-Sep-2007	10-Jun-2008	266	26-Aug-2008	27-Aug-2008	FR	WAES0808USA03452	27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1113U	2	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Oedema, Retinal detachment, Vitrectomy, Vitreous haemorrhage

Symptom Text: Information has been received from a health authority (HA ref No PEI2008012082) concerning a 23 year old female with myopia and astigmatism, who on 18-SEP-2007, was vaccinated with the first dose of GARDASIL, on 20-NOV-2007 was vaccinated with the second dose of GARDASIL and on 09-JUN-2008, was vaccinated with a third dose of GARDASIL (lot# 1113U batch# NH04240) i.m., into the left upper arm. On 10-JUN-2008, the patient experienced left retinal detachment with fissure of ora serrata. On 13-JUN-2008, the patient was hospitalized at an ophthalmic clinic where she underwent surgery (pars-plana-vitrectomy) on 16-JUN-2008. The retina was attached without complications. Postoperatively, secondary bleeding of vitreous body occurred. On 24-JUN-2008, the patient was discharged with the following results: ultrasound showed attached retina and secondary bleeding of vitreous body. Further examination on 01-AUG-2008 showed attached retina and rest edema. At the time of reporting the patient had not yet completely recovered. The previous two vaccinations with GARDASIL were well tolerated. Other business partner numbers included E2008-07746. No further information is available.

Other Meds: None

Lab Data: ultrasound, 24Jun08, attached retina and secondary bleeding of vitreous body

History:

Prex Illness: Myopia; Astigmatism

Prex Vax Illns:

Vaers Id: **323268-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Jun-2008	28-Jun-2008	0	26-Aug-2008	27-Aug-2008	FR	WAES0808USA03273	27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left leg	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Dizziness, Feeling hot, Injection site reaction, Lividity, Malaise, Pallor, Vertigo

Symptom Text: Information has been received from health authorities (reference number SE20080293) concerning a 16 year old female with a history of Kawasaki's disease 5 days after vaccination of MMR II (Enders-Edmonston, Jeryl Lynn, HPV-77) (MSD) at the age of 18 months (WAES #0808USA03489). At 11 AM on 28-JUN-2008 she was vaccinated with a first dose of GARDASIL IM in the left thigh. At the moment of withdrawing the needle, she experienced a sensation of malaise without pain; however she had to lie down for 15 to 20 minutes. It was also reported that the patient experienced an injection site reaction. On 29-JUN-2008, after she went swimming, she developed livedo on the anteroexternal face of the vaccinated thigh, at a distance from the site of injection. On 30-JUN-2008, she was pale and still had a sensation of malaise. She awoke with abdominal pain, however her periods had just started. At 10:30 AM, as she got up from bed, she experienced vertigo associated with a sensation of heat which obliged her to lie down to prevent a fall. She was hospitalised for surveillance. She had a pulse at 60, normal blood pressure, no adenopathy, no fever and the spleen was unpalpable. It was also reported a heart rate of 70 beats per minute, a respiratory rate of 20/minute, a blood pressure of 102/59, arterial blood oxygen saturation of 100%. Physical examination showed no abnormality and electrocardiogram (ECG) was normal. At 2 PM, at lunch time, she experienced malaise again, with dizziness and heat and abdominal pain, which obliged her to lie down. She progressively improved and fully recovered at 2:30 PM. She was discharged from the paediatrics unit on 01-JUL-2008 after a 2-day hospitalisation. No further information is available. Other business partner numbers included: E2008-07728. The case was closed.

Other Meds: Unknown

Lab Data: blood pressure measurement, 28Jun08, 102/59; electrocardiogram, 28Jun08, normal; blood pressure measurement, 30Jun08, normal; arterial blood O2 saturation, 28Jun08, 100%; total heartbeat count, 28Jun08, 70 bpm; respiratory rate measurement,

History: Kawasaki's disease

Prex Illness:

Prex Vax Illns:

Vaers Id: 323269-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	23-Jul-2008	23-Jul-2008	0	26-Aug-2008	27-Aug-2008	WI	WAES0808USA03199	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	2	Left arm	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Back pain, Clostridial infection, Diarrhoea, Gastroenteritis, Hiatus hernia, Inappropriate schedule of drug administration, Injection site mass, Injection site pain, Migraine, Muscular weakness, Night sweats, Paraesthesia, Pyrexia

Symptom Text: Information has been received from a registered nurse concerning a 23 year old female with no history of drug reactions or allergies who on 19-JUL-2007 was vaccinated with the first dose of GARDASIL and on 23-JUL-2008 was vaccinated with the second dose of GARDASIL (lot# 660557/0072X) in left upper arm. Subsequently, on 23-JUL-2008 the patient experienced a sore lump at the injection site of her left upper arm. The left arm "felt weak" and the patient was unable to lift her child, which caused a significant disability. The patient initially tried a cold compress on the injection site but did not notice any improvement. On 03-AUG-2008 the patient experienced diarrhea and a stool culture was performed. On 08-AUG-2008 the patient was diagnosed with Clostridium difficile and was treated with ibuprofen, TYLENOL, hydrocodone and BENTYL. The patient's sore lump at the injection site and Clostridium difficile diarrhea persisted. Sore lump at the injection site was considered to be disabling. The patient sought medical attention with a telephone call. Additional information has been requested. 10/2/08-records received-visit 7/23/08-for HPV4 vaccine. Migraines. Diarrhea. 7/31/08-C/O diarrhea, shoulder pain and headache. Diarrhea worse at night actually for last three weeks. Fevers, night sweats, low back pain. Migraines. 8/12/08-Continued C/O abdominal pain, epigastric discomfort, cramping when urinating. 8/26/08-C/O lump at injection site. 9/11/08-C/O tingling in hands and feet. DX with enterogastritis suggestive of NSAID use and moderate hiatal hernia.

Other Meds: Unknown

Lab Data: stool culture, 08/03/2008, Clostridium difficile 10/2/08-records received-CT scan abdomen negative. Stool study-C.difficile.

History: Unknown 10/2/08-records received-HX of kidney stones. Gave birth 4 months ago. Tooth infection 3 weeks ago.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323270-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		26-Aug-2008	27-Aug-2008	--	WAES0808USA03111	27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Pancreatitis

Symptom Text: Information has been received from a registered nurse concerning a female patient who in approximately 2006, one and a half years ago was vaccinated with the first dose of GARDASIL. On an unspecified date was vaccinated with the second dose of GARDASIL. On an unspecified date was vaccinated with the third dose of GARDASIL. After the three doses the patient experienced pancreatitis and was hospitalized for 8 weeks but has been discharged from the hospital on 18-AUG-2008. On an unspecified date, the patient recovered from pancreatitis. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323271-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		26-Aug-2008	27-Aug-2008	--	WAES0808USA03097	27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Muscle twitching

Symptom Text: Information has been received from a registered nurse concerning a female patient with a history of intermittent asthma, fainted and dehydrated on 28-SEP-2007 during a county fair, who on an unspecified date was vaccinated with the first dose of GARDASIL, injection (route) (Lot # 659964/1978U). Subsequently, the patient experienced seizures after receiving the first dose and 15 minutes later they notice that the patient's muscles were twitching. On an unspecified date, the patient recovered from seizures and muscles twitching. The patient sought the nurse for medical attention. Upon internal review seizures were considered to be an other internal medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Syncope; Dehydration

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **323272-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		26-Aug-2008	27-Aug-2008	FR	WAES0808AUS00241	27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Gaze palsy, Lethargy, Malaise, Pallor, Syncope

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning a 17 year old female who was vaccinated with GARDASIL. Subsequently after vaccination with GARDASIL, the patient experienced convulsion, lethargy, eye rolling, malaise, pallor and syncope. At the time of reporting to the agency on 28-FEB-2008, the patient had recovered from the convulsion, lethargy, eye rolling, malaise, pallor and syncope. The agency considered that convulsion, lethargy, eye rolling, malaise, pallor and syncope were related to therapy with GARDASIL. The original reporting source was not provided. Additional information has been requested from the agency regarding the seriousness of the events. In follow up information received on 22-AUG-2008, the agency considered convulsion to be serious for the following reason: medically significant. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323273-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	10-Mar-2008	10-Mar-2008	0	26-Aug-2008	27-Aug-2008	FR	WAES0808AUS00151	27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Back pain, Dizziness, Fatigue, Feeling cold, Hyperhidrosis, Immediate post-injection reaction, Injected limb mobility decreased, Injection site pain, Injection site rash, Insomnia, Loss of consciousness, Myalgia, Oedema peripheral, Pain, Pain in extremity, Paraesthesia, Presyncope, Pyrexia, Rash, Tinnitus

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 24 year old female who on 10-MAR-2008 was vaccinated with GARDASIL. On 10-MAR-2008, immediately after vaccination, the patient experienced back pain, dizziness, injection site pain, injection site rash, insomnia, myalgia, pain, paraesthesia and pyrexia. It described by the patient that she presented to the physician with the flu on 10-MAR-2008. The physician thought she was fine and advised her that she should get the GARDASIL. The patient advised that she was put on the spot and agreed to get the injection. The nurse was called and she received her first injection. That night all through the night her arm became swollen and sore. She had intense pain in her lower back, groin and shooting pains down her legs. She had tingling in her feet and arms, pain down her arm to her fingers with tingling. The next day she nearly fainted when she sat up and every time she moved she had chronic dizziness coupled with ringing in her ears and blackouts. Later that evening a red rash started to appear on her arm and she could not move her arm without extreme pain. She felt paralyzed. A rash appeared on her lower back and looked like a heat rash. She had high fevers and intense pain, lots of sweat and then she would feel very cold as if her spine was frozen. The back rash disappeared but the arm rash increased in size. The patient went back to the physician who said the rash would go down. (the physician did not administer anything). The rash did not go down. By 13-MAR-2008 the rash had increased in size, her upper arm was swollen and itchy, could not move her arm, was pale, dizzy, feverish and she had pains in her back and legs. She had insomnia. The patient consulted a homeopath (as the patient no longer trusted the physician) who administered "china and apis and other herbs". The patient reported that it wasn't until she started taking these that the rash went down and the f

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323274-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	24-Apr-2008	24-Apr-2008	0	26-Aug-2008	27-Aug-2008	FR	WAES0808AUS00142	27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1949U		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Concussion, Dizziness, Fall, Head injury, Headache, Loss of consciousness, Nausea, Somnolence, Syncope, Syncope vasovagal, Urinary incontinence

Symptom Text: Information was obtained on request by the Company from the agency, via a Public Case Detail Form and a Case Line Listing, concerning a 20 year old female who on 24-APR-2008 was vaccinated with GARDASIL (Batch No. K0532, Lot No. 659053/1949U, expiry date 12-JUN-2010). Subsequently, on 24-APR-2008 the patient experienced vasovagal syncope, dizziness, fall, head injury, headache, nausea, somnolence and syncope. It was described that the patient "felt dizzy, faint and had a fall. She was unconscious for 2-3 minutes. She hit her head on the floor and had concussion. She lost bladder control and had a headache, nausea and was drowsy". On 24-APR-2008 the patient was admitted to the emergency department of hospital. She was reviewed by a neurosurgeon and observed for 5 to 6 hours. On 26-APR-2008 the patient recovered from vasovagal syncope, dizziness, fall, head injury, headache, nausea, somnolence and syncope. The agency considered that vasovagal syncope, dizziness, fall, head injury, headache, nausea, somnolence and syncope were certainly related to therapy with GARDASIL due to the timing of the events after vaccination with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323275-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Feb-2008	23-Feb-2008	1	26-Aug-2008	27-Aug-2008	FR	WAES0808AUS00132	27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Nausea, Photophobia, Sleep disorder, Vomiting

Symptom Text: Information has been received from a mother via CSL as part of a business agreement (manufacturer control # GARD 2008 08 15 001) concerning a 16 year old (also reported in follow-up information as 15 year old) female who on 22-FEB-2008 was vaccinated with GARDASIL. On 23-FEB-2008 the patient experienced headache and was hospitalised. She also experienced photophobia, nausea and one episode of vomiting. CT scan, MRI scan and blood tests were all found to be normal. At the time of reporting on 15-AUG-2008, the patient's headache persisted. The patient recovered from photophobia, nausea and vomiting. Follow-up information was received from the reporting physician. On 02-MAY-2008 the patient was vaccinated with her second dose of GARDASIL. At the time of reporting on 18-AUG-2008 the patient's headache persisted and woke her during the night. Additional information has been requested.

Other Meds: Unknown

Lab Data: computed axial tomography, ??Feb08, normal; magnetic resonance imaging, ??Feb08, normal; diagnostic laboratory test, ??Feb08, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323276-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		26-Aug-2008	27-Aug-2008	FR	WAES0808AUS00240	27-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness, Somnolence

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning a 21 year old female who was vaccinated with GARDASIL. Subsequently 6 days after vaccination with GARDASIL, the patient experienced convulsion, somnolence and loss of consciousness. At the time of reporting to the agency on 28-FEB-2008, the patient had recovered from the convulsion, somnolence and loss of consciousness. The agency considered that convulsion, somnolence and loss of consciousness were related to therapy with GARDASIL. The original reporting source was not provided. Additional information has been requested from the agency regarding the seriousness of the events. In follow up received on 22-AUG-2008, the agency considered convulsion to be serious for the following reason: medically significant.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323285-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	08-Aug-2008	08-Aug-2008	0	26-Aug-2008	23-Sep-2008	MI		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	
	HEPA	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	VARCEL	UNKNOWN MANUFACTURER	NULL	1	Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL	5	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction, Loss of consciousness

Symptom Text: Passed out in office, had seizure 3-5 minutes after vaccines.

Other Meds: none

Lab Data: Cat scan - head, X-rays - neck, EEG - brain

History:

Prex Illness: none

Prex Vax Illns:

Vaers Id: **323286-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-Aug-2008	19-Aug-2008	0	26-Aug-2008	02-Sep-2008	WV	WV0827	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B027AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bacterial infection, Chills, Cystitis, Headache, Nausea, Pyrexia, Vomiting

Symptom Text: 8-19-08 Fever 102.7 axillary, nausea, headache, chills. Mother gave TYLENOL, checked temp every 2 hrs. Came down to 99.7. 8-20-08 Saw put phys., still having fever, chills, now also vomiting. Diagnosed as bacteria in bladder, prescribed BACTRIM.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323290-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Aug-2008	20-Aug-2008	2	26-Aug-2008	02-Sep-2008	GA		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2998BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0229X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Ear pain, Facial palsy, Pharyngolaryngeal pain

Symptom Text: Seen on 8/21/08 - dx with Bell's palsy - sx include L ear pain, sore throat, "can't move L side of face". Placed on prednisone 20mg bid x5d.

Other Meds: albuterol MDI-prn

Lab Data:

History: RAD

Prex Illness: none

Prex Vax Illns:

Vaers Id: 323291-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	14-Jul-2008	12-Jul-2008	-2	26-Aug-2008	02-Sep-2008	VA		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Rash on the face since 1st injection with symptoms slowly improving, no treatment.

Other Meds: None

Lab Data: None

History: Allergic to Erythromycin

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323294-1** **Related reports:** 323294-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Mar-2007	08-Sep-2007	177	26-Aug-2008	02-Sep-2008	OK		04-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abscess, Arthralgia, Arthropod bite, Asthma, Cellulitis, Dizziness, Eye swelling, Fatigue, Headache, Hypersensitivity, Incisional drainage, Lip swelling, Menstrual disorder, Menstruation irregular, Nausea, Pruritus generalised, Rash generalised, Swelling

Symptom Text: Swelling all over - rash all over her body. Dizzy headed, body aches in joints - tired a lot - headaches - period not regular, can run 2 weeks or longer - asthma. 8/25/08-records received-office notes. 3/7/07-C/O shortness of breath, fever, chills times 2 days with cough today. Assessment URI, herpes simplex, asthma. C/O fatigue, weight loss. received HPV4 and meningococcal vaccines. Assessment: hypothyroidism. 8/27/07-see in office for follow-up after ED visit for spider bite on left thigh. Assessment: abscess and cellulitis. Followed by visit 8/29/07-for incision and drainage of abscess. 9/5/07 second HPV 4 vaccine given. On 12/10/07-C/O rash for 2 months, itching all over body. 12/14/07-rash continues, asthma acting up, nausea. 12/21/07 rash all over, eyes swollen. Treated with steroids. Allergic reaction. 1/30/08 lips swollen times 2 days. 3/26/08-menstral cycle every 2 weeks. 8/6/08-rash continues but not as severe, occurs on waking and diminishes through the day.

Other Meds: Thyroid - Synthroid

Lab Data: A lot of test - 1st 3-15-07, 2nd 5-24-07, 3rd 9-6-07. Shots were in threes. 8/25/08-records received- TSH on 8/14/08 7.25. Antigliadin ABS IGA elevated at 6. - TSH 5.59.

History: Seasonal allergies - thyroid problems

Prex Illness: None 8/25/08-/7/07-C/O shortness of breath, fever, chills times 2 days with cough today. Assessment URI, herpes simplex, asthma

Prex Vax Illns:

Vaers Id: **323294-2** **Related reports:** 323294-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Mar-2007	01-Sep-2007	170	23-Sep-2008	11-Nov-2008	OK		12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	08026	3	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Headache, Pain, Rash, Swelling

Symptom Text: Rash-swelling of body- severe rush that doesn't go away - body pains- tired a lot headaches every day periods a lot more of them 3 weeks at a time

Other Meds: Thyroid

Lab Data: Blood testing - Skin biopsy

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323298-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Aug-2008	18-Aug-2008	0	26-Aug-2008	02-Sep-2008	CA		02-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0170X	1	Unknown	Subcutaneously	
MNQ	SANOFI PASTEUR	U2665AA	0	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	0072X	0	Unknown	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB239AA	0	Unknown	Intramuscular	
TDAP	SANOFI PASTEUR	C998BA	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dyskinesia, Eye rolling, Syncope

Symptom Text: Pte. felt dizzy and was fainting. She sat on a chair and her body became very still she rolled over her eyes and had jerky movements for a few seconds.

Other Meds: PPD, Sanofi, C2998, Lt ID

Lab Data: Pte taken to ER

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323324-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Aug-2008	25-Aug-2008	0	26-Aug-2008	01-Sep-2008	FL		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X EXP 11-10	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Pain in extremity

Symptom Text: TEMP 100 08-25-08 NIGHT,7:30AM 08-26-08 101.4,@8:50AM 102.2.C/O LEG PAIN(STARTED 08-25-08 NIGHT)

Other Meds: ATENOLOL(TENORMIN)25MG TID,METHIMAZOLE(TAPAZOLE)10MG TID

Lab Data:

History: HYPERTHYROID,HYPERTENSION

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323327-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-Aug-2008	09-Aug-2008	0	26-Aug-2008	01-Sep-2008	TX		02-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB233AA	1	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2966AA	5	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Pt. had an emesis 30 minutes after receiving vaccine. Immediately had pt. put her head down between her legs and applied a cold compress on back of her neck. After 10 minutes pt. stated she no longer felt nauseated. Pt. left with mother. Spoke to mother on 8/22/08 and stated daughter went thereafter to the emergency room and was sent home with an epinephrine pen.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323334-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Aug-2008	07-Aug-2008	1	26-Aug-2008	01-Sep-2008	AZ		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB291AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2659AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral

Symptom Text: Red, swollen area approx 3cm X 6cm to left deltoid

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: None~ ()~NULL~~In Patient|None~ ()~NULL~~In Sibling1

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323336-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Aug-2008	16-Aug-2008	2	26-Aug-2008	01-Sep-2008	OH		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0273X	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Induration, Oedema peripheral, Skin warm

Symptom Text: On 08/16/08 parent reported by phone 3-1/4" X 4" area on R arm that was red, swollen, warm to touch. Pt was afebrile. Tx'd with cold compresses and ibuprofen. Pt was seen in our office on 08/18/08, had 12cm X 12cm area of mild induration over R upper arm, no warmth or erythema, afebrile. No add'l tx recommended.

Other Meds: None

Lab Data: None

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323354-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	M	26-Aug-2008	26-Aug-2008	0	26-Aug-2008	03-Sep-2008	MI		03-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3027AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2606AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Fainting

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323355-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-Aug-2008	19-Aug-2008	0	26-Aug-2008	03-Sep-2008	ME		03-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MMR	MERCK & CO. INC.	1409F		Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0245U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Within 5 minutes of receiving HPV vaccine, patient passed out. Was receiving MMR vaccine at the time of fainting. But was within the time frame of HPV precautions.

Other Meds:

Lab Data: None

History: Amoxicillin/Penicillin

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323356-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	25-Aug-2008	25-Aug-2008	0	26-Aug-2008	03-Sep-2008	OH		03-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: After vaccinated patient to waiting room for 20 min to see if any side effects. Patient was dizzy and light headed. RN at side. Cool cloth and water given; Patient had not eaten all morning. Patient sent home with family when stable AM

Other Meds:

Lab Data: None

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323357-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Aug-2008	25-Aug-2008	0	26-Aug-2008	03-Sep-2008	OH		03-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2632AA	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2994AA	0	Left arm	Intramuscular	
FLUN	MEDIMMUNE VACCINES, INC.	500541P	1	Unknown	Unknown	
HPV4	MERCK & CO. INC.	0279X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: After vaccinated patient to waiting room to see if has any side effects. Patient became dizzy. After 5 min. Patient was well enough to drink water and home with mom.

Other Meds:

Lab Data: None

History: Previous MRSA boil underarm 3 years ago

Prex Illness: none

Prex Vax Illns:

Vaers Id: **323358-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	18-Apr-2008	Unknown		26-Aug-2008	03-Sep-2008	OH		03-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Complaint of hair loss (patch) following administration of 2nd dose of GARDASIL.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323429-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Mar-2008	17-Mar-2008	0	27-Aug-2008	28-Aug-2008	FR	WAES0808AUS00150	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	J5666		Unknown	Intramuscular	
	HEP	MERCK & CO. INC.	J6045		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Convulsion, Status epilepticus

Symptom Text: Information has been received from an agency concerning a 12 year old female who on 17-MAR-2008 was vaccinated with GARDASIL. Other suspect therapy included RECOMBIVAX HB, MSD (Batch # J6045, Expiry date 21-FEB-2010). On 17-MAR-2008 the patient developed status epilepticus and was hospitalised. It was reported that a number of atypical seizures were witnessed in the emergency department and the ICU and along with the normal investigations a diagnosis of functional seizures associated with anxiety was reached. At the time of reporting to the agency on 27-MAR-2008 the patient had not yet recovered from the status epilepticus. The agency considered that status epilepticus was possibly related to therapy with GARDASIL and included RECOMBIVAX HB (unspecified). The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: laboratory test, ??08, functional seizures with anxiety

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323430-1 (D)** **Related reports:** 323430-2; 323430-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	13-Jul-2007	01-Apr-2008	263	27-Aug-2008	28-Aug-2008	UT	WAES0808USA03969	20-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	0	Right arm	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	C2734AA	0	Left arm	Intramuscular	
	HEPA	SMITHKLINE BEECHAM	AHAVB143AA	0	Right arm	Intramuscular	

Seriousness: DIED, HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Amyotrophic lateral sclerosis, Asthenia, Ataxia, Axonal neuropathy, Blood product transfusion, Constipation, Cough, Dehydration, Depression, Dysarthria, Dysphagia, Dysphonia, Dyspnoea, Dysstasia, Facial paresis, Fatigue, Gastrointestinal tube insertion, Guillain-Barre syndrome, Headache, Intensive care, Motor dysfunction, Motor neurone disease, Muscle contractions involuntary, Muscular weakness, Musculoskeletal pain, Nausea, Neck pain, Nervous system disorder, Neurological examination abnormal, Neuromyopathy, Oral intake reduced, Pneumonia aspiration, Progressive bulbar palsy, Respiratory failure, Tachycardia

Symptom Text: Information has been received from a neurologist concerning a 21 year old female previously in good health who in March 2008, was vaccinated with the first dose of GARDASIL (lot# not provided). Concomitant medication included several other vaccinations (not including MENACTRA). Subsequently, the patient developed motor neuron disease consistent with amyotrophic lateral sclerosis (ALS). Her progressive clinical course began in April 2008. The patient had not received a second dose of GARDASIL or any other vaccines since onset of symptoms. She developed upper extremity weakness which had become generalized and much more severe. She had been hospitalized in intensive care for several weeks with respiratory failure. Her condition deteriorated despite treatment with immunoglobulin. She had upper and lower motor neuron features with fasciculations. There is no sensory loss. Diagnostic workup included cerebrospinal fluid analysis (CSF) and muscle biopsy that ruled out other conditions (such as Guillaine Barre) and clinical picture is consistent with amyotrophic lateral sclerosis. Antineuronal antibodies were pending. A Superoxide dismutase (SOD) was pending and Stathmin (SMN) test will be ordered if SOD was normal. The reporting physician did not believe that illness was related to GARDASIL. Additional information has been requested. This is one of several reports from the same source. 9/9/08 Autopsy states COD as unclassified neurologic process, clinically presumed to be atypical GBS vs bulbar varient of ALS. FINAL DX 8/17-8/21/08 admission: amyotrophic lateral sclerosis & death by respiratory collapse. Developed cough, difficulty breathing, difficulty swallowing, poor oral intake, constipation, lack of energy 6 days prior to admit; had received Depo-Provera & outpatient IVIG prior to admit w/o any improvement. Admitted to ICU. Gradually worsened over the hospital stay, had NGT for feeding but refused PEG tube placement or tracheostomy. Referred to hospice & expired. FINAL DX 7/28-8/1/2008 admission: axona

Other Meds: therapy unspecified

Lab Data: None LABS: EMG/NCS abnormal. Brain MRI abnormal; c-spine MRI WNL. CSF WNL. West Nile IgG (+), IgM (-)but testing done s/p IVIG. ANA (+). Echocardiogram WNL, SPI-C MRI. Muscle biopsy (+) marked neurogenic changes. CXR (+) for possibl

History: None 11/28/2007 - Received Twinrix, IM, RA, lot# AHABB100AA PMH: purpura fulminans age 5 or 8 s/p chickenpox. Pulmonary HTN in childhood. Underweight at birth & Nissen surgery w/G-tube as newborn for 1st year of life, repair of pectus excavatum age 17. Oral contraceptives, hypothyroidism. Allergic sulfa. Family hx of seizures

Prex Illness:

Prex Vax Illns:

Vaers Id: **323430-3 (D)** **Related reports:** 323430-1; 323430-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	13-Jul-2007	04-Apr-2008	266	16-Sep-2008	16-Sep-2008	UT		09-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2734AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0522U	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB143AA	0	Right arm	Intramuscular	

Seriousness: DIED, ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Death, Dyspnoea, Muscular weakness

Symptom Text: April 2008, started experiencing symptoms of muscle weakness in arms and neck, they progressed to interfering with muscle weakness in throat and breathing. Patient died on August 21, 2008.

Other Meds: LEVOXYL .88 mcg; Birth Control

Lab Data:

History: Hypothyroid

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323431-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-May-2008	31-May-2008	0	27-Aug-2008	28-Aug-2008	FR	WAES0806USA08890	28-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy, Pregnancy test positive

Symptom Text: Information has been received from a gynaecologist for the Pregnancy Registry for GARDASIL concerning a 17 year old female who started a spontaneous pregnancy (estimated conception date: 25-MAY-2008) 6 days before receiving the third dose, on 31-MAY-2008, of GARDASIL (Lot#, batch # and route of administration not reported). She had received the first and second doses in December 2007 and February 2008. The patient was concomitantly treated with ALDARA for vulvar condylomae she probably had since February 2008 and were noticed in May 2008. The patient had stopped contraception. ON 10-MAY-2008, she experienced miscarriage followed by bleeding lasting 5 to 6 days (WAES # 0807USA00520). It was also reported that the patient had unprotected sexual intercourse on 25-MAY-2008. She was seen by her gynaecologist on 25-JUN-2008 due to her positive pregnancy test on 17-JUN-2008. She was then approximately one month pregnant. No adverse reaction was reported. Upon internal review this case was linked to case number E2008-06249 (events experienced by the patient following the second dose of GARDASIL). Follow-up information was received which reported that the case was upgraded to serious. The reporting physician considered the induced abortion to be an other important medical event. In a letter dated 10-AUG-2008, the reporter specified that on 12-JUL-2008 the patient had a voluntary termination of pregnancy. This case is closed. Other business partner numbers included: E2008-05982 and E2008-06249. No further information is expected.

Other Meds: ALDARA, Unk - 2008

Lab Data: Unknown

History: Pregnancy; Miscarriage

Prex Illness: Pregnancy NOS (LMP = Unknown); Condyloma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323478-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	13-Feb-2008	01-Mar-2008	17	27-Aug-2008	08-Sep-2008	KY		08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Herpes zoster, Inappropriate schedule of drug administration

Symptom Text: Pt complains that 31/2 wks after receiving 3rd GARDASIL injection - came down with shingles. (Pt just wanted to notify us with information

Other Meds: Loogentered (OCP)

Lab Data: Went to her PCP for Tx

History: None

Prex Illness: Pt developed shingles first week of March

Prex Vax Illns:

Vaers Id: **323479-2** **Related reports:** 323479-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Dec-2007	15-Dec-2007	14	18-Aug-2008	01-Oct-2008	--	WAES0808USA00138	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abasia, Arthralgia, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning her approximately 15 year old daughter, who in December 2007, the end of January 2008 and the end of May 2008 was vaccinated with the first, second and third doses of GARDASIL vaccine. Within two weeks after receiving each shot, the patient experienced severe pain in her hips. The pain was so severe she couldn't walk. She had a magnetic resonance imaging of her hips and it was reported "ok." To this day, the mother reports that her daughter (the patient) experiences hip pain. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance - hips: reported results = "ok"

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323481-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Aug-2008	13-Aug-2008	2	27-Aug-2008	08-Sep-2008	AZ		08-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Hot flush, Hyperhidrosis, Vaccine positive rechallenge

Symptom Text: 2 days to 1 week after receiving HPV, started with "hot flashes," face gets red and has increased perspiration. This happened with all three doses of HPV vaccine.

Other Meds: None

Lab Data: CBC, Thyroid screen, VMA in 24 hr urine

History: None

Prex Illness: None

Prex Vax Illns: Yes~HPV (Gardasil)~3~15~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323482-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	27-Aug-2008	27-Aug-2008	0	27-Aug-2008	08-Sep-2008	PA		08-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C2995BA	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U264CAA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Dizziness, Malaise

Symptom Text: Patient was given 3 vaccines she described feeling sick after Tdap and MENACTRA had been given and then dizzy after GARDASIL was given BP was 70/50 at that time

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323485-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Aug-2008	11-Aug-2008	5	27-Aug-2008	01-Sep-2008	OK		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0171U	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2573AA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Fatigue, Headache, Pyrexia

Symptom Text: fatigue, headache, weakness & fever onset 1 week after vaccine

Other Meds: N/A

Lab Data: n/a

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: 323496-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Jun-2007	15-Aug-2007	49	27-Aug-2008	28-Aug-2008	CO		03-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	2	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Diarrhoea, Dysthymic disorder, Fatigue, Fibromyalgia, Influenza like illness, Insomnia, Irritability, Myalgia, Sleep disorder, Weight decreased

Symptom Text: Started as flu like symptoms (diarrhea, original weight loss of 11 pounds, achy/sore muscles and joints, exhaustion. The diarrhea eventually went away and she regained the lost weight; however, the achy/sore muscles/joints, chronic pain and exhaustion have never gone away. Morgan was eventually diagnosed with fibromyalgia, although we have no family history of fibromyalgia, nor had she ever had any related symptoms prior to the Gardasil vaccination. 8/29/08-records received for DOS 4/9/08-initial clinic visit, Fibromyalgia by history. Travel to Mexico August 2007 and developed GI upset and nausea. Developed diffuse joint pain. Presently on Lyrica. Office visit 5/13/08-for follow-up. Assessment chronic insomnia improved. New diagnosis by psychologist dysthymia and may have ADD as well. Office visit 7/30/08-C/O decline in mood state and diffuse body pain over past 2 weeks. Irritable not sleeping well.

Other Meds: Depovera shot to help with pre-existing problems with menstral cycle. Currently she is taking the following medications for her condition: multiple pain medications (ibuprofen 800, darvocet, celebrex, and more), lyrica (for fibromyalgia),

Lab Data: Morgan has been seen by the following physicians since her symptoms began, resulting in thousands of dollars worth of tests on her. Dr Scott Vincent (Family Physician) Dr Barrios (Gastronologist at Lone Tree Medical Center) Dr Etcheverry

History: Heart murmur, harmless - she's had since she was a baby 8/29/08-records received-Depression. Chronic insomnia. Migraines. Hypokalemia. August 2007 death of grandmother, depression began 2 years prior and stopped Zoloft May 2007.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323498-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-Aug-2008	12-Aug-2008	0	27-Aug-2008	01-Sep-2008	MS	MS072008	02-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1267U	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2661AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: GARDASIL, MANACTRA, TDAP GIVEN. PATIENT C/O GETTING DIZZY AND THEN FAINTED. USED AMMONIA INHALENT AND SHE RECOVERED WITHIN 1-2 MINUTES

Other Meds: VALTREX 500 MGM 1 PO DAILYSEASONIQUE 1 DAILY

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323501-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	19-Aug-2008	26-Aug-2008	7	27-Aug-2008	01-Sep-2008	GA		03-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dysarthria, Hypoaesthesia, Neurological examination normal, Paraesthesia, Presyncope

Symptom Text: 1st inj on 6/17/2008;2nd inj 8/19/2008; on 8/26/2008 pt presented to office with dizzines, tingling in hands to numbness and then slurred speech that happened while at school; when she presented to the office within 1 hour of onset, she had completely recovered from s/s; due to these s/s family defers further vaccination8/28/08-records received for DOS 8/26/08-Chief complaint-dizzy spells/tingling in hands and not able to speak well. C/O dizziness while getting up from sitting position. Neurologic exam, no focal deficit, normal cranial nerves-II-XII sensory and motor WNL. DTR 2 plus, gait normal, no cerebellar signs, no focal signs, normal strength, tone and reflexes, sensory test normal. Assessment: Near-syncope. Suspect orthostatic hypotonia trigger with possible hyperventilation as secondary. Follow-up as needed.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323504-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	24-Jul-2008	25-Jul-2008	1	27-Aug-2008	01-Sep-2008	MI		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2994AA	5	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2484AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Local reaction

Symptom Text: RED LOCAL REACTION CENTERED AROUND INJECTION SITE

Other Meds:

Lab Data:

History:

Prex Illness: ECZEMA

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323516-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	08-Aug-2008	08-Aug-2008	0	27-Aug-2008	08-Sep-2008	OK		08-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea

Symptom Text: Difficulty breathing - 1800 8/8/08; Dizziness - 1800 8/8/08; Went to ER, given Benadryl IM and observed approx 3 hours.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: None~ ()~~0~In Patient|None~ ()~~0~In Sibling

Vaers Id: **323517-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	27-Aug-2008	27-Aug-2008	0	27-Aug-2008	08-Sep-2008	TX		08-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea, Dizziness, Nausea

Symptom Text: Patient called & stated that she begin having symptoms of diarrhea, nausea & dizziness 1 1/2 hours after her injection. No redness or swelling at injection site.

Other Meds:

Lab Data:

History: None except penicillin allergies.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323522-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Aug-2008	26-Aug-2008	0	27-Aug-2008	08-Sep-2008	MN		08-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	2	Right arm	Intramuscular	HEPA
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB268EA	1	Gluteous maxima	Intramuscular	HPV4

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: (1) Hepatitis A #2 given early; 1st dose 7/28/08 - 2nd dose given 8/26/08; (2) GARDASIL #3 given too early; #1 given 6/24/07, #2 given 7/28/08, #3 given 8/27/08

Other Meds: Albuterol

Lab Data: none

History: Exercise - Induced Asthma

Prex Illness: none

Prex Vax Illns:

Vaers Id: **323576-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Aug-2008	12-Aug-2008	0	28-Aug-2008	29-Aug-2008	FR	WAES0808ZAF00009	29-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Headache, Syncope, Syncope vasovagal, Vomiting

Symptom Text: Information has been received via a company representative from a pharmacist concerning a 13 year old female who on 12-AUG-2008 was vaccinated with GARDASIL. On 12-AUG-2008, straight after receiving the vaccine the patient fainted and experienced a mild seizure that lasted a few seconds. She recovered from the fainting and seizure. Four hours later she experienced vomiting and a headache. The patient's vomiting and headache has resolved. The reporter and the attending doctor felt that fainting and mild seizure were not related to therapy with GARDASIL, but they can not rule out the association. Both reporter and doctor felt that the patient may have experienced a vasovagal response. She was very scared at the time of the vaccination. The term fear has been added as a concurrent condition. Vasovagal response has been coded as an event. The patient was not hospitalized due to any of the adverse events. Syncope has been deleted as an adverse event since it was a symptom of the vasovagal response. Mild seizure is considered to be an other medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Fear

Prex Vax Illns:

Vaers Id: **323577-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	12-Jun-2008	12-Jun-2008	0	28-Aug-2008	29-Aug-2008	RI	WAES0808USA04416	29-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a physician concerning a 19 year old female patient who was vaccinated with the first dose of GARDASIL on 12-JUN-2008. Immediately post vaccination the patient fainted and had convulsions and seizure which lasted for approximately 1 minute. The patient sought medical attention in the office. At the time of the reporting the patient had recovered. Upon internal review, convulsion was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 323578-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Aug-2008	12-Aug-2008	0	28-Aug-2008	29-Aug-2008	CA	WAES0808USA02672	29-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received from a physician and a nurse practitioner, for the Pregnancy Registry for GARDASIL, concerning a 16 year old female who on 12-AUG-2008 was vaccinated with a first dose of GARDASIL (lot number, injection site and route not reported). The nurse practitioner reported that the patient denied sexual activity and by mistake requested a urine pregnancy test on the patient that came back positive. The nurse practitioner reported the patient had elected to have an abortion unrelated to the vaccine on 21-AUG-2008. The nurse practitioner also reported that the patient also had a HIV and Hepatitis test after it was discovered she was pregnant because of the history of baby's father. Follow-up information was received from the nurse practitioner which reported that the patient did have an elective abortion on 21-AUG-2008. Upon internal review, elective abortion was determined to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: diagnostic laboratory, hepatitis test; urine beta-human, positive; HIV antibody screen

History:

Prex Illness: Pregnancy NOS (LMP = 7/28/2008)

Prex Vax Illns:

Vaers Id: **323587-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		28-Aug-2008	29-Aug-2008	FR	WAES0808AUS00256	29-Aug-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been obtained by the Company from the agency via a Case Line Listing, concerning a 15 year old female who was vaccinated with GARDASIL. Subsequently the patient experienced convulsion and syncope. At the time of reporting to the agency on 07-MAR-2008 the patient had recovered from convulsion and syncope. The agency considered that convulsion and syncope were related to therapy with GARDASIL. The original reporting source was not provided by the agency. The agency considered convulsion to be serious for the following reason: medically significant. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323589-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Jan-2007	Unknown		28-Aug-2008	29-Aug-2008	NY		23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Adrenal insufficiency, Alopecia, Arthralgia, Attention deficit/hyperactivity disorder, Autoimmune disorder, Chills, Contraception, Decreased appetite, Dehydration, Depression, Diarrhoea, Dizziness, Dysphagia, Dyspnoea, Fatigue, Gastroenteritis, Hypothyroidism, Infectious mononucleosis, Lumbar puncture, Lymphadenopathy, Myalgia, Nausea, Obsessive-compulsive disorder, Pallor, Pharyngeal oedema, Pharyngolaryngeal pain, Pyrexia, Staring, Stomatitis, Tonsillar hypertrophy, Tonsillar inflammation, Tremor, Weight decreased

Symptom Text: Autoimmune adrenal insufficiency. Dx: Aug 08. Several months severe fatigue, myalgia. 9/12/08 Reviewed endocrinologist medical records of 6/10-8/18/08. FINAL DX: adrenal insufficiency Records reveal patient experienced episodes of excessive fatigue beginning 2/2007 which progressed. Included dizziness, lightheadedness, overheated with activities, pale, hair loss, nausea, diarrhea for 2 mos, weight loss. Was on oral contraception which was d/c 6/08. 9/16/08 Reviewed ER medical records of 2/20/07 & 9/12/07. 2/20/07 Final ER Dx: gastroenteritis w/mild dehydration Records reveal patient exprienced N/V/D, chills & abdominal discomfort x 24 hours. Tx w/IVF & antiemetics. Responded well & d/c to home. LABS: UA WNL. 9/12/07 Final ER Dx: sore throat secondary to mononucleosis Records reveal patient recently dx w/mono had increasing throat swelling & difficulty breathing, decreased appetite, nausea, difficulty swallowing, abdominal pain, slight SOB. Exam revealed enlarged & red tonsils, cervical lymph node enlargement. Tx w/steroids & pain meds. D/C to home. 9/19/08 Reviewed PCP medical records of 10/3/07-8/5/08. FINAL DX: adrenal insufficiency, hypothyroidism, ADHD, anxiety/depression, OCD. Records reveal patient experienced anxiety/depression, OCD, fatigue, lower abdominal pain & fever when see 10/07. Only able to attend school for 1/2 days. Referred to neuro & admitted 10/26/07 for questionable seizure, w/u neg. Had shotty cervical nodes bilaterally. 1/2008 referred to rheumatologist. Hosp d/c summary, neuro consult, eye exam, rheum consult, sleep center consult, endocrine, psychiatric consult all included. D/C summary of 10/26-10/29/2007 states final dx: anxiety, depression, s/p inf mono. LP done. Had episodes of staring & RLE shaking. Neuro exam revealed asthenia, slow mentation, HA, possible seizures, ankle clonus. Rheum consult for chronic fatigue, recurrent mouth sores, joint aches/pains & muscle aches/pains.

Other Meds:

Lab Data: LABS: Electrolytes & LFTs WNL. Brain MRI fall 2007 WNL. Sleep study abnormal. MRI of brain & c-spine & EEG WNL. ESR 11, CRP 0.3. CSF: WNL. ANA neg. RA factor neg. CPK 48(L). UA WNL.

History: PMH: OCD & ADD. adenoidectomy age 6. Allergic to sulfa (hives)& benadryl. MVA 2003. Dysmenorrhea. Contraception(Yaz). Anxiety. Heavy menses
Family hx: hypercholesterolemia, celiac disease, MVP, cerebral palsy, DM, thyroid disease.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323591-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-Aug-2008	14-Aug-2008	0	28-Aug-2008	08-Sep-2008	OR	OR200823	08-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	02560AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B015AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1486U	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB245AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: After receiving HPV # 1 client waited in reception area for 10-15 minutes and with departure in hall vomited.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323593-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-Aug-2008	11-Aug-2008	0	28-Aug-2008	08-Sep-2008	OR	OR200822	08-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1796U	1	Left arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC528015AA		Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2560AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1486U	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB235BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Loss of consciousness, Nausea

Symptom Text: 08/11/08, adolescent received 5 recommended vaccines (HepA, HPV, MCV4, Tdap, Varicella), client lost consciousness for 5-10 seconds; fell to floor in exam room landing on left side hitting left temporal. Nauseated immediately afterward.

Other Meds: None

Lab Data: None

History:

Prex Illness: Mother states fainted recently

Prex Vax Illns:

Vaers Id: **323594-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	29-May-2008	Unknown		28-Aug-2008	08-Sep-2008	NY		08-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB256AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives "everywhere" noted approximately 1 week after immunization with HPV #1. Small area of hives reported 1 1/2-2 weeks after immunization with HPV #2. Benadryl po used with effect.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323595-1** **Related reports:** 323595-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-Sep-2007	04-Sep-2007	0	28-Aug-2008	08-Sep-2008	MD		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2233CA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0927U	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Burning sensation, Computerised tomogram normal, Confusional state, Decreased appetite, Diplopia, Disturbance in attention, Dizziness, Fatigue, Head discomfort, Head injury, Headache, Impaired driving ability, Impaired work ability, Laboratory test normal, Lethargy, Loss of consciousness, Memory impairment, Middle ear effusion, Musculoskeletal stiffness, Myalgia, Neck pain, Nervous system disorder, Pain, Pain in extremity, Paraesthesia, Pharyngolaryngeal pain, Photophobia, Photosensitivity reaction, Somnolence, Syncope, Vision blurred, Weight decreased

Symptom Text: Four minutes post injection, she fainted on her feet and struck the front of her head on the checkout window frame. A receptionist, nurse and attending physician came to her aid. The next 30 days brought severe debilitating headaches, confusion, decreased consciousness, extreme muscle aches, weakness, eye sensitivity, dizziness, decreased appetite, lack of energy, and weight loss. We returned to the pediatrician's office four days after injections because she suffered from these symptoms. She was diagnosed with fluid behind her ears. Blood was drawn twice, tests were run; all results were negative. A CT scan showed no abnormal development. Still she was suffering from severe persistent headaches. Two months after shots, she visited a neurologist. A 2 1/2 hour screening was done; showed impairment. A copy of the lab report was sent to pediatrician who called our home with sentiments. The neurologist prescribed two different drugs that didn't touch her headaches, but rendered her unable to drive, work or do school work. Four months after shots, she begins chiropractic care to ease pain. No success. Six months after shots, she has blurred vision. Eye exam performed; no abnormalities detected (20/20 vision). Nine months later; MRI-all normal. Begins physical therapy; persistent pain. Twelve months later; additional problems. Sudden onset of stiff neck & neck pain, joint stiffness, tingling in fingers, burning in lower back muscles, strong aching in arms, and all body muscles. Exhaustion and headaches, headaches! 9/3/08-records received-9/7/07-9/18/07-presented with C/O fatigue and headaches since 9/4/07 date HPV and meningitis vaccines were administered at which time she passed out but recovered. 9/7/07 C/O weakness and fatigue. Head feels heavy and there is pressure. Lethargic, sleeping. Sore throat. Appetite decreased. 10/29/07-evaluation for possibility of concussion after hitting right side of head on 9/4/07. C/O blurry vision and occasional double vision and sensitivity to light. Difficulty concentrating and

Other Meds:

Lab Data: Neurological screening-impairment; CT Scan, MRI, muscle breakdown, mononucleosis, Lyme, thyroid, pregnancy, see pediatrician for others she ordered. Vision exam-20/20 vision 9/3/08-records received-CT normal.All lab values normal.

History: None-She was physically active / healthy.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323595-2** **Related reports:** 323595-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-Sep-2007	04-Sep-2007	0	15-Dec-2008	14-Jan-2009	MD	WAES0811USA00681	22-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back injury, Bone pain, Burning sensation, Chest discomfort, Heart rate increased, Migraine, Musculoskeletal discomfort, Myalgia, Paraesthesia, Syncope

Symptom Text: Information has been received from a consumer concerning her daughter, a 17 year old female who on 04-SEP-2007 was vaccinated with the first dose of GARDASIL, 0.5ml. Concomitant therapy included meningococcal vaccine (manufacturer unspecified). Subsequently the patient fainted soon after and hurt her spine "a little over a year ago". Since then the patient has experienced extreme muscle pain, pressure in her chest, burning pain in her back, rapid heart beat, and extreme migraines. The patient is also experiencing tingling in her fingers. The patient had Blood work, MRI, and CT Scan. The patient' events did not improve. At the time of the report, the patient was not recovered. The patient sought medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323616-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	26-Aug-2008	26-Aug-2008	0	28-Aug-2008	08-Sep-2008	MA		08-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Unresponsive to stimuli

Symptom Text: Fainting - within 5 minutes. Unresponsive x 30sec. - Responsive after

Other Meds: None

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323629-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Aug-2008	22-Aug-2008	0	28-Aug-2008	01-Sep-2008	AL		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	14484	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Malaise, Nausea, Oedema peripheral, Pain in extremity

Symptom Text: Report sore arm with redness and mild swelling. Felt nauseous after getting shot. State "just don't feel good". Counseled to apply cool cloth to area and take Tylenol. If persist, see private PMD or go to ER.

Other Meds: Unknown

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323651-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Jul-2008	21-Jul-2008	11	28-Aug-2008	02-Sep-2008	OH		16-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	00704	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dyspnoea, Oral intake reduced, Panic attack, Pharyngitis, Pharyngolaryngeal pain, Pyrexia, Tonsillar inflammation

Symptom Text: Developed a fever, sore throat on 7/20/08. Seen on 7-21-08 tested and treated for mono w/ Medrol Dose Pack. Mono test came back neg, condition worsened on 7-23, had severe sore throat and trouble breathing. Was admitted to hospital. 10/16/08-records received for DOS 7/23-7/26/08-DC DX: Pharyngitis, likely viral. Panic Attacks. Presented to ED with C/O sore throat, fever and decreased oral intake, difficulty breathing. Temperature 38.6. Tonsils erythematous with ulcers and white exudate.

Other Meds:

Lab Data: Hgb = 11.6; EBV titer (-); WBC = 6.3 10-16/08-records received-CT lymphadenopathy. Throat culture negative. Monospot negative.

History: None

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: 323656-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	26-Aug-2008	26-Aug-2008	0	28-Aug-2008	08-Sep-2008	CA		08-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB284		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0072X		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U264AA		Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1801U		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature, Loss of consciousness, Oxygen supplementation, Syncope, Urinary incontinence

Symptom Text: On Tuesday August 26,2008 we had a 18 year-old female patient who came in with mother for vaccines, that were in need promptly requested by school. Patient information, vaccine questioner, and VFC application were given to the patient due to the fact that it was the patients first time at the facility. After the patient had concluded inputting here information she was registered in LINK. Patient at the moment was due for a total of 4 vaccines which are as follows: VARICELLA, HPV, MENINGOCOCCAL, and HEPATITIS A. The patients mother was then informed that the subsequent vaccines mentioned were due along with IIPV, but that GARDASIL was not needed by school system. After the mom was informed about GARDASIL and what it prevents, mother agreed to render that vaccine along with the other three. The patient was then taken to the triage room and vitaled. The temperature recorded at the time was 97.9 oral-temperature. Routing slip from LINK was then given to PAC to approve all vaccines that were in need. After PAC approval all four vaccines were administered. Patient was advised by medical assistant to have a seat in the waiting room, while vaccine card was being printed. While the patient was seated at the waiting area she collapsed while being seated. The patient was unconscious and ammonia was passed by nasal area. The patient gained conscience, but immediately went unconscious again. While patient collapsed again she urinated at the same time. Ammonia was passed for the second time and gained conscience permanently. Oxygen tank was then put on the patient to help the oxygen flow. Paramedics were called and arrived 5 minutes latter at the scene. Paramedics vitaled the patient and recommended for her to go with them. Patient was adamant and denied the advice and she signed the AMA for the paramedics. The patient left 5 minutes after the paramedics were gone. Patients was called the following day of the incident and mother stated daughter was fine and no problems were noticeable.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323659-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jul-2008	05-Aug-2008	20	28-Aug-2008	08-Sep-2008	MT		30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	D092X	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hyperaesthesia, No reaction on previous exposure to drug, Oedema peripheral

Symptom Text: Had HPV #1 4/10/08 Merck 1758U left DEL; No problems. HPV #2 9/16/08. On 8/7/08 went to focus med, left arm swollen x 2days, had to cut ring off, sensitive to touch. Saw Pediatrician on 8/11 - given Medrol dose pack Rx. Saw ped 8/15 still swollen - mom filled Rx; saw Dr 8/18 neurologist.

Other Meds: None

Lab Data: 8/9/08 CBC, Comp Panel -> WNL

History: NKA; None

Prex Illness:

Prex Vax Illns:

Vaers Id: 323673-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		29-Aug-2008	02-Sep-2008	RI	WAES0808USA04156	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Amnesia, Encephalitis, Monoplegia, Vomiting

Symptom Text: Information has been received from a physician concerning a 16 year old (also reported as 15 year old) female who on an unspecified date was vaccinated with a first dose of GARDASIL (route and administration site not reported), and was vaccinated with a second dose of GARDASIL (route and administration site not reported) (also reported as having been given the week of 08-AUG-2008). Two months after she received the initial vaccine, the patient developed memory loss. It was also reported that shortly after the second vaccination, the patient developed paralysis of her arm. The patient was evaluated by her pediatrician, whose initial impression was that the symptoms may have been a psychology issue. Following this office evaluation the patient experienced other symptoms such as vomiting and was evaluated at an emergency room. The patient underwent numerous unspecified tests and saw unspecified specialists (results not provided). Subsequently the patient was hospitalized for encephalitis and has since been discharged. The physician doubts there was a link between the diagnosis of encephalitis and the vaccination. The physician reported that someone at the emergency room may have suggested to the patient's mother that there may be a link between the diagnosis and GARDASIL. The patient's encephalitis persisted. The physician considered the encephalitis to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323674-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	25-Jun-2008	25-Jun-2008	0	29-Aug-2008	02-Sep-2008	--	WAES0808USA04190	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness

Symptom Text: Information has been received from a nurse practitioner concerning a female who on an unspecified date was vaccinated with the first dose of GARDASIL (lot # was not available). Per nurse practitioner, the patient passed out and had a small seizure for 30 seconds after receiving the first dose of GARDASIL about 2 weeks ago. To date, patient only received the first dose of GARDASIL. No further information provided. It was reported that hepatitis B virus vaccine (unspecified) and TB test on the day that the patient is supposed to get the second dose of GARDASIL but the patient refused to receive the second dose. Upon internal review, "small seizure" was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323675-1 (S)** **Related reports:** 323675-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	30-Jul-2008	31-Jul-2008	1	29-Aug-2008	02-Sep-2008	CA	WAES0808USA04438	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Acne, Activities of daily living impaired, Blood glucose fluctuation, Burning sensation, Chest discomfort, Condition aggravated, Dermatitis, Diarrhoea, Disorientation, Fatigue, Food allergy, Headache, Insomnia, Malaise, Migraine, Myalgia, Nausea, Neurological examination normal, Night sweats, Presyncope, Road traffic accident, Syncope, Vulvovaginal disorder, Vulvovaginal pruritus

Symptom Text: Information has been received from a consumer concerning her approximately 16 year old daughter with penicillin allergy and sulfonamide allergy who on 30-JUL-2008 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. The first adverse experiences were nausea, diarrhea and headache which started on 31-JUL-2008, the day after she received the vaccine. The patient then began to experience insomnia, night sweats, heaviness in her chest, burning and aching in her muscle, extreme fatigue and migraines. The patient then began to experience unexplained fluctuations in her blood sugar levels and she was disoriented. It was noted that the patient fainted approximately two weeks after she received the vaccine. It was also noted that the patient was in a car accident on an unspecified date after she received GARDASIL. Medical attention was sought. At the time of the report, the patient had not recovered. The patient experience was reported as disabling. Additional information has been requested. 9/19/08 Reviewed PCP medical records of 7/30/08-9/4/08. FINAL DX: none provided Records reveal patient experienced malaise, extreme fatigue, insomnia, HA on 8/13. Had prior episodes of same w/extensive testing. Had near syncope on 8/13 & seen in ER. Neuro consult done 9/4 & WNL. 1/19/09 Reviewed PCP medical records of 10/6-10/28/2008. FINAL DX: vaginal irritation, acne, dermatitis around nose & eyes, food allergies Records reveal patient experienced vulvar itch/burn, skin breakouts on face. Missed several days of school.

Other Meds: Unknown

Lab Data: electrocardiogram; complete blood cell; thyroid function test; blood glucose LABS: all WNL. LABS: pap smear neg for HPV. Echocardiogram done 9/3/08 WNL. EKG done 8/13/08 WNL. CBC & chemistry done 8/13/08 WNL.

History: PMH: allergic penicillin & sulfa. Irregular menses, TMJ, eustachian tube dysfunction. PMH: yeast allergy per parent. Family hx of DM.

Prex Illness: Penicillin allergy; Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **323675-2** **Related reports:** 323675-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	30-Jul-2008	31-Jul-2008	1	06-Nov-2008	18-Dec-2008	CA		22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acne, Alopecia, Anxiety, Appetite disorder, Asthenia, Balance disorder, Blood glucose fluctuation, Burning sensation, Chest discomfort, Constipation, Convulsion, Depression, Dizziness, Food allergy, Insomnia, Loss of consciousness, Muscle atrophy, Night sweats, Pain, Pallor, Psoriasis, Vulvovaginal pruritus

Symptom Text: Extreme burning down to finger tips on side of body of injection,insomnia, night sweats, extreme hunger,heaviness in chest, depression, anxiety,achiness, loss of hair, dizziness, blood sugar extremes: low and high, weakness,loss of balance,fallor, passing out, seizure,loss of muscle mass, vaginal itching, consitpation, psorias,acne,food allergies to yeast and eggs.

Other Meds: NONE

Lab Data: Thyroid T3 and T4, mononucelousus,heart, full blood work up iron, protein, B12 ETC,Diabetes HGA1C,Nuerological, Adrenal,Echo Cardiogram, PAP, HPV testing

History: Lactose intolerant, Penicillian Allergy,Sulfa Drug Allergy

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: 323676-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	03-Jul-2007	Unknown		29-Aug-2008	02-Sep-2008	FR	WAES0808USA04551	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0513F	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthritis, Oral contraception

Symptom Text: Information was received on 15-AUG-2008 from a gynaecologist concerning a 19-year-old female who on 14-JAN-2008 was vaccinated with a third dose of GARDASIL (route and site not reported). In June 2008 the patient developed arthritis. The adverse event was ongoing at the time of reporting. The patient was vaccinated with P1 of GARDASIL on 02-JUL-2007 and with P2 of GARDASIL on 17-SEP-2007. No information about vaccination reaction is given. Follow-up information of hospital report was received from the gynaecologist on 22-AUG-2008 and the case was upgraded to serious because of hospitalization. It was reported that the previous doses of GARDASIL given to the patient, P1 (lot # 655101/0513F, batch # NE35170) on 03-JUL-2007 (not 02-JUL-2007 as previously reported) and P2 (lot # 1339F, batch # NF23310) on 17-SEP-2007, were well tolerated. On 14-JAN-2008, the patient was vaccinated with the third dose of GARDASIL (lot # 0277U, batch # NG00020, route and injection site not reported). Concomitant medication included hormonal contraceptives. In May 2008, the patient developed swelling of joints. The patient was hospitalized on an unknown date and seronegative early arthritis since May 2008 was suspected. Treatment with prednisolone was initiated. Under this therapy her symptoms improved. After stopping the steroid therapy in the end of July 2008, the patient experienced relapsing symptoms and was admitted in hospital again (exact date not available). X-ray of both hands on 08-AUG-2008 showed swelling of soft tissue, but no lesions. Rheumatoid arthritis or an early Bouchard's poly-arthrosis was suspected. Extensive blood tests showed normal results. And also test on borrelia antibodies was negative. The suggestion of methotrexat therapy was denied by the patient and a further therapy with prednisolone was intended. The patient was not recovered at the time of reporting. Other business partner numbers included: E2008-07762. No further information is available.

Other Meds: hormonal contraceptives (unspecified), unk, unk

Lab Data: X-ray, 08Aug08, X-ray of both hands showed swelling of soft tissue, but no lesions; Diagnostic laboratory test, normal, extensive blood tests showed normal results; Serum Borrelia burgdorferi antibody test, negative.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323677-1 (S)** **Related reports:** 323677-2; 323677-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Dec-2007	Unknown		29-Aug-2008	02-Sep-2008	MA	WAES0808USA04680	22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Acne, Arthralgia, Asthenia, Cough, Diarrhoea, Dizziness, Ear pain, Exposure to communicable disease, Fatigue, Headache, Hyperhidrosis, Hypersomnia, Hypoaesthesia, Joint stiffness, Joint swelling, Lymph node pain, Lymphadenopathy, Mixed connective tissue disease, Nausea, Oedema peripheral, Pain in extremity, Paraesthesia, Peripheral coldness, Pharyngeal erythema, Pharyngitis, Pharyngolaryngeal pain, Photophobia, Photosensitivity reaction, Raynauds phenomenon, Rheumatoid arthritis, Rhinorrhoea, Skin discolouration, Systemic lupus erythematosus, Viral infection, Vomiting, Weight decreased

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a 17 year old female with no pertinent medical history or drug allergies who on 28-JUN-2007 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot #654535/0960F), on 29-AUG-2007, was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL (lot #654535/0960F) and on 21-DEC-2007, was vaccinated intramuscularly with the third 0.5 ml dose of GARDASIL (lot #657621/0387U). Concomitant therapy included MENACTRA. In January 2008, the patient complained of numbness, cold hands and feet, joint pain in ankles, knees and wrists. The patient was seen by a rheumatologist and in April 2008, and she was diagnosed with Raynaud's lupus. Smith antigen antibodies test indicated positive. SM/RNP antibody was positive. The patient's Raynaud's lupus persisted. No product quality complaint was involved. Raynaud's lupus was considered to be disabling due to numbness and joint pain. Additional information has been requested. 10/21/08 Reviewed rheumatology outpatient clinic records of 04/02-7/30/2008. FINAL DX: mixed connective tissue disease w/components of both lupus & RA Records reveal patient experienced color changes & numbness of hands/feet in cold weather; progressively worsening joint pain, swelling & stiffness since 1/08; fatigue; weakness; lymphadenopathy of neck, resolved; HA w/photophobia; nausea; weight loss following flu-like illness 1 mo prior; irregular periods on BCP. Tx w/plaquenil, nsaids, methotrexate & folic acid w/improvement. 9/9/06 Reviewed PCP medical records of 6/28/07-7/10/2008. FINAL DX: Records reveal patient experienced general good health on date of 1st HPV & menactra vaccination. RTC 10/2/07 w/fatigue, falling asleep inappropriately, runny nose, cough, ear pain & sore throat x 3 days; vomiting & diarrhea week before. Also complaining of numbness of hands. Exam revealed tender lymph nodes, reddened throat. Dx w/viral illness. RTC 10/19 w/continued c/o of exhaution, fatigued going up s

Other Meds:

Lab Data: diagnostic laboratory, positive SM/RNP antibody; Smith antigen, positive LABS: WBC 12.27(H), ANC 9.77(H). ESR 34(H). CRP 5.30(H). ANA ab IgG 1:5120(H), SSA/RO IgG 118(H), ribonucleic protein IgG .1 Throat c/s neg. IgG 1740(H), RF 50.

History: None PMH: periorbital cellulitis age 3. HPV #1 0960F, given 6/28/07, HPV #2 0960F given 8/29/07. Menactra U2107AA, given 6/28/07. Smoker, depression/anger, occasional ETOH, contraception. UTI w/normal renal US, avulsion fibula fx, migraine HA, scoliosis, dysmenorrhea.

Prex Illness:

Prex Vax Illns:

Vaers Id: **323677-2** **Related reports:** 323677-1; 323677-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	02-Mar-2007	Unknown		03-Sep-2008	09-Sep-2008	MA		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	2	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2107AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Hypoaesthesia, Peripheral coldness, Raynauds phenomenon, Systemic lupus erythematosus

Symptom Text: January 2008 complained of numbness and cold in hands; feet with joint pain of ankles, knees, wrist, fingers, feet. Seen at hospital 4/08 Diagnosed with Reynauds; Lupus.

Other Meds:

Lab Data: Lab work. SM Antibody 1.6 positive, SM RNP Antibody >8 positive.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323678-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	31-Jul-2007	06-Jun-2008	311	29-Aug-2008	02-Sep-2008	FR	WAES0801AUS00011	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NE43240	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a health professional via CSL as part of a business agreement (manufacturer control # GARD 2007 12 21 004) concerning an 16 year old primipara female who on 31-JUL-2007 (in follow-up reported as 19-JUN-2007) was vaccinated with the first dose of GARDASIL (invalid Batch # NE43240 provided). On 10-SEP-2007 (in follow-up reported as 25-JUL-2007) the patient was vaccinated with the second dose of GARDASIL (invalid Batch # NE43230 provided). On 13-DEC-2007 (in follow-up reported as 14-NOV-2007) the patient was administered third dose of GARDASIL (invalid Batch # NE43240 provided) inadvertently while at 13 weeks gestation. No adverse symptoms were experienced at the time of reporting on 21-DEC-2007. Follow-up information has been received from a completed first Encounter Questionnaire. The date of the patient's last menstrual period was unknown. The patient's pregnancy was confirmed by an ultrasound on 04-DEC-2007 (gestation 13 weeks). The estimated delivery date is 10-JUN-2008. On 22-Aug-2008, a completed "Use in Pregnancy - Pregnancy Outcome Questionnaire" was received from a health professional. it was unknown whether the patient had any diagnostic tests or if the patient had taken any prescription drugs during her pregnancy. It was also unknown whether the patient had any infections/illnesses during her pregnancy. On 06-JUN-2008, the patient had to have a LUSCS (lower uterine segment cesarean section) delivery for a suspicious CTG (cardiotocography) reading. The patient delivered a normal, healthy female baby weighing 2790 grams at approximately 39 weeks gestation. The infant was 50 cm in length and had a head circumference of 35 cm. The infant's APGARS was "6'9s". The infant did not have any congenital anomalies or any complications. Upon internal medical review, LUSCS delivery for a suspicious CTG reading was considered an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: ultrasound, 04Dec07, pregnancy confirmed - gestation 13/52; fetal monitoring tests, 06Jun08, LUSCS delivery for a suspicious CTG reading

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **323680-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	20-Apr-2008	30-Apr-2008	10	29-Aug-2008	02-Sep-2008	FR	WAES0808ISR00015	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breast cancer

Symptom Text: Information has been received from a 25 year old female with chemotherapy who on 19-FEB-2008 was vaccinated with GARDASIL first dose. On 20-APR-2008 was vaccinated with GARDASIL second dose. On approximately 30-APR-2008 the patient experienced breast cancer. The patient's breast cancer persisted. Upon internal review, breast cancer was considered to be an other important medical event. On 16.7.2008 the patient was placed on the first chemotherapy cycle with DOCETAXEL TAXOTERE and CYCLOFOSFAMIDE (dose and duration not reported). The patient was placed on the second chemotherapy cycle with DOCETAXEL TAXOTERE and CYCLOFOSFAMIDE (Date, dose and duration not reported). Patient stated that prior to each therapy with chemotherapy she was placed on therapy with STEROIDS. Also once a month therapy with ZOLADEX injection, and NEUPOGEN injection on the eighth and twelfth day post chemotherapy. The patient is scheduled for the third course of chemotherapy in a few days time. The patient is scheduled for a total of 4 chemotherapy cycles. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Chemotherapy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323682-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-Aug-2008	19-Aug-2008	0	29-Aug-2008	02-Sep-2008	MD	WAES0808USA03545	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Fatigue, Feeling hot, Hypotonia, Tremor

Symptom Text: Information has been received from a physician and a medical assistant, concerning a 12 year old female who on 30-NOV-2006 was vaccinated with the first dose of GARDASIL (lot # 653735/0688F). On 10-MAY-2007, the patient was vaccinated with the second dose of GARDASIL (657736/0389U). On 19-AUG-2008, the patient was vaccinated with the third dose of GARDASIL (lot # 660612/0229X) and had a seizure. The patient went to the car with her mother after the vaccination and complained of feeling hot and tired. The patient slumped over and had a generalized shaking that lasted 5 seconds. The patient was being monitored in the office at the time of the call. the patient did not have any problems with the first and second dose of GARDASIL. Laboratory data included glucose test reading 81. The patient sought medical attention. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: serum glucose, 81

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 323683-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Mar-2008	Unknown		29-Aug-2008	02-Sep-2008	AZ	WAES0808USA04178	12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2376BA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1978U	0	Right arm	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Back pain, Blood product transfusion, Epstein-Barr virus infection, Eye movement disorder, Facial palsy, Headache, Hyporeflexia, Lumbar puncture, Lymphadenopathy, Meningitis viral, Musculoskeletal pain, Neurological examination abnormal, Paraesthesia, Pyrexia, Sleep disorder, Throat lesion, Tonsillar inflammation, VIIth nerve paralysis

Symptom Text: Information has been received from a physician concerning a 14 year old female patient who on 13-MAR-2008 was vaccinated with her first dose of GARDASIL. Concomitant therapy included MENACTRA. On 09-APR-2008, the patient experienced back pain, fever and headache. The patient was given Z-PAK. On 14-APR-2008, the patient presented at the office with complete facial paralysis and was admitted to the hospital. On 18-APR-2008, the patient was discharged. A neurologist in the hospital diagnosed her with possible Guillain-Barre and bilateral 7th cranial nerve palsy. On 24-APR-2008, the patient was seen by a physician and her adverse events were resolving but not complete. On 15-MAY-2008, the neurologist felt her symptoms were resolving and possibly not related to Guillain-Barre or GARDASIL. The neurologist diagnosed her as having Epstein-Barr meningitis. Back pain, fever, headache, facial paralysis and Epstein-Barr meningitis were considered to be disabling, immediately life-threatening and an other important medical event. Additional information has been requested. 10/3/08 Reviewed neuro medical records of 5/15/2008. FINAL DX: Epstein Barr viral meningitis with montherapy multiplex Records reveal patient experienced HA x 2 weeks in 4/2008. Developed shoulder pain, LBP, sleep disturbance & fever. Seen in ER, dx w/throat lesion & tx w/antibiotics. No response to antibiotic therapy although throat lesion did improve. Developed severe pain, facial weakness, tingling in fingertips. Hospitalized & brain MRI revealed inflammation of VII crainal nerve bilaterally. LP showed WBC (H), protein (H) & marginal glucose indicating viral meningitis. EBV IgM (H). Neuro exam on 5/15/08 revealed right facial weakness w/depressed UE reflexes. 10/31/08 Reviewed hospital medical records of 4/14-4/18/2008. FINAL DX: bilateral 7th cranial nerve palsy, possible variant of GBS triggered by acute Epstein-Barr infection. Records reveal patient experienced HA, muscle aches, fevers, strep throat, mono x approx 2 wks. D

Other Meds: MENACTRA

Lab Data: Unknown LABS: MRI revealed enhanced facial nerves c/w neuritis CSF: protein 386(H), glucose (L) WBC 60(H), lymphs 96%, macrophages 4%c/s neg. EBV (+).

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323684-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		29-Aug-2008	02-Sep-2008	--	WAES0808USA04237	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paralysis

Symptom Text: Information has been received from a consumer concerning her daughter who on a date not reported was vaccinated with GARDASIL. Subsequently the patient was temporarily paralyzed. Upon internal review paralysis was consider to be an other important medical event. It was unknown if the patient sought medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323685-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	05-Aug-2008	05-Aug-2008	0	29-Aug-2008	02-Sep-2008	RI	WAES0808USA04381	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from an office manager concerning an 18 year old female who on 05-AUG-2008 was vaccinated with a second dose of GARDASIL (route and administration site not reported). Immediately post the vaccination the patient fainted and had convulsions and seizures which lasted for approximately 1 minute. Subsequently, the patient recovered from seizures and faint. The adverse events happened in the office. Upon internal review the seizure was considered to be an other important medical event. Additional information has been requested. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323686-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Apr-2008	Unknown		29-Aug-2008	08-Sep-2008	GA		08-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0524U	2	Right arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHA1B163AB	1	Left arm	Unknown	
HEP	MERCK & CO. INC.	0608F	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: No adverse events. HPV #3 given to early. No event/misadministration.

Other Meds:

Lab Data: N/A

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 323705-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	08-Jan-2008	Unknown		29-Aug-2008	02-Sep-2008	FR	WAES0805CAN00017	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Polyarthritis, Tendonitis

Symptom Text: Information has been received from a physician (initial reporter) concerning a 15 year old female who on 08-JAN-2008 was vaccinated with the first dose of GARDASIL, lot # not available. On 24-MAR-2008 the patient was vaccinated with the second dose of GARDASIL, lot # not available. Concomitant therapy included vaccination with ADACEL. In March 2008, the patient was diagnosed with polyarthropathy with positive ANA and negative for rheumatoid factor. In May 2008, the patient was found to be HLA B27 positive. The physician (primary source) reported that the patient was hospitalized twice for pulse steroids and in June 2008 that patient was started on therapy with sulfasalazine 500 mg BID for the treatment of Enthesitis-related arthritis (described also as polyarthropathy with positive ANA and negative rheumatoid and HLA B27 positive). The primary source physician also reported that the patient's condition is improved, but activity is tricky. A magnetic resonance imaging of sacro-iliac joint was negative. ANA positive 1:80. The initial reporter physician felt that polyarthropathy with positive ANA was possibly related to therapy with GARDASIL. The primary source physician was uncertain whether Enthesitis-related arthritis (also described as polyarthropathy with positive ANA and negative rheumatoid and HLA B27 positive) was related to therapy with GARDASIL. Final outcome of events not provided. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, SI joint negative; steroid therapy, Pulse steroids; steroid therapy, Pulse steroids; serum ANA, ??Mar08, positive 1:80; serum rheumatoid factor, ??Mar08, negative; whole blood HLA antigen test, ??May08, positive

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323707-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		29-Aug-2008	02-Sep-2008	FR	WAES0808AUS00259	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Pallor, Somnolence, Urinary incontinence

Symptom Text: Information has been obtained on request by the Company from the agency via a Case Line Listing, concerning a 14 year old female who was vaccinated with GARDASIL. Subsequently the patient experienced convulsion, dizziness, pallor, somnolence and urinary incontinence. At the time of reporting to the agency on 12-MAR-2008, the patient had recovered from convulsion, dizziness, pallor, somnolence and urinary incontinence. The agency considered that convulsion, dizziness, pallor, somnolence and urinary incontinence were related to therapy with GARDASIL. The original reporting source was not provided by the agency. The agency considered convulsion to be serious for the following reason: medically significant. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323709-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		29-Aug-2008	02-Sep-2008	FR	WAES0808AUS00257	02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been obtained by the Company from the agency via a Case Line Listing, concerning a 26 year old female who was vaccinated with GARDASIL. Subsequently, 49 days post-vaccination, the patient experienced a complete spontaneous abortion. At the time of reporting to the agency on 07-MAR-2008 the patient had recovered from complete spontaneous abortion. The agency considered that complete spontaneous abortion was related to therapy with GARDASIL. The original reporting source was not provided by the agency. The agency considered complete spontaneous abortion to be serious for the following reason: medically significant. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP=Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323722-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Jul-2007	18-Sep-2007	70	29-Aug-2008	03-Sep-2008	FL		24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2334AA	0	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Activities of daily living impaired, Asthenia, Autoimmune disorder, Axillary pain, Back pain, Biopsy stomach normal, Body temperature fluctuation, Central nervous system lesion, Cerebral disorder, Chest X-ray normal, Chest pain, Costochondritis, Diplopia, Double stranded DNA antibody, Dyspnoea, Dysstasia, Endoscopy abnormal, Epstein-Barr virus test negative, Eye pain, Face and mouth X-ray normal, Facial pain, Fatigue, Feeling of body temperature change, Gait disturbance, Headache, Infectious mononucleosis, Lumbar puncture, Lymphadenitis, Lymphadenopathy, Mononucleosis heterophile test positive, Muscular weakness, Myalgia, Nodule, Pharyngeal erythema, Pharyngitis, Pharyngolaryngeal pain, Pleuritic pain, Rash, Rash papular, Rash pruritic, Stomach discomfort, Swelling, Systemic lupus erythematosus, Tenderness, Ultrasound scan normal, Vision blurred, Weight decreased

Symptom Text: Pt, a strong, athletic fourteen year old volleyball player received the GARDASIL vaccine at her pedatirician's office on July 10, 2007. At that time she weighed approx 131 lbs. and had no other medical conditions other than a previously diagnosed thyroiditis (Hashimoto's) treated with SYNTHROID 75 mcg. On the day of her visit to the pediatrician for a school and sports physical she received the GARDASIL along with the Hepatitis A vaccine because we were planning on traveling outside the country later in the year. She began her volleyball training a few weeks later and although she was keeping pace she often complained of exhaustion. Because the training was vigorous, no one thought of it. School began in late August and she continued a vigorous regiment. By mid September she was complaining of back muscle pain which we thought was simply from playing. She had also begun complaining of stomach pains. By the first of October there was a marked difference in her stamina and the pain and obvious muscle weakness became more obvious. As a player who could easily seven ten to fifteen hard serves in a row during a game, she could barely put two or three serves over the net. In mid October she was seen by her pediatrician who could find nothing medically wrong with her. But by the end of October, she could barely carry her book bag in school and could barely walk the hallways during a full day of school. She was seen by her endocrinologist during the first week of November for her regular check up and this exhaustion was brought up. Lab work done revealed that if there was something wrong, it was not due to her thyroid which was functioning normally. Two weeks later she was seen again by her pediatrician, again nothing was diagnosed. Another week later she was seen again and lab work was done to rule out Strep and mononucleosis. Seven days later we were told her mono titer was positive so everyone assumed that was the cause for her fatigue. After days of bed rest, no real improvement was noted. Three weeks later, she was

Other Meds:

Lab Data: positive ANA-which later (months later reverted back to negative-Brain MRI showed cerebral peduncle lesion-followed up-repeat MRI scheduled for Sept 08. Labs and Diagnostics: 1/18/08:Soft tissue US (-). Total bili 2.3, direct 0.3, indirec

History: thyroiditis-Hashimotos. PMH: Strabismus surgery. Autoimmune Thyroiditis and Goiter DX: 5/23/07

Prex Illness:

Prex Vax Illns:

Vaers Id: **323723-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-May-2007	01-Jul-2007	61	29-Aug-2008	02-Sep-2008	NJ		30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	2	Left arm	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Affect lability, Agitation, Blindness, Eye pain, Headache, Hyperhidrosis, Hyperreflexia, Hypoaesthesia, Mobility decreased, Muscular weakness, Neck pain, Photophobia, Pyrexia, Sensory loss, Visual disturbance

Symptom Text: 7/07 Severe headaches going from neck to front of head and eye socket, numbness, muscle weakness, difficulty work mostly left leg. Problems with sight. 9/04/2008 Pt seen 5/1/2007 for 3rd HPV. Pt c/o R middle finger and ankle swelling. 11/3/2008 MR received from neurologist which includes H&P and consult for admission 9/27/08 for intractable headache, agitation, sweating, photophobia, low grade fever. Admitted to r/o meningitis. DTRs 3+ in upper extremities, decreased sensation on L side. 12/16/2008 Additional records received. DX: Severe h/a as adverse effect of steroids. Pt developed loss of vision of L eye in summer 2007 and given dx of MS. Had been started on Solumedrol for MS exacerbation and developed severe h/a with photophobia unrelieved by pain meds. PE (+) for decreased sensation in the L face and extremities, DTRs elevated in upper extremities. Pt agitated with labile emotions. Admitted for o/n observation.

Other Meds: Albuterol; Birth control pills

Lab Data: Test - MRI - 7/08 diagnosed M.S. Spinal taps. Labs and Diagnostics: CBC with WBC 14.8 (89% segs, 6% lymphs), RBC 3.74, Hgb 11.9, Hct 35.1. Total protein 5.9. Albumin 3.1. Alk Phos 35.

History: Asthma; Endometriosis. PMH: endometriosis

Prex Illness:

Prex Vax Illns:

Vaers Id: 323729-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Jun-2008	15-Jul-2008	21	29-Aug-2008	23-Sep-2008	PA		23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: "none"

Other Meds: Allegra 180mg

Lab Data: Labs - quemia

History: NKDA

Prex Illness: Fatigue - Anemia

Prex Vax Illns:

Vaers Id: 323731-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Sep-2007	24-Oct-2007	30	29-Aug-2008	08-Sep-2008	MA		17-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2395BA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1062U	0	Left arm	Intramuscular	
FLU	SANOFI PASTEUR	U2436AA	1	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B015BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain lower, Activities of daily living impaired, Adhesiolysis, Asthenia, Contraception, Diarrhoea, Dysmenorrhoea, Endometriosis, Fatigue, Flatulence, Galvanocauterisation, Gastroenteritis viral, Headache, Irritable bowel syndrome, Laparoscopy abnormal, Nausea, Pelvic peritoneal adhesions, Vomiting

Symptom Text: Began 10/07, patient developed chronic abdominal pain, fatigue, after receiving GARDASIL vaccine. Being followed by GI/GYN. 9/19/08 Reviewed GYN/GI consults of 2/19-8/13/08. FINAL DX: Stage II endometriosis, adhesions of left tube to pelvic sidewall; cauterization of endometriosis & lysis of adhesions. Records reveal patient experienced lower abdominal pain every day which worsened w/nausea during menses. Missing significant amounts of school. Tx for IBS & started on contraception for dysmenorrhea. No pain improvement on meds & had diagnostic operative laparoscopy on 8/13/08. 9/9/08 Reviewed PCP medical records of 9/24/07-5/6/2008. FINAL DX: Records reveal patient experiened general good health on 9/24 when received TDaP, Menactra, Gardasil #1 & influenza vaccinations. RTC 10/24 w/nausea, vomiting, diarrhea, abdominal cramps & HA x 1 week. Dx w/gastroenterieitis, likely viral. RTC 11/5 w/N/V/D, weakness, decreased energy, abdominal pain & HAx 3 wks. Labs done. RTC 11/13 for N/V/D, gas, abdominal pain, HA x 1 mo. Dx w/probable IBS. RTC 11/21 w/continued s/s & sore throat, hoarseness, cough/sneezing & rash on stomach. Dx w/pharyngitis. RTC 12/3 w/nausea, gas, abdominal pain, vomiting. Referred to GI. RTC 2/27 w/stomach & thigh pain, HA & vomiting. Referred to GYN for possible endometriosis. RTC 3/24 for conjunctivitis & URI. Had shotty cervical lymph nodes. RTC 5/3 for URI symptoms, HA & stomach aches. RTC 5/6 for sore throat & stomach pain. Exam found exudative tonsillitis w/neg throat c/s. Tested for mono, no results provided.

Other Meds:

Lab Data: Endoscopy Colonoscopy LABS: EGD & colonoscopy WNL. US of pelvis WNL. Stool c/s neg, ESR 3. Throat c/s neg.

History: NKA; dysmenorrhea; MRSA; ADHD HPV #2 1266U, given 12/3/07 PMH: ADHD, anxiety, athlete's foot & MRSA feet infection. Menstrual cramps. Chickenpox, enuresis (resolved age 12), s/p mechanical pleurodesis, pneumothorax w/prolonged hospitalization for resection of pulmonary cyst

Prex Illness: None Known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323734-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Sep-2007	Unknown		29-Aug-2008	08-Sep-2008	NY		09-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	GLAXOSMITHKLINE BIOLOGICALS	NULL	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2222AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B013AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0188U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Patient received Tdap, MCV4, varicella, and HPV vaccine during routine well child visit on 9/24/07. It was later discovered that she was pregnant at the time, approximately 19 weeks. Patient delivered on 1/29/08, no adverse event known to this practice.

Other Meds: TYLENOL and MOTRIN PRN for pain

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323735-1** **Related reports:** 323735-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	09-Mar-2008	25-Jul-2008	138	29-Aug-2008	23-Sep-2008	IL		23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0755U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Abdominal pain upper, Anxiety, Asthenia, Back pain, Condition aggravated, Dyspnoea, Fatigue, Headache, Helicobacter infection, Malaise, Nausea, Neurological examination normal, Pain in jaw, Peptic ulcer, Photophobia, Urinary tract infection, Weight decreased

Symptom Text: Shortly after 3rd HPV vaccine developed extreme fatigue, weakness, headache 2/26/09 Received hospital medical records of 8/6-8/7/08. FINAL DX: generalized weakness, intermittent spisodes of dyspnea & HA s/p vaccination Records revea patient experienced weakness, fatigue x 3 weeks. Had been eval at outlying ER & PCP referred to higher level of care for concerns of GBS. Neuro consult WNL & referred to PCP on d/c to home. 2/27/09 Received ER records of 8/5/08. FINAL DX: HA, malaise, fatigue Records reveal patient experienced weakness, anxiety, dyspnea, possible medication reaction x 2 wks. Currently on meds for UTI & PUD. 9/23/08 Reviewed PCP medical records of 1/2/08-8/8/08. FINAL DX: Records reveal patient experienced good health day of first HPV vaccine. Developed UTI & low back pain, tx w/antibiotics. On 7/2 vs, c/o stomach pain & burning, nausea. RTC 8/8/08 w/extreme fatigue, HA w/photophobia, weight loss, jaw pain. Tx for H. pylori infection.

Other Meds: Septra DS x 3 days; Prev Pak x 14, started 8/08/08

Lab Data: Neurology consult; echocardiogram; CBC; Chemistry; ANA; ESR; CT brain LABS: CMP, blood c/s, UA, mono, D-dimer, echocardiogram, CT head, EKG, CXR all WNL. H/H 10.8/31.2(L). Total protein 6.0(L), calcium 8.6(L). Mono neg.

History: None PMH: UTI, PUD, panic attacks, GERD.

Prex Illness: UTI; nausea; H. Pylori

Prex Vax Illns:

Vaers Id: **323735-2 (S)** **Related reports:** 323735-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	25-Jul-2008	28-Jul-2008	3	02-Sep-2008	03-Sep-2008	IL	WAES0808USA04814	23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Dyspnoea, Fatigue, Gait disturbance, Headache

Symptom Text: Information has been received from a physician concerning a 21 year old female with iron deficiency and helicobacter pylori infection and with no known drug reactions/allergies who in January 2008, was vaccinated with a first dose of GARDASIL (route and administration site not reported). In March 2008, the patient was vaccinated with a second dose of GARDASIL (route and administration site not reported). On 25-JUL-2008 the patient was vaccinated with a third dose of GARDASIL (route and administration site not reported). There was no concomitant medication. A few days after her third dose of GARDASIL on approximately 28-JUL-2008 the patient experienced headache, extreme fatigue and difficulty breathing and walking. She was seen in two emergency rooms and has been evaluated by a neurologist. A computed axial tomography (CT) scan and an unspecified brain scan were performed, but no result provided. The patient's headache, extreme fatigue, difficulty breathing and difficulty walking persisted. The headache, extreme fatigue, difficulty breathing and difficulty walking were considered to be disabling by the reporting physician. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Iron deficiency; Helicobacter pylori infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323736-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Aug-2008	18-Aug-2008	0	29-Aug-2008	08-Sep-2008	WI		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Left leg	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Syncope

Symptom Text: Dizziness- followed-up by syncope & pallor. TRENDELENBURG position, after approximately 2 minutes color back. Kept patient approximately 1/2 hour for observation.

Other Meds: TOPICORT OINTMENT

Lab Data:

History: Eczema

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323738-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Aug-2008	19-Aug-2008	0	29-Aug-2008	08-Sep-2008	WI		09-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0103X	1	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2636AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024DB	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted in exam room after receiving vaccinations. No trauma occurred. Had not eaten anything or had anything to drink prior to vaccinations. Patient responsive almost immediately after fainting. Given watermelon to eat. Kept patient in clinic for about 15 minutes.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323740-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	12-Nov-2007	25-Feb-2008	105	29-Aug-2008	08-Sep-2008	IL		15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Attention deficit/hyperactivity disorder, Basedows disease, Blood pressure increased, Dermographism, Eye disorder, Fatigue, Feeling jittery, Goitre, Heart rate increased, Hypersensitivity, Insomnia, Local swelling, Malaise, Myalgia, Periorbital oedema, Scoliosis, Speech disorder, Throat irritation, Tremor, Upper respiratory tract infection, Urticaria, Weight increased

Symptom Text: Graves Disease 10/14/08 Reviewed PCP medical records of 6/2007-9/2008. FINAL DX: Graves disease Records reveal patient experienced usual state of good health on 6/8/2007 visit & received HPV#1 & varicella. Received HPV#2 8/10/2007. HPV#3 11/12/2007. Referred to ortho 10/07 for chest deformity & scoliosis. Dx w/ADHD 11/07. Had fatigue/malaise & acute URI 11/07. RTC 2/25 w/swollen neck, throat pressure, increased HR & BP & dx w/goiter. Labs & US ordered & referred to endocrine. Exam revealed prominent eyes w/periorbital edema, tremors of tongue & extremities, jittery, speech fast, difficulty sleeping. Tx w/meds. Developed allergic reaction & seen in ER where dx w/dermatographic urticaria. Referred to allergist. Referred for second endocrine opinion which concurred. Developed myalgias & frequent hives. Developed weight gain & hair loss, meds adjusted.

Other Meds: None

Lab Data: Free T4, TSH LABS: 2/25/08 Free T4 5.2, TSH 0.03. Thyroid US & thyroid uptake scan revealed diffuse enlargement w/53% uptake in 6 hours.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323755-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	U	07-Aug-2008	07-Aug-2008	0	29-Aug-2008	01-Sep-2008	MI		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Flushing

Symptom Text: C/O DIZZINESS & FLUSHED CHEEKS

Other Meds: N/A

Lab Data: N/A

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: **323762-1** **Related reports:** 323762-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	21-Aug-2008	22-Aug-2008	1	29-Aug-2008	01-Sep-2008	MD		10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	2	Unknown	Intramuscular	
	HEPA	UNKNOWN MANUFACTURER	AHAVB243AA		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain lower, Hypersensitivity, Muscle contractions involuntary, Neurological examination normal, Tremor, Vaccination complication

Symptom Text: Received Gardisil and Hepatitis A vaccine. Noticed uncontrollable "shaking" to left side of body and face 24 hours later. Seen in ER, bloodwork normal. Neurological exam normal. Sent home. No further problems. 9/5/08 Reviewed PCP medical records which included ER medical records of 8/23/08. FINAL DX: allergic reaction to vaccine Records reveal patient experienced lower abdominal pain, uncontrollable shaking of left arm, shoulder & face. When seen in ER, noted to have rhythmic movement of left face & arm. Dx in ER: possible extrapyramidal symptoms & muscle contractions.

Other Meds: None

Lab Data: CBC and Chemprofile WNL LABS: LFTs WNL.

History: None PMH: contraception

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323762-2** **Related reports:** 323762-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	21-Aug-2008	23-Aug-2008	2	19-Sep-2008	22-Sep-2008	--	WAES0809USA01621	22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain lower, Convulsion, Hypersensitivity, Tremor

Symptom Text: Initial and follow up information has been received from a nurse practitioner in form of medical record, concerning a healthy 21 year old female patient with no previous medical history reported, who on 21-AUG-2008 was vaccinated with the third dose of GARDASIL. On the same date, the patient was vaccinated with a first dose of hepatitis A (unspecified) (manufacturer unknown). Vaccines were administered in preparation of travel abroad. The nurse reported that the patient experienced seizure after receiving her third dose of GARDASIL. Subsequently, the patient experienced lower abdominal pain and seizure described as uncontrollable left sided shaking to left arm face and shoulders. On 23-AUG-2008, the patient started to have the same shakes and was taken to the emergency room but was not admitted. She had no headache, nausea, vomiting, numbness or weakness. While being examined in the emergency room, the patient had the same rhythmic movement of face and arm. Possible extrapyramidal and muscular contraction symptoms were noted by the emergency room. Liver function tests were check and were within normal limits. The patient was prescribed benztropine mesylate (manufacturer unknown), BENADRYL, and dexamethasone (manufacturer unknown). On 28-AUG-2008, the patient was seen in the reporting nurse practitioner's office for follow-up to the emergency room visit. It was noted that the patient had no problems since the emergency room visit. Assessment noted as an allergic reaction, possible reaction to GARDASIL. On an unknown date, the patient recovered. There was no product quality complaint. Upon internal review, the patient's seizure was considered an other important medical event. No additional information is expected. All available medical records will be provided on request.

Other Meds:

Lab Data: serum sodium, 08/23/08, 185 mmol; serum potassium, 08/23/08, 3.3 mmol; serum glucose, 08/23/08, 92 mg/d; serum aspartate, 08/23/08, 15 IU/L; serum alkaline, 08/23/08, 51 IU/L; white blood cell, 08/23/08, 10.4; serum alanine, 08/23/08, 8 IU/

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323763-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	25-Aug-2008	26-Aug-2008	1	29-Aug-2008	01-Sep-2008	WI		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0318X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	174DU	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Induration, Mass, Pruritus, Skin warm

Symptom Text: Received injection on 8/25/08. On the 26th on the (R) arm. Area red and warm to the touch. Hard to the touch and the size of a 50 cent piece. No temperature. Itchy. Not red on 8/29, but still hard and a lump.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323772-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	29-Aug-2008	29-Aug-2008	0	29-Aug-2008	01-Sep-2008	ND		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Head injury, Loss of consciousness, Vision blurred

Symptom Text: Patient and witnesses state at approx. 10:35 am patient became lightheaded and dizzy, vison became fuzzy and she passed out hitting her head on a door. Patient given orange juice and animal crackers.Evaluated by medical provider with no further interventin required.

Other Meds: Tri-sprintec

Lab Data: N/A

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: **323775-1** **Related reports:** 323775-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Aug-2008	29-Aug-2008	0	29-Aug-2008	01-Sep-2008	VA		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Confusional state, Dizziness, Dyskinesia, Mydriasis, Syncope

Symptom Text: Patient developed lightheadedness, weakness, dilated pupils and bucking of legs approx 30 minutes post vaccine, recovered after 15 minutes, then developed another episode with syncope this time for a few seconds and then confusion for a few seconds. Sent to ER for evaluation -- EKG was normal, Compr met panel was normal, urinalysis was normal, patient no orthostatic, vital signs were stable,

Other Meds:

Lab Data: Note, private pediatrician to supply additional information concerning manufacturer and lot number

History: mild seasonal allergies no asthma

Prex Illness: none, at band camp x 4 days, but well hydrated, mildly to moderately stressful for her.

Prex Vax Illns:

Vaers Id: **323775-2** **Related reports:** 323775-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Aug-2008	29-Aug-2008	0	03-Sep-2008	09-Sep-2008	VA		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2687AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0517X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient had 3 syncopal episodes in the office and was transported via EMS to the hospital after vaccine admin.

Other Meds:

Lab Data:

History: Allergies

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323776-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	29-Aug-2008	Unknown		29-Aug-2008	01-Sep-2008	NC		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: LAST GARDASIL VACCINE WAS GIVEN BEFORE THE DATE IT WAS DUE.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323797-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Aug-2008	29-Aug-2008	1	30-Aug-2008	01-Sep-2008	NJ		02-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Malaise, Nausea, No reaction on previous exposure to drug, Pyrexia

Symptom Text: presented to ED with complaints of fever, malaise and nausea since 8/29. received 2nd dose of hpv vaccine on 8/28. had no adverse reactions to first vaccine.history of seasonal allergies and yeast allergy

Other Meds: zyrtec, birth control

Lab Data: strep screen negative

History: seasonal allergies, yeast allergy

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323817-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Aug-2008	Unknown		29-Aug-2008	23-Sep-2008	NM		23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0169X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	19684	0	Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: 15 y/o female given VARIVAX and GARDASIL while pregnant, uncertain age but likely 1st trimester. No adverse events but harmful for fetus.

Other Meds:

Lab Data:

History: None

Prex Illness: Pregnancy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323818-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Aug-2008	13-Aug-2008	0	29-Aug-2008	23-Sep-2008	TN		23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Hypoaesthesia, Pain, Pruritus, Urticaria

Symptom Text: 2-3 hrs after injection c/o itching, burning, numbness and pain all rec. Severe itching, no whelps noticed until after child began vaccinating. No fever in site area. Unable to move arm when woke up. Now full range of injection

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323822-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	20-Jun-2008	01-Jul-2008	11	29-Aug-2008	23-Sep-2008	CA		02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Hypoaesthesia, Inappropriate schedule of drug administration, Musculoskeletal pain

Symptom Text: Upper Right Shoulder Pain. Low Back Pain. Numbness (R) foot

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323854-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		02-Sep-2008	03-Sep-2008	OK	WAES0808USA04715	03-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for GARDASIL, concerning a 17 year old female who was vaccinated with GARDASIL. It was reported that the patient was pregnant when she was given GARDASIL. The patient had a miscarriage 1 week after the third dose of GARDASIL was given (date unspecified). It was unspecified if the patient sought medical attention or not. Upon internal review miscarriage was considered to be other important medical event. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323855-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	13-Sep-2007	01-Nov-2007	49	02-Sep-2008	03-Sep-2008	FR	WAES0808USA04762	03-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1473F	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Autoimmune thyroiditis, Multiple sclerosis, No reaction on previous exposure to drug

Symptom Text: Information has been received from a health authority. It was reported that a 20 years old female patient was vaccinated with the first dose of GARDSASIL (Batch #NF 23310, Lot # 1339F) on 09-JUL-2007 and was well tolerated. On 13-SEP-2007, the patient was vaccinated with the second dose of GARDASIL (Batch #NF46730, Lot #1473F, route and site not reported). The patient developed multiple sclerosis in November 2007. She was hospitalized on an unspecified date. In hospital, MRI and neurological examinations confirmed diagnosis of multiple sclerosis. Despite ongoing multiple sclerosis the patient was vaccinated with a third dose of GARDASIL (Batch #NG00020, Lot # 0277U) on 20-DEC-2007. Hashimoto's thyroiditis was diagnosed in December 2007. She was hospitalized on an unspecified date. The patient has not yet recovered. Other business partner numbers included: E2008-07866 and E2008-07903. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, multiple sclerosis; neurological examination, multiple sclerosis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323856-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Feb-2008	20-Feb-2008	0	02-Sep-2008	03-Sep-2008	FR	WAES0808USA04578	03-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hepatitis, Incorrect route of drug administration

Symptom Text: Information has been received from a general practitioner concerning a 18 year old female who on 01-AUG-2007, was vaccinated with the first dose of GARDASIL, on 03-OCT-2007 with the second dose of GARDASIL and on 20-FEB-2008, with the third dose of GARDASIL via subcutaneous route recommended route, I.M. In April 2008, the patient developed post vaccination hepatitis. Test found Gamma G3 at 33 and transaminases at 52.9, serologies for hepatitis B and C were negative and alcohol etiology was ruled out. At the time of reporting, CMV serology was still questioned. The patient was not hospitalized and fully recovered. It was noted that the patient's mother had cervical dysplasia. The hepatitis was considered an other important medical event. Other business partner numbers included E2008-07935. No further information is available.

Other Meds: Unknown

Lab Data: serum alanine aminotransferase, 52.9; serum gamma glutamyl transferase, 33; serum hepatitis B Ab, Comment: negative; serum hepatitis C antibody test, Comment: negative

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323857-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	20-Aug-2008	20-Aug-2008	0	02-Sep-2008	03-Sep-2008	NJ	WAES0808USA04143	03-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Muscle spasms, Trismus

Symptom Text: Information has been received from a physician concerning a 19 year old female who on 20-AUG-2008 was vaccinated with the first dose of GARDASIL 0.5 ml IM (lot # 659184/0843X). The patient was given a TB test at the same visit that she received the vaccine. On 20-AUG-2008 the patient experienced lockjaw, lightheadedness and cramping of her right leg within twenty minutes after vaccination. The patient was seen at the emergency room where she was given intravenous VALIUM and intramuscular TORADOL. The patient recovered from lockjaw, lightheadedness and cramping of her right leg on 20-AUG-2008. Upon internal review, the patient's events were determined to be other important medical event (IV and IM treatment required). Additional information has been requested.

Other Meds: tuberculin

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 323858-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Apr-2008	05-Apr-2008	4	02-Sep-2008	03-Sep-2008	FR	WAES0806USA01811	03-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Arthritis, Gastroenteritis, Incorrect route of drug administration, Oedema

Symptom Text: Case of misuse received from a gynaecologist through the pharmacovigilance form and by phone. Information has been received from a gynaecologist concerning a 19 year old female, who on 08-FEB-2008 was vaccinated with a first dose of GARDASIL in the left shoulder via the subcutaneous route instead of the recommended intramuscular route. No adverse reaction was reported. Concomitant therapy included hormonal contraceptives (unspecified). In April 2008 the patient was vaccinated with a second dose of GARDASIL. The batch number was not reported. Four days after vaccination with the second dose the patient experienced arthralgias with inflammatory joints on knees, wrist, and ankle. She was hospitalized and biological work-up was negative. The patient was treated with NSAID's and corticosteroids. At the time of the report, the patient was recovering. Follow-up information received from the gynaecologist via the pharmacovigilance form and by phone: The patient's weight and height were reported. She received the second dose of GARDASIL (batch number not reported) in APR-2008. The patient had concomitant oral contraception with HOLGYEME since 2007. Fifteen days after the second injection, she developed arthritis of the major joints, reported as moderate and not serious. In an attached letter from a rheumatologist dated 26-APR-2008, it was reported that arthralgia also appeared 48 hours after an episode of gastroenteritis. Tests performed on 24-APR-2008 also found sedimentation rate at 15 mm and CRP at 5 mg. The rheumatologist added that the patient had not been relieved by NEXEN nor APRANEX associated to analgesics, and consequently, corticotherapy was started at 30 mg/day and gradually tapered. The gynaecologist reported that the patient had recovered, however at the time of the reporting there was a residual oedema on the right wrist and the left ankle. Other business partner numbers included: E2008-05323 and E2008-07884. No further information is available. The case was closed.

Other Meds: cyproterone acetate/ethinyl estradiol, 2007 - Unk

Lab Data: serum C-reactive protein, 24Apr08, 5 mg; erythrocyte sedimentation rate, 24Apr08, 15 mm

History:

Prex Illness: Oedema; Contraception

Prex Vax Illns:

Vaers Id: **323859-1 (S)** **Related reports:** 323859-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		02-Sep-2008	03-Sep-2008	FR	WAES0808USA04932	03-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hemianopia homonymous, Multiple sclerosis

Symptom Text: Information has been received from a general practitioner concerning a female patient who on unspecified dates was vaccinated with the first and second dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). On 08-MAY-2008, a few time after the second dose vaccination, the patient suffered from a lateral homonymous hemianopia. An MRI showed hypersignals of T2 with a contrast uptake. The lumbar puncture revealed an oligoclonal band. Suspicion of multiple sclerosis was diagnosed during a hospitalization. The patient had only recovered from the symptoms. The patient had no personal medical history reported, but her father had medical history of ulcerative colitis and ankylosing spondylitis. Further information is expected. Other business partner numbers include E2008-08042.

Other Meds: hormonal contraceptives (unspecified), Unk - Unk

Lab Data: magnetic resonance imaging, hypersignals of T2 with a contrast uptake; spinal tap, revealed an oligoclonal band

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323859-2 (S)** **Related reports:** 323859-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	19-Feb-2008	08-May-2008	79	29-Sep-2008	30-Sep-2008	FR	WAES0809USA03227	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT CSF oligoclonal band present, Central nervous system lesion, Demyelination, Familial risk factor, Hemianopia homonymous

Symptom Text: Initial information has been received from a general practitioner, concerning a 21 year old female patient, who on 18-DEC-2007 was vaccinated with the first dose of GARDASIL via intramuscular route in left deltoid (Batch number not reported). On 19-FEB-2008, the patient was vaccinated with the second dose of GARDASIL (Batch number not reported) IM in the left deltoid. On 08-MAY-2008, a few time after vaccination with the second dose of GARDASIL, the patient suffered from a lateral homonymous hemianopsia. A MRI showed hypersignals of T2 with a contrast uptake. The lumbar puncture revealed an oligloclonal band. Suspicion of multiple sclerosis was diagnosed during an hospitalization. The patient had only recovered from the symptoms. She had concomitant hormonal contraceptives (JASMILLENE) since November 2006. She had no personal medical history reported but her father had medical history of ulcerative colitis and ankylosing spondylitis. Follow-up information has been received, concerning the patient who, 30 minutes later she received the second dose of GARDASIL, developed a slight nodosity of mild intensity resolved in 24 hours. On 08-MAY-2008, she developed a right bilateral homonymous hemianopsia of severe intensity resolved by the end of June 2008. Diagnosis was impairment demyelinating and evoqued diagnosis was a suspicion of multiple sclerosis. A cerebral MRI performed on 10-JUN-2008 showed four nodular lesions in hypersignal T2 of subcortical substance: three of them were located at the level of the left frontal lobe, the third one was just ahead of left ventricle of anterior horn and the fourth one was facing porterieur foot of posterior knee of corpus callosum, lateralized on the left just inside of lateral ventricle. No visible ischemic lesion. No visible anomaly at the level of chiasma or orbital cavity. No abnormal peri-cerebral collection. Conclusion was small nodular pictures of white cortical substance leading to persue the work up in particular to find a demyelinating pathology and an evolutive follo

Other Meds: drospirenone (+) ethinyl estradiol, Nov06 - Unk

Lab Data: magnetic resonance imaging, 10Jun08, four nodular lesions in hypersignal T2 of subcortical substance (see narrative); spinal tap, 12Jun08, revealed pure intrathecal inflammatory process and absence of detectable anti-myelin IgM reactivity;

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 323863-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Jun-2008	11-Jul-2008	24	02-Sep-2008	08-Sep-2008	NE		25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2571AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0063X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Arachnoid cyst, Blood product transfusion, Gait disturbance, Guillain-Barre syndrome, Headache, Hypoaesthesia, Hypokinesia, Malaise, Muscular weakness, Myalgia, Nausea, Paraesthesia, Sinusitis

Symptom Text: 081108 Intolerable head/muscle pain, muscle weakness "all over" arms, legs difficulty walking, nausea, change in responsive 911, ambulance to ER CT Scan, bloodwork, West Nile 0 mother states all OK, home w/ diagnosis possible viral infection. 082108 Dr. visit weakness; HA (7), not feeling well continued. Sent to Dr. (neurologist) ER for MRI/Spinal Tap - GBS diagnosis. 8/26/08 Improving @ this time 10/03/08 Reviewed hospital medical records of 8/21-8/24/2008 FINAL DX: Guillain Barre syndrome Records reveal patient experienced HA, progressive numbness & weakness distal to proximal. Tx w/IVIG. HA & paresthesias resolved except for feet. Strength improved & was to receive final IVIG as outpatient. D/C to home to complete antibiotics for sinusitis. 9/3/08-ER records received for DOS 8/11/08-presented to ED with C/O servere headache which began 10 days ago. Today noticed numbness in toes which progressed up to past ankles and then into hands. Noticed feet were weak. Abnormal sensation just above umbilicus. 2/20/09-records received-for DOS 8/11/08-presented with C/O numbness in toes porgressed up past ankles and into hands, feet weak sensation absent. Headache.

Other Meds: None

Lab Data: MRI, Spinal tap, EEG LABS: MRI of brain & spine were essentially WNL. CBC & chemistry WNL CSF: WNL, c/s neg. CT head small cyst in right middle cranial fossa: probably arachnoid cyst. WNV IgG negative. 8/20/09-records received for D

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: 323865-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	30-Jan-2008	30-Jan-2008	0	02-Sep-2008	08-Sep-2008	NH		02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2549AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1266U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Abdominal pain upper, Anger, Asthenia, Ataxia, Atrophy, Blood product transfusion, Cerebellar syndrome, Depression, Dizziness, Eye movement disorder, Hyperglycaemia, Hyperreflexia, Hyporeflexia, Malaise, Mood altered, Motor dysfunction, Muscular weakness, Myoclonus, Nausea, Opsoclonus myoclonus, Oropharyngeal pain, Sensory loss, Social avoidant behaviour, Steroid therapy, Tremor, Vertigo, Wheelchair user

Symptom Text: In December of 2007 and January of 2008, patient became withdrawn and concerned that she did not lose weight despite diet and exercise, and she started having opsoclonus. She had no illnesses around the time of onset of those symptoms. Brother had been quite ill (thought initially to be meningitis, but turned out to be unknown) and is now better. She had a meningitis vaccine and HPV vaccine at the time that she started to be withdrawn. Over the course of 1-2 weeks she became ataxic, and had very "jumpy arms". This myoclonus spread to her legs such that she could not walk. She denied headaches, nausea, and or vomiting. No muscle aches or leg pain. No tinnitus or hearing loss. At the time of a February 11, 2008 admission she had severe opsoclonus, myoclonus, dysmetria, and perhaps a wide amplitude tremor. An extended evaluation was started looking for a neuroblatoma and a ganglioneuromal, mitochondrial disease, inflammatory diseases, and other diseases. There were a few abnormal lab results, which normalized later. The lactate normalized only after starting mitochondrial vitamins. No evidence of a ganglioneuroma or neuroblastoma was found. Blood mitochondrial mutations were sent and later returned as normal. Because the lactate was high, we added Thiamine 25 mg twice daily and riboflavin 50mg twice daily, CoQ, and Keppra was started later at 1mg/kg/day, and advanced as tolerated, then lowered when she started feeling nauseated. She received steroid x 1 week courses, with marked hyperglycemia, but no improvement. She received IVIG, then sent to hospital. She was discharged from hospital with improved opsoclonus, but still unable to walk or reach easily. She returned to hospital for a second course of IVIG. After that, the mitochondrial meds were stopped, she remained unable to walk, and had variable but usually less opsoclonus. Physical therapists noted some weakness and atrophy, and she had one episode when she would fall to the left side when the tuning fork was put near her left ear. She had

Other Meds:

Lab Data: Blood lactate 6.6, followed by 5.4 both in free flowing blood, without tourniquet; Pyruvate, requested but not obtained; CPK 103; Blood mitochondrial mutations, normal 14 mutations and 3 deletions, including MERRF mutations; Urine spot HVA:

History: History derived from review of medical record, several of my prior exams and visits, and discussion with PCP; Seasonal allergies.' PMH: Asthma. Allergic to Augmentin and Benadryl.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323869-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		02-Sep-2008	09-Sep-2008	GA		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0629X	1	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	UFU52AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0843X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Crying, Gaze palsy, Musculoskeletal stiffness

Symptom Text: Patient was having vaccines administered- HPV, then ADACEL, then VARIVAX - all left arm. During last injection (VARIVAX), patient stated, "I'm going to have a seizure" then all four extremities stiffened -> eyes rolled back about 15 seconds -> immed. recovered alert, crying

Other Meds: Trileptol 15 mg qd

Lab Data: None of note patient followed by neurologist for seizure disorder; takes Trileptol.

History: Seizure disorder

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323870-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Aug-2008	27-Aug-2008	0	02-Sep-2008	09-Sep-2008	LA		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB253BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0063X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Fatigue, Rash papular, Rash pruritic

Symptom Text: Raised rash on face and neck about 3-4 hrs after vaccines administered. Pruritic. Plans to go to PMD today. And shortness of breath, difficulty breathing, extreme fatigue.

Other Meds: Advair; Singulair; Vera Mist; Pataday drops

Lab Data:

History: Allergy shots with doctor

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323872-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Aug-2008	Unknown		02-Sep-2008	09-Sep-2008	CT		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: "Patient" has asymmetry of skin of lower axillary area (fuller on right than left). Given extent of asymmetry an ultrasound of the area was oveder, which was normal.

Other Meds:

Lab Data: Ultrasound as above

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323873-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Aug-2008	15-Aug-2008	0	02-Sep-2008	09-Sep-2008	TX		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	AC52B027AA	1	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2429AA	1	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	0319X	2	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1968U	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Syncope

Symptom Text: Patient fainted in lobby 5-8 minutes after immunization. Positioned on back with knees up. Came around in two mts. BP was 94/64 - in 1/2 hour BP was 103/72, color back to normal.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323880-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
55.0	F	26-Oct-2006	Unknown		02-Sep-2008	03-Sep-2008	MN		03-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: MD order HPV for pt, she recieved her first dose 10/26/06, 2nd dose on 1/5/07, 3rd dose on 4/27/07

Other Meds:

Lab Data:

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **323882-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-Aug-2008	11-Aug-2008	0	02-Sep-2008	03-Sep-2008	PA		03-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Dizziness, Gait disturbance, Headache, Hypoaesthesia, Nausea, Neck pain, Paraesthesia, Vision blurred

Symptom Text: headache, chestpain, nausea and dizziness immediately following receiving the 2nd HPV vaccine on 8/11/08 in the left deltoid muscle.Seen in emergency room on 8/26/08 with persistent symptoms and new symptoms: numbness and tingling on the left arm, unstady gait, neck pain, blurry vision and chest pain.In ER given ketolac and IV fluids. U/A negative, CMP normal, LFTs normal, CK normal CBC and didd normal. Urine pregnancy normal, rapid strep Neg. CT Brain without contrast negative. Symptoms resolved by 9-2-08

Other Meds: Metformin

Lab Data: U/A negative, CMP normal, LFTs normal, CK normal CBC and didd normal. Urine pregnancy normal, rapid strep Neg. CT Brain without contrast negative. on 8-26-08

History: Migraine headaches, Asthma, Seasonal allergies, PCOS, Morbid obesity

Prex Illness: No

Prex Vax Illns:

Vaers Id: **323893-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Aug-2008	29-Aug-2008	2	02-Sep-2008	03-Sep-2008	CA		03-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1486U	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2430AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52BO19AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pain in extremity, Skin warm, Swelling

Symptom Text: Right and Left upper arm with round,red, slightly raised, warm and painful areas. Temp 98.4. Client reports that last noc both arms hurt more, today 8/29/08 @ 3:20pm the pain is still present but less.

Other Meds: PPD 08/27/08

Lab Data:

History: Unknown

Prex Illness: None noted

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323903-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	27-Aug-2008	27-Aug-2008	0	02-Sep-2008	03-Sep-2008	CA		03-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB289BA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0843X	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2659AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B021AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0272X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: syncopal episode after receiving 5 IZs & PPD

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **323907-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Aug-2008	21-Aug-2008	3	02-Sep-2008	09-Sep-2008	PA		10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal pain

Symptom Text: Developed posterior shoulder pain within 3 days of administration. No injection site reaction.

Other Meds: Allegra

Lab Data: None

History: Seasonal allergies

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323908-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Aug-2008	28-Aug-2008	0	02-Sep-2008	09-Sep-2008	TN		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Left arm	Unknown	
	TD	SANOFI PASTEUR	U1954CD	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2661AA	0	Right arm	Unknown	
	IPV	SANOFI PASTEUR	A1060	3	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	0432X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature, Convulsion, Headache, Pharyngeal oedema, Syncope

Symptom Text: Temperature was 97.7 after patient got her injection; she fell into a seizure and fainted complaining of headache, and throat swelling; Patient was sent to the ER by the physician.

Other Meds:

Lab Data:

History: none

Prex Illness: Well check up

Prex Vax Illns:

Vaers Id: 323910-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Jul-2008	18-Aug-2008	28	02-Sep-2008	09-Sep-2008	GA		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysmenorrhoea, Fatigue, Metrorrhagia, Nausea, Oligomenorrhoea, Vomiting

Symptom Text: 7/21/08 received HPV injection - 8/16/08 pelvic cramp. 8/18/08 - 8/25/08 menstrual cycle with severe cramping, fatigue, nausea and vomiting x 1 day. Menstrual cycle lasted 7 days instead of usual 3 days. 8/28/08 spotting for 1 day only.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323913-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	17-Sep-2007	17-Sep-2007	0	02-Sep-2008	09-Sep-2008	NY		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Somnolence

Symptom Text: Patient had reaction after Gardasil, a sensation where her left arm became numb. She also was reported to be sleepy and had a decreased appetite. Her symptoms disappeared after 4 days with no permanent sequelae.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323917-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Aug-2008	28-Aug-2008	6	02-Sep-2008	09-Sep-2008	VT		09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2686AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0381X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pharyngolaryngeal pain, Rash

Symptom Text: Please see hospital notes - skin rash. Patient has developed a rash over the last 2 hours on her arms and left knees. She is now complaining of throat pain. She got her first GARDASIL shot and her meningitis vaccine about 7 days ago and her mom says when patient was five she had a reaction to a tetanus shot 6 days after she got the vaccine. Mom is concerned.

Other Meds:

Lab Data:

History: ?Tetanus toxoid

Prex Illness: None

Prex Vax Illns: ~DTaP (no brand name)~5~4~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 323969-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	13-Aug-2008	13-Aug-2008	0	03-Sep-2008	04-Sep-2008	NY	WAES0808USA05031	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1426F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Constipation, Diarrhoea, Dizziness, Gastritis, Vomiting

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a 0.5 dose of 9/9/08-GARDASIL IM. Secondary suspect therapy included VARIVAX. About one week later, the patient was hospitalized with severe abdominal pain. She has since been released. The patient sought unspecified medical attention. At the time of reporting, the outcome of the patient was unknown. Additional information has been requested. On the evening of 13-AUG-2008 the patient started to vomit. The next day on 14-AUG-2008, the patient was complaining of abdominal pain and vomiting. She was taken to the ER that night. The patient was not admitted to the hospital at that time. The patient was sent home on the night of 14-AUG-2008. On 15-AUG-2008 the patient developed diarrhea and complaint of abdominal pain and vomiting. The patient was admitted to the hospital on 16-AUG-2008 and discharged on 18-AUG-2008 (diagnosis not provided). 12/22/08-records received for ED visit 8/14/08 C/O abdominal pain, vomiting waxing and waning, began day of presentation to ED. Difficulty moving bowels. Dizzy when has pain. Constipation. DX: Gastritis.

Other Meds: Unknown

Lab Data: Unknown 9/9/08-Urine and blood work (unspecified) were performed (results came back normal). 12/22/08-records received-KUB negative.

History: Unknown 9/9/08- The physician also noted that the patient does have a history of abdominal pain and that the patient had been on Miralax for quite some time.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323970-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		03-Sep-2008	04-Sep-2008	--	WAES0808USA05001	04-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a consumer at a public exhibit concerning her daughter who was vaccinated with a dose of GARDASIL. Subsequently the patient experienced seizure. The patient's mother reported that the patient would have to take seizure medication "for the rest of her life". At the time of this report, the event persisted. Upon internal review, seizure was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **323971-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	16-Oct-2007	06-Apr-2008	173	03-Sep-2008	04-Sep-2008	FR	WAES0808USA04956	04-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0251U	1	Gluteous maxima	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Back pain, Drug administered at inappropriate site, Inappropriate schedule of drug administration, Paraesthesia, Paraplegia

Symptom Text: Information has been received from a physician concerning a female who on 31-JUL-2007 was vaccinated with the first dose of GARDASIL (lot # 1341F batch#NF12410) I.M. right gluteal. On 16-OCT-2007, was vaccinated with the second dose of GARDASIL (lot # 0251 batch# NF56480) I.M. right gluteal and on 20-MAY-2008, was vaccinated with the third dose of GARDASIL (lot # 1113U batch# NH10080). On 06-APR-2008, the patient presented acute back pain as a case of emergency. The patient was treated with diclofenac and osteopathic therapy and the symptoms fully resolved. On 11-APR-2008, the back pain recurred, accompanied by weakness and paresthesia of the legs. The patient was admitted to the outpatient department of the hospital where the suspicion of paraparesis was established. The differential diagnosis of conversion disorder was assumed. After a chiropractic treatment the patient recovered. On 14-APR-2008, the patient was admitted to hospital due to relapsing symptoms. Cranial MRI, EEG, CSF showed no pathologies. Functional paraplegia was diagnosed. Despite ongoing symptoms the patient was vaccinated with a third dose of GARDASIL. In June-2008, the symptoms relapsed and the patient was hospitalized on 10-JUN-2008 again. Suspicion of severe conversion disorder with recurrent hysterical paralysis was diagnosed. The physician did not assess a causal relationship with GARDASIL vaccinations (second and third doses). At the time of reporting the outcome was unknown. Other business partner numbers included E2008-07850. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, Normal; electroencephalography, Normal; cerebrospinal fluid analysis, Normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 323972-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	19-Mar-2008	28-Apr-2008	40	03-Sep-2008	04-Sep-2008	--	WAES0808USA04005	25-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Anticoagulant therapy, Antiphospholipid antibodies positive, Antiphospholipid syndrome, Axillary vein thrombosis, Chest pain, Deep vein thrombosis, Dyspnoea, Musculoskeletal pain, Oedema peripheral, Pain in extremity, Paraesthesia, Pulmonary embolism, Sensory disturbance, Subclavian vein thrombosis, Vaccine positive rechallenge, Vena cava thrombosis

Symptom Text: Information has been received from an office manager, concerning a 25 year old female patient who on an unspecified date was vaccinated with the second dose of GARDASIL. The patient experienced pain and swelling in her left arm after the vaccine was given. The patient was given GARDASIL in another clinic but she presented to the physician's office with this reaction. The reporter stated the patient had pain and swelling after the first dose but was not this severe. The pain and swelling lasted one week after this second dose was given. The patient was sent to the hospital and admitted. The patient recovered on an unknown date. The patient sought medical attention at physician's office. There was no product quality complaint. Follow up information has been received from medical records and the office manager, concerning a 25 year old female patient who on an unknown date was vaccinated with 0.5 mL of the second dose of GARDASIL IM. On 01-MAY-2008, the patient was seen in office for swelling and pain in arm which began on 28-APR-2008. The patient was sent over for ultrasound and it was determined she had a hypoechoic thrombus that completely occluded and moderately expanded the left subclavian vein, axillary vein, mid and proximal basilic vein, mid and proximal brachial vein and proximal - most cephalic vein. No blood flow identified within these particular structures. The thrombus did not extend distal to the antecubital fossa. The patient was hospitalized for an unspecified number of days. Approximately, on 05-MAY-2008 (also reported as one week) the patient was recovered. The reporter considered the event to be life-threatening and an other important medical event. No further information is expected. All available medical records will be provided upon request. 9/15/2008 MR received from PCP including some hospital records. Pt presented to PCP on 4/28/08 with c/o shoulder pain x 5 days, tingling fingertips. Pain from shoulder to elbow with movement. DX: LUE radiculopathy. Sent for X-ray and

Other Meds: Unknown

Lab Data: ultrasound - acute thrombus present within the left subclavian, axillary, basilic, brachial, proximal cephalic veins. Labs and Diagnostics: X-ray shoulder (-). CT shoulder (-). Doppler/duplex exam of LUE (+) for thrombus within L subclavi

History: Unknown. PMH: Spondylolisthesis at L5, tonsillectomy 1997, cholecystectomy 3/08. Oral contraceptives.

Prex Illness:

Prex Vax Illns:

Vaers Id: **323973-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	02-Nov-2007	Unknown		03-Sep-2008	04-Sep-2008	FR	WAES0808USA05119	04-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Contraception, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with her second dose of GARDASIL (Lot number not reported) into the deltoid muscle on 02-NOV-2007. Despite use of unspecified hormonal contraceptives the patient fell pregnant. The date of her last menstrual period was on 19-OCT-2007. The patient had a spontaneous abortion after 6 to 8 week (exact date could not be provided by the physician). No hospitalization. Spontaneous abortion was considered to be an other medical important event. Other business partner numbers included: E2008-07954. No further information is available.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 19Oct07)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **323987-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-Aug-2008	13-Aug-2008	0	03-Sep-2008	11-Sep-2008	MT		11-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB291CA	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	UF452AA	5	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2660BA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	00063X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Fall, Muscle rigidity

Symptom Text: Was in sitting position; fell onto mother 3 minutes after shots. Jerking movements of both upper limbs, rigidity of body; lasted 30 seconds; then asked what happened

Other Meds: None

Lab Data: CBC and Comprehensive Metabolic Panel done (see results). 08/13/2008; Random Glucose 100 mg/dL (70-110); Blood urea Nitrogen 8 mg/dL (7-18); Creatinine 0.6 mg/dL (0.6-1.0); Sodium Level 138 mEq/L (136-145); Potassium Level 4.0 mEq/L (3.5-5.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **323999-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	U	22-Aug-2008	22-Aug-2008	0	03-Sep-2008	10-Sep-2008	NC		10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB234BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	174OU	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Confusional state, Convulsion, Immediate post-injection reaction, Somnolence, Syncope

Symptom Text: Immediate syncope with brief seizure of few seconds. Obeserved for 20 minutes then back to normal. Went home and mom called back later that afternoon stating child was very sleepy, confusional. Advised to go to ER. Mom observed at home and stated child had been up late the night prior and felt that was the issue. She stated she seemed ok.

Other Meds:

Lab Data:

History: acne, migrane headaches, left ankle torasl colination

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324001-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Aug-2008	15-Aug-2008	1	03-Sep-2008	10-Sep-2008	WI		11-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0338X	2	Unknown	Subcutaneously	MNQ
MNQ	SANOFI PASTEUR	U2616AA	1	Unknown	Intramuscular	TDAP
HPV4	MERCK & CO. INC.	0250X	3	Unknown	Intramuscular	VARCEL
TDAP	SANOFI PASTEUR	C2863AA	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Accidental overdose, Inappropriate schedule of drug administration

Symptom Text: Health Department administered Menactra, Adacel, and 2nd Varvax on 4/17/08. Client then presented to Dr. office with office for physical, and was vaccinated with additional doses of all three vaccines and a fourth dose of HPV on 8/14/08. This resulted in 4 Gardasil, 2 Menactra, 2 Adacel, and 3 Varivax vaccines administered. Parent stated that MD office administered vaccines, despite patient instructing them that she already received these vaccines in April at the Health Department Clinic. Parent was verbally upset and wanted to report this to the health department. Health Department is therefore reporting this error on behalf of the parents request. Vaccines were entered into the Immunization Registry following the 4/17/08 clinic, and were present at the time of re-vaccination at the MD office. Parent did not report any adverse reactions at the time of the call which was 24 hrs after the duplicate adminstration.

Other Meds:

Lab Data:

History: None

Prex Illness: none

Prex Vax Illns:

Vaers Id: **324002-1 (D)** **Related reports:** 324002-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	26-Feb-2008	12-Mar-2008	15	03-Sep-2008	04-Sep-2008	OH		05-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	2	Right arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Circulatory collapse, Dehydration, Diabetic ketoacidosis, Pulmonary embolism, Sudden death

Symptom Text: Sudden death occured on 3/12/2008. 9/4/08-records received-Cause of Death:cardiovascular collapse as a consequence of pulmonary emboli, dehydration and diabetic ketacidosis.

Other Meds: none

Lab Data: Full Autopsy done. Immediate cause of death was massive pulmonary embolus. Secondary was Type 1 Diabetes (previously undiagnosed). Vitreous Humor glucose was 767 9/4/08-records received- Vitreous glucose 767.

History: none

Prex Illness: none noted

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324002-2 (D)** **Related reports:** 324002-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		11-Sep-2008	12-Sep-2008	OH	WAES0809USA00836	12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: DIED, LIFE THREATENING, SERIOUS

MedDRA PT Autopsy, Blood glucose increased, Death, Pulmonary embolism

Symptom Text: Information has been received from a physician concerning a 16 year old female who on an unspecified date, was vaccinated with the first dose of GARDASIL. On an unspecified date, was vaccinated with the second dose of GARDASIL. On an unspecified date, was vaccinated with the third dose of GARDASIL. Three weeks after the third vaccination, the patient had pulmonary embolus and died. Her "autopsy revealed her blood sugar was elevated and death occurred due to the pulmonary embolism." Pulmonary embolus and blood sugar elevated were considered to be life-threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324014-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-Jan-2008	21-Jan-2008	0	03-Sep-2008	10-Sep-2008	CA		11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness, Injection site pain, Lymphadenopathy, Malaise, Oral herpes

Symptom Text: Within 24 hours my daughter felt really sick, similar to the flu. A small lymph node on her lower jaw area swelled up (appeared like a cyst under her jaw) and she got what appeared to be a large fever blister on her lip, only it didn't hurt. She has never had fever blisters (herpes simplex) before. Her symptoms lasted a few days. My daughter rarely gets very sick, even with common cold/flu, so this was very peculiar. Fortunately, the symptoms only occurred after her first shot, which she said hurt going in. The final two shots were not painful and she did not get sick. Gardasil.

Other Meds:

Lab Data: Doctor's office said her symptoms were not a result of the shot. Telephone call only.

History: None.

Prex Illness: None.

Prex Vax Illns:

Vaers Id: **324033-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	28-Jul-2008	29-Jul-2008	1	03-Sep-2008	15-Sep-2008	NC		16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Migraine, Phonophobia, Photophobia

Symptom Text: Severe throbbing headache - mostly one-sided with photophobia and sensitivity to sound started. Diagnosed as migraine. Required pain shot. Patient never had a migraine before.

Other Meds: Yaz; Zyrtec

Lab Data: CT of head reported neg; CBC, Thyroid fx's and basic metabolic panel and exam neg

History: Ceclor and Bactrim; Gilbert's

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324037-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Mar-2008	23-Mar-2008	0	03-Sep-2008	11-Sep-2008	MA		11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Neck pain, Vaccine positive rechallenge

Symptom Text: Received 1st vaccine, developed severe headache (possible migraine); Patient never had history of heachache, migraines before vaccine. Headache lasted 3 weeks. Received 2nd vaccine, developed severe headache, lasting for 3 days. Both headache developed within 24-48 hours. Head pain accompanied with posterior neck pain usually over back of head from neck pain

Other Meds: Aviane

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **324039-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Aug-2008	27-Aug-2008	2	03-Sep-2008	11-Sep-2008	WI		11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2551AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Lymphadenopathy, Pyrexia, Vomiting

Symptom Text: + fever starting 48 hours after the shots. + HA, + emesis and dizziness 3 hours after shots (emesis x 1). + enlarged anterior cervical nodes.

Other Meds: None

Lab Data: None

History: H/O SVT

Prex Illness: None

Prex Vax Illns:

Vaers Id: **324049-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Jun-2008	17-Jun-2008	0	03-Sep-2008	11-Sep-2008	MA		11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2560AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Muscular weakness, Pyrexia

Symptom Text: Mom reported on 8/21/08 patient feeling dizzy, having difficulty breathing, muscle weakness and fever; temperature 103.7 approximately 12 hours after vaccines given lasting for 24 hours.

Other Meds: None

Lab Data: None

History: Allergies: Septra. Dx: Gilles de la tourette's syndrome, OCD, obesity.

Prex Illness: No

Prex Vax Illns:

Vaers Id: **324051-1** **Related reports:** 324051-2; 324051-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	08-Jul-2008	22-Jul-2008	14	03-Sep-2008	16-Sep-2008	PA		16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2623AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Anaemia, Arthralgia, Asthma, Bone marrow failure, Breath sounds abnormal, Bronchitis, Bronchospasm, Chest discomfort, Condition aggravated, Cough, Decreased appetite, Dyspnoea, Eructation, Exercise tolerance decreased, Fatigue, Headache, Hypoaesthesia, Lymph node palpable, Lymphadenopathy, Malaise, Muscle fatigue, Myalgia, Nausea, Pain, Paraesthesia, Pharyngeal erythema, Pharyngitis, Pyrexia, Sinus congestion, Steroid therapy, Upper respiratory tract congestion, Viral infection, Wheezing

Symptom Text: GARDASIL and MENACTRA were given 7/8/08. First adverse symptoms appeared around 7/22/08. Numbness and tingling extending down left arm were noted. Nausea, headache, fatigue, arthralgias throughout body were noted on 7/23/08. Complaints of fevers, swollen glands in neck, belching, increased nausea, extreme muscle fatigue on exertion, shortness of breath leading to bronchospasms and asthma type symptoms continued with progression through current day of 8/27/08. Originally treated with antibiotics around 7/28/08 thinking it was bronchitis. Tested for mono, CBC done with mono spot which was negative. Progression continued and course of MEDROL dose pack given for 5 days for breathing difficulty and bronchospasms. Inhaler added 8/7/08. Extreme fatigue is interfering with daily live. Breathing difficulties are interfering with athletics as she is a division I soccer athlete unable to currently participate fully due to fatigue and breathing difficulties. 9/12/08 Reviewed PCP medical records of 7/8/08-8/28/2008. FINAL DX: Records indicate patient was in good health on day of vaccination. RTC 7/28/08 w/malaise, aches, red throat, lymph node swelling. Dx w/pharyngitis & tx w/antibiotics. RTC 8/4/08 w/cough, SOB & fatigue. Tx w/steroids. 8/7/08 contacted office w/wheezing & tx w/inhaler. 9/23/08 Reviewed student health services records of 8/27-9/10/08. FINAL DX: persistent fatigue, myalgias, bronchospasm, anemia Records reveal patient experienced viral infection & bronchitis approx July, 2008 & tx w/antibiots, steroids & inhaler. When seen 8/27 had SOB, chest/head congestion, chest tightness, exhaustion & decreased appetite. Labs revealed mild bone marrow suppression, decreased peak flos & decreased aeration. Tx w/additional meds. RTC 9/10 w/persistent extreme fatigue, myalgia & bronchospasm. 4/13/09 received additional student health services records of 11/24/08-3/25/2009. FINAL DX: fatigue, myalgias, bronchospasm, decreased exercise performance, etiology unclear Records reveal patient experienced

Other Meds: None

Lab Data: CBC, MONO SPOT negative; Spirometer LABS: H/H 11.2/33.5(L), absolut lymphs 1116(L). . CK 257(H). Additional labs & CXR were ordered but not reported. Viral c/s neg. CK elevation (thought to be related to weight lifting).

History: SVT, requiring no treatment

Prex Illness: None

Prex Vax Illns: abnormal bleeding~HPV (Gardasil)~1~20~Sibling

Vaers Id: **324051-2 (S)** **Related reports:** 324051-1; 324051-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	08-Jul-2008	22-Jul-2008	14	08-Sep-2008	09-Sep-2008	PA	WAES0809USA00006	23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Chest discomfort, Dyspnoea, Fatigue, Headache, Hypoaesthesia, Lymphadenopathy, Muscular weakness, Myalgia, Nausea, Paraesthesia, Pyrexia

Symptom Text: Information has been received from a nurse concerning her daughter, a 18 year old female patient with a history of supraventricular tachycardia, who on 08-JUL-2008 was vaccinated with a dose of GARDASIL (lot# 660555/0279X) I.M. into left arm. Concomitant therapy included MENACTRA. On 22-JUL-2008, the patient developed numbness and tingling of her left arm and fingers. She then developed fever, nausea, headache, widespread myalgia and cervical lymphadenopathy. On 26-JUL-2008, the patient experienced tightness in her chest and shortness of breath. The patient was examined by the physician on 28-JUL-2008 and was prescribed a "Z-pack" ZITHROMAX. A mono test and complete blood count were normal. On 01-AUG-2008, a MEDROL dose pack and PROVENTIL inhaler were added. The patient began to experience extreme fatigue and bilateral lower extremity muscle weakness. She was unable to participate in team sports and a soccer competition because of her incapacity. The patient was examined by an unspecified physician at the college on 22-AUG-2008. A repeat mono test and complete blood count were normal. The patient has a follow-up appointment scheduled for 05-SEP-2008. The patient's numbness and tingling of her left arm and fingers, tightness in her chest, shortness of breath, fever, nausea, headache, widespread myalgia, cervical lymphadenopathy, extreme fatigue and bilateral lower extremity muscle weakness persisted. Numbness and tingling of her left arm and fingers, tightness in her chest, shortness of breath, fever, nausea, headache, widespread myalgia and cervical lymphadenopathy, extreme fatigue and bilateral lower extremity muscle weakness were considered to be disabling by the nurse. No further information is available.

Other Meds:

Lab Data: Epstein-Barr virus, 07/28?/08, Normal; Complete blood cell, 07/28?/08, normal; Epstein-Barr virus, 08/22?/08, Normal; Complete blood cell, 08/22?/08, normal.

History: Supraventricular tachycardia

Prex Illness:

Prex Vax Illns:

Vaers Id: **324051-3** **Related reports:** 324051-1; 324051-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	08-Jul-2008	11-Jul-2008	3	24-Mar-2009	25-Mar-2009	PA		25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2623AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0279X		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Back pain, Bronchospasm, Influenza like illness, Paraesthesia, Pyrexia

Symptom Text: Persistent weakness, Fever, Bronchospasm, Recurring bouts of flu-like illness, parasthesias, low back pain

Other Meds:

Lab Data: Multiple blood tests showed no specific diagnoses, MRI back-negative

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324056-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Aug-2008	19-Aug-2008	1	03-Sep-2008	11-Sep-2008	GA		11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1490U	1	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Local reaction

Symptom Text: Local reaction onset x 24 hours after vaccination. Cool compresses/OTC antihistamine.

Other Meds:

Lab Data: Local reaction

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **324058-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Aug-2008	22-Aug-2008	0	03-Sep-2008	11-Sep-2008	WA		11-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2977AA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2665AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	X6220	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB243AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Headache x5 days

Other Meds:

Lab Data: none

History: None; Allergy = Penicillin

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324063-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	29-May-2008	Unknown		03-Sep-2008	11-Sep-2008	NC		11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	U2354CA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1968U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Patient was given DTaP instead of Tdap.

Other Meds:

Lab Data: N/A

History: PCN

Prex Illness: None

Prex Vax Illns:

Vaers Id: **324064-2** **Related reports:** 324064-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	23-Oct-2008	--	WAES0808USA04448	23-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a nurse concerning a teenager female who was vaccinated with all 3 doses of GARDASIL vaccine (yeast) and contracted the high risk type of HPV. It is unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324065-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Aug-2008	16-Aug-2008	1	03-Sep-2008	11-Sep-2008	CO		11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB264AA	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U26588AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0843X	0	Left leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Muscle spasms, Neck pain, Torticollis, Vertigo

Symptom Text: Torticollis, vertigo, back and neck pain with significant muscle spasm

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **324068-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	31-Jul-2008	31-Jul-2008	0	03-Sep-2008	11-Sep-2008	IN		11-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1447F	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure, Cold sweat, Dizziness, Heart rate, Pallor

Symptom Text: Felt faint, skin clammy, BP 98/60, pale, pulse 76. Cool packs placed on forehead and back of neck - laid down on exam table and rested.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **324114-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jun-2007	Unknown		04-Sep-2008	05-Sep-2008	FR	WAES0710AUS00108	05-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaginal ulceration

Symptom Text: Information has been received as part of a business agreement (manufacturer's report number: unknown). The information was received via a mail list discussion group set up by a center. A Program Officer of a district division General Practice (GP) reported that, in 2007, 'several months ago' (in follow up approximately June 2007), a non-sexually active female patient, with an infected toe and a history of negative Herpes Simplex antibody tests in May 2008, was vaccinated with GARDASIL on approximately June 2007. The patient developed vaginal ulceration a few days after the vaccination with GARDASIL. Concomitant therapy included included LEVLEN ED and KEFLEX. Herpes simplex PCR swabs were done 2 times and were negative each time. In follow up Herpes Simplex antibody tests were done 2 x with negative results. This is one of several reports from the same source. Additional information was received from the physician on 26-AUG-2008. It was reported that the patient has one sexual partner and developed severe genital ulceration which was described as deep punched out ulcers not typical of herpes virus. At the time of reporting the patient had recovered from the genital ulceration. Severe genital (vaginal) ulceration was considered as an other medical event by the reporting physician. Additional information is not expected.

Other Meds: cephalexin, 13Jun07 - 19Jun07; ethinyl estradiol (+) levonorgestrel

Lab Data: diagnostic laboratory test, 20Jun07, NAD; Herpes simplex virus culture, 15Jun07, negative; serum Herpes virus Ab, 20Jun07, negative; Herpes simplex virus culture, 20Jun07, negative; serum Herpes virus Ab, 27Jun07, negative; serum Herpes vir

History:

Prex Illness: Not sexually active; Contraception; Infected toe

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324115-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Jul-2008	Unknown		04-Sep-2008	05-Sep-2008	--	WAES0808USA05392	05-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Malaise, Pain, Pharyngitis, Pyrexia, Swelling

Symptom Text: Information has been received from a certified nurse midwife concerning a 14 year old female who on 10-JUL-2008 was vaccinated with a second 0.5 ml dose of GARDASIL by intramuscular injection (lot number and injection site not reported). Several days later, the patient developed pharyngitis, pain (unspecified), swelling (unspecified), fever, dizziness and malaise. The patient was hospitalized for several days. She was treated with a MEDROL dose pack. At time of this report, the patient's events persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324116-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-May-2008	01-Jun-2008	31	04-Sep-2008	05-Sep-2008	FR	WAES0808USA05399	05-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Information has been received from a health authority (reference number ES-AGEMED-716903335) concerning a 17 year old female with no other relevant history who in May 2008 was vaccinated intramuscularly with a dose of GARDASIL (exact date, batch number and site of administration not reported). One month after in June 2008, the patient presented genital warts. Outcome was unknown. The case was considered medically relevant by the reporter. Presented genital warts was considered to be an other important medical event. Other business partner numbers included E2008-08048. No further information is available. Case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324125-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Aug-2008	28-Aug-2008	1	04-Sep-2008	09-Sep-2008	PA		15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0485X	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0571X	1	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chest pain, Dizziness, Non-cardiac chest pain, Tremor

Symptom Text: 24 hours after immunizations, developed L sided chest pain, worse on pressure being applied to the L parasternal area. 28 hours after immunization, involuntary tremors for 3 hours. 9/12/08 Reviewed hospital medical records of 8/28-8/29/08. FINAL DX: chest pain due to skeletal muscle injury; tremors of unknow origin Records reveal patient experienced intermittent left sided substernal chest pain day after vaccinations. Developed dizziness & trembling. Progressed well & was d/c but during d/c had recurrent chest pain. Repeat labs & EKG WNL & d/c to home.

Other Meds: None

Lab Data: CK elevated at 725 with normal Troponin I LABS: CXR WNL. Repeat EKG WNL. Initial CK 721, CK-MB 10.5(H). Repeat CK 633, CK-MB 6.3. ALT 12(L). Blood c/s neg.

History: Allergies to hot dogs, strawberries, apples, and bananas. PMH: Asthma, bronchitis, recurrent sinusitis last one approx 2 wks prior to admit, scoliosis.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **324132-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	22-Aug-2008	26-Aug-2008	4	04-Sep-2008	10-Sep-2008	VA		10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TD	UNKNOWN MANUFACTURER	NULL	6	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	NULL	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anorexia, Anxiety, Burning sensation, Diarrhoea, Dissociative disorder

Symptom Text: Vaccine HPV received on 8-22-08 at CVS pharmacy. On 8-26-08 developed anxiety, dissociative type feelings, burning sensation in head, appetite loss, loose stools. Symptoms gradually improved over 5 days.

Other Meds: Yasmin

Lab Data:

History: Note: HPV vaccine given at CVS pharmacy at about 3 pm on 8-22-08 and Td vaccine given at Virginia Department of Health same day at 12:30 pm.

Prex Illness: Mild upper respiratory infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324139-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Sep-2008	03-Sep-2008	0	04-Sep-2008	10-Sep-2008	TN		10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema of eyelid, Eyelid oedema

Symptom Text: BILATERAL UPPER EYELIDS ERYTHEMA AND SWELLING FIRST NOTED AT 10:30 PM 09/03/08, WORSENED UPON WAKING THE AM OF 09/04/08. PATIENT EXAMINED BY DOCTOR AND ADVISED TO USE OTC BENADRYL 25 MG Q 6 HOURS PO AND COLD COMPRESSES TO EYES.

Other Meds: OTC MULTIVITAMIN

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: 324141-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Apr-2007	Unknown		04-Sep-2008	09-Sep-2008	MA		12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	C2609AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0263U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Anxiety, Chest pain, Chills, Dizziness, Dysuria, Eye pain, Gait disturbance, Headache, Hyperreflexia, Hyperventilation, Influenza like illness, Multiple sclerosis, Myalgia, Photophobia, Pyrexia, Vision blurred

Symptom Text: Julissa received her 1st HPV vaccine on 4/11/07 (Merck 0263U), 2nd HPV vaccine on 7/5/07 (Merck 0279X), and her 3rd HPV vaccine on 7/11/08 (Merck 0279X). She also received her MCV4 on 7/5/07 (Sanofi Pasteur u2222aa) and Tdap on 4/11/07 (GSK C2609AA). At her annual physical on 8/21/08, she described dizzyness, headache, blurry vision, eye pain, and gait disturbance. She subsequently had a head CT and head MRI. The head MRI was suspicious for multiple sclerosis, and on 8/23/08 she was hospitalized at Brigham and Women's Hospital, which was a 7 day hospitalization and she was given the diagnosis of multiple sclerosis. In retrospect, Julissa's mother feels that her symptoms described at her annual physical had been had been going on for some time, and had been exacerbated each time she had an HPV vaccine. It is not entirely clear to me how long she has been symptomatic with her MS. 11/10/08-records received for DOS 8/23-8/29/08-DC DX: Multiple sclerosis. Anxiety. Presented with dizziness, generalized weakness and weakness of lower extremities. Summer 4/2008 after receiving HPV4 C/O pain in right eye and blurriness, light bothered the eye and had floaters. Significant fatigue. Two months prior developed flu-like symptoms with muscle aches, headaches, low grade chills and fever. Seen in ED normal labs and thought to had a viral infection. Week later developed abdominal pain and burning with urination. Urinary tract infection. Developed unsteady walking and increased reflexes in legs.

Other Meds: Lo/Ovral

Lab Data: Head MRI 8/22/08: "Findings: Multiple periventricular and subcortical white matter T2 hyperintense lesions are present many of which have the perivenular morphology perpendicular to the lateral ventricles. The largest lesion is located

History: none 11/10/08-records received-PMH: intussusception. Oral contraception.

Prex Illness: a wart

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324146-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Jul-2008	18-Jul-2008	0	04-Sep-2008	10-Sep-2008	AZ	AZ0813	10-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB284DA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0523X	1	Right arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B018CA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2639AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Heart rate normal, Hypotonia, Loss of consciousness, Syncope, Tremor

Symptom Text: Received Tdap, varicella, Hep A, MCV, and HPV. HPV was the last vaccine; fainted approx. 1 minute after HPV given. Slumped forward, eased to floor. Regained consciousness in approx. 45 seconds. Remained shakey; 1:20pm BP 138/76, AP-96; 1:30pm 130/82, AP-98; 1:45pm 120/80, AP-80; Gatorade x3 provided; Per Dad B/P runs low, fainted before. Released to Dad at 2:20pm.

Other Meds: N/A

Lab Data: N/A

History: N/A

Prex Illness: None. Hx of fainting per father--not vaccine related.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324148-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Jul-2008	04-Jul-2008	2	04-Sep-2008	10-Sep-2008	WI		10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	4	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2574AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024EA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal pain

Symptom Text: COMPLAINED OF LEFT SCAPULAR PAIN STARTING 2 DAYS AFTER THE VACCINE AND LASTING UP TO 2 WEEKS. HOME CARE COSISTED OF DAILY ICE PACKS TO RELIEVE THE DISCOMFORT.

Other Meds: NONE

Lab Data: NONE

History: ALLEGRIC RHINITIS

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **324169-1 (S)** **Related reports:** 324169-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	22-Feb-2008	01-Jun-2008	100	04-Sep-2008	09-Sep-2008	NY		15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Anaemia, Anxiety, Arthralgia, Constipation, Convulsion, Diplopia, Dizziness, Electromyogram normal, Fatigue, Grand mal convulsion, Headache, Inflammation, Intensive care, Joint stiffness, Lumbar puncture normal, Lupus-like syndrome, Malignant hypertension, Myalgia, Neck pain, Neuropathy peripheral, Nuclear magnetic resonance imaging abnormal, Ophthalmological examination abnormal, Oral contraception, Pain, Pain in extremity, Photosensitivity reaction, Pyrexia, Rash, Renal failure, Sinusitis, Viral infection, Vomiting

Symptom Text: Headache, seizures, fever, dizziness, lupus like syndrome; Started - approximately 4 months after last injection, patient hospitalized several times placed in intensive care unit 11/17/08 records received-for DOS 7/27/08-admitted via ED for C/O abdominal pain for 5 days, no bowel movement in 5 days. Seen by PCP on 7/24/08 with no diagnosis. Seen 2 days prior in ED with negative workup. Signed out AMA. Notes for DOS 8/18/08-DX-Drug-induced lupus, questionable. Possible underlying systemic lupus. Viral syndrome, questionable viral encephalitis. Inflammatory renal disease. Myalgias with possible peripheral neuropathy. Possible reaction to vaccination. Anemia. Elevated erythrocyte sedimentation rate suggesting underlying inflammatory disease. Abdominal pain possibly secondary to renal inflammation. Presented with C/O abdominal pain, intermittent joint and neck pain and headache.Records for 8/30-9/02/08 DC DX: new-onset seizure activity. Possible benign vasculitis to inflammatory vasculitis. Possible cerebral infarct evolving nature with edema involving multiple areas of brain as per MRI. History of lupus positivity possibly drug induced lupus. Questionable viral meningitis with negative CSF. Generalized pain and fatigue. Peripheral neuropathy. Possible meningitis inflammatory nature. Renal failure with reversal. Normal creatinine. Transferred.12/8/08-records received for DOS 9/2-9/12/08-DC DX:PRES. Hypertensive Disorder. Presented with 2 month history of headahces, joint pains, and abdominal pain. Presented to ED 3 days prior with severe headache, vomiting and multiple generalized tonic clonic seizures. Headaches began end of June and diagnosed with sinusitis. Subsequently developed leg aches, wrist aches, joint stiffness and mild rash on legs. Extreme headache, double vision vomiting. Symptoms improved but developed severe stomach pains and constipation. Improved with Prednisone but symptoms began after Prednisone taper. Rheumatology thinks this is a vasculitis secondary to OCPs. Ophthalmology mild esophoria visib

Other Meds: 493 Oral Contraceptive

Lab Data: CAT Scan, Lab work 11/17/08-rcords received-negative CSF. CT negative. C-reactive protein elevated. Elevated erythrocyte sedimentation rate. Hypoalbuminemia. Positive lupus antigens. Possible cerebral infarct evolving nature with edema in

History: Seasonal allergies

Prex Illness: none

Prex Vax Illns:

Vaers Id: **324169-2 (S)** **Related reports:** 324169-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	22-Feb-2008	01-Jun-2008	100	07-Oct-2008	08-Oct-2008	--	WAES0809USA02806	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Convulsion, Dizziness, Headache, Lupus-like syndrome, Pyrexia

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. On 22-FEB-2008 a 21 year old female with seasonal allergies was vaccinated with her third dose of GARDASIL (lot # 658560/1062U) IM. Concomitant therapy included oral contraceptive. Approximately four months post the vaccination, she experienced headache, seizures, fever, dizziness and lupus-like syndrome. She was hospitalized several times and placed in intensive care unit. Computed axial tomography (CT) scan and lab work were performed. The original reporting source was not provided. The VAERS ID # is 324169. A lot check has been requested. A standard lot check investigation was performed. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the center and was released. No additional information is expected.

Other Meds: hormonal contraceptives

Lab Data: computed axial; diagnostic laboratory

History:

Prex Illness: Seasonal allergy

Prex Vax Illns:

Vaers Id: **324176-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Sep-2008	03-Sep-2008	0	04-Sep-2008	11-Sep-2008	SC		12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB171AA	0	Right arm	Unknown	MNQ TDAP
	HPV4	MERCK & CO. INC.	0843X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature, Nausea, Vomiting

Symptom Text: 9/4/08 - arrived in office. Complained of vomiting 2 hours after shot yesterday. And x1 today; nausea, T98.1

Other Meds:

Lab Data: CBC - WBC - 6200; Hgb 12.0; poly 47; Lymph 47; Mono2; SP. 1.300- Ph 6. UA, Blood 3+, Prot 2+

History:

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324187-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	02-Sep-2008	02-Sep-2008	0	05-Sep-2008	11-Sep-2008	NJ		12-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Oedema peripheral

Symptom Text: L arm swollen & decrease sensation.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324283-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		05-Sep-2008	08-Sep-2008	CA	WAES0809USA00081	08-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Monoplegia

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a second dose of GARDASIL (lot number, injection site and route not reported). Subsequently the patient's injection arm was paralyzed. The patient was seeing a neurologist. The outcome of the patient was unspecified. Upon internal review, the injection arm paralyzed is determined to be an other important medical events. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324284-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		05-Sep-2008	08-Sep-2008	--	WAES0808USA05043	08-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction

Symptom Text: Information has been received from a nurse concerning a 14 year old female who was vaccinated with the first dose of GARDASIL. Subsequently the patient experienced seizure right after received the vaccine. Dosing schedule will be discontinued due to the patient's reaction. The had patient recovered. Upon internal review, seizure was determined to be an other important medical event. The test was performed (results not provided). Additional information has been requested.

Other Meds: [therapy unspecified]

Lab Data: Tuberculin skin test

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324285-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Jun-2007	01-May-2008	335	05-Sep-2008	08-Sep-2008	FR	WAES0808AUS00324	08-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal distension, Cervix carcinoma, Genital haemorrhage, Vaginal discharge

Symptom Text: Information has been received from the mother of a 19 year old female patient via CSL as part of a business agreement (manufacturer control number GARD 2008 08 28 002). In June 2007, August 2007 and December 2007, the patient was vaccinated with her first, second and third dose of GARDASIL respectively. On 27-AUG-2008 the patient was diagnosed with cervical cancer following investigations of 3 months of spotting, bloating and vaginal discharge. Upon internal medical review the adverse event of cervical cancer was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324286-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	03-Jun-2008	07-May-2008	-27	05-Sep-2008	08-Sep-2008	FR	WAES0807USA00996	30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: This is a case of pregnancy follow-up reported by a specialist through the Sanofi Pasteur Pregnancy Registry on 01-Jul-2008. A female patient started a spontaneous pregnancy on 21-May-2008 (estimated conception date) and received the third dose injection of GARDASIL (batch number not reported) in the first week of June 2008. Her last menstrual period was on 07-MAY-2008. At the time of reporting the patient had no adverse effect. Follow-up information received from the specialist through the Sanofi Pasteur MSD Initial Questionnaire of Pregnancy Registry: Case upgraded to serious as the patient had a spontaneous abortion (OME). Patient's date of birth and weight were completed. An echography performed on 23-JUL-2008 showed no signs of fetal vitality. On 27-JUL-2008 she experienced a spontaneous abortion. The patient had a medical history of legally induced abortion in 2007. Other business partner numbers include E2008-06142. The case is closed. No further information is available.

Other Meds: Unknown

Lab Data: ultrasound, 23Jul08, no signs of fetal vitality

History: Legally induced abortion

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324287-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
37.0	F	09-Feb-2008	09-Feb-2008	0	05-Sep-2008	08-Sep-2008	FR	WAES0803PHL00006	08-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Drug exposure during pregnancy, Inappropriate schedule of drug administration, Pain, Premature labour, Uterine hypertonus

Symptom Text: Information has been received from a 37 year old female with a history of gestational diabetes, 1 pregnancy and 1 live birth, 0 miscarriage and 0 stillbirth, who on 09-FEB-2008 was vaccinated with her first dose of GARDASIL. Subsequently she became pregnant, as confirmed by a pregnancy test kit. Estimated date of delivery is on 23-OCT-2008. There were no concomitant medications or diseases at time of vaccination. Vaccination schedule will be deferred until after delivery. Additional information has been received on 27-AUG-2008. On 19-AUG-2008, the patient started to experience pain and contractions. Patient was given isoxsuprine HCL TID. Upon return consultation with physician on 25-AUG-2008, the patient still complained of pain and contractions. The patient was hospitalized on 25-AUG-2008. Treatment medication include Isoxsuprine HCl given intravenously. It was noted that her cervix was still closed/not dilated and both ultrasound and urinalysis tests done on approximately 25-AUG-2008 showed normal results. Subsequently, the patient was discharged improved on 27-AUG-2008. Aside from being advised to continue her low-salt, low-fat, low-sugar diet, the patient was also advised to have complete bed rest until follow up evaluation by the physician approximately next week. Thus, pre-mature labor was considered disabling. Vitamin supplements such as IBERET and CACI-AID were continued. The patient thinks that pre-term labor is probably not related to GARDASIL. This might have been brought about by her extensive traveling which required her to drive for long hours the past couple of weeks. No further information is available at the moment. Pregnancy outcome will be followed up on the estimated date of delivery.

Other Meds: Unknown

Lab Data: Ultrasound, 15?Aug08, normal; Urinalysis, 15?Aug08, normal

History: Gestational diabetes

Prex Illness:

Prex Vax Illns:

Vaers Id: **324292-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Nov-2007	20-Nov-2007	1	05-Sep-2008	10-Sep-2008	DE		24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	UT2458BA	5	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1266U	0	Left arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Headache, Immediate post-injection reaction, Lethargy, Malaise

Symptom Text: Severe headaches (immed. after 1st course) continuing almost daily. Joint aches, extreme malaise and lethargy. (2 visits to eye specialist - reported to physician). 9/23/08 Reviewed PCP medical records & vaccine records. PCP office called parent for status check as they were unaware of any problems patient had. Office states patient had severe HA after 1st & 3rd HPV vaccines. Parent reports patient is completely asymptomatic now. Eye exam of 12/31/07 reveals clear vision & no pain.

Other Meds:

Lab Data: Eye exams (2 different Opt.)

History: None PMH: cupping of optic disc. Eye itch & burn. Hypermetropia, painful menses, using contraception to regulate. Excision of chalazia bilateral lower eyelids. Adopted. Family hx cancer. HPV #2 given 1/29/08, Lot # 1265U; HPV #3 given 6/10/08, Lot # 1757Y, RA.

Prex Illness: N/A

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324296-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	02-Sep-2008	02-Sep-2008	0	05-Sep-2008	11-Sep-2008	MD		12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis

Symptom Text: One hour after receiving vaccine patient felt sweaty, lightheaded & faint. Did not pass out.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324319-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Sep-2008	04-Sep-2008	1	05-Sep-2008	12-Sep-2008	KY		12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B028AA	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2656AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Nausea, Pyrexia

Symptom Text: Fever 102 degrees, nausea, weak.

Other Meds:

Lab Data:

History: none

Prex Illness: pharyngitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324353-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	19-Jun-2008	19-Jun-2008	0	05-Sep-2008	10-Sep-2008	MO	MO-2008-23	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Migraine, Nausea, Vomiting

Symptom Text: Had nausea with vomiting - migraine headache - dizzy

Other Meds:

Lab Data: none

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **324360-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Dec-2006	20-Feb-2007	76	05-Sep-2008	11-Sep-2008	WA		16-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	01716	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Anxiety, Arthralgia, Back pain, Constipation, Dyspnoea, Electromyogram normal, Headache, Hyperacusis, Hyperhidrosis, Hyperreflexia, Hypoaesthesia, Influenza like illness, Muscle spasms, Muscular weakness, Myalgia, Nerve conduction studies normal, Pain in extremity, Pain of skin, Paraesthesia, Radiculopathy, Sensation of heaviness, Sensory loss, Sleep disorder, Tachycardia, Vaginal discharge

Symptom Text: Feb 07 has left leg pain(sensations), thought maybe a pinched nerve, pained worsened. 8/07 pain more severe, went to Dr for blood work, MRI, to rule out Arthritis. Leg feels, weak, heavy and numb. Experiencing severe headaches. 12/07 sensations now in Left arm. Pain continues. 2/08 more blood work, comes back fine. Unable to continue select Volleyball. Had more MRI's to rule out pinched nerve. Experiencing muscle spasms. 3/08 brain MRI, experiencing back pain(more severe than usual). 5/08 visited hospital Neurology. Had another brain MRI, came back good. 6/08 had nerve study conducted at Med. Center. No abnormal result found. 9/15/08 MR received from PCP 10/5/06-8/13/08. Seen 8/7/07 for WCC with chronic knee pain and 8/25/07 with toe fx 2' injury-hematoma under nail. Seen 10/10/07 for h/a, nausea & dizziness 2' ball injury. C/o hypersensitive hearing. Assessment: Hyperacousis/H/A 2' to contracorp injury. O/V 1/9/08 with flu-like illness. Seen 2/7/08 for back pain, vag d/c and anxiety-with occ SOB, tachycardia. Seen 2/26/08 with c/i impaired sllep 2' to pain. On PE DTRs R>L. Assessment: Radiculopathy. Hyperhidrosis. OV 8/1/08 for neck pain, arm pain low back pain. Also scalp tenderness, R numbness. Assessment: Myalgia/ muscle cramps. OV 8/13/08 for constipation. 9/30/08 Neuro and Neurosurg consults received dated 5/6/08 and 5/30/08. Referred for increasing bilateral leg and L arm numbness and paresthesias. Neuro exam (+) for decreased sensation L leg, otherwise WNL. Referred to neuro. PE (+) for anxiety, sweaty palms, decreased vibration sensation lower extremities. Referred for EMG/NCS-reported as normal by PCP. Assessment: ? motor/sensory neuropathy, ? mild myopathy, ? psychogenic.

Other Meds:

Lab Data: As stated above, blood work, MRIs', nerve study test. Labs and Diagnostics: MRI lumbar spine (+) for mild disc degeneration at T11-12 and L4-5. Small disc protusion at L4-5. facet and ligamentum hypertrophic changes. Head CT (-). Abd US

History: Had previously had minor back discomfort. PMH: low back pain, acne, on BCP for heavy periods, h/a with menses

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324371-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	28-Aug-2008	28-Aug-2008	0	05-Sep-2008	10-Sep-2008	IL		10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2621AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral

Symptom Text: C/o feet swelling about double sizes after receiving vaccines. Mother states patient had not pain in feet. States feet starting swelling about 45 minutes after receiving vaccines. Swelling went away after 1 1/2 hours. Denies any other problems.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **324375-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	30-Jul-2008	20-Aug-2008	21	05-Sep-2008	09-Sep-2008	NH		01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Dehydration, Malnutrition, Vomiting, Weight decreased

Symptom Text: Vomiting for 2 months. Lost of 25lbs (she weighs 87 lbs now!) hospitalized for dehydration and malnutrition. 9/11/08 Vax rec and office notes received from OBGYN. Weight 110# at time of 1st HPV 8/15/07. Wt 100# at time of Gardasil #3 on 7/30/08. No problems noted at that time. 09/23/2008 MR received for DOS 9/6-8/2008 with D/C DX: Intractable vomiting, questionable 2' to HPV vaccine. Pt presented with 7 month hx of intractable vomiting with 20# wt loss. Pt reports sx coincide with receipt of Gardasil vax. Tx with Rocephin for UTI and Reglan for symptomatic relief. Was able to tolerate diet and D/C to f/u as out pt. 9/26/08 PCP records received. Seen 8/15/08 with c/o intermittent unexplained vomiting since spring 2008 about the time Paxil was abruptly discontinued. For past week pt has been vomiting almost everything she eats. Wt 94#. PE WNL. F/U 8/22/08 with 2# weight loss since 8/15. Referred to GI.

Other Meds: ADVIL

Lab Data: GI tests, pregnancy tests, Blood tests. Labs and Diagnostics: Upper GI with SB grossly WNL. H pylori (-). CBC&Chem unremarkable. Labs and Diagnostics: Upper GI (-). TSH low at 0.319, free T4- 1.40 and free T3-2.7 WNL. CT of abd WNL. CT

History: unknown. PMH: Depression and Anxiety, kidney infection

Prex Illness:

Prex Vax Illns: vomiting~HPV (Gardasil)~3~18~In Patient

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324397-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-Aug-2008	29-Aug-2008	2	05-Sep-2008	12-Sep-2008	KY		23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Facial pain, Heart rate irregular, Hemiparesis, Hypoaesthesia, Hypoaesthesia facial, Immunisation reaction, Pain in extremity

Symptom Text: Weakness, numbness R side of body, numbness R side of face. 9/12/2008 Link to 324856./pc 9/12/2008 PCP records received. WCC 6/27/08 with normal exam except ecchymosis doe to a ball injury of the L hand. HPV#1. Seen 9/5/08 with c/o weakness, R sided numbness and R sided facial pain which began after HPV#2 on 8/27/08. Sx had resolved by OV. DX: HPV reaction. Seen again 9/10/08 for L sided lower back pain and R sided leg pain. Irregular heartbeat noted on PE as well and tenderness of the R calf. DX: Leg and back pain, irregular heartbeat. Sent for EKG Holter monitoring and X-rays.

Other Meds: none

Lab Data: none. Labs and Diagnostics: X-ray of the R tib/fib WNL. EKG with occ PVCs. Holter monitor (+) for PVCs

History:

Prex Illness: none

Prex Vax Illns:

Vaers Id: **324398-1** **Related reports:** 324398-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Sep-2008	02-Sep-2008	0	05-Sep-2008	15-Sep-2008	AL		16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	1	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C2774AA	5	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Pallor, Respiratory arrest, Syncope, Urinary incontinence

Symptom Text: Pt became pale, quiet and fainted. She then went into a seizure, stopped breathing and urinated on herself. Cold compresses were applied, feet and legs elevated. Soft drink given when she came to 5-10 minutes

Other Meds: None

Lab Data:

History: Allergy to Lorabid antibiotic

Prex Illness: None

Prex Vax Illns:

Vaers Id: **324398-2** **Related reports:** 324398-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Sep-2008	02-Sep-2008	0	08-Sep-2008	18-Sep-2008	AL		23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2774AA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0523U	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cyanosis, Dyspnoea, Eye rolling, Hyperhidrosis, Pallor, Posturing, Unresponsive to stimuli, Urinary incontinence

Symptom Text: Approx. 5 mins post-vaccination, pt became pale, diaphoretic. She was positioned with head down. She then became unresponsive. Assisted to floor with feet elevated, resp. WNL-she was somewhat responsive & talking. A few seconds later her eyes rolled back, no resp., no response to painful stimuli, posturing (arms drawn up or in towards trunk) face turned blue. Pt gasped and resumed normal breathing within 30-40 seconds. She also lost urinary continence. Patient quickly became alert, oriented x3 and drank a coke. Mom reported one other episode previously that she called "passing out" 6 years ago where patient passed out at school. Mom took her directly to E.R. Only thing identified then was +strep. CT scan was done & normal at that time. Patient was referred to her doctor.

Other Meds:

Lab Data:

History: none-allergy to LORBID

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324444-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Sep-2007	14-Oct-2007	20	08-Sep-2008	09-Sep-2008	NY	WAES0712USA01431	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Drug exposure during pregnancy, Live birth, Postpartum haemorrhage, Transfusion, Urinary tract infection

Symptom Text: Information has been received through the Merck pregnancy registry from a registered nurse concerning an 18 year old female who on 02-JUL-2007 was vaccinated with the first dose of GARDASIL (655205/1426F). On 24-SEP-2007 the patient was vaccinated with the second dose of GARDASIL (657617/0384U). The patient was seen in the emergency room on approximately 27-NOV-2007 with stomach aches and had a positive blood pregnancy test (LMP = 14-OCT-2007). On 04-DEC-2007 the patient was seen in the physician's office and had a positive urine pregnancy test. Concomitant therapy included pre-natal vitamins + Vitamin C. On 28-FEB-2008, the patient had an amnio test done, and the results were within normal limits. On approximately 17-MAR-2008, the patient experienced urinary tract infection and was treated with MACROBID, 100mg, BID during 5 days. On 21-JUL-2008, at 40 weeks from LMP, the patient had a male liveborn infant normal who weighed 7lbs 5 ounces, length 21.5 inches, and had a head circumference of 14 inches. There were no complications, infections or illnesses during the pregnancy or the labor/delivery. The registered nurse reported that the patient had heavy bleeding post partum and required transfusion x 2. The patient sought medical attention. Upon internal review heavy bleeding post partum requiring blood transfusions x 2 was determined to be an other important medical event. No further information is available.

Other Meds: Vitamins (unspecified)

Lab Data: Amniocentesis, 02/28/08, WNL = within normal limits; Serum beta-human, 11/27?/07, positive; Urine beta-human, 12/04/07, positive

History:

Prex Illness: Pregnancy NOS (LMP = 10/14/2007)

Prex Vax Illns:

Vaers Id: 324445-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Jul-2008	25-Jul-2008	1	08-Sep-2008	09-Sep-2008	FR	WAES0808USA05436	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1172U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blindness unilateral, No reaction on previous exposure to drug, Optic neuritis retrobulbar, Pupillary reflex impaired, Visual acuity reduced

Symptom Text: Information has been received from a pediatrician concerning a 15 year old female who on 20-MAY-2008 was vaccinated with the first dose of GARDASIL (lot no. 1113U; batch no. NH10090) and was well tolerated and on 24-JUL-2008, the patient received the second dose of GARDASIL (lot no. 1172U; batch no. NH10130). On 25-JUL-2008 the patient developed decreased vision (left eye) within 24 hours post-vaccination and was hospitalized as a case of emergency. The patient showed a positive RAPD (Rapid afferent pupillary defects). Retrobulbar neuritis was diagnosed. On 26-JUL-2008, the vision aggravated and visual evoked potential (VEP) nearly showed no signals anymore, the patient had blindness of the left eye. A cranial MRI was performed that showed no indications of demyelinating foci. The cause of retrobulbar neuritis had not been clarified as of 26-AUG-2008. The physician reported that parainfectious or paravaccination events might also be possible at this age (15 years old). On 31-JUL-2008, the patient was discharged with resolving symptoms, the patient was treated with cortisone, but the symptoms relapsed and aggravated. In Aug 2008, the patient was hospitalized again. Other business partner numbers included: E2008-08009. Additional information has been requested.

Other Meds: Unknown

Lab Data: visual evoked potential, 26Jul08, no signals; magnetic resonance imaging, 26Jul08, no indication of demyelinating foci; ophthalmological exam, 26Jul08, rapid afferent pupillary defect positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 324446-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	11-Oct-2007	11-Oct-2007	0	08-Sep-2008	09-Sep-2008	FR	WAES0808AUS00325	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0734U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Pancreatitis

Symptom Text: Information has been received from a physician as part of a business agreement (manufacturer control number GARD 2008 08 28 001) concerning a 20 year old female who on 11-APR-2007 was vaccinated with her first dose of GARDASIL (Lot No. 657874/0582U, Batch No. J2299, Expiry date 26-FEB-2010). Subsequently, on 11-OCT-2007, the patient received her second dose of GARDASIL (Lot No. 658214/0734U, Batch No. J2926, Expiry date 13-MAR-2010) (considered as inappropriate schedule of vaccine) and on 25-FEB-2008 she received her third dose of GARDASIL (Lot No. 658214/0734U, Batch No. J2926, Expiry date 13-MAR-2010). Concomitant therapy included LEVLEN. On 04-AUG-2008 the patient experienced pancreatitis (also reported as sudden onset of acute pancreatitis) and was hospitalized. On 4-AUG-2008, the patient's lipase result was 2025 (units not specified) and was reported as abnormal. It was also reported that the patient's lipase and amylase increased. The patient was treated with IV rehydration and "settled quickly". No cause for the pancreatitis was identified. Subsequently, the patient was "well" since discharge. The patient was reviewed by her physician 3 weeks later at which time all bloods had returned to normal. Additional information has been requested.

Other Meds: ethinyl estradiol (+) levonorgestrel, Unk - Unk

Lab Data: diagnostic laboratory test, 25?Aug08, all bloods returned to normal; serum lipase test, 04Aug08, 2025, abnormal; serum amylase test, ??08, increased

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324448-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	21-Jan-2008	30-Jan-2008	9	08-Sep-2008	09-Sep-2008	FR	WAES0809USA00385	09-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0352U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abscess

Symptom Text: Information has been received from a health authority (reference no. PEI2008013021), concerning a 23 year old female patient with no previous medical history reported, who on 21-JAN-2008 was vaccinated with the first dose of GARDASIL (Lot #0352U and Batch #NG00320) IM into the left upper arm. On 30-JAN-2008, the patient developed recurrent formation of abscess on the whole body, in particular on the thighs (less than 30 abscesses) and was hospitalized on an unspecified date. Diabetes mellitus, abnormalities of blood count and of renal function values were ruled out. The patient has not recovered at the time of reporting. FILE IS CLOSED. Other business partner numbers included E200808150. No further information is available.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, diabetes mellitus: rule out; renal function study, rule out; WBC count, abnormalities of blood count: rule out

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **324450-1 (S)** **Related reports:** 324450-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Aug-2008	20-Aug-2008	13	08-Sep-2008	11-Sep-2008	OH		21-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	NULL	0	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Areflexia, Ataxia, Blood product transfusion, Concussion, Contusion, Decreased appetite, Dizziness, Fatigue, Gait disturbance, Guillain-Barre syndrome, Headache, Muscular weakness, Myalgia, Nausea, Paraesthesia, Sensation of heaviness, Weight decreased

Symptom Text: Guillian Barre Syndrome - symptoms started 8/20/08 - diagnosed by MRI and lumbar puncture. 1/12/09 Reviewed hospital d/c summary for 8/26-9/1/2008 admission. FINAL DX: GBS; head concussion. 9/16/08 Reviewed hospital medical records of 8/26-9/1/2008. FINAL DX: no discharge summary dictated Records reveal patient experienced progressive worsening of ascending weakness & heaviness of legs, tingling of feet, myalgias & HA since sports collision, difficulty walking, then tingling of hands, fatigue, weight loss, decreased appetite, intermittent nausea, abdominal pain, ataxia over 5-6 days prior to admit. Seen by PCP when had continued dizziness & lower abdominal pain. UA showed large amount of RBCs & sent for US. Admit exam revealed areflexia of LEs & had abnormal gait, trouble lifting LEs. Tx w/IVIG x 3 days. Peds neuro, pulm consult done. Improved & d/c to home w/neuro & PCP f/u along w/EMG/NCS as outpatient. 9/12/08 Reviewed ER records of 8/23/2008. FINAL DX: s/p concussion syndrome w/no LOC, multiple contusions from sports collision. Records reveal patient experienced sports injury 5 days prior. Had immediate HA but no LOC. Dx w/concussion w/o LOC. Returned to ER 8/23 after developed intermittent numbness in hands & had continued HA. Had c-spine muscle tenderness & lower abdominal & CVA tenderness. Also had intermittent leg heaviness & tingling in feet. Neuro exam was completely WNL at that time.

Other Meds: None

Lab Data: MRI; L.P. LABS: Brain MRI & MRI spine WNL.. Admit CBC & chemistry WNL. CK 206(H), AST 39(H), ALT 53(H), CSF: RBC 2400, WBC 2, glucose 80 (N), protein 238.7(H). Mycoplasma Ab, Igm (+). Blood, CSF & urine c/s neg. CXR WNL. ER LABS: C

History: None PMH: allergic penicillin

Prex Illness: None

Prex Vax Illns:

Vaers Id: **324450-2 (S)** **Related reports:** 324450-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	26-Aug-2008		16-Sep-2008	17-Sep-2008	OH	WAES0809USA00508	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Concussion, Dyspnoea, Gait disturbance, Guillain-Barre syndrome, Headache, Hypoaesthesia, Muscular weakness, Paraesthesia

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female patient who on an unspecified date was vaccinated with GARDASIL. Concomitant therapy included tetanus toxoid (manufacturer unknown). The medical assistant reported that the patient was diagnosed with Guillain-Barre Syndrome after receiving a dose of GARDASIL vaccine. After receiving GARDASIL vaccine, the patient suffered a concussion in a soccer game. She was taken to an emergency room and released. However she was taken to the emergency room again because she complained of headaches along, tingling in her hands and feet. She also felt weakness on her legs. She was then released from the emergency room. Then on 26-AUG-2008, she was admitted to the hospital because she complained of shortness of breath, headaches and numbness of her extremities. She could not walk without assistance. After she was admitted to the hospital, she was diagnosed with Guillain-Barre Syndrome. On 12-SEP-2008, follow-up information was received from a medical assistant who provided the primary physician's name and telephone number. The patient's Guillain-Barre Syndrome was considered to be disabling. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324453-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	25-Jul-2008	Unknown		08-Sep-2008	17-Sep-2008	OH		17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Headache

Symptom Text: headaches. has been under treatment for headaches, parent feels headaches were under more control before vaccine, headaches started to get intensified after receiving vaccine

Other Meds:

Lab Data:

History: allergic to penicillin

Prex Illness: migraines/headaches

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324454-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Aug-2008	25-Aug-2008	0	08-Sep-2008	17-Sep-2008	NJ		25-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2614AA	0	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	0279X	0	Unknown	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB254A	0	Unknown	Intramuscular	
VARCEL	MERCK & CO. INC.	0737X	0	Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye movement disorder, Partial seizures, Posturing

Symptom Text: 16 y/o female at office for well child care. Received varicella; MENACTRA; GARDASIL & Hep A. 20 mins after vaccine focal seizure in office lasting <1 min. Eye deviation to left & posturing of L hand.

Other Meds:

Lab Data: referred to ED per EMS

History: Dysmenorrhea

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324455-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	26-Aug-2008	27-Aug-2008	1	08-Sep-2008	17-Sep-2008	CA		17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	MSD1995U		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	APMU2561AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	MSD1758U		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	AVPC2935AA		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Pain 8/10 pain scale/noticed 8/27/08 after 12pm. No redness. No induration.

Other Meds: TYLENOL PRN

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **324460-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	21-Aug-2008	22-Aug-2008	1	08-Sep-2008	17-Sep-2008	TX		17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle tightness, Myalgia

Symptom Text: Patient reported muscle pain/tightness in her legs only. Starting AM of 8/22/08. Upon speaking with her again on 8/25/08, she noticed that her conditioned had improved, and felt the residual pain was due to standing for a long period of time on 08/24/08.

Other Meds: NUVARING

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324466-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Aug-2008	16-Aug-2008	0	08-Sep-2008	18-Sep-2008	IL		18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Syncope

Symptom Text: syncopal episode after Gardasil injection. Awakened in seconds after feet elevated. c/o lightheadedness. Given crackers and soda and monitored x 1 hr. BP 108/72. Left with parent and walked out on own and started felt fine. Client was very nervous before vaccination.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324467-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	04-Sep-2008	04-Sep-2008	0	08-Sep-2008	18-Sep-2008	IL		18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2567AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1266U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Injection site pain, Nausea

Symptom Text: Client waited approximately 15 minutes at clinic after receiving vaccine and felt fine. Experienced onset of headache and nausea on way home. Called doctor's office from home and advised to take 2 Tylenol and rest. Client had relief of symptoms approximately 5 hours after receiving vaccine. No symptoms 9/5 except some soreness at Gardasil injection site.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **324470-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	12-Nov-2007	Unknown		08-Sep-2008	18-Sep-2008	CA		24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain lower, Abdominal pain upper, Anxiety, Back pain, Constipation, Dyspepsia, Fatigue, Gastritis, Gastrooesophageal reflux disease, Headache, Hypoaesthesia facial, Lymphadenopathy, Milk allergy, Muscle spasms, Nasopharyngitis, Nausea, Upper respiratory tract infection, Weight increased

Symptom Text: (1) numb face - half on face after vaccine. (? which of 3); (2) per parent, -> Resolved. Seemed tired, leg cramps, abdominal cramps, fatigue (Lost 10# in 1 month -> per parent but notes she gained 10# in 6 months 1st and 3rd shot; after series. 9/16/08 Reviewed PCP medical records of 5/2/07-9/2/08. FINAL DX: Records reveal patient c/o abdominal pain x 6 mo on 5/2/07 vs. Exam revealed right ear hearing loss, bilateral eye problems, gynecomastia. Dx w/non-specific abdominal pain. Was in good health w/o complaint on 7/2 visit. Next vs 11/2/07 showed pt had gained 10# in 6 mo but had no complaints after first 2 HPV vax. RTC on 12/26/07 with somach pain, constipation & low back pain x 2 weeks esp when drinking milk. Dx with r/o milk allergy. RTC 1/17/08 w/chronic abdomen pain, anxiety & HA. RTC 2/8/08 w/lump on right side of neck, cold s/s, heartburn & lower abdominal pain. Dx w/URI, cervical lymphadenopathy, GE reflux/gastritis. RTC 3/12/08 w/heartburn, nausea, epigastric pain. Dx w/gastritis/GE reflux. Labs done, results not reported.

Other Meds: None

Lab Data:

History: abdominal pain PMH: allergic rhinitis.

Prex Illness: Wk 1st vaccination - had ab pain; allergic rhinitis; allergic conjunctivitis

Prex Vax Illns: none known~ ()~~0~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324471-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
5.0	F	27-Aug-2008	28-Aug-2008	1	08-Sep-2008	18-Sep-2008	CA		02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Vomiting

Symptom Text: Dizziness, severe headache, emesis (x5), resolved the following day.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324472-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Aug-2008	11-Aug-2008	0	08-Sep-2008	18-Sep-2008	IL		02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity, Skin warm, Tenderness

Symptom Text: 8/11/08 Received vaccine arm pain from shoulder to elbow with radiation to the fingers. 8/25/08 Arm pain persisted, moderate tenderness, warm to touch and treated with Cephalexin for possible cellulitis. 9/4/08 No change in arm pain, swelling and warmth not present.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 324475-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Jun-2007	01-Jun-2008	363	08-Sep-2008	11-Sep-2008	FL		06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	2	Right arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Deafness, Deafness neurosensory, Tinnitus

Symptom Text: Previously undiagnosed, sensorineural hearing loss - symmetric. Specialist thinks pattern is consistent with congenital insert, however, mom feels child's hearing was excellent before Gardasil series. 09/10/2008 PCP records received including 2 ENT and audiological evals with DX: Sensorineural hearing loss-symmetric. Deafness. WCC 6/4/07 with normal exam. RTO 7/2/08 with c/o hearing problems after failing school hearing test. Did not pass audiogram given in office. Refered to ENT. ENT visit 7/15/08. Pt states first noticed a change in hearing approx 2 yrs ago. Occasional ringing in ears. ENT PE WNL.

Other Meds: None

Lab Data: Labs and Diagnostics: Audiogram-fail. Audiologic eval c/w sensorineural hearing loss with abnormal DPOAS, normal typanograms. CT Temporal bones unremarkable. TSH 6.616.

History: None. PMH: none noted

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324498-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	22-Aug-2008	03-Sep-2008	12	08-Sep-2008	11-Sep-2008	CO		24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Appendicitis, Diarrhoea, Dizziness, Dysuria, Haematochezia, Headache, Injection site bruising, Injection site swelling, Laparoscopy, Malaise, Migraine, Nausea, Surgery, Vomiting

Symptom Text: I have received the 3 vaccines, first one 1-22-08,4-1-2008 and 8-21-2008 I became ill in February 2008, had bloody stools, diarrhea, nausea, cbc was done at that time i had a wbc of 13.0 a colonoscopy was done in April 2008 this was negative. i have had headaches(migraines) that have occured more often. I received my 3rd shot on 8-22-08 i had a bruise and swelling from this. I started to feel ill, lightheaded, nausea and vomiting as well as diarrhea and stomach pains times 1 week before , i ended up in the ER on 9-4-8 with excruitiating abdominal pain, painful urination. My WBC at that time was 17.5, my urinalysis was within normal limits and the CT confirmed an appendicitis. I had surgery that evening. 9/22/08-records received for DOS 9/4-9/5/08-DC DX: Appendicitis. Presented with C/O abdominal pain times one day and diarrhea times one week. Surgery, laparoscopic appendectomy.

Other Meds:

Lab Data: cbc with wbc of 13.0 done on 2/13/08 cbc with wbc of 17.5 on 9/4/08 CT scan with inflammed appendix 9/22/08-records received-WBC 17.0 and CT with a positive appendix.

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324504-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Nov-2007	Unknown		08-Sep-2008	18-Sep-2008	PA		18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Menstruation irregular

Symptom Text: Parents report hair loss and irregular menses at 1/28/08 PE visit.

Other Meds:

Lab Data: Patient has not had a normal endocrine dermatalogic evaluation; Rheum evaluation is pending.

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **324506-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-May-2008	13-May-2008	0	08-Sep-2008	18-Sep-2008	SC		18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling, Pruritus

Symptom Text: Has 1/2 cm raised area where GARDASIL vaccine was given on 5-13-08. Extreme itching still.

Other Meds: Albuterol; Levsin; Anaprox; Desogen

Lab Data:

History: Asthma; GERD; Depression

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324597-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	07-Apr-2008	27-May-2008	50	09-Sep-2008	10-Sep-2008	FR	WAES0809USA00495	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1068U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Carcinoma in situ, Cervical conisation, Cervical dysplasia, Human papilloma virus test positive, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a physician concerning a 27 year old female, who on 24-JAN-2008 was vaccinated IM in the deltoid muscle with a first dose of GARDASIL (Lot# 0352U; Batch# NG00320). No adverse event occurred. On 07-APR-2008 the patient was vaccinated IM in the deltoid muscle with a second dose of GARDASIL (Lot# 1068U; Batch# NH06410). On 27-MAY-2008 PAP IVa (suspicion of carcinoma in situ) was diagnosed. A conisation was performed in an outpatient department. The result showed carcinoma in situ (CIN III). On 21-NOV-2007 a PAP smear showed normal finding (PAP II). The patient recovered on an unspecified date. The physician considered the cervical intraepithelial neoplasia III, carcinoma in situ, abnormal Pap smear, and positive Human papilloma virus serology test to be other important medical events. Other business partner numbers included: E2008-08110. Additional information is not available.

Other Meds: Unknown

Lab Data: cervical smear, 21Nov07, PAP II; cervical smear, 27May08, PAP IVa

History: No reaction on previous exposure to vaccine

Prex Illness:

Prex Vax Illns:

Vaers Id: **324598-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	13-Jul-2008		09-Sep-2008	10-Sep-2008	FR	WAES0809USA00089	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cerebrovascular accident, Depressed level of consciousness, Dysstasia, Eye movement disorder, Facial palsy, Fall, Hemiplegia, Hypoaesthesia, Ischaemic stroke

Symptom Text: Information has been received from a Health Authority in a foreign country (HA ref. no. LM20080247) concerning a 15 year old female with pollen allergy and asthma who in MAR-2008 was vaccinated with the first dose of GARDASIL. In MAY-2008 the patient was vaccinated with the second dose of GARDASIL IM. On 13-JUL-2008 the patient experienced a fall with the impossibility to stand up. She was found 3 1/2 hours later. The patient had spent the night at a nightclub, had drunk alcohol and energising drinks and had smoked. Physical examination showed slight obnubilation, spontaneous deviation of the head and eyes towards the right, left hemiplegia, left facial paralysis and hypoaesthesia of the left hemibody. Brain MRI with magnetic resonance angiography found hyperintensity in the right sylvian territory related to recent ischaemic cerebrovascular accident. Thrombophilic work-up was normal. Auto-immune work-up showed speckled positive antinuclear antibodies on the first test with 1/640, of centromere type. Toxic assay in urine found negative opioid, cocaine, cannabinoid, amphetamines and GHB. Viral serologies, ie HIV, HCV and EBV were negative. The patient was not using contraceptive pill. She had concomitant medication with AERIUS or CLARITIN and VENTOLINE. At the time of reporting, she had not recovered. Other business partner numbers include E2008-08198. Additional information has been requested.

Other Meds: AERIUS; CLARITIN; VENTOLINE

Lab Data: Magnetic resonance imaging, brain MRI with MRA found hyperintensity in the right sylvian territory related to recent ischaemic c; diagnostic laboratory test, thrombophilic work-up negative; Serum ANA, 1/640, of centromere type; Urine drug s

History:

Prex Illness: Pollen allergy; Asthma; Smoker; Alcohol use

Prex Vax Illns:

Vaers Id: 324599-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Jul-2007	02-Mar-2008	226	09-Sep-2008	10-Sep-2008	FR	WAES0808USA05475	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Demyelinating polyneuropathy, Hypoaesthesia, Inappropriate schedule of drug administration, Lymphadenopathy, Monoparesis, Paresis, Radiculitis brachial

Symptom Text: Information has been received from a health authority concerning a 17 year old female who on 20-JUL-2007 was vaccinated with the first dose of GARDASIL (lot n. not reported). It was well tolerated. On 07-JAN-2008, the patient was vaccinated with a second dose of GARDASIL (lot n. not reported). Concomitant medication included unspecified hormonal contraceptives. On 02-MAR-2008, the patient developed numbness in the right arm, hand and shoulder and was hospitalized. Neurological examination revealed paresis of the right arm, hypoaesthesia of right arm and shoulder especially of forearm and hand on radial side and less important paresis of right leg. The patient didn't experience pain. CSF was normal, no local IgG, IGA and IGG synthesis. Oligoclonal IgG was negative. Borreliosis was ruled out. On 02-MAR-2008, was performed a serum C-reactive protein test (CRP) and the result was 21.8 mg/L. On 03-MAR-2008, was performed a motor evoked potential (MEP): central motor conduction time to arms normal as well as to the right leg. The central motor conduction time to the left leg was extended. A nerve conduction velocity was performed on 04-MAR-2008, which showed demyelinating axonal sensomotoric polyneuropathy (tibial nerves were not concerned). Native MRI of plexus on 06-MAR-2008, was in favor of neuritis of the right plexus cervicobrachialis. Detection of several enlarged lymph nodes in the course of the cervical vasomotor nerve sheath on both sides. Lab findings performed on 08-MAR-2008 including serum thyroid-stimulating hormone test (TSH), vitamins B1, B6, B12, E, serum folic acid, cryoglobulins, rheumatoid factors, serum antinuclear antibodies test (ANA), serum antineutrophil cytoplasmic antibody test (ANCA), ganglioside autoantibodies, GM1-antibodies, antibodies against Campylobacter intestinalis and jejuni and HIV, Treponema pallidum hemagglutination assay (TPHA), were normal, except elevated serum C-reactive protein test (CRP) which the result was 40.4 mg/L. Cranial and cervical magnetic resonance imaging (MRI) we

Other Meds: hormonal contraceptives (unspecified), Unk - Unk

Lab Data: nerve conduction study, 04Mar08, demyelinating axonal sensoromotoric polyneuropathy (tibial nerves were not concerned); nerve conduction study, 04Mar08, MEP: central motor conduction time to arms normal. Central motor conduction to the L le

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324601-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Aug-2007	20-Sep-2007	45	09-Sep-2008	10-Sep-2008	FR	WAES0808USA05474	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Central nervous system lesion, Demyelination, Headache, Migraine with aura, Nausea, Paraesthesia, Paraesthesia oral, Speech disorder, Visual disturbance

Symptom Text: Information has been received from a health authority concerning a 17 year old female who on 11-JUN-2007 was vaccinated with the first dose of GARDASIL, lot n. not reported and was well tolerated. On 06-AUG-2007, the patient was vaccinated with a second dose of GARDASIL (lot n. not reported). On 20-SEP-2007, the patient developed visual disorder ("sparkling in the right visual field"), later paresthesia spreading from the fingers to the whole right hand. Additionally, she experienced paresthesia of the tongue and speech disorder. The symptoms resolved after 5 to 10 minutes and were followed by headache with nausea. She recovered completely within 2 days. It was noted the patient's father had a history of migraine in his youth. On an unspecified date, an electroencephalography was performed and showed normal results. Migraine accompagnee was suspected. Cranial MRI on 09-OCT-2007, showed a lesion of 1 cm diameter in the front part of the corpus callosum and lesion of nearly 1 cm diameter in the right temporal medullary layer. It was suspected that the lesion could be a residual of a inflammatory demyelinating focus without signs of activity. On 04-DEC-2007, she was vaccinated with a third dose of GARDASIL (lot n. not reported). A control MRI on 08-DEC-2007 showed unchanged results. The clinical relevance of these cerebral lesions remained unclear. CSF in December 2007 showed a slight increase of cells (not otherwise specified), no oligoclonal bands were detected. At the time of reporting the patient had recovered. File closed. Migraine accompagnee and residual of inflammatory demyelinating focus without signs of activity were determined to be an other important medical events. Other business partner numbers included: E2008-07962. Additional information is not expected.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 09Oct07, cranial- inflammatory demyelinating focus without signs of activity; diagnostic laboratory test, ??Dec07, CSF: slight increase of cells (not otherwise specified), no oligoclonal bands were; magnetic reso

History: Information has been received from a health authority concerning a 17 year old female who on 11-JUN-2007 was vaccinated with the first dose of GARDASIL, lot n. not reported and was well tolerated.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324603-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	07-Apr-2008	07-Apr-2008	0	09-Sep-2008	10-Sep-2008	OH	WAES0808USA01664	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Gluteous maxima	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site, Mucosal inflammation, Papilloma viral infection

Symptom Text: Initial and follow-up information has been received from a nurse concerning a 20 year old female who on 07-APR-2008 was vaccinated intramuscularly into the left gluteus with the first 0.5 ml dose of GARDASIL (lot no. 659655/1486U). On 29-May-2008, the patient had a colposcopy done which showed positive for human papilloma virus. The biopsy showed squamous mucosa and attached endocervical glandular mucosa with mild chronic inflammation and reactive changes. Focal changes suggestive of human papillomavirus-associated cytopathic effect. The patient stated that she had only one sexual partner (1st partner for each other). On 06-JUN-2008 the patient was vaccinated intramuscularly into the left deltoid with the second 0.5 ml dose of GARDASIL (lot no. 660387/1967U). At the time of this report, the patient was still positive for human papilloma virus. The patient sought unspecified medical attention. The reporter considered human papilloma viral infection to be other important medical event. Additional information is not expected. All medical records are available upon request.

Other Meds: Unknown

Lab Data: Colposcopy, 05/29/08, positive HPV; Cervix biopsy, 05/29/08, 11 o'clock - squamous mucosa and endocervical glandular mucosa with mild chronic inflammation; Cervix biopsy, 05/29/08, 11 o'clock - squamous mucosa and attached endocervical glan

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324610-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	12-Aug-2008	13-Aug-2008	1	09-Sep-2008	10-Sep-2008	FR	WAES0809USA00362	10-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain lower, Laboratory test normal, Pyrexia

Symptom Text: Information has been received from a gynaecologist concerning a 12 year old female who on 12-AUG-2008 was vaccinated with the first dose of GARDASIL (Batch # NH15200; lot # 1427U), intramuscularly into the left deltoid. There was no concomitant medication. On 13-AUG-2008, one day post vaccination, the patient experienced fever and severe lower abdominal pain and was hospitalized for clarification. The gynaecologist reported that no inflammation values were detected, and appendicitis could be excluded. At the time of the report the patient had recovered. On an unknown date a lab test was performed which inflammation values were not detected. The case is closed. Other business partner numbers included: E2008-08132. No further information is expected.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324663-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	08-Sep-2008	09-Sep-2008	1	09-Sep-2008	17-Sep-2008	CT		17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0263U	2	Left arm	Intramuscular	
	IPV	SANOFI PASTEUR	A1188	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Dizziness, Flushing, Nausea, Pain, Palmar erythema, Pruritus, Syncope

Symptom Text: 0658 9-9-08 SYNCOPE, BODY ACHES, CHILLS, NAUSEA, LIGHT HEADED, FLUSHED FACIAL CHEEKS, PALMS ERYTHEMIC, PRUITIS PALMS,DIPHENHYDRAMINE 25MG PO TIMES ONE,TYLENOL 975MG PO TIMES ONE GIVEN;

Other Meds: ETHINYL ESTRA/NOREL 20-150 TDRM ;TUCKS PADS;HYDROCORTISONE TOPICAL 1%CREAME,COLACE 100MG PO BID

Lab Data: NONE

History: NKDA,NO BIRTH DEFECTS,HEMORRHOIDS

Prex Illness: MILD COLD S/S

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324667-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-May-2007	31-Dec-2007	221	09-Sep-2008	17-Sep-2008	PA		17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Arthralgia, Dizziness, Headache, Menorrhagia

Symptom Text: "HAIR LOSS,AND IRREGULAR MENSES,JOINT PAIN, HEADACHES ETC: Our daughter, who had completed her series of 3 vaccinations of "Gardisil" has been experiencing considerable hair loss. Her first shot was in May 24, 2007, the second on July 26, 2007 and the third and final on November 27, 2007. Here are the other specifics....our daughter was 13 turning fourteen. She has had every blood test imaginable to rule out the obvious which may cause hair loss such as thyroid disease, polycystic ovary disease, diabetes, and the list goes on and on. Everything came back negative. We even have a future appointment scheduled with a rheumatologist this coming November 08. We have seen the Endocrinologist and two dermatologists (a scalp biopsy proved negative to any infection, disease, etc. Granted, she had a typical amount of stress during the school year, as any young teen would, but nothing to cause this. Everyday our daughter says to us, "you should see how much hair fell out in the shower today". She's so afraid to brush or comb it because of the extreme shedding. She literally, to date has half the amount of hair she had one year ago. Let me tell you she had beautiful hair. The hair loss is becoming quite visible at the forward part of her scalp. This has been devastating, hair is everything to a teen. (to anyone this is devastating) We must also mention that her periods have been totally out of whack. She went 6 months at one point without one. It finally came back, but it is so sporadic, getting every two weeks, at times extremely heavy, etc... She also complains of intermitent dizziness.

Other Meds:

Lab Data: PLEASE SEE #7

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324674-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Aug-2008	19-Aug-2008	5	09-Sep-2008	17-Sep-2008	CA		19-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Hypoaesthesia, Paraesthesia

Symptom Text: On set of tingling in left pinky finger started about one week after second injection. Symptoms have gotten worse and now have traveled to ring finger, hand, arm, leg, foot and toes all centralized to the left side. She is experiencing dizzy spells and headaches that last days at a time. We are in the third to forth week of this and she has been taken to her pediatrician who is consulting with a neurologist. No word back yet. We do not know if there will be permanent damage at this time. 9/18/08-records received-presented to PCP on 9/8/08- C/O left arm and leg numbness for past 2 weeks. Started with left pinky and progressed to arm. Left leg becomes numb and tingly. Headache off and on for few months some dizziness a month ago. PE normal. Seen in PCP office on 9/11/08-C/O recurrent headaches and recurrent numbness. To see neurologist.

Other Meds:

Lab Data:

History: N/A 9/18/08-records received-Family history of migraines.

Prex Illness: NO

Prex Vax Illns:

Vaers Id: **324684-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-May-2008	26-May-2008	17	09-Sep-2008	19-Sep-2008	NY		19-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: See attached does; The patient presents with headache. These symptoms began 2 months ago. Other comments Include: seen here for headaches about 6 weeks ago was referred to Dr at that time mother has been unable to get through to the neurology department though (and Dr now on maternity leave); bad headaches twice a day now has been able to continue her job went to ER last month for a headache, there head CT normal. Comments: patient said that she has been getting headaches on and off since June she would like some bloodwork done.

Other Meds:

Lab Data: See attached: Physical Exam: General Appearance: alert, NAD

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 324687-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	12-Oct-2007	15-Oct-2007	3	09-Sep-2008	11-Sep-2008	NE		23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	9725102	2	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Appendicectomy, Chest pain, Constipation, Decreased appetite, Diarrhoea, Gastritis, Haematuria, Helicobacter infection, Ileus, Malaise, Nausea, Pyrexia, Skin papilloma, Vomiting

Symptom Text: Patient's mom say first vaccine was 8-2-07. (Patient got sick on 8-31-07. (Vomiting, diarrhea x 2 days) no doctor visit). Second vaccine 10-12-07. Patient had abd pain, pain 1 week later and was in hospital. Oct 14 left hospital. Last dose 2-26-08 - patient got sick March 7th and pain now has warts on knees. 9/15/2008 MR received for 3 admssions: 10/16-20/07 with D/C Dx: Abdominal pain with persistance after multiple evaluations. 10/27-30/2007 with D/C DX: Nausea, Vomiting, Abdominal Pain, mild non-erosive gastritis. helicobacter pylori. Recent appendectomy. hematuria, need outpt f/u. Constipation. 02/8-15/2008 with D/C DX: Intractable nausea and vomiting. Severe epigastric pain NOS. Mild ileus. Pt initially presented to ER 10/16/07 with c/o RLQ abd pain, nausea, decreased appetite and fever. W/u (-) but sent for laparoscopy with appendectomy. D/C stable. Returned 10/27/07 and admitted with chest pain, nausea, vomiting and abd pain. Required PCA for pain mgmt. Sx improved with PPI and Carafate and D/c. Returned 2/8/08 with recent return of sx, now with epigastric pain. pt awakens from sleep screaming in pain. Again required PCA. Etiology of sx unclear per GI consult.

Other Meds:

Lab Data: Labs and Diagnsotics 10/16/07: CT Abd with low probability for appendicitis. Pelvic ascites. S/P cholecystectomy. Pelvic US unremarkable. CT/Pelvis/Abd (+) for amll amt of fluid in pelvis and a retroaortic renal vein noted. CBC WNL. CMP wit

History: PMH: cholecystectomy

Prex Illness:

Prex Vax Illns:

Vaers Id: **324690-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		09-Sep-2008	19-Sep-2008	NC		19-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB239AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0317X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0571X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Immediate post-injection reaction, Urticaria

Symptom Text: 30-60 seconds after injection redness, 2 min after inj hives. 10 min. after inj. gave BENADRYL PO. 10 min after oral BENADRYL, Hive gone and redness decreasing.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324692-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	31-Jul-2007	Unknown		09-Sep-2008	19-Sep-2008	AZ		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysmenorrhoea

Symptom Text: Since completing vaccines she has developed dysmenorrhea

Other Meds:

Lab Data: Pelvic ultrasound

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **324724-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Feb-2008	23-Feb-2008	1	10-Sep-2008	22-Sep-2008	WA		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Dizziness, Nausea

Symptom Text: At 4:30 am 2/23/08 she developed nausea, abdominal cramping and dizziness that slowly resolved and was gone by midnight of the next day. Patient reported reaction when she came in for her 3rd HPV

Other Meds: None

Lab Data:

History: IBS

Prex Illness: none

Prex Vax Illns: None~ ()~~0~In Patient|None~ ()~~0~In Sibling|None~ ()~~0~In Sibling

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324729-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Aug-2008	30-Aug-2008	1	10-Sep-2008	22-Sep-2008	NH		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	2	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2635AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Mother called 8/30/08 at 10:30 am states "patient" has a splotchy rash on her face, neck, and upper back that she feels is caused by the meningitis shot she received 8/29. Mom states rash was noticed this AM is improving. Mom advised to give Benadryl. If no improvement to call back. Injection site per mom looks fine.

Other Meds: Yaz; Midrin

Lab Data:

History: Migraines

Prex Illness:

Prex Vax Illns:

Vaers Id: **324730-2** **Related reports:** 324730-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Aug-2008	19-Aug-2008	0	27-Oct-2008	06-Nov-2008	MI	MI2008023	01-Dec-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2623AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0513X	1	Left arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B027AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acne, Oedema peripheral, Pain in extremity, Scab, Skin discolouration

Symptom Text: Client states approx. 1 hour after receiving immunizations on 8/19/08 both arms became swollen and painful. Client states this lasted 4 days then resolved. Then on 9/1/08 client reports she had swelling and black and blue marks in her upper arms with approx 20-30 "pimples" on her arms, face, and head. She states they were painful to the touch. Client visited the Western Univ. Health Center 9/3/08 for evaluation. PP gave client a prescription for BACTRIM, took culture of her "pimples" that are now scabbed over and made a follow up appt for next week. On 9/3/08 physician at Health Center took samples to culture from scabbed spots on client's head. 9/29/08- POI to be sent to Med. Clinic for details.

Other Meds: ZYRTEC - 10 mg only as needed

Lab Data:

History: environmental allergies

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324732-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	27-Aug-2008	27-Aug-2008	0	10-Sep-2008	22-Sep-2008	IA		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0393	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1446U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted after getting her shot. Mom had told us ahead of time she might. We had the back of the exam table in sitting position so she could lean against it. We laid her down and gave her a sucker. After she felt better we sat her up in stances and leg exercises and gave her a mountain dew. She fainted a 2nd time. Had her lay down for about 1/2 hour then had her rest in waiting room then escorted her to her car.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324740-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	27-Aug-2008	27-Aug-2008	0	10-Sep-2008	22-Sep-2008	WI		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2996AA		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2638AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0135X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0571X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration

Symptom Text: "Patient" got the 4 immunizations listed below on 8/27. on the right arm, the only shot given subq which was a varicella developed an area of erythema which was slightly hard but non tender.

Other Meds:

Lab Data:

History:

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324743-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	21-Jul-2008	25-Jul-2008	4	10-Sep-2008	22-Sep-2008	MD		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Skin warm, Urticaria

Symptom Text: Client complained of hives/welts, red, hot, and itchy over upper extremities; trunk. client has been using Benadryl.

Other Meds: Levora

Lab Data:

History: Latex allergy

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324745-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	29-Aug-2008	31-Aug-2008	2	10-Sep-2008	22-Sep-2008	VA		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash pruritic

Symptom Text: Itchy rash 2d after HPV # 2. No other symptoms

Other Meds:

Lab Data: none

History: None

Prex Illness: None

Prex Vax Illns: resp~HPV (no brand name)~1~12~In Patient

Vaers Id: **324773-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	29-Jan-2008	01-Feb-2008	3	10-Sep-2008	11-Sep-2008	PR	PR0807	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0583U	2	Unknown	Unknown	HPV4 MNQ

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Condition aggravated, Demyelination, Lumbar puncture, Migraine, Multiple sclerosis, Muscular weakness, Neuralgia, Neurological symptom, Optic neuritis, Visual disturbance

Symptom Text: Neurological changes,visual problems. Diagnosed as Multiple Sclerosis by ophtalmologist and neurologist. All after second dose of HPV (Gardasil) worsed after third dose. 10/14/08-records received-2/26/08-Admitting DX: Demyelinating Disease, left optic neuritis. Multiple Sclerosis-outpt records for lumbar puncture. Records for DOS 6/11-6/15/08-received-presented with acute exacerbation of MS, right lower extremity weakness and neuropathic pain. Migraine. Possible adverse reaction HPV vaccine and interferon.

Other Meds:

Lab Data: Confirmation of diagnosis done by MRI and spinal tap. 10/14/08-records received-Sed rate 65, c-reactive protein negative. CSF culture negative.

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324778-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	30-Aug-2007	15-Aug-2007	-15	10-Sep-2008	17-Sep-2008	PA		15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain lower, Alopecia, Arthralgia, Autoimmune disorder, Fatigue, Joint swelling

Symptom Text: Extreme hair loss, fatigue, auto-immune problems, joint swelling and pain. 10/1/08 Reviewed vaccination & medical records. 6/26/07-C/O lower abdominal pain on right side. Vaccine records indicate different dates than originally reported: HPV #1 given 8/30/07, #2 9/20/07 & #3 12/13/07.

Other Meds: Birth Control

Lab Data: Had full blood panels, tested for thyroid and auto immune problems. X-rays of hands and wrists.Saw Rheumotologist and dermatologist. 10/1/08-records received-LABS: pelvic US WNL

History: None HPV #2 given 9/20/07, Lot # 0524U, LA; HPV #3 given 12/13/2007, Lot # 0524U, LA 10/1/08-records received-PMH: contraception (Yasmin), smoker. Depression. (+) HPV w/abnormal PAP smears RLQ abdominal pain since 2006. Right kidney stones & UTIs. Right ovarian cyst. Family hx: cardiovascular disease, thyroid disease.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324783-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	17-Sep-2007	01-Oct-2007	14	10-Sep-2008	22-Sep-2008	PA		01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Colposcopy, Papilloma viral infection

Symptom Text: Previous pap smear before vaccine was normal, all pap smears after vaccine have been abnormal. I now have cervical dysplasia and presence of HPV. I've had 3 colposcopy's because of abnormal cells. My partner of over 2 years developed genital warts following the second dose of garadisil. I was administered one shot on 7-11-07 and a second shot 9-17-07. In October of 2007, he started developing bumps in his genital region and in December of 2007 he routinely began getting them burned/lasered off. His dermatologist initially thought it was contagisom molluscum, but now over a year later and with them still not gone, she believes it to be genital warts. He has never had any previous problems/signs of this disease ever before and neither have I. I was never asked what medications I was on prior to the shots or if i was sick and might have a low immune system. (I have ashtma, severe allergies, and often get sick). Also, I was not tested prior to the shots to see if i had been infected with the HPV virus in the past. I believe that these incidents are a direct result of the gardasil vaccine. I had been in a monogomous relationship for a year without any problems or symptoms. It was not until I started getting the gardasil vaccinne that we both started noticing adverse side effects. I do not think that doctors are asking the proper questions before administering this shot. Whose to say everyone's body can fight off the virus in the vaccines, especially if the person has already been infected and has a low immune system?

Other Meds: albuterol, flovent, zyrtec, singular, prilosec, nuva ring, nasonex

Lab Data:

History: allergies, ashtma, gerd, endometriosis, scoliosis

Prex Illness: no illness directly after vaccine, problems developed later

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324786-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	05-Sep-2008	06-Sep-2008	1	10-Sep-2008	22-Sep-2008	CA		23-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Grand mal convulsion, Oropharyngeal pain

Symptom Text: Had a seizure within 24 hours after receving the vacinne. No seizure history. 12/19/08-records received for DOS 9/22/08 C/O sore throat, seizures. Few weeks prior had a tonic/clonic gran mal seizure. Had scratchy throat 2 days prior to seizure.

Other Meds:

Lab Data: MRI Brain 12/19/08-records received-MRI normal. EEG results unknown.

History:

Prex Illness: none 12/19/0-8records received-Had scratchy throat 2 days prior to seizure.

Prex Vax Illns:

Vaers Id: **324795-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Jul-2008	17-Jul-2008	8	10-Sep-2008	22-Sep-2008	MI		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0270X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0063X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysphonia, Pain, Pharyngeal oedema, Swollen tongue, Urticaria

Symptom Text: Patient recevied both varicella and HPV on 7/9/08. The mother called our clinic on 7/18/08 with the note documented below.Nurse Comments: Placed call back to mom. Mom states patient had reported to mom last night that her throat felt swollen. Mom gave Benadryl. Mom states today she has her voice back. Questioned if patient had hives yesterday or just itching. Mom states patient did have hives and she gave Benadryl yesterday. States right now patient is reporting that her tongue feels thick and her throat feels swollen. Mom states patient says she aches all over. Patient recently just went off of her Florinef that she had been on x 2 years and wondered if that could be contributing. Recommended mom give Benadryl again now. Discussed with Dr. here in the office who states patient should go to ER at this time. Mom informed of this and states understanding. Completed by Nurse: July 18, 2008 11:52 AM Patient was taken to clinic by mother. The physician form there called and discussed the case with Dr. She ordered a referral to an allergist. The patient has an appointment with an allergist on 9/17/08 for this and other past allergic reactions.

Other Meds:

Lab Data: None

History: Syncope-vasovagel/postural orthostatic/ tachycardia syndrome. ICD-9 780.2

Prex Illness: Preexisting condition at right. Not ill at that time.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324806-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	04-Sep-2008	05-Sep-2008	1	10-Sep-2008	22-Sep-2008	AZ		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2665AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C2937AA	5	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nodule, Oedema peripheral, Rash pustular, Skin warm

Symptom Text: Swelling, with small pustules, warm to touch. Seen in ER - Given oral antibiotics; Sub-cutaneous nodule 3x4cm.

Other Meds:

Lab Data:

History:

Prex Illness: None known

Prex Vax Illns:

Vaers Id: 324826-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Jun-2007	10-Oct-2007	117	11-Sep-2008	12-Sep-2008	--	WAES0809USA00739	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1404F	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Decreased appetite, Fatigue, Gait disturbance, Joint stiffness, Laceration, Malaise, Nasopharyngitis, Nausea, Oedema peripheral, Pain, Pharyngitis, Pharyngolaryngeal pain, Pyrexia, Sinusitis, Surgery, Viral infection

Symptom Text: Information has been received from a physician assistant concerning her daughter who on an unspecified date was vaccinated with a second dose of GARDASIL (lot number, injection site and route not reported). Three weeks after the vaccination, the patient experienced paralysis. The patient had to quit the volleyball team because her walking was effected. The patient underwent "a full work up" that was negative for any medical reason for the paralysis. Therapy with HPV was discontinued. The event was transient in nature and completely resolved in four weeks. It was reported that the patient completed the series of GARDASIL last year. Upon internal review, paralysis is considered to be an other important medical event. Additional information has been requested. 9/19/08 Reviewed PCP #2 medical records of 10/10/07-6/26/08. FINAL DX: viral syndrome & polyarthralgia Records reveal patient experienced morning joint pain & stiffness & swelling of hands & feet for approx 2 wks prior to 10/10/07 visit. Had cold s/s prior to symptoms start. Received HPV #2 on 3/21/08. 5/5/08 Had finger laceration w/nerve & tendon involvement & was referred to ortho/hand surgeon, required surgery. Received HPV #3 on 5/22/08 but no Lot # provided. Seen 6/26 for sore throat, nausea, malaise, fatigue, decreased appetite, body aches & fever x 1 day. Tx w/ antibiotics for sinusitis & pharyngitis.

Other Meds: unknown

Lab Data: diagnostic laboratory - negative LABS: 10/11/07 CBC w/neutros 74%(H), lymphs 25%(L), monos 1%(L). RA factor 3.1(N). ESR 8(N). UA WNL. EBV neg. 5/6/08 CBC, chemistry WNL. 6/26/08 WBC 13.0(H), Grans 89%(H), lymphs 8.0(L), mono 3.0%(L

History: Unknown PMH: acne. HPV#2, given 3/21/08, Lot #1757U. HPV#3 given 5/22/08, no Lot # available.

Prex Illness:

Prex Vax Illns:

Vaers Id: 324834-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Jul-2008	03-Jul-2008	1	11-Sep-2008	22-Sep-2008	NJ		24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0960F	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Headache, Nausea, Vaccination complication, Vomiting

Symptom Text: Dizziness - feeling she will "pass out" if doesn't lie down. Nausea, weakness, headaches. 9/23/08 Reviewed PCP medical record of 8/15/08. FINAL DX: adverse reaction Record reveals patient experienced dizziness, HA, feeling like passing out daily x 3 wks but now 3-5x/week, nausea/vomiting if doesn't rest & general weakness. Instructed to increase oral fluids.

Other Meds:

Lab Data: None

History: None HPV #1 given 5/1/08, Lot# 1967U

Prex Illness: None

Prex Vax Illns:

Vaers Id: **324835-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	24-Jun-2008	24-Jun-2008	0	11-Sep-2008	22-Sep-2008	CT		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB264CA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives, 6 hours after vaccination

Other Meds: None

Lab Data:

History: History of asthma

Prex Illness: Abdominal Pain

Prex Vax Illns:

Vaers Id: **324851-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
45.0	M	26-Jun-2008	26-Jun-2008	0	11-Sep-2008	22-Sep-2008	--		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0755U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Tinnitus

Symptom Text: After the second dose of study drug on 06/26/2008, the subject had a recurrence of the AE tinnitus on 06/26/2008 (there is no grade 1 tinnitus on the CTCAE.) The subject stated that this second episode of tinnitus was much milder than the previously reported episode that had resolved on 05/13/2008. The patient had discussed his tinnitus and the vaccine study with his physician on 5/22/08. The subject felt strongly that he wanted to continue on study. This 06/26/2008 episode resolved fully without treatment on 07/09/2008.

Other Meds: NURVIR, REYATAZ

Lab Data:

History: Medical history of tinnitus (over a year ago)

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324852-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	M	27-Mar-2008	29-Mar-2008	2	11-Sep-2008	22-Sep-2008	--		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0755U		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Muscle strain

Symptom Text: Subject received the second course of GARDASIL vaccine on 3/27/2008. He experienced pain at the injection site, grade 2 on 3/27/08 through 3/29/08. Then on 3/29/08, he experienced muscle strain grade 2, while performing his yoga routine in the same muscle that was sore from the injection site.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **324862-1 (S)** **Related reports:** 324862-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jun-2008	21-Jun-2008	5	11-Sep-2008	16-Sep-2008	IL		08-May-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2770AA	0	Left arm	Unknown	
HPV4	MERCK & CO. INC.	0067	0	Right arm	Unknown	
MNQ	SANOFI PASTEUR	U2537AA	0	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Confusional state, Convulsion, Epilepsy, Fatigue, Insomnia, Postictal state, Syncope, Syncope vasovagal, Tongue biting

Symptom Text: June 16, 2008 / First Gardasil Vaccine and Menactra Vaccine June 21, 2008 / Diagnosed Vaso Vagal at Hospital Emergency Room after being taken by ambulance for fainting August 19, 2008 / Second Gardasil Vaccine September 2, 2008/ Has one apparent seizure in her dormitory and is taken by ambulance to facility. The diagnosis on her release paper states 'possible seizure disorder early onset' and she is instructed to follow-up with a doctor in 24 hours or to return to Provena if her condition gets worse. She experiences a second seizure outside the facility Front Door and is admitted to the hospital. 5/7/2009 Records received neurology DOS 9/9/08-2/10/09. FINAL DX: Epileptic seizure Several visits, feeling tired, difficulty sleeping. Several seizures c tongue biting, followed by postictal confusion. Pt does not recollect events.

Other Meds: n/a

Lab Data: EKG, Urinalysis, CT Scan, MRI, EEG, 5/7/2009 Records received neurology DOS 9/9/08-2/10/09. EEG mildly abnormal, MRI brain WNL.

History: n/a HPV #2, given 8/13/08, Lot # 0229X, LA.

Prex Illness: n/a

Prex Vax Illns:

Vaers Id: **324862-2 (S)** **Related reports:** 324862-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jun-2008	16-Jun-2008	0	18-Sep-2008	19-Sep-2008	IL	WAES0809USA01775	19-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Injection site pain, Syncope, Syncope vasovagal, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning her daughter an 18 year old female with no known drug allergies/reactions and no pertinent medical history reported who on 16-JUN-2008 was vaccinated with the first dose of GARDASIL. On 19-AUG-2008, the patient was vaccinated with a second dose of GARDASIL. Concomitant therapy included MENACTRA. On 16-JUN-2008, and after receiving the first dose of GARDASIL, the patient had severe pain at the injection site. Then, on 21-JUN-2008, she was taken by ambulance to the emergency room because she had fainting spells. While in the emergency room she had an electrocardiogram (EKG) done and the emergency room physician diagnosed with vasovagal, and she was able to gone that day. The consumer reported that the patient then received the second dose of GARDASIL, and she also had severe pain at the injection site again. Then, on 02-SEP-2008, she had two seizures. The consumer reported that the patient was then sent to the hospital at 10:30 PM on 02-SEP-2008 by ambulance because of the seizures and was then admitted to the hospital at 12:00 AM. At the time the patient was admitted she had a computed axial tomography (CAT scan), a magnetic resonance imaging (MRI) and a electroencephalography (EEG) done. The patient was the diagnosed with early onset seizure disorder and was prescribed KEPPRA (manufacturer unspecified)) and she can not drive for 6 months. The consumer reported the patient was then able to leave the hospital on 03-SEP-2008 at 8:30 PM. The consumer stated that the patient has not had a seizure since but it may because of the medication she is taking. The patient will not receive the third dose of GARDASIL. Additional information has been requested.

Other Meds:

Lab Data: electrocardiogram, 06/21/08, vasovagal; computed axial, 09/03/08, seizure disorder; magnetic resonance, 09/03/08, seizure disorder; electroencephalography, 09/03/08, seizure disorder

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **324876-1** **Related reports:** 324876-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	05-Sep-2008	06-Sep-2008	1	11-Sep-2008	22-Sep-2008	MN		01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2996AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Immunisation reaction, Injection site erythema, Injection site rash, Injection site swelling, Injection site warmth, Musculoskeletal pain, Pain in extremity, Paraesthesia, Radiculitis brachial

Symptom Text: pt presented to clinic 9-8-2008 with about a 6 cm red, raised, warm area around injection site. pt also reported arm pain from shoulder to hand. pt advised to take ibuprofen 800mg tid and use ice on area tid, if no better follow up in clinic in 2 days. pt returned to clinic on 9-11-08 with less redness, but still had pain from shoulder to elbow. diagnosis brachial neuritis. 9/22/08 Office records received for DOS 9/8 & 9/11/2008 with DX: Reaction to Adacel causing Brachial Neuritis. Pt initially presented 3 days s/p Adacel and HPV vax with c/o injection site redness and arm pain. Instructed to use ice and ibuprofen and RTO in 48 hrs if not better. Seen 9/11/08 for recheck. PE (+) for 8x8cm area of warmth, redness and pain with palpation initially, now reduced in size but with numbness and tingling in the hand

Other Meds: Alesse

Lab Data:

History:

Prex Illness: otitis media

Prex Vax Illns:

Vaers Id: **324876-2** **Related reports:** 324876-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	05-Sep-2008	06-Sep-2008	1	17-Sep-2008	18-Sep-2008	MN	200802854	30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2996A	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0052X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling, Injection site warmth, Pain in extremity, Radiculitis brachial

Symptom Text: Initial report was received 11 September 2008 from a health care professional. A 21-year-old female patient had a past history of amoxicillin allergy, had received a first dose intramuscular right arm injection of ADACEL, lot number C2996AA and a first dose intramuscular left arm injection of GARDASIL (manufacturer Merck), lot number 0052X on 05 September 2008 and one day later, she developed a red raised 6cm diameter hot area at the injection site (arm not specified). On 08 September 2008, three days post vaccination, the patient developed right arm pain from her shoulder to her hand. She was evaluated by her physician on 11 September 2008 who diagnosed the patient with brachial neuritis. Laboratory and diagnostic testing had not been performed. The reporter stated that the patient had previously experienced a "swollen arm after TB test". At the time of the report, the patient's recovery status was unknown. No further information was provided.

Other Meds: ALESSE

Lab Data:

History: The patient had a past history of amoxicillin allergy and had been taking Alesse (birth control) at the time of vaccination. The patient also had a past history of a "swollen arm after a TB test".

Prex Illness:

Prex Vax Illns:

Vaers Id: 324883-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	31-May-2007	31-May-2007	0	11-Sep-2008	15-Sep-2008	--	WAES0707USA00777	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	0	Unknown	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Live birth, Oral contraception

Symptom Text: Information has been received from a nurse through a Merck pregnancy registry concerning a 26 year old female patient with a history of 4 pregnancies and 2 live births who was on oral contraceptives in the first trimester, with gestational diabetes and insulin dependency, who on 31-MAY-2007 was vaccinated with the first dose of GARDASIL (lot# 657737/0522U). The patient was pregnant with a LMP of 09-Apr-2007. Follow up information indicated that on 09-Jan-2008 the patient delivered a normal liveborn male infant weeks from LMP 37 2/7 with a Apgar score 8/9. Follow up information has been received in the form of medical records. On 09-JAN-2008, the baby was born with hyperbilirubinemia and bilateral cephalohematomas. The weight was 8 lbs, the length 21 inches, head circumference 13.8 inch. On 12-JAN-2008 and 13-JAN-2008, the patient was admitted for phototherapy. Saturday, 12-JAN-2008, the patient's bilirubin was 19 and Sunday, 13-JAN-2008, rebound bilirubin was 11 (5 hours off phototherapy). A total bilirubin measurement with a heel stick was performed. The lab results were reported as: -12-JAN-2008: 18.0 mg /dl 19.2 mg /dl. -13-JAN-2008: 12.3 mg/dl 10.8 mg/dl 11.2 mg/dl 16.1 mg/dl. On 14-JAN-2008, the baby had a sick visit to the doctor and still had jaundice and cephalohematoma, with icteric sclera and hyperbilirubinemia. Some lab test was performed, which included a measurement of Total bilirubin with a heel stick. The results was : 12.2 mg/dl. On 18-JAN-2008, the baby had a sick visit date, and it was noted that the baby had jaundice from chest to upper abdomen (seedy yellow) and hyperbilirubinemia. The pediatrician was concerned about the baby's head swollen. The baby still had cephalohematoma. On examination on 25-JAN-2008, it was noted that the baby still had bilateral cephalohematoma; the left side greater the right side. It was also noticed that the baby had urine frequently, had jaundice in the face, and diaper rash. The baby was 15 days. A lab test was performed which included a PKU (result not reported)

Other Meds: Unknown

Lab Data: ultrasound, 06/15/07 - 7.47 week gestation; total serum bilirubin, 01/13/08, 16.1 mg/dl; total serum bilirubin, 01/13/08, 10.8 mg/dl; total serum bilirubin, 01/13/08, 12.3 mg/dl; total serum bilirubin, 01/13/08, 11.2 mg/dl; total serum bili

History: Gestational diabetes

Prex Illness: Pregnancy NOS (LMP = 4/9/2007); Diabetes mellitus insulin-dependent; Hypertension; Hypercholesterolaemia

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324886-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Aug-2008	22-Aug-2008	1	11-Sep-2008	22-Sep-2008	NC		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Pyrexia, Rash

Symptom Text: Fever, rash on stomach, legs, arms. Dizzy, headache.

Other Meds: FOCALIN XR

Lab Data:

History:

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324888-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	25-Jul-2008	25-Jul-2008	0	11-Sep-2008	22-Sep-2008	--		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB284CA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1978U	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2766AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0170X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Heart rate normal

Symptom Text: Pt given Tdap, GARDASIL, varicella, Hep A => dizzy x few seconds. VSS (T=97.8, P=76, RR=20, BP=106/60) => Pt observed for 1 1/2 hours => VSS repeated T=97.9, P=76, RR=20, 108/60 s/p 1 1/2 hr.

Other Meds:

Lab Data: None

History: Small osteochondral fx of R knee -> surgery scheduled next week.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **324890-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-Sep-2008	10-Sep-2008	1	11-Sep-2008	22-Sep-2008	CO		23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	U523U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blindness unilateral, Eye pain, Headache, Hypoaesthesia, Hypoaesthesia facial, Migraine, Paraesthesia, Photophobia, Sensation of heaviness, Sensory loss, Vision blurred, Vomiting

Symptom Text: One hour after awaking on 9/10, left eye became blurry, right eye painful, then left side of face felt numb, lasted 5-6 minutes. Then left hand felt numb and heavy for 50 minutes. Headache developed over right side of head, could not see out of left eye. Headache through the day; Tx:Advil 9/17/08 MR received from PCP. Returned to office 1 day after HPV #3 with c/o tingling to L side of face and L hand. Loss of sensation began near the mouth and spread toward the L side of face. Developed blurry vision eye which lasted ~5 minutes. L hand numbness lasted 30 minutes- unable to grab things. Developed severe R sided H/A and vomited 5x. Has become photopobic. PE WNL. Assessment: Migraine headache. No further f/u at this time.

Other Meds: Advil PRN

Lab Data: None

History: NKDA, history of sinusitis, headache 4/08. PMH: sinus infection, fx R arm, URI 3 wks ago. H/A with visual disturbance 1 yr ago

Prex Illness: None

Prex Vax Illns:

Vaers Id: 324902-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Aug-2007	14-Sep-2007	18	07-Jul-2008	12-Sep-2008	FR	WAES0806USA03499	12-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Aphthous stomatitis, Appendicectomy, Appendicitis, Arthralgia, Arthritis, Arthropathy, Back pain, Bone pain, Enthesopathy, Iron deficiency, Juvenile arthritis, Lymphadenopathy, Mastication disorder, Meningism, Microcytic anaemia, Mobility decreased, Night sweats, Oedema peripheral

Symptom Text: Information has been received from a general practitioner concerning a 15 year old female who in springtime 2008 was vaccinated with a dose of GARDASIL. Subsequently the patient experienced meningism from which she recovered within a not reported time. Afterwards the patient developed rheumatic disease (not otherwise specified) and was hospitalised (exact date not yet reported). At the time of reporting the patient was not recovered. Follow up information has been received. On 11-APR-2008, the patient was vaccinated with a 3rd dose of GARDASIL. She underwent an appendectomy due to appendicitis starting on 12-APR-2008. She also complained about pain in mandibular joint and difficulty in mastication. In the course swelling of feet and she was unable to walk. Concomitantly the patient complained about enlarged axillary lymph nodes, oral aphthae and night sweat. The patient was hospitalised from 13-MAY-2008 to 15-MAY-2008 due to suspicion of juvenile rheumatic disease. Symptoms had started about 1 year ago with relapsing pain in cervical spine and pain in knee. Due to increased ESR and IgA values (see lab date) differential diagnoses of a chronic gastrointestinal inflammation with extraintestinal manifestation and a reactive arthritis couldn't be definitely ruled out. Under treatment with VOLTAREN symptoms improved notedly. A check up in the rheumatological outpatient department was arranged in six weeks. The patient was told to continue the medication with VOLTAREN and physiotherapy. Upon medical letter dated 05-JUN-2008 the following diagnoses were established: multiple joint disorders (symptoms included arthritis, mobility decreased, juvenile rheumatoid arthritis, pain in joint, mastication disorder, unable to walk, swelling of feet); microcyteic anaemia, iron deficiency, enthesopathy and mandibular joint arthritis. No further information is available. The case was closed. Other business partner numbers included E2008-05437.

Other Meds: Unknown

Lab Data: ultrasound, 13May08, joint sonography: no signs for arthritis in examined joints; electrocardiogram, 13May08, no pathological findings; transthoracic echocardiography, 13May08, slight mitral insufficiency; magnetic resonance imaging, 14May0

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324904-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Aug-2007	01-Aug-2007	0	18-Aug-2008	16-Sep-2008	--	WAES0807USA03705	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Immediate post-injection reaction, Injection site pain

Symptom Text: Information has been received from a physician's assistant concerning a female with no drug reactions/allergies, who in August 2007, was vaccinated intramuscularly with a first dose of GARDASIL (lot # not reported) 0.5 mL. There was no concomitant medication. In August 2007 after the GARDASIL was administered, the patient experienced immediate severe pain at the injection site of the left arm. Due to the pain, the patient was unable to participate in sports. The pain resolved in one week without requiring treatment. The patient contacted the physician's office via phone. The patient has not received the second or third dose of GARDASIL. No further information was available. Immediate severe pain at the injection site was considered to be disabling. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324905-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	17-Aug-2007	27-Aug-2007	10	18-Aug-2008	16-Sep-2008	NJ	WAES0807USA03575	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 20 year old female with allergies and attention deficit disorder who on 17-AUG-2007 was vaccinated with the first dose of GARDASIL, the second dose was given on 18-OCT-2007, and the third dose was given on 21-FEB-2008. Concomitant therapy included montelukast sodium and CONCERTA. On 27-AUG-2007 the patient developed hives and the hives continued throughout the series and then disappeared in May 2008. The hives appeared on her face, legs, arms, feet and stomach. The hives were described as "large welts, like golf ball size". The patient was seen twice in the emergency room and received EPIPEN administration on each of the visits, she was then discharged home. The patient had been seen by two allergists. Skin testing was performed, but it could not determine the cause for the hives. The physician stated that the allergist believed that the hives were hormone related. Upon internal review, hives requiring epinephrine was determined to be and other important medical event. Additional information has been requested.

Other Meds: Concerta; Singulair

Lab Data: Allergy test, negative

History:

Prex Illness: Hypersensitivity; Attention deficit disorder

Prex Vax Illns:

Vaers Id: **324906-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	06-May-2008	06-May-2008	0	18-Aug-2008	16-Sep-2008	TX	WAES0807USA03278	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia

Symptom Text: Information has been received from a nurse concerning a 10 year old female who on 26-JUN-2007 was vaccinated with the first dose of GARDASIL (lot no. 655619/1427F). The first dose was administered concomitantly with VARIVAX (Oka/Merck) (MSD). The patient tolerated with the first dose without incident. On 06-MAY-2008 the patient was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL (lot no. 657006/0188U) into the deltoid muscle of the left arm. There was no concomitant therapy. On 14-MAY-2008, "eight days after the second dose", the patient experienced pain in hip joint and was hospitalized. The patient was discharged on 16-MAY-2008. On an unspecified date the patient was recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324907-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-May-2008	15-Jul-2008	53	18-Aug-2008	16-Sep-2008	FL	WAES0807USA03269	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Migraine

Symptom Text: Information has been received from a physician concerning a 12 year old female with asthma and allergy to pertussis and a history of tension headache who on 23-JUN-2008 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL 9lot no. 659437/12660) into the right deltoid. Concomitant therapy included tetanus toxoid and albuterol. The physician's office got a call "last night", on approximately 15-JUL-2008, stating that the patient experienced severe migraine and went to the emergency room. The patient was treated with IV fluids, REGLAN and released. The patient was not hospitalized. The outcome was unknown. Additional information has been requested.

Other Meds: albuterol; tetanus toxoid

Lab Data: Unknown

History: Tension headache

Prex Illness: Asthma; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **324908-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Aug-2007	07-Jul-2008	328	18-Aug-2008	16-Sep-2008	MA	WAES0807USA03288	23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0187U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Muscular weakness, Pain in extremity, Sensory loss

Symptom Text: Information has been received from a nurse concerning her 17 year old daughter who in 2007 received the first and on an unspecified date a second dose of GARDASIL. On 14-AUG-2007 was vaccinated with the third dose of GARDASIL (lot # 655618/0186U) 0.5 ml, IM. On 07-JUL-2008, the patient experienced pain, weakness and numbness in her right thumb and arm. Medical attention was sought, she had blood tests, was seen by a neurologist and will have an Magnetic Resonance Imaging (MRI) the week of 21-JUL-2008. The primary care doctor thought this may be associated with GARDASIL until he saw on the chart that the third dose was given in the opposite arm. At the time of reporting, the patient's pain and weakness and numbness persisted. No additional information at this time. Additional information has been requested. 9/16/2008 MR received from PCP. Seen 7/9/2008 with c/o acute onset of numbness which began in the R thumb and spread up to the level of mid triceps. PE (+) for decreased strength of the fingers, wrist and elbow. Sensory deficit to R mid tricep. Tearful and anxious re: symptoms. Ascending sensory deficit on R hand to upper arm with motor weakness. Reflexes intact. Referred to neuro. Neuro consult 7/11/08-improving numbness of unknown etiology. Numbness improving, now only to elbow. Pinprick and touch sensation diminished on R arm. F/U visit 3 weeks later with continued improvement. Still some numbness and decreased sensation of the hand. Will f/u with EMG and/or MRI PRN.

Other Meds: Unknown

Lab Data: magnetic resonance 07/21?/08. Labs and Diagnostics: CBC with WBC 11.6, Hgb 14.3, Hct 41.7, RBC 4.89Platelets 477. ESR 19.

History: Unknown. PMH: knee injury

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324909-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	IA	WAES0807USA03302	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with the first dose of GARDASIL. On an unspecified date was vaccinated with the second dose of GARDASIL 0.5 ml, injection (route). 24-48 hours after receiving her second dose of GARDASIL, the patient experienced rash on her face that went into her ears. The patient sought medical attention. The outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324910-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-May-2008	15-May-2008	1	18-Aug-2008	16-Sep-2008	MA	WAES0807USA03310	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Gastroenteritis, Vomiting

Symptom Text: Information has been received from a physician concerning a 16 year old female with attention deficit disorder who on 14-MAY-2008 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot no. 659182/1757U). Concomitant therapy included ADDERALL TABLETS and ZOLOFT. On approximately 15-MAY-2008, "within 24 hours", the patient had severe gastroenteritis (vomiting, diarrhea). It was unknown if the patient had fever. On an unspecified date the patient was recovered. The patient's mother called the office to seek unspecified medical attention. Additional information has been requested.

Other Meds: ADDERALL; ZOLOFT

Lab Data: Unknown

History:

Prex Illness: Attention deficit disorder

Prex Vax Illns:

Vaers Id: **324911-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	08-Jul-2008	11-Jul-2008	3	18-Aug-2008	17-Sep-2008	VA	WAES0807USA03321	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysarthria, Headache, Hypersensitivity, Loss of consciousness, Nausea, Palpitations

Symptom Text: Information has been received from a registered nurse concerning an approximately 25 year old female who on 08-JUL-2008 was vaccinated with the first dose of GARDASIL in an Ob/Gyn office. On 11-JUL-2008 the patient experienced severe allergic reaction, severe headaches, nausea, heart racing and slurred speech. Per nurse, the patient also blacked out. The patient was treated in the reporter's office. The patient was referred to a neurologist and was brought to the emergency room. It was unknown if the patient was hospitalized. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324912-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	10-Jul-2008	10-Jul-2008	0	18-Aug-2008	16-Sep-2008	TX	WAES0807USA03334	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Erythema, Nausea, Pharyngeal oedema, Pharyngolaryngeal pain, Pyrexia

Symptom Text: Information has been received from a mother concerning her daughter, a 23 year old female with penicillin allergy and "cold medicines" allergy and a history of bipolar and shaken baby syndrome who on 10-JUL-2008 was vaccinated with the first dose of GARDASIL. (Dose, route of administration and lot number were not provided). Concomitant therapy included SEROQUEL, LEXAPRO and TEGRETOL. The patient felt faint after the vaccination. Two days later her throat began to swell and was sore. The mother reported "Her throat was so swollen that she could not eat cereal." The patient also had a red face, fever and was nauseous. The patient sought medical attention via telephone. She started taking BENADRYL on 16-JUL-2008. Her symptoms were improving since starting the therapy with BENADRYL. Additional information has been requested.

Other Meds: Tegretol; Lexapro; Seroquel

Lab Data: None

History: Bipolar disorder; shaken baby syndrome

Prex Illness: Penicillin allergy; drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324913-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	--	WAES0807USA03336	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lactose intolerance

Symptom Text: Information has been received from a nurse practitioner concerning one of three girls in the same family who "a few months ago" in 2008, were vaccinated with GARDASIL. Subsequently, the patient became lactose intolerant after receiving GARDASIL. It was not specified whether the patient sought medical attention. The patient's lactose persisted. Additional information has been requested. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324914-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Mar-2008	12-Mar-2008	0	18-Aug-2008	16-Sep-2008	ID	WAES0807USA03355	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician and a nurse concerning an approximately 17 year old female who on 05-JAN-2008 and 12-MAR-2008 was vaccinated with her first and second doses, respectively, of GARDASIL (Lot # 655327/1287U and 0515X). The patient experienced shortness of breath after her first and second doses of GARDASIL. Subsequently the patient recovered from the events. The reporting physician did not think the reactions were vaccine-related, especially since the patient did not mention the reactions after they happened and came into the office to let the doctor know she would not be getting the third dose. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324915-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	--	WAES0807USA03361	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstrual disorder, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered nurse concerning a female who on unspecified dates was vaccinated intramuscularly with 0.5 ml of first and second doses, respectively, of GARDASIL (lot#s not provided). It was reported that the patient claims that her period started thirty minutes after each dose of GARDASIL was given. Unspecified medical attention was sought. At the time of this report the outcome was unknown. No additional information available. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324916-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	NC	WAES0807USA03362	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Red blood cell sedimentation rate increased

Symptom Text: Information has been received from a physician concerning a female with a family history of rheumatoid arthritis and Lupus who in April 2008, was vaccinated intramuscularly with a first dose of GARDASIL (lot # unspecified). It was reported that on an unspecified date post vaccination (date reported as "few weeks later") the blood test was performed and the readings showed that there was an increase in patient's sedimentation rate. Unspecified medical attention was sought. It was reported that the patient went for more "blood work" where the readings went back to normal. Additional information has been requested.

Other Meds: Unknown

Lab Data: Erythrocyte, 05?/??/08, increase; Erythrocyte, ?/?/08, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324917-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Mar-2008	Unknown		18-Aug-2008	16-Sep-2008	TX	WAES0807USA03363	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Ataxia, Dysarthria, Extensor plantar response, Hyperreflexia, Speech disorder, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning an 18 year old female with a history of severe scoliosis and histiocytosis x at age 1 who in September 2007, was vaccinated with the first dose of GARDASIL. In March 2008, the patient was vaccinated with the third 0.5 ml dose of GARDASIL. The patient experienced ataxia after receiving all three dose of GARDASIL, her speech was slurred and slowed and she was hyper reflexic with present Babinskis bilaterally. The ataxia started and worsened about the time she started the GARDASIL. Neurologist had no diagnosis. At time of reporting patient outcome was not recovered. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Histiocytosis; Scoliosis

Prex Illness: Ataxia

Prex Vax Illns:

Vaers Id: 324919-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Mar-2007	07-Mar-2007	0	18-Aug-2008	16-Sep-2008	--	WAES0705USA00396	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1424F	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received for the pregnancy registry for GARDASIL from a nurse practitioner concerning a 16 year old female with no drug reactions/allergies, reflux, migraine and a history of cardiac surgery who on 07-MAR-2007 was vaccinated with the first dose of GARDASIL IM (Lot# 654885/1424F). Concomitant therapy included rizatriptan benzoate (MSD), propranolol HCl and ranitidine. The patient was pregnant when she was vaccinated with GARDASIL. The patient had a positive pregnancy test. As of 01-MAY-2007, she was noted to be 2.5 months gestation. Follow-up phone call information was received from the nurse practitioner who reported that the patient delivered a healthy, normal, baby that is now 7 months old and not experiencing any problems. During the pregnancy, the patient did have some symptoms of pre-term labor, but went on to deliver full-term, vaginally. No additional information is expected.

Other Meds: propranolol hydrochloride, ranitidine, MAXALT (rizatriptan benzoate)

Lab Data: beta-human chorionic, +

History: Cardiac operation

Prex Illness: Pregnancy NOS (LMP = 2/14/2007); Gastrooesophageal reflux; Migraine

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324920-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	M	21-Jul-2007	21-Jul-2007	0	18-Aug-2008	16-Sep-2008	MA	WAES0707USA04605	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1426F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Initial and follow information has been received from a physician concerning a 17 year old white male who on 21-JUL-2007 at 1:00 PM was inadvertently vaccinated IM with a first dose of GARDASIL (Lot # 655205/1426F) instead of MENACTRA. On 31-JUL-2007, the patient was seen in the office and he was healthy, and had to adverse event at all. No further information is expected.

Other Meds: unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324921-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	02-Jul-2007	02-Jul-2007	0	18-Aug-2008	16-Sep-2008	UT	WAES0709USA03225	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0212U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Live birth, Nausea

Symptom Text: Initial and follow up information has been received through the Merck pregnancy registry for GARDASIL from a registered nurse concerning a 16 year old female with depression and anxiety with no prior pregnancies who on 02-JUL-2007 was vaccinated IM with the first dose (0.5 ml) of GARDASIL (Lot# 0212U). Concomitant therapy included ZOLOFT and EFFEXOR. Subsequently, the patient became pregnant. Last menstrual period was 18-JUN-2007 and estimated date of delivery was 24-AR-2008. On 24-OCT-2007 the patient had a routine ultrasound which was within normal limits. On an unspecified, the patient developed nausea and was placed on therapy with PHENEGRAN and ZOFRAN. On 08-MAR-2008 at 37 weeks/4 days the patient had a 7 lb. 2 oz. live born infant with an Apgar score of 8/9. It was reported that the baby was adopted out. Additional information is not expected.

Other Meds: ZOLOFT; EFFEXOR

Lab Data: ultrasound, 10/24/07, WNL - routine; beta-human chorionic, 7/25/07, posit; Apgar score, 03/08/08, 8/9

History:

Prex Illness: Pregnancy NOS (LMP = 6/18/2007); Anxiety; Depression

Prex Vax Illns:

Vaers Id: **324922-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	05-Jul-2007	10-Jul-2007	5	18-Aug-2008	16-Sep-2008	LA	WAES0709USA03272	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Herpes simplex, Vaginal infection

Symptom Text: Initial and follow-up information has been received from a physician concerning a 27 year old female with a history of three previous pregnancies, 3 full term deliveries with no birth defects or complications, and condyloma, who on 02-MAY-2007 was vaccinated with a first dose of GARDASIL (Lot# 657006/0188U). On 05-JUL-2007, the patient was vaccinated with a second dose of GARDASIL (Lot# 657621/0387U). Subsequently, the patient became pregnant after receiving second dose of the vaccination. On 09-OCT-2007 and 06-DEC-2007 ultrasounds were performed for dating and fetal screening, the results were within normal limits. On 20-NOV-2007 a serum alpha-fetoprotein test was performed for screening, the results were within normal limits. The patient's last menstrual period was 10-JUL-2007 and her estimated delivery date was 15-APR-2008. At the time of the report, the patient's outcomes was unknown. No product quality complaint was involved. On 15-APR-2008, forty weeks from her last menstrual period the patient gave birth to a female infant that weighed 9 pounds 2 ounces. The infant was 20 3/4 inches long, her apgar score was 9/10, and her head circumference was "13 1/2." The infant was normal, with no congenital anomalies, complications, or abnormalities. Other medications used during the pregnancy were REPLIVA 21/7 from 13-MAR-2008 to 18-OCT-2008 once a day as an iron supplement, PRIMACARE ONE from 13-MAR-2008 to 18-OCT-2008 once a day, GYNAZOLE 1 started on 24-SEP-2007 once at bedtime for vaginitis, CLINDESSE started on 24-SEP-2007 once at bedtime for vaginitis, CLINDESSE started on 24-SEP-2007 once at bedtime for vaginitis, and VALTREX 500mg started on 09-OCT-2007 (reported as 09-OCT-2008; two times a day for Herpes simplex outbreak. Additional information is not expected.

Other Meds: Unknown

Lab Data: ultrasound, 09/27/07, reason-for dating and fetal survey; result-within normal limits; ultrasound, 12/12/07, reason-for dating and fetal survey; result-within normal limits; serum alpha-fetoprotein, 11/20/07, reason-screening; result-within

History: Condyloma

Prex Illness:

Prex Vax Illns:

Vaers Id: **324923-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	29-May-2007	17-Jun-2007	19	18-Aug-2008	16-Sep-2008	PA	WAES0710USA03634	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0388U		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received from a physician and a registered nurse for the Pregnancy Registry for GARDASIL concerning a 20 year old female (demographics not reported) with migraines (also reported as headaches), a sinus disorder, and a history of an abnormal pap (CIN I) who on 28-MAR-2007 was vaccinated intramuscularly with the first dose of GARDASIL (Lot 656049/0187U; site not reported). On 29-MAY-2007, the patient was vaccinated intramuscularly with the second dose of GARDASIL (Lot 657622/0388U). Concomitant therapy included montelukast sodium (MSD), AVIANE, and albuterol inhaler (manufacturer unspecified) and ibuprofen (manufacturer unspecified). On 09-SEP-2007, the patient had a positive home pregnancy test, and on 10-SEP-2007, a quantitative HCG blood test confirmed the pregnancy. On 20-Sep-2007, the patient sought unspecified medical attention in the office. On 04-DEC-2007, the patient has an ultrasound for history of prominent fetal stomach (not further specified). On 03-JAN-2008 the patient had a ultrasound which was normal. The patient was treated with an iron supplement for 2 weeks and prenatal vitamins (not further specified). On 26-APR-2008, the patient gave birth to a normal, healthy male infant (8 lb. oz; 22 in). The baby had an Apgar score of 9/9. The infant had no congenital anomalies, complications or abnormalities. There were no complications during pregnancy or during labor and delivery. Additional information is not expected.

Other Meds: albuterol; AVIANE; ibuprofen; SINGULAIR

Lab Data: ultrasound, 12/04/07, prominent fetal stomach; ultrasound, 01/03/08, normal; beta-human chrorionic, 09/09/07, positive; serum beta-human, 09/10/07, positive

History: Papanicolaou smear abnormal

Prex Illness: Pregnancy NOS (LMP = 6/17/2007); Migraine; Sinus disorder

Prex Vax Illns:

Vaers Id: **324924-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	29-Jun-2007	04-Oct-2007	97	18-Aug-2008	16-Sep-2008	PA	WAES0711USA03134	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Inappropriate schedule of drug administration, Seasonal allergy

Symptom Text: Initial and follow up information has been received from the Merck Pregnancy Registry for GARDASIL via a physician concerning a "healthy" 18 year old white female smoker with a history of some problems with her menses who on 29-JUN-2007 was vaccinated intramuscularly into the left arm with a 0.5 ml first dose of GARDASIL. On 05-NOV-2007, the patient was vaccinated with a second dose of GARDASIL. On 05-NOV-2007, the patient was vaccinated with a second dose of GARDASIL (Lot #655620/0170U). Concomitant therapy included SEASONALE. Subsequently, the patient called the doctor's office and stated her home pregnancy test was positive. On 14-NOV-2007, she was seen in the doctor's office and a urine test confirmed pregnancy. A Quantitative blood test for pregnancy was also performed, but the results were not available yet. The patient's last menstrual period was on 04-OCT-2007, estimated date of conception was 18-OCT-2007 and the estimated date of delivery was 10-Jul-2008. On an unspecified date, the patient developed seasonal allergies and was treated with montelukast (MSD). On 22-FEB-2008 and 19-MAY-2008 the patient had routine ultrasound tests with "good" results. It was reported the patient delivered a normal, 18 1/4 inch, 6 lb. 7 oz. female at 38 weeks, 5 days with a had circumference of 12 3/4 inches (Apgar score not reported). Additional information has been requested.

Other Meds: SEASONALE

Lab Data: diagnostic laboratory, 11/14/07 - Quantatitive blood test -- Results not reported; ultrasound, 02/22/08 "good - Routine; ultrasound, 05/19/08 "good - Routine; urine beta-human, 11/14/07 - Positive - confirms pregnancy; Apgar score, 07/05/08

History: Menstrual irregular

Prex Illness: Pregnancy NOS (LMP = 10/4/2007; Smoker

Prex Vax Illns:

Vaers Id: **324925-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	26-Sep-2007	Unknown		18-Aug-2008	16-Sep-2008	TX	WAES0711USA06548	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0530U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Drug exposure during pregnancy, Pregnancy induced hypertension

Symptom Text: Initial and follow-up information has been received through the Merck pregnancy registry from a physician and a licensed vocational nurse (LVN) concerning a 19 year old female with a history of depression and anxiety. The patient had a history of an elective termination of 1 previous pregnancy. On 26-SEP-2007, the patient was vaccinated with her first dose of GARDASIL (Lot # 0530U). Concomitant therapy included "CLONAZEPAK" (therapy unspecified). Subsequently, the patient found out she was pregnant. The patient's last menstrual period (LMP) was 02-OCT-2007, with an estimated delivery date of 09-JUL-2008. The patient sought medical attention. On 16-JUN-2008, the patient was treated with VISTARIL 50 mg, 1 every 6 hours PRN for anxiety. During the pregnancy, the patient had complication of mild pregnancy induced hypertension (PIH). On 02-JUL-2008, 39 weeks from LMP, the patient delivered a normal female infant with Apgar score of 9/9. Additional information is not expected.

Other Meds: [therapy unspecified]

Lab Data: Apgar score, 02/07/08, 9/9

History: Depression; Anxiety; Termination of pregnancy - elective

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324926-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	28-Sep-2007	Unknown		18-Aug-2008	16-Sep-2008	OH	WAES0712USA08593	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Genital haemorrhage, Live birth

Symptom Text: Initial and follow up information has been received from a registered nurse through the Merck pregnancy registry for GARDASIL concerning a 26 year old female with no previous pregnancies, no pertinent medical history, and no known allergies who on 27-JUL-2007 was vaccinated with her first dose of GARDASIL (Lot #658100/0525U) intramuscularly. On 28-SEP-2007 the patient received her second dose of GARDASIL (Lot #658100/0525U) intramuscularly. There was no concomitant medication. On 28-SEP-2007, before the second dose, a urine pregnancy test was administered. The result was negative for pregnancy. The patient called the office stating that she was pregnant and an OB intake appointment was on 14-DEC-2007. A urine pregnancy test was performed on this day with positive results. On 27-DEC-2007 an ultrasound was performed, and on 24-JAN-2008 a maternal serum alphafeto protein was done, both tests were within normal limits. The patients last menstrual period was 02-OCT-2007 and the estimated delivery date was 08-JUL-2008. During the first trimester, the patient had complication of first trimester spotting. On 10-JUL-2008, 41 weeks from the LMP, the patient delivered a normal live born female infant weighing 7lbs 14ozs and apgar of 9/9. Additional information is not expected.

Other Meds: None

Lab Data: Ultrasound, 12/27/07, NT scan - within normal limits; Urine beta-human, 09/28/07, results were negative; Serum alpha-fetoprotein, 01/24/08, screening - within normal limits; Urine beta-human, 12/14/07, results were positive.

History:

Prex Illness: Pregnancy NOS (LMP = 10/2/2007)

Prex Vax Illns:

Vaers Id: **324927-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
48.0	M	20-May-2008	20-May-2008	0	18-Aug-2008	16-Sep-2008	MO	WAES0805USA04536	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Initial and follow up information has been received from a registered nurse concerning a 48 year old male, with a thyroid nodule, tick bite, allergies to FLEXERIL and SYNTHROID and a history of a positive PPD tuberculin test who on 20-MAY-2008 was vaccinated intramuscularly in the left deltoid with a single dose of GARDASIL (Lot # 658556/1060U). The nurse reported that the patient was intended to received a tetanus toxoid vaccine (unspecified), but GARDASIL was inadvertently administered. The nurse confirmed that this was a case of human error and not product confusion. No problems were reported. The nurse reports that there were no known adverse events. The patient was at the office "to evaluate area of tick bite". The patient had a negative "Lyme's titer" (not further specified). On 21-May-2008, the office called the patient and the patient reported no ill effects. The patient has not contacted the office subsequently. No additional information was provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Lyme disease assay, negative

History: PPD skin test positive

Prex Illness: Tick bite; Drug hypersensitivity; Thyroid nodule

Prex Vax Illns:

Vaers Id: **324928-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	04-Jun-2008	04-Jun-2008	0	18-Aug-2008	16-Sep-2008	IN	WAES0806USA01507	16-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1740U	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B021CB	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ear pain, Injection site pain, Wrong drug administered

Symptom Text: Initial and follow-up information has been received from a registered nurse concerning a now 12 year old male who on 04-JUN-2008 was vaccinated IM in the left arm with a dose GARDASIL (lot# 659962/1740U) 0.5 ml. Concomitant therapy included BOOSTRIX. The nurse had indicated that the patient had inadvertently received the GARDASIL vaccine. No adverse effects were reported at the time. Follow-up information from the nurse indicated that on 05-JUN-2008, the patient complained of pain at the injection site for 2-3 days and complained of earache of the left ear for a day following the injections. The patient did not seek medical attention. The patient recovered on 08-JUN-2008. Follow-up information from a phone call was received on 01-AUG-2008. The nurse had clarified that the patient had inadvertently received the GARDASIL due to wrong drug being administered. The nurse also stated that "the family stated he has had earaches before." No other information is available. No further information is available.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **324930-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Apr-2008	Unknown		18-Aug-2008	16-Sep-2008	PA	WAES0806USA03814	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Joint swelling

Symptom Text: Information has been received from a licensed practical nurse concerning a female who on an unspecified date was vaccinated intramuscularly with 0.5 ml second dose of GARDASIL. Subsequently the patient experienced swelling and redness in ankles. No additional adverse event was provided. Follow up information was received which reported that at 4:30 PM on 01-APR-2008 the patient with no pre-existing allergies, birth defects, medical conditions who was vaccinated intramuscularly with 0.5 ml first dose of GARDASIL in her left deltoid. No illness at the time of vaccination. Subsequently the patient experienced swelling and redness in ankles. No treatment was given. On an unspecified date, the patient recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324931-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		18-Aug-2008	16-Sep-2008	CA	WAES0807USA00292	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse mid-wife concerning a patient who on an unspecified date was vaccinated with a third dose of GARDASIL (lot number, injection site and route not reported). Subsequently the patient fainted. It was unknown whether the patient sought medical attention. This is one of two reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324932-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	--	WAES0807USA00302	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female who on an unspecified date, also reported as in August 2008, was vaccinated with GARDASIL in the arm (lot number and injection route not reported). Subsequently the patient developed unspecified arm pain at the injection site. Subsequently, the patient recovered from arm pain at the injection site without treatment. The patient did not sought any medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324933-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	--	WAES0807USA00332	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Myalgia, Nuclear magnetic resonance imaging, Vertigo

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female who was vaccinated with the third dose of GARDASIL. The patient experienced severe vertigo followed by severe muscle and joint pain after vaccination. It was noted that the vertigo began three weeks after the patient received the third dose. The patient was performed magnetic resonance imaging (MRI) test. The patient's severe vertigo and severe muscle and joint pain persisted. The patient sought medical attention and seen by practice. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324944-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-May-2007	07-May-2007	0	12-Sep-2008	15-Sep-2008	FR	WAES0705AUS00169	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0138U		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactic reaction, Anxiety, Cardiac murmur, Choking sensation, Dyspnoea, Feeling cold, Haematemesis, Muscle twitching, Nausea, Oxygen saturation decreased, Stridor, Syncope, Tachypnoea, Throat tightness, Vision blurred, Vomiting

Symptom Text: Information has been received from a physician via another company as part of a business agreement (manufacturer control # GARD 2007 05 25001) concerning a 15 year old female who was vaccinated with GARDASIL. On the day of vaccination with GARDASIL the patient "fainted and kept fainting". The physician advised that the patient developed a new heart murmur. Echocardiography and Holter monitoring were done and the results were normal. The physician advised that the patient may be "histrionic". Further Information has been received from the NSW Department of Health, via CSL as part of a business agreement, with follow-up information received on request by the Company via a Line Listing from the NSW Department of Health. As part of the regular school-based immunisation program funded by the government, on 07-MAY-2007, the patient was vaccinated with GARDASIL (Lot No. 655742/0138U, Batch No. J0798, Expiry date 07-AUG-2009). Half an hour after the vaccination the patient fainted. The patient complained of nausea, blurred vision, mild twitching prior to fainting. The patient has continued to faint since. Total 12 times in 13 days. The patient was referred to general physician and cardiologist. Nothing abnormal was detected by a cardiologist. The outcome was reported as ongoing. The reporter considered that repeated syncope was probably related to therapy with GARDASIL. The original reporting source was not provided. Information was also obtained on request by the Company from the agency via a Case Line Listing and a Public Case Detail Form. It was reported that on 07-MAY-2007 after vaccination with GARDASIL the patient developed muscle twitching, nausea and blurred vision which required consultation with a specialist physician. At the time of reporting to the agency on 29-MAY-2007 the patient had not yet recovered from the syncope, muscle twitching, nausea, blurred vision and syncope. The agency considered that syncope, muscle twitching, nausea and blurred vision were probably related to therapy with

Other Meds: Unknown

Lab Data: echocardiography, normal; Holter monitoring, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324945-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-May-2007	11-May-2007	0	12-Sep-2008	15-Sep-2008	FR	WAES0707AUS00072	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0138U		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Anaphylactic reaction, Asthenia, Back pain, Dyspnoea, Eye pruritus, Hypersensitivity, Tachycardia, Vision blurred

Symptom Text: Information has been received from the agency, via CSL as part of a business agreement, with follow-up information received on request by the Company via a Line Listing from the agency. This case was also reported in a newspaper article. On 11-MAY-2007, as part of the regular school-based immunisation program funded by the government, a 16 year old female was vaccinated with GARDASIL (Lot No. 655742/0138U, Batch No, J0798, Expiry date 07-AUG-2009). 1 hour post vaccination on 11-MAY-2007, the patient developed an allergic reaction described as shortness of breath, feeling weak, stomach ache, backache, itchy eyes, blurred vision and elevated pulse rate (100/min). The patient was transferred to an emergency department at a hospital, however no treatment was given and the patient was subsequently discharged. The agency considered that allergic was possibly related to therapy with GARDASIL. The original reporting source was not provided. Information was obtained on requested by the Company from the agency via a Public Case Detail Form and a Case Line Listing. It was reported that on 11-MAY-2007, 1 hour post vaccination with GARDASIL, the patient experienced shortness of breath, stomach ache, felt weak, backache, itchy eye, tachycardia and blurred vision (In follow-up it was reported that on 11-MAY-2007, the patient also experienced anaphylactic reaction). On 11-MAY-2007, the patient recovered from shortness of breath, stomach ache, felt weak, backache, itchy eye, tachycardia and blurred vision (In follow-up it was reported that on 11-MAY-2007, the patient also recovered from anaphylactic reaction). The agency considered that shortness of breath, stomach ache, felt weak, backache, itchy eye, tachycardia and blurred vision were possibly related to therapy with GARDASIL (In follow-up it was reported that the agency considered that anaphylactic reaction was probably related to therapy with GARDASIL. The original reporting source was not provided. Information has been received from media monitors advising that the patient'

Other Meds: Unknown

Lab Data: Physical examination, 01May07, pulse rate 100/min

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324946-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-May-2007	Unknown		12-Sep-2008	15-Sep-2008	FR	WAES0712AUS00143	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0138U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Allergy to vaccine, Anaphylactic reaction, Chest discomfort, Chest pain, Cough, Drug eruption, Dyspnoea, Feeling cold, Immediate post-injection reaction, Injection site pain, Nausea, Paraesthesia, Rash generalised, Rash pruritic, Tachypnoea, Throat tightness, Urticaria papular, Wheezing

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing with follow-up received from the agency via a Public Case Details Form. This case was also reported in a newspaper article. On 17-MAY-2007 a 16 year old female was vaccinated with GARDASIL, intramuscularly as prophylaxis (Lot No. 655742/0138U, Batch No. J0798, expiry date 07-AUG-2009). Subsequently after vaccination with GARDASIL, the patient developed papular urticaria and drug eruption, starting on the inside of wrists and progressively spreading over entire body. The rash was extremely itchy. On 24-JUL-2007 the patient's papular urticaria and drug eruption resolved. A skin biopsy was conducted by a dermatologist and the result was discussed with a specialist. It was thought that GARDASIL was the cause. The agency considered the papular urticaria and drug eruption were certainly related to therapy with GARDASIL. The original reporting source was not provided. Information was received from the media monitors advising that the patient's experience was subsequently reported in an article. Subsequently, the patient's experience was reported in a published article. It was reported that this patient's experience was classified as anaphylaxis. It was described that less than 5 minutes post vaccination, the patient reported symptoms of immediate pain at the injection site, rash on face, neck and chest, generalized prickle sensation, sensation of throat closure, cough, difficulty breathing or talking, tight painful chest, felt wheezy, nausea and felt cold. The observed signs and symptoms witnessed by the school nurses were urticarial rash to face and neck and tachypnea. The patient was treated with salbutamol. This patient fulfilled level 2 of Brighton level of diagnostic certainty of anaphylactic reaction. The authors of the article considered that anaphylaxis was certain or very likely related to therapy with GARDASIL. The article also discussed the experiences of 7 other patient's who experience anaphylaxis following vaccinatio

Other Meds: Unknown

Lab Data: skin biopsy, 14Aug07, lesion biopsied by dermatologist. GARDASIL thought to be the cause

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324947-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jun-2008	29-Jul-2008	58	12-Sep-2008	15-Sep-2008	FR	WAES0809USA00954	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anisocytosis, Asthenia, Cell death, Cholestasis, Chromaturia, Febrile infection, Haemolytic anaemia, Hyperbilirubinaemia, Jaundice, Rash pruritic, Steroid therapy, Transfusion

Symptom Text: Information has been received from a health authority concerning a 17 year old female with chronic urticaria and family history of rheumatoid arthritis (mother) who in June 2008, was vaccinated with the third dose of GARDASIL IM (lot # not reported). On 29-JUL-2008 the patient developed pruritic rash on the hands and the back, treated with H1 antihistamines, which asthenia and seemingly dark urine. She was admitted on 02-AUG-2008 due to febrile icterus revealing haemolytic anaemia. Tests found anaemia with haemoglobin at 6.5g, regenerative with 276,000 reticulocytes, macrocytic, and also anysocytosis with 10% spherocytes. Initial work-up (values not provided) found cytolysis, cholestasis, bilirubinaemia, significantly decreased haptoglobin but normal hemostasis, absence of vitamin deficiency and schizocytes. Coombs test was positive for IgG. The following serologies were negative: hepatitis A, B, C, HIV, mycoplasma, parvovirus B19. Infectious mononucleasis test was negative. Abdominal ultrasound and CT scan of abdomen and chest were negative; thymoma was ruled out and there was no adenopathy. Antinuclear antibodies were slightly positive with 1/60. The following antibodies were negative: native anti-DNA, anti smooth muscle, antiribosome, antimitochondrial, antireticulum, anticardiolipid, anti-SSA, anti-Sm, anti-Jol. The patient received blood transfusion and corrective treatment with corticosteroids, which enabled her discharge on 18-AUG-2008 with hemoglobin rate of 8.6 g and 9.9 g on 20-AUG-2008. Follow-up consultation was scheduled one month later. The patient was reported to have recovered. The case is closed. Other business partner numbers included: E2008-08298 and NT20080392. Additional information is not expected.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, 02?Aug08, cytolysis; Diagnostic laboratory test, 02?Aug08, cholestasis; Diagnostic laboratory test, 02?Aug08, bilirubinaemia; Diagnostic laboratory test, 02?Aug08, significantly decreased haptoglobin but normal h

History:

Prex Illness: Urticaria chronic

Prex Vax Illns:

Vaers Id: **324948-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Apr-2008	01-Apr-2008	0	12-Sep-2008	15-Sep-2008	FR	WAES0809USA00959	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chillblains

Symptom Text: Information has been received from a health authority concerning a 18 year old female with history of acne who in April 2008, was vaccinated with the first dose of GARDASIL (lot # not reported) IM. Suspect therapy reported by the health authority also comprised isotretinoin in April 2008 for the treatment of acne and ethinylestradiol (+) drospirenone on May 2008 for contraception. A few days after vaccination, the patient experienced flares of childblain suggestive of lupus eruption. Antinuclear antibodies were positive at 1/320. In a dermatological consultation, it was decided to discontinue isotretinoin, then ethinylestradiol (+) drospirenone one month later. Further testing of antinuclear antibodies was scheduled. The health authorities specified that flares of childblain already existed before the first injection of GARDASIL. At the time of reporting, the patient had not recovered. Flares of childblain suggestive of lupus eruption and positive antinuclear antibodies were considered to be other important medical events. Other business partner numbers included: E2008-08308 and SE20080306. Additional information has been requested.

Other Meds: JASMINE, isotretinoin

Lab Data: serum ANA, positive at 1/320

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324949-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Sep-2007	01-Sep-2007	0	12-Sep-2008	15-Sep-2008	MA	WAES0809USA01194	15-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Injection site cellulitis

Symptom Text: Information has been received from a nurse practitioner (N.P.) concerning a 16 year old female who in September 2007, was vaccinated intramuscularly with the third 0.5 ml dose of GARDASIL. On the same day, the patient developed cellulitis at the injection site, on her arm. The patient was evaluated in an emergency room and admitted to the hospital overnight for IV antibiotic treatment. On an unspecified date, the patient recovered. No product quality complaint was involved. Cellulitis at the injection site, on her arm was also considered to be disabling and a other important medical event (IV antibiotics) by the NP. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **324959-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Sep-2007	01-Oct-2007	27	12-Sep-2008	25-Sep-2008	OH		20-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Alopecia, Anorexia, Arthralgia, Back pain, Bone scan normal, Chest pain, Contusion, Fatigue, Full blood count normal, Headache, Joint effusion, Joint swelling, Musculoskeletal pain, Myalgia, Nausea, Pain in extremity, Photosensitivity reaction, Rash, Rash erythematous, Red blood cell sedimentation rate normal, Scab, Swelling, Weight decreased

Symptom Text: 3rd dose 1/5/2008. 1/11/08 - seen with complaints of intermittent joint pain -severe stages her activity - lasts from seconds to hours had been happening for several months. CBC, Sed Rate normal. Seen 2/6/08 - increasing frequency of episodes. Bone scan done which was normal. 4/22/08. Returned again with shoulder/scapula, leg pain. Nausea with occasional swelling and facial rash. No fever. Referred to Rheumaotogly. - Normal work up- continues to have intermittent bone, leg pain and swelling. 9/22/2008 Office notes recd from PCP beginning 1/5/08 with HPV#3. Returned 2/6/08 with c/o episodic back pain x 4 months. Located in lower and thoracic regions, as well as R scapula, L hand and both legs. PE WNL. Returned 4/22/08 with c/o constant body pain x 6 months. Recent R knee effusion with joint pain and swelling, myalgias. Referred to Rheum. 10/21/08 Partial record received from rheum dated 6/12/08. Pt questionaire with c/o tiredness, H/A, loss of hair, chest pain, loss of appetitite, abdominal cramping, joint pain, low back pain, muscle pain, neck pain, bruising, rash on cheeks and sun sensitivity. 11/10/08 Reaminder of Rheumatology consult received. Pt reports pain began in Oct 2007 with back pain which then spread to bone pain of the arms and legs. Pain is intermittant and associated with joint swelling and rash. ROS (+) for weight loss which has been regained, frontal H/As, R upper chest wall apin, occ abd pain, back pain, myalgias, hair loss, scabbing. No objective abnormalities on PE. No Dx.

Other Meds:

Lab Data: Labs and Diagnostics: Lyme (-), ANA (-), Ferritin low at 7, IgA, IgG, IgM, C3, C4, ESR, CRP all WNL. SGOT 36. Bili-unconjugated 1.2. Alk Phos 59. CBC WNL UA (+) for 10-14 WBC, 5-9 RBC, trace mucus, 4+

History: PMH: Varicella age 3

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324960-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Sep-2008	06-Sep-2008	1	12-Sep-2008	25-Sep-2008	CA		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB268EA	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1758U	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	0336X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral

Symptom Text: Red/swollen left arm

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **324964-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	05-Aug-2008	05-Aug-2008	0	12-Sep-2008	25-Sep-2008	MO		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Patient describes pain in left arm at injection site. Has had pain constantly since injection on 8/5/08. Pain not relieved by NSAIDS. Patient is referred to neurologist for further evaluation.

Other Meds: None

Lab Data:

History: No known drug allergies. History of bilateral breast implants.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **324969-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Sep-2008	04-Sep-2008	0	12-Sep-2008	25-Sep-2008	NC		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Left arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB529AA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Approximately 15 minutes following the injections, patient had syncopal episode lasting less than 1 minute. After episode, patient reports not having had anything to eat or drink all day. Patient's blood sugar = 85. Patient given granola bar and H2O. Stated that she felt much better. Discharged home with mother. No injury reported. Physician aware.

Other Meds: None

Lab Data: (Normal) Glucometer blood sugar (performed in-house) = 85.

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324973-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	03-Sep-2008	05-Sep-2008	2	12-Sep-2008	25-Sep-2008	NJ		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Onset of symptoms occurred 48 hours post vaccine. Symptoms were nausea and vomiting. Spoke with patient today, 9/8/08. Feels much better. Able to tolerate solids and liquids.

Other Meds: N/A

Lab Data: N/A

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324977-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	05-Sep-2008	05-Sep-2008	0	12-Sep-2008	25-Sep-2008	MA		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Migraine

Symptom Text: Migraine headache within 30 minutes after vaccine.

Other Meds: Yaz - 28

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **324985-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	05-Sep-2008	Unknown		12-Sep-2008	25-Sep-2008	IN		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0847X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: No adverse events or treatment. Patient not the appropriate age for the vaccine.

Other Meds: Asacol; Allegra D

Lab Data:

History: Allergic rhinitis; Proctatitis

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324991-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	U	02-Jul-2008	03-Jul-2008	1	12-Sep-2008	22-Sep-2008	PR		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C290AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1740U	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2564AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: She Had her first menstruation after the vaccine. She has not have other menstruation after that.

Other Meds: none

Lab Data: none

History: none

Prex Illness: She Had her first menstruation after the vaccine. She has not have other menstruation after that.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **324995-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Aug-2008	15-Aug-2008	0	12-Sep-2008	22-Sep-2008	SD		22-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0392X	1	Right arm	Subcutaneously	
TDAP	SANOFI PASTEUR	C2995AA	0	Right arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB243AA	0	Left arm	Unknown	
HPV4	MERCK & CO. INC.	0279X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Joint range of motion decreased, Pyrexia

Symptom Text: Child had high fever of 104.3 Could not bed fingers and toes next 2 days after vaccine

Other Meds:

Lab Data:

History: Allergy-Penicillin

Prex Illness:

Prex Vax Illns:

Vaers Id: **325004-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	05-Aug-2008	11-Sep-2008	37	13-Sep-2008	22-Sep-2008	CA		24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Ageusia, Facial palsy, Headache, Muscle twitching, Pharyngolaryngeal pain, Steroid therapy

Symptom Text: Gardasil vaccine was given to my daughter on August 5th, 2008. On the morning of September 11th, 2008 my daughter woke up with the right side of her face paralyzed. She is unable to smile on the right side. She can not blink well with the right eye. She also can not taste. She has had a headache on the right side of her head behind her ear. We went to the emergency room immediately and after a thorough exam she was diagnosed with Bell's Palsy. Needless to say she is not going to be getting the 2nd and 3rd dose of Gardasil. We have been reading that Bell's Palsy has been reported as a side effect of Gardasil. I feel strongly that others need to be aware of the possible serious side effects. Merck should not downplay these very serious side effects. We are very upset that it has been marketed as "very safe". 9/16/08 Reviewed ER medical records of 9/11/08. FINAL DX: Bell's palsy Records reveal patient experienced HA, taste alteration, right eye twitching x 2 days, right facial paralysis, mouth drooping & unable to completely close right eye x 1 day. Had sore throat 1 week prior. Tx w/steroids & referred to PCP on d/c to home.

Other Meds:

Lab Data: LABS: UA WNL.

History: PMH: lupus. School out of country.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **325007-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Sep-2008	03-Sep-2008	0	13-Sep-2008	22-Sep-2008	VA		23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2656AA	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Dizziness, Fall, Flank pain, Headache, Injection site pain, Loss of consciousness, Presyncope, Pyrexia, Tenderness, Urinary tract infection, Vaccination complication

Symptom Text: Black out, headache, fever, weakness, and dizziness. 9/22/08 WCC dated 9/3/08 and vax info received from PCP. Healthy adolescent with normal G&D. Vax given. ER record received dated 9/6/08 with Final DX: Drug reaction-medicinal substance given or taken. UTI. Vaccine Reaction. Pt presented with c/o onset of fever, injection site pain, R hip/flank pain, severe dizzinessand profound weakness. Pt passed out and fell at home with another episode of near syncope. PE (+) for CVA tenderness. Pt given pain meds and abx and D/c.

Other Meds:

Lab Data: Labs and Diagnostics: EKG WNL. UA (+) for trace leukocyte esterase. CBC WNL. Chem unremarkable. Mono (-). Blood cx (-). Strep (-). CXR WNL

History: no

Prex Illness: no

Prex Vax Illns:

Vaers Id: **325018-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Jul-2008	23-Jul-2008	0	12-Sep-2008	25-Sep-2008	MA		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives occurred evening of immunization and continued for several days.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325021-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	12-Sep-2008	12-Sep-2008	0	12-Sep-2008	25-Sep-2008	KY		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Child received Gardasil and then fainted. Doctor examined, no adverse findings. B/P: WNL.

Other Meds: N/A

Lab Data: Physician exam

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: **325032-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jan-2008	01-Jan-2008	0	18-Aug-2008	16-Sep-2008	IA	WAES0807USA00339	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vaginal haemorrhage

Symptom Text: Information has been received through the Merck pregnancy registry from a nurse concerning a female with no pertinent medical history and no history of drug reactions or allergies on prior pregnancies who between January and April 2008 received at least 2 doses of GARDASIL at a different facility. There was no concomitant medication. The patient was pregnant. Her last menstrual period was approximately 26-DEC-2007. The estimated due date is 02-OCT-2008. The patient was seen in the reporter's office in April 2008 for obstetric care. On 23-APR-2008, the patient had a normal ultrasound and negative serum alpha-fetoprotein test. On approximately 26-MAY-2008, the patient developed vaginal bleeding. On 25-MAY-2008, an ultrasound was performed and was normal. At the time of the report, the patient's outcome was unknown. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound, 04/23/08, normal; ultrasound, 05/26/08, normal; serum alpha-fetoprotein, 04/23/08, negative

History:

Prex Illness: Pregnancy NOS (LMP = 12/26/2007)

Prex Vax Illns:

Vaers Id: **325033-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	18-Jun-2008	19-Jun-2008	1	18-Aug-2008	16-Sep-2008	CA	WAES0807USA00347	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site swelling, Local reaction

Symptom Text: Information has been received from a medical assistant concerning a 24 year old female with no relevant medical history or allergies who on 18-JUN-2008 was vaccinated with a first dose of GARDASIL (lot number 659964/1978U) 0.5 ml by intramuscular injection into the left deltoid. There was no concomitant medication. On 19-JUN-2008 the patient developed local injection site reaction. The injection site was red, itchy and swollen. The patient said it looked like a "Cheetos chip" was inside the arm. The patient sought unspecified medical attention. At the time of reporting, the patient's events were recovering. Follow-up information was received which reported that on 25-JUN-2008, the patient was recovered from all the events. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325034-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	11-Jun-2008	12-Jun-2008	1	18-Aug-2008	16-Sep-2008	--	WAES0807USA00373	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Hypoaesthesia facial, Hypoaesthesia oral, Pain in extremity

Symptom Text: Information has been received from a medical assistant concerning a 19 year old female with no known pertinent medical history or drug reactions/allergies who on 11-JUN-2008 was vaccinated with a first dose of GARDASIIL (lot# 660391/0063) 0.5 ml, IM. Concomitant therapy included ZOLOFT. On 12-JUN-2008 the patient experienced face and mouth numbness, pain in her left arm and leg and shortness of breath after receiving GARDASIL. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: ZOLOFT

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **325035-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	CA	WAES0807USA00412	25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HEP	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Information has been received from a medical assistant concerning a female who was inadvertently vaccinated with a dose of GARDASIL, instead of the hepatitis vaccine (manufacturer unknown). The medical assistant reported that it was staff error only, and that the patient was at the appropriate age for GARDASIL. The patient sought medical attention at the physician's office. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325036-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	30-Jun-2008	30-Jun-2008	0	18-Aug-2008	16-Sep-2008	KY	WAES0807USA00414	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Flushing, Rash pruritic, Rash pustular

Symptom Text: Information has been received from a physician concerning an 18 year old female who on 30-JUN-2008 was vaccinated with the first dose of GARDASIL. The physician reported that she was vaccinated around 1 PM that day, and took a nap at home, then woke up at 7 PM with a rash on her back and sides of arms that had pustules like pimples, and on her chest had flushing. The bumps were itching and she scratched them. On 01-JUL-2008, the physician saw the patient had gave her BENADRYL. The physician planned to recommend a 2nd dose of GARDASIL. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325037-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	M	Unknown	Unknown		18-Aug-2008	16-Sep-2008	TX	WAES0807USA00419	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site anaesthesia, Injection site pain, Off label use

Symptom Text: Information has been received from a nurse concerning a male who on an unspecified date was inadvertently vaccinated with GARDASIL. No concomitant medication was reported. The patient experienced injection site pain and numbness. The patient sought medical attention in the office. On an unspecified date, he recovered. There was no product quality complaint. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325038-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	12-Jun-2008	12-Jun-2008	0	18-Aug-2008	16-Sep-2008	--	WAES0807USA00491	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Nervousness

Symptom Text: Information has been received from a consumer for the pregnancy registry concerning her 25 year old daughter, who was vaccinated with the first dose of GARDASIL (Lot and batch # not reported). It was reported that the patient got her GARDASIL vaccine "two weeks ago", was tested and had negative pregnancy test, now has found she is six weeks pregnant, "is a nervous wreck". No further information is available.

Other Meds: Unknown

Lab Data: Beta-human chorionic, 05/??/08, negative

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 325039-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	18-Jun-2008	Unknown		18-Aug-2008	16-Sep-2008	--	WAES0807USA00572	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Axillary pain, Fatigue, Musculoskeletal chest pain

Symptom Text: Information has been received from a nurse midwife concerning a 21 year old female with asthma and no allergies who on 02-APR-2008 was vaccinated with a first dose of GARDASIL (lot number 658100/0525u) (injection site and route not reported). On 18-JUN-2008 the patient was vaccinated with a first dose of GARDASIL (lot number 658100/0525U) 0.5 ml by intramuscular injection in the left arm. Concomitant therapy included DEPO-PROVERA. Subsequently the patient experienced pain in the left axilla and left ribs, and tiredness. The patient sought unspecified medical attention. Subsequently, the patient recovered from the events. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: None

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: 325040-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Jun-2008	27-Jun-2008	0	18-Aug-2008	16-Sep-2008	--	WAES0807USA00574	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0544X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Dizziness, Feeling jittery, Fibrocystic breast disease, Hyperhidrosis, Hypoaesthesia, Migraine, Nausea, Neuralgia, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 20 year old female with no allergies who on 27-JUN-2008 was vaccinated with a first dose of GARDASIL 0.5ml by intramuscular injection (lot number 657874/0544X) (injection site not reported). Concomitant therapy included hormonal contraceptives (unspecified) and omeprazole (MSD). On 27-JUN-2008, after the vaccination the patient experienced lightheaded, jittery and sweating. Later on the same day the patient began to experienced nausea which increased in severity over the following days. The patient also experienced tingling and numbness on the right side of her head which persisted 24 hours. Unspecified medical attention was sough. Until the time reporting, the patient was not recovered from the events. Additional information has been requested. 10/14/08 Reviewed OB/GYN medical records of 6/25-8/14/2008. FINAL DX: migraine w/o aura w/right occipital neuralgia Records reveal patient experienced usual state of good health on 6/22 w/breast fibrocystic changes. RTC for vaccination on 6/25/08 & immediately experienced sweating, dizziness, jitters which recurred appprox every 10-15 min x 1 hour before d/c to home. RTC 7/2/08 c/o right sided head pain w/tingling & numbness x 24 hours, increasing nausea s/p vaccine on 6/25. Seen by neuro 8/14/08 for increased HA s/p vaccine.

Other Meds: hormonal contraceptives; PRILOSEC

Lab Data: None LABS: CT head 7/16 revealed probable lipoma in corpus callosum. MRI brain WNL w/incidental corpus callosum lipoma.

History: Unknown PMH: GERD, contraception, non-smoker. Migraine HAs.

Prex Illness:

Prex Vax Illns:

Vaers Id: 325041-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Jul-2008	02-Jul-2008	1	18-Aug-2008	16-Sep-2008	--	WAES0807USA00588	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Pyrexia

Symptom Text: Information has been received from a consumer concerning her 12 year old daughter who on 01-JUL-2008, "yesterday", was vaccinated with the first dose of GARDASIL. There was no concomitant medication. On 02-JUL-2008, in the morning, the patient woke up with a fever of 102 and also had pain at the injection site. At the time of this report, the patient's symptoms persisted. The patient sought unspecified medical attention. No further information is available.

Other Meds: None

Lab Data: Diagnostic laboratory, 07/01/08, took a blood sample for routine check-up

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 325042-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jul-2008	01-Jul-2008	0	18-Aug-2008	16-Sep-2008	TX	WAES0807USA00591	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Pain, Pyrexia

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 01-JUL-2008 was vaccinated intramuscularly with the third dose of GARDASIL. On the same day, the patient developed a fever of 102.6 and had chills and just felt achy. The patient was taken to the emergency room where she was given medication for the fever. At the time of this report, the patient's symptoms persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325043-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	--	WAES0807USA00595	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Pain, Pyrexia

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL. Subsequently, the patient developed fever and experienced chills and achiness after receiving vaccination. On approximately 24-JUN-2008, "within the last ten days" the patient was seen by emergency room physician. The outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325044-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Jul-2008	01-Jul-2008	0	18-Aug-2008	16-Sep-2008	IL	WAES0807USA00600	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Musculoskeletal stiffness, Pallor, Unresponsive to stimuli

Symptom Text: Information has been received from a registered nurse concerning a 13 year old female who on 25-OCT-2007 was vaccinated with the first dose of GARDASIL (lot no. 659435/1265U). On 01-JUL-2008 the patient was vaccinated with the second dose of GARDASIL (lot no. 660387/1967U). On the same day, the patient became pale and stiff after receiving the second dose. The patient was also non responsive and the symptoms lasted for 30-45 seconds. The patient was recovered. The patient sought unspecified medical attention in office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325045-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	--	WAES0807USA00612	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Information has been received from a physician assistant concerning her 26 year old female friend with diagnosed cervical papilloma viral infection who in May 2008, was vaccinated with the first dose of GARDASIL. There was no concomitant medication. In approximately May 2008, "within the past two months" the patient developed genital warts. The patient had had two outbreaks. The outcome was unknown. The patient contacted her physician to seek unspecified medical attention. Follow-up information was received from the physician assistant stating that the patient was her personal friend and she did not see the patient in clinic. Further information was unknown. Additional information is not expected.

Other Meds: None

Lab Data: None

History:

Prex Illness: Papilloma viral infection

Prex Vax Illns:

Vaers Id: **325046-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Aug-2007	22-Aug-2007	0	18-Aug-2008	16-Sep-2008	TN	WAES0807USA00625	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site, Pyrexia

Symptom Text: Information has been received from a registered nurse concerning her daughter, an 18 year old female with no known pertinent medical history or drug reactions/allergies who on 22-AUG-2008 was vaccinated with a first dose of GARDASIL 0.5 ml IM. The patient developed a fever after receiving the first dose of GARDASIL. There was no concomitant medication. On 23-AUG-2007 the patient recovered from fever. On 25-OCT-2007 the patient was vaccinated with a second dose of GARDASIL 0.5 ml IM. On 26-FEB-2008 the patient was vaccinated with a third dose of GARDASIL 0.5 ml IM. It was noted that all doses were administered "in hip". The patient sought medical attention in the office at a later visit. Additional information has been requested. The patient's sister also had an adverse experiences with vaccination with GARDASIL (WAES# 0807USA01027).

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325047-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Jul-2008	02-Jul-2008	1	18-Aug-2008	16-Sep-2008	CO	WAES0807USA00663	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Headache, Nausea

Symptom Text: Information has been received from a certified medical assistant concerning a 25 year old female patient with no pertinent medical history and no allergies who on 01-JUL-2008 was vaccinated with the third dose of GARDASIL (lot# 660555/0279X). Concomitant therapy included hormonal contraceptives (unspecified). On 02-JUL-2008 the patient experienced headache, chills and nausea. The patient's headache and chills and nausea persisted. No symptoms were reported from the first and second doses. The patient sought medical attention and called the physician's office. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **325048-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	KY	WAES0807USA00671	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning a teenager female who was vaccinated with the first dose of GARDASIL. The patient experienced dizziness after vaccination. Subsequently, the patient recovered from dizziness. The patient sought medical attention. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325049-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
31.0	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	OH	WAES0807USA00677	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning a 31 year old female who was vaccinated with GARDASIL. The patient experienced severe nausea and vomiting for about a week. The physician would not administer any more doses to the patient. The patient recovered from severe nausea and vomiting. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325050-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	CA	WAES0807USA00683	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Discomfort, Incorrect route of drug administration, Injection site mass

Symptom Text: Information has been received from a physician concerning a female who in approximately May 2008, was vaccinated with GARDASIL SC instead of IM. On approximately 02-JUN-2008 the patient experienced discomfort. The patient experienced a bump under the skin at the injection site on approximately 02-JUL-2008. The patient's bump at the injection site and discomfort persisted. The patient sought medical attention and called the physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325051-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Jun-2008	26-Jun-2008	0	18-Aug-2008	16-Sep-2008	--	WAES0807USA00697	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Eye irritation, Eye pain, Headache, Pyrexia

Symptom Text: Information has been received from a nurse and a nurse practitioner concerning a 14 year old female patient with no pertinent medical history and no allergies who on 26-JUN-2008 was vaccinated with GARDASIL 0.5 ml IM in the deltoid. There was no concomitant medication. On 26-JUN-2008 evening or 1-2 days later, the patient experienced a mild fever that came and went, headaches, pressure on the head and eye and eye pain. On 02-JUL-2008 the patient developed a barky cough. The patient's mild fever that came and went and headaches and pressure on the head and eye and eye pain and barky cough persisted. The patient sought medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325052-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	KY	WAES0807USA00783	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning a teenager female who was vaccinated with the first dose of GARDASIL. The patient experienced dizziness after vaccination. Subsequently, the patient recovered from dizziness. The patient sought medical attention.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325053-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	KY	WAES0807USA00784	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning a teenaged female who was vaccinated with the first dose of GARDASIL. The patient experienced dizziness after vaccination. Subsequently, the patient recovered from dizziness. The patient sought medical attention. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325054-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	--	WAES0807USA00787	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Pain, Pyrexia

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL. Subsequently, the patient developed fever and experienced chills and achiness after receiving vaccination. On approximately 24-JUN-2008, "within the last ten days" the patient was seen by emergency room physician. The outcome was unknown. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325055-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Jul-2008	01-Jul-2008	0	18-Aug-2008	16-Sep-2008	PA	WAES0807USA00791	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest discomfort, Inappropriate schedule of drug administration, Nausea

Symptom Text: Information has bee received from a 25 year old female patient with no pertinent medical history and concomitant medication who in approximately 2006 "at an unspecified time about 2 1/2 years ago by another provider was vaccinated with the first and second dose of GARDASIL. On 01-JUL-2008 the patient received the third dose of GARDASIL (frequency, therapy route and Lot# unspecified). On 03-JUL-2008, the patient developed tightness in her chest and a feeling of nausea two days after she received the third dose of GARDASIL on 01-JUL-2008. The patient has not sought treatment for the symptoms. The patient's adverse events persisted. No other symptoms or treatment reported. No other information provided. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **325056-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	MI	WAES0807USA00792	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling, Lethargy, Pyrexia

Symptom Text: Information has been received from a consumer concerning her 10 year old daughter who on an unspecified date was vaccinated with a dose of GARDASIL. On the same day, the patient was vaccinated with a dose of VARIVAX in the same arm. Subsequently, the patient experienced swelling at the injection site, fever and lethargy. Subsequently, the patient recovered. The patient's mother called the physician to seek unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325057-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	28-Jan-2008	28-Jan-2008	0	18-Aug-2008	16-Sep-2008	WA	WAES0807USA00804	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injected limb mobility decreased, Injection site pain

Symptom Text: Information has been received from a physician concerning a 28 year old female with no medical history or drug allergies who on 28-JAN-2008 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot # 659439/1267U) and on 07-APR-2008 was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL (lot # 658558/1061U). There was no concomitant medication. On 07-APR-2008 the patient experienced pain at the injection site. The patient had constant soreness and pain without redness or bruise. The patient got worse when she moved her arm over her head. At the time of this report, the patient's pain at the injection site persisted. The patient was seen by the physician. The patient did not have any symptoms when she received her first dose of GARDASIL (lot # 659439/1267U). No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325058-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	NJ	WAES0807USA00811	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with the third dose of GARDASIL. The patient experienced tingling and numbness at midnight the same day of the vaccination. The patient went to the emergency room and was "discharged" several hours later. Unspecified tests were performed at the emergency room (results not reported). The patient sought unspecified medical attention by phone call. The patient did not have any problems with the first and second doses of GARDASIL. On an unknown date the patient recovered from tingling and numbness. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, unspecified

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325059-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Jun-2008	02-Jul-2008	7	18-Aug-2008	16-Sep-2008	OH	WAES0807USA00817	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Herpes zoster, Lymphadenopathy, Myalgia

Symptom Text: Information has been received from a physician concerning an 18 year old female who on 25-JUN-2008 was vaccinated with the first dose of GARDASIL (lot number was not provided). On 02-JUL-2008 the patient developed sore muscles all over, swollen lymph nodes underarm and a small patch of herpes zoster on her back. At the time of this report, the outcome was unknown. Unspecified medical attention was sought. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325060-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		18-Aug-2008	16-Sep-2008	PA	WAES0807USA00821	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia of pregnancy, Drug exposure during pregnancy

Symptom Text: Information has been received through the Merck pregnancy registry from a licensed practical nurse at an OB/GYN office concerning a 13 year old female with asthma, sickle cell trait, cardiac murmur and no known allergies who in March 2008, was vaccinated with the third dose of GARDASIL at her primary health care provider's office. The dates of the previous 2 doses of GARDASIL were unknown. The patient was pregnant. On 03-JUL-2008 the patient was seen in the office for her first obstetric visit. The patient's last menstrual period was unknown. Ultrasound confirmed the estimated delivery date is 24-AUG-2008. Based on this, the patient's last menstrual period was estimated to be 15-NOV-2007. The patient was anemic in the pregnancy. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Ultrasound, EDD = 24-Aug-2008

History:

Prex Illness: Pregnancy NOS (LMP = 11/15/2007); Asthma; Sickle cell trait; Cardiac murmur

Prex Vax Illns:

Vaers Id: **325061-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Jun-2008	11-Jun-2008	0	18-Aug-2008	16-Sep-2008	WA	WAES0807USA00832	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Genital haemorrhage

Symptom Text: Information has been received through the Merck pregnancy registry for GARDASIL from a physician (also reported as medical assistant) concerning an 18 year old female with no pertinent medical history and no history of drug reactions or allergies who on 11-JUN-2008 was vaccinated with GARDASIL (dose unspecified). Concomitant therapy included birth control pills (unspecified). Subsequently, the patient reported a positive home urine pregnancy test. The patient's last menstrual period was the last week in May 2008 (dates unspecified). However, the patient had menstrual spotting from 24-JUn-2008 to 25-JUN-2008. No other adverse symptoms or treatment reported. The reporter is the patient's gynecologist and the patient received the GARDASIL elsewhere. The estimated delivery date is 02-MAR-2009. The patient sought medical attention with a telephone call. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: beta-human chorionic, 07?/??/08 - positive

History:

Prex Illness: Pregnancy NOS (LMP = 5/26/2008)

Prex Vax Illns:

Vaers Id: **325063-1 (D)** **Related reports:** 325063-2; 325063-3; 325063-4; 325063-5

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Jul-2008	01-Aug-2008	8	15-Sep-2008	16-Sep-2008	KS	WAES0809USA00837	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Unknown	Unknown	

Seriousness: DIED, ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Asthenia, Azotaemia, Cardiac failure congestive, Cardiomyopathy, Chest pain, Chills, Death, Dizziness, Dyspnoea, Hypotension, Hypoxia, Intensive care, Intra-aortic balloon placement, Malaise, Myocardial infarction, Myocarditis infectious, Pain, Pyrexia, Respiratory distress, Shock, Tachycardia, Ventricular tachycardia, Viral cardiomyopathy, Viral myocarditis

Symptom Text: Information has been received from a physician concerning a 17 year old female with acne who on 24-JUL-2008 was vaccinated with the first dose of GARDASIL. Concomitant therapy included erythromycin, solution, topical. On 04-AUG-2008, the patient experienced abdominal pain, chest pain and aching everywhere and was hospitalized. On 05-AUG-2008, the patient experienced myocarditis and died. Diagnosis was myocarditis but the doctor said it was not related to GARDASIL. The last time she was seen in this office was 2005. No additional information at this time. Additional information has been requested. 10/01/08 Death certificate states COD as myocarditis & CHF as contributing factor. 9/22/08 Reviewed PCP medical records. Reveals patient experienced abdominal pain, chest pain & aching everywhere. Expired 8/5/08 w/viral infection of the heart. Concomitant med was erythomycin topical solution for acne. Patient noted to be in good health on day of vaccination. 4/2/09 Received hospital medical records for 8/3-8/4/2008. FINAL DX: deceased secondary to severe nonischemic cardiomyopathy secondary to viral myocarditis Records reveal patient experienced fever, chills, feeling unwell x 2-4 days. Presented to ER w/abdominal & chest pain, weakness, dizziness, hypotensive, tachycardia, SOB, respiratory distress w/hypoxemia, azotemia, shocklike symptoms. EKG w/diffuse ST changes & ST elevations. Dx w/acute anteroseptal MI Emergent cardiac cath revealed EF 23% & balloon pump placed. Intensive care, deteriorated, V-tach, decompensation, extensive resuscitation efforts failed.

Other Meds: erythromycin

Lab Data: Unknown LABS: WBC 10.3(H). Troponin greater than 100(H) & CPK 5492(H), CKMB 313.1(H) c/w infectious myocarditis, possibly viral. TSH 0.09(L). CRP 38.3(H). BNP 533(H). ANA neg. ASO 200(+). CXR abnormal w/water bottle appearing hea

History:

Prex Illness: Acne

Prex Vax Illns:

Vaers Id: **325063-2 (D)** **Related reports:** 325063-1; 325063-3; 325063-4; 325063-5

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		30-Oct-2008	31-Oct-2008	--	WAES0810USA04332	14-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, EXTENDED HOSPITAL STAY, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Coma, Death

Symptom Text: Information has been received from a nurse practitioner concerning a 19 year old female who was vaccinated with a dose of GARDASIL. The nurse practitioner stated that the patient "was admitted to the hospital while in a coma and died shortly afterward. The physician at the hospital felt that this was caused by GARDASIL". The cause of death was not reported. The vaccine was not given to the patient at the nurse practitioner's office, so she was unsure of further details. The reporter considered the event to be immediately life threatening and disabling. Attempts are being made to verify the existence of an identifiable patient and reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325063-3 (D)** **Related reports:** 325063-1; 325063-2; 325063-4; 325063-5

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Jul-2008	31-Jul-2008	7	02-Dec-2008	03-Dec-2008	KS		03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Unknown	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Abdominal discomfort, Cardiac enzymes increased, Catheterisation cardiac, Chest discomfort, Chest pain, Death, Dizziness, Dyspnoea, Ejection fraction decreased, Hypoaesthesia, Nausea, Resuscitation, Ventricular tachycardia

Symptom Text: This is a 17-year-old patient who presents ON 8/3/08 with an approximately 4-day history of nonspecific nausea and abdominal discomfort. This was initially thought to be dyspepsia. The patient was treated with Pepto-Bismol. There may have been some initial improvement; however, the patient continued to have persisting abdominal discomfort. Upon admission, patient had increased symptoms of shortness of breath with dizziness and left upper extremity and left lower extremity numbness. The patient also has crushing substernal left-sided chest discomfort. The patient presented to the Emergency Department, at which point cardiac enzymes ordered were significantly elevated. Patient was given Zofran for her nausea. Patient was also given aspirin 81 mg x3. D-dimer was checked (2). Patient was started on dopamine drip. Due to the patient's deteriorating status, the patient was taken emergently by Cardiologist for a right and left heart catheterization. Based on report, left heart catheterization shows no evidence of coronary disease. Ejection fraction was measured at 23%. Based on the verbal report from MD, there is no tamponade physiology on right heart catheterization. Patient has no previous surgical or significant medical history. She had recently received the Gardasil vaccine from her PCP. Patient denies history of asthma, cardiac disease. Secondary to her EF, an intraaortic balloon pump was placed and the patient was returned to CCU. However, over the next 6-8 hours, her function continued to deteriorate, she went into V tach which led her to further decompensate. She was resuscitated for more than 1-1/2 hours to maintain her blood pressure above 90. Cardiothoracic surgery was consulted to place her on bypass and place her on an assistive device. However, due to her current status, it was elected not to do so. CPR continued until the priest was available, and care was withdrawn. Patient was pronounced dead on 8/4/08.

Other Meds:

Lab Data: Coxsackie virus antibody panel negative; streptolysin antibody 200 (pos); Adenovirus, Echovirus, Influenza A neg; Influenza B (32 - past or recent inf), ANA negative. Autopsy found: Fulminant lymphocytic myocarditis, myocardial hypoperfusi

History: None

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **325063-4 (D)** **Related reports:** 325063-1; 325063-2; 325063-3; 325063-5

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Jul-2008	31-Jul-2008	7	17-Feb-2009	18-Feb-2009	--	WAES0901USA03879	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Unknown	Intramuscular	

Seriousness: DIED, ER VISIT, SERIOUS

MedDRA PT Abdominal discomfort, Chest discomfort, Death, Dizziness, Dyspnoea, General physical health deterioration, Hypoaesthesia, Hypoperfusion, Myocarditis, Nausea, Surgery, Ventricular tachycardia

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 17 year old female was vaccinated with the second dose of GARDASIL (Lot # 659962/1740U) intramuscularly on 24-JUL-2008. The patient presented on 03-AUG-2008 with an approximately 4-day history of nonspecific nausea and abdominal discomfort. This was initially thought to be dyspepsia. The patient was treated with Pepto-Bismol. There may had been some initial improvement; however, the patient continued to have persisting abdominal discomfort. Upon admission, patient had increased symptoms of shortness of breath with dizziness and left upper extremity and left lower extremity numbness. The patient also had crushing substernal left-sided chest discomfort. The patient presented to the emergency department, at which point cardiac enzymes ordered were significantly elevated. Patient was given Zofran for her nausea. Patient was also given aspirin 81 mg x3. D-dimer was checked (2). Patient was started on dopamine drip. Due to the patient's deteriorating status, the patient was taken emergently by Cardiologist for a right and left heart catheterization. Based on report, left heart catheterization showed no evidence of coronary disease. Ejection fraction was measured at 23%. Based on the verbal report from the doctor, there was no tamponade physiology on right heart catheterization. Patient has no previous surgical or significant medical history. She had recently received the GARDASIL from her primary care physician. Patient denies history of asthma, cardiac disease. Secondary to her ejection fraction, an intraaortic balloon pump was placed and the patient was returned to critical care unit. However, over the next 6-8 hours, her function continued to deteriorate, she went into V tach which led her to further decompensate. She was resuscitated for more than 1-1/2 hours to maintain her blood pressure above 90. Cardiothoracic surgery was consulted to place her on bypass and place her on an assi

Other Meds: Unknown

Lab Data: Diagnostic laboratory, 08/??/08, 200 pos for streptolysin antibody; Diagnostic laboratory, 08/??/08, negative for coxsackie antibody panel; Autopsy, 08/??/08, fulminant lymphocytic myocarditis; Cardiac catheterization, 08/??/08, right heart

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325063-5 (D)** **Related reports:** 325063-1; 325063-2; 325063-3; 325063-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Jul-2008	31-Jul-2008	7	19-Feb-2009	20-Feb-2009	KS		20-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: DIED, ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Death, Dyspnoea, Hypoaesthesia

Symptom Text: On July 31st, she had complaints of stomach pains. She took Pepto Bismol. The coming Saturday her left arm became numb. On Sunday afternoon around 1PM she couldn't breathe and we took her to the emergency room. Shortly after one of her legs became numb too so she was placed in a wheelchair. She passed away the following morning at 1:15AM on 8/4/08.

Other Meds:

Lab Data: LYMPHACYTIC CARDITIS 8/5/2008

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **325068-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		15-Sep-2008	16-Sep-2008	NJ	WAES0809USA01387	22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia facial, Hypoaesthesia oral, Lumbar puncture, Multiple sclerosis

Symptom Text: Information has been received from a physician concerning an 18 year old female with no pertinent medical history or no drug allergies who on an unspecified date, was vaccinated with the first dose of GARDASIL. There was no concomitant medication. After receiving GARDASIL at an unspecified time, the patient developed left sided facial numbness. The patient was diagnosed with multiple sclerosis six months after receiving first dose from a magnetic resonance imaging test and from a spinal fluid test. At the time of reporting, the patient was recovering. Medical attention was sought via office visit. No product quality complaint was involved. Upon internal review, multiple sclerosis was determined to be an other important medical event. Additional information has been requested. 10/21/08 Reviewed neurology medical records of 8/28-9/9/2008. FINAL DX: multiple sclerosis Records reveal patient experienced left facial & tongue numbness x 6 days on initial evaluation 8/28. RTC 9/9 for spinal tap w/abnormal CSF c/w MS. Referred for repeat MRI w/gadolinium which had been denied by insurance previously.

Other Meds: None

Lab Data: magnetic resonance - multiple sclerosis; cerebrospinal fluid - multiple sclerosis LABS: brain MRI abnormal. MRI c-spine WNL.

History: None

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325069-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Aug-2008	16-Aug-2008	1	15-Sep-2008	16-Sep-2008	FR	WAES0809USA00962	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NG31280	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dyspnoea, Fatigue, Pneumonia, Pyrexia, Sepsis

Symptom Text: Information has been received from a health care professional concerning a 15 year old female patient who on 10-JUN-2008 was vaccinated with a first dose of GARDASIL (batch number NG31280) (route and site of administration not reported), with no adverse event. On 15-AUG-2008 the patient was vaccinated with a second dose of GARDASIL (batch number, route and site of administration not reported). On 15-AUG-2008 the patient developed breathing difficulties and fever. On 16-AUG-2008 the symptoms were worsening and the patient was admitted to hospital where pneumonia and sepsis were diagnosed. The patient was treated with antibiotics (not specified) intravenously and after a week she was discharged. The patient was completely healthy at the time of vaccination. At the time of reporting the patient was tired and blood values not yet normal, but otherwise recovered. Other business partner numbers included: E200808299. Additional information is not expected. Case is closed.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, 04Sep08, not yet normal - at time of reporting.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325070-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Jun-2008	15-Jul-2008	26	15-Sep-2008	16-Sep-2008	FR	WAES0809USA00951	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1113U	2	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Inflammation, Multiple sclerosis, Nervous system disorder

Symptom Text: Information has been received from the health authority (reference no. PEI2008013320) concerning a 16 year old female patient who on 06-DEC-2007 was vaccinated into the left deltoid muscle IM, with a first dose of GARDASIL (batch # NF58550/lot # 0276U), and on 07-FEB-2008 was vaccinated into the left deltoid muscle, IM with a second dose of GARDASIL (batch # NF58550/lot # 0276U) and were well tolerated. On 19-JUN-2008, the patient was vaccinated into the left deltoid muscle, IM with a third dose of GARDASIL (batch # NH10080/lot# 1113U). On 15-JUL-2008 the patient developed an inflammatory disease of the nervous system which was confirmed by CSF and MRI findings (no otherwise specified). The patient was hospitalized on an unspecified date. Suspicion of the first manifestation of multiple sclerosis was established. The patient has not recovered. Other business partner numbers included: E2008-08316. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, Inflammation of the nervous system (no otherwise specified); cerebrospinal fluid culture, Inflammation of the nervous system (no otherwise specified)

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325071-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		15-Sep-2008	16-Sep-2008	CA	WAES0809USA00942	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Dizziness, Head injury, Headache, Syncope

Symptom Text: Information has been received from a physician concerning her niece, a 21 year old female patient who about a year ago, in 2007, was vaccinated with the first dose of GARDASIL. The patient received the first dose of GARDASIL and fainted and she hit her head about 10 minutes after receiving the first dose. The patient was transported to the emergency room for the treatment. The patient experienced numerous days of headache and dizziness that went on for at least one month. The patient was unable to compete in sports and missed the rest of her sport season. The patient completed the remaining two doses of GARDASIL without problems. The patient recovered from delayed syncope event, head injury, headache and dizziness. The delayed syncope event, headache and dizziness were considered to be disabling by the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325072-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Sep-2008	16-Sep-2008	FR	WAES0809PHL00006	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervix carcinoma

Symptom Text: Information has been received from a physician concerning a female with a history of condyloma who in 2008 was vaccinated with GARDASIL. The physician noted that the patient was cauterized and subjected to biopsy prior to vaccination. The result of the biopsy was negative. In 2008, after three weeks from vaccination, the patient was again subjected to another biopsy as part of check up and monitoring. The result was (+) for cervical cancer. Relationship of cervical cancer with GARDASIL is unknown at the time of reporting. The physician did not indicate stage of CIN. It was advised by another physician that her patient undergo MICROARRAY procedure to pinpoint the real cause of infection. Cervical cancer is considered serious. Upon internal medical review, cervical cancer is also considered an important medical event. Additional information has been requested. This is an amended report. Other important medical event serious criteria has been changed from "no" to "yes'.

Other Meds: Unknown

Lab Data: biopsy, ??08, (-) cancer; biopsy, ??08, (+) cancer

History: Condyloma

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325073-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	15-Mar-2008	24-Mar-2008	9	15-Sep-2008	16-Sep-2008	FR	WAES0809USA01258	16-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Motor dysfunction, Neuritis, Paraesthesia

Symptom Text: Information has been received from a general practitioner concerning a female patient with no medical history reported who in mid-March 2008, was vaccinated with GARDASIL (batch number not reported). Approximately 9 to 15 days later she developed a neuritis with cephalgia, paraesthesia and motor troubles of lower limbs. At the time of reporting the outcome was not specified. The general practitioner felt that neuritis was considered to be an other medical event. Other business partner numbers included are: E2008-08372. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **325081-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	29-Aug-2008	29-Aug-2008	0	15-Sep-2008	25-Sep-2008	NM	NM090801	25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: About 30 seconds after administering vaccine, GARDASIL, patient fainted, lot consciousness for approximately 5 seconds. Patient states she felt fine after awakening.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns: fainted~HPV (Gardasil)~2~11~In Patient

Vaers Id: 325082-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	08-Sep-2008	08-Sep-2008	0	15-Sep-2008	25-Sep-2008	CA		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Patient fainted after needle was withdrawn, lost consciousness for 2 seconds. Mother of patient called our office the next day stating that patient collapsed in coffee shop after having left the clinic. Patient was observed in exam room for 15 minutes, and was released without problem.

Other Meds: Doxycycline

Lab Data: none

History: None reported

Prex Illness: None reported

Prex Vax Illns: None Reported~ ()~~0~In Patient|None Reported~ ()~~0~In Sibling|None Reported~ ()~~0~In Sibling

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325085-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	02-Sep-2008	03-Sep-2008	1	15-Sep-2008	25-Sep-2008	TX		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Dysphonia, Feeling hot, Migraine, Pharyngolaryngeal pain, Rash generalised, Rash pruritic

Symptom Text: Patient awoke the next day with rash on arm in which GARDASIL given; Rash spread to abd with leg and gradually all over her body. Rash was slightly itchy and she took OTC Benadryl which helped. She states she felt feverish but did not check her temp. She had hoarse voice and complained of slightly sore throat; complained of GI puffiness and loose stools and migraine

Other Meds: none

Lab Data: none

History: Patient states allergic to Zithromax

Prex Illness: none noted

Prex Vax Illns:

Vaers Id: 325111-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Jun-2008	18-Jun-2008	0	15-Sep-2008	25-Sep-2008	NY		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063Y	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pruritus, Musculoskeletal stiffness, Rash

Symptom Text: Mom reports (on 8/12/08); Patient experience rash quarter -> palm sized, a little stiffness and itching at injection site for a few days after injection

Other Meds: none

Lab Data:

History: Bactrim

Prex Illness: none

Prex Vax Illns:

Vaers Id: 325114-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	12-Sep-2008	12-Sep-2008	0	15-Sep-2008	25-Sep-2008	NY		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF452CA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fear of needles, Immediate post-injection reaction, Syncope

Symptom Text: Syncopal episode after receiving GARDASIL, ADACEL and PPD. ADACEL and PPD given 1st. Reaction (fainted) occurred immediately after receiving GARDASIL. Pt does have a fear of needles but has never fainted before.

Other Meds: BCP

Lab Data:

History: Pollen dust mites

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325128-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Aug-2007	07-Aug-2007	5	15-Sep-2008	24-Sep-2008	MI		28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	UI968AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0389U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Adjustment disorder, Anxiety, Asthma, Asthma exercise induced, Autoimmune hepatitis, Crying, Depressed mood, Depression, Fatigue, Insomnia, Liver function test abnormal, Lymphadenopathy, Mononucleosis syndrome, Musculoskeletal stiffness, Neck pain, Nervousness, Pharyngitis, Pharyngolaryngeal pain, Tonsillar hypertrophy, Tonsillar inflammation, Tonsillitis, Transaminases increased

Symptom Text: Within one week of recieving Guardacil and meningitis vaccine on same day, had mono-like symptoms, with elevated LFTs. 10/24/2008 MR received from PCP. OV 8/7/07 for c/o swollen glands in the neck with neck stiffness and soreness, fatigue. PE (+) for redness and swelling in the tonsil area and prominant cervical nodes. Assessment: Swollen lymph nodes, very minimal pharyngitis. Liver clinic visit 10/17/07 with DX; autoimmune hepatitis. Abnormal Liver Enzymes/Transaminitis. Rapidly improved on steroids. Behavioral Health intake 11/2/07 with c/o anxiety and depression with crying spells, feeling nervous, difficulty sleeping. DX: Adjustment d/o with anxiety and depressed mood. OV 4/30/08 with sore throat and asthma. Tonsils enlarged. Recently increased EIA. Returned 8/10/08 with continued c/o swollen glands and sore throat. Assessment Severe pharyngitis. Returned 8/13/08 No improvement on abx. L tonsil more enlarged w/ erythema. Large anterior cervical lymph nodes. Assessment: One sided tonsillitis, mono-like infection.

Other Meds:

Lab Data: Weekly lab draws. Labs and Diagnostics: 8/7/07 Strep test (-). Mono screen (-). 8/13/07 LFTs-AST 113, ALT 141, Bili-total 2.7, bili-direct 2.3, Alk phos 399. 8/21/07 AST 424. ALT 650. Alk Phos 182. improving by 9/3/07 4/30/08 Mono scre

History: PMH: ear tubes, wisdom tooth removal. NKDA

Prex Illness: flu or mono like symptoms

Prex Vax Illns:

Vaers Id: **325129-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	09-Sep-2008	10-Sep-2008	1	15-Sep-2008	24-Sep-2008	GA		24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52BO29AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0381X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash macular

Symptom Text: ON 9-9-2008 PATIENT RECEIVED TDAP AND HPV, ON 09/10/2008 MOHTER BROUGHT CHILD IN FOR A DISCRETE MACULAR RASH ON TOP OF HANDS AND FEET.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **325130-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-Sep-2008	13-Sep-2008	0	15-Sep-2008	24-Sep-2008	IN		24-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2643AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0390X	1	Right arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024BA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0070X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope episode after receiving 4 injections

Other Meds: NONE

Lab Data: none

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **325139-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	U	15-Sep-2008	Unknown		15-Sep-2008	24-Sep-2008	MI		24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB239AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0072X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Pt given HPV and Hep A vaccines. After vaccines given, pt wanted a pregnancy test and she was pregnant.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 325152-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	15-Jul-2008	16-Jul-2008	1	18-Aug-2008	17-Sep-2008	PA	WAES0807USA03217	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a nurse concerning a 25 year old female who on 16-JUL-2008 was vaccinated with the first dose of GARDASIL IM (lot # not reported). On 16-JUL-2008 the patient fainted almost immediately after receiving vaccine. The patient took a little longer to come out of it than what they have seen in the past. Subsequently, the patient recovered from fainted immediately after receiving vaccine. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325153-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	01-Jul-2008	08-Jul-2008	7	18-Aug-2008	17-Sep-2008	PA	WAES0807USA03388	24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Axillary mass

Symptom Text: Information has been received from a nurse concerning a 26 year old female who on 01-JUL-2008 was vaccinated IM with the first 0.5 ml dose of GARDASIL (Lot # 660391/0063X). Concomitant therapy included hormonal contraceptives (unspecified). The patient developed a swollen, 2 cm, right, axillary lymph node, on the same side that she was vaccinated with her first dose of GARDASIL. She was referred to have an ultra sound of the area. At time of reporting, patient was not recovered. Unspecified medical attention was sought through a call to the office. Additional information has been requested. 9/23/08-records received for DOS 7/8/08-C/O lump under arm status post Gardasil. Right axilla small nodule questionable cyst.

Other Meds: hormonal contraceptives

Lab Data: Unknown 9/23/08-records received- Ultrasound right axillary region: single prominent reactive lymph node with no there findings of note.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325154-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	NJ	WAES0807USA03394	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	
	TTOX	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Swelling

Symptom Text: Information has been received from a physician concerning an approximately 11 year old female who was vaccinated IM with a dose of GARDASIL. Concomitant therapy included tetanus toxoid (manufacturer unknown) received within the same visit. Unspecified medical attention was sought. Patient recovered on an unspecified date, swelling healed on its own with ice. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325155-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	--	WAES0807USA03397	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (lot number not provided) and fainted. It was reported that the patient recovered and went to an on site Pharmacy, where she had fainted for a second time. Unspecified medical attention was sought. At the time of this report the patient recovered from her experiences. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 325158-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	22-Jul-2008	22-Jul-2008	0	16-Sep-2008	17-Sep-2008	FR	WAES0809USA01474	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1114U	0	Right arm	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Incorrect route of drug administration, Paraesthesia mucosal, Paraesthesia oral, Sensation of heaviness

Symptom Text: Information has been received from a gynaecologist concerning a 22 year old female with not reported medical history, who on 22-JUL-2008 was vaccinated with the first dose of GARDASIL (lot # 1114U; batch NG10940) SC into the right upper arm. Therapy included doxycycline for an unspecified indication, starting on 29-JUL-2008 for 10 days. On 13-AUG-2008, the patient experienced paresthesia of the lips, the tip of the tongue and the buccal mucous membrane. Since 14-AUG-2008 she also developed paresthesia and feeling of heaviness of the left upper and lower arm. The patient was hospitalized from 15-AUG-2008 to 16-AUG-2008. Neurological examination was normal except for the paresthesia in the upper and lower arm and feeling of heaviness of the left arm. CSF showed normal results for cells and protein. Results of oligoclonal bands were not available at the time of reporting. Cranial magnetic resonance imaging (MRI) showed two small lesions at the anterior and posterior horn. At time of reporting, the patient had not recovered. No final diagnosis was established. Other business partner numbers included: E2008-08313. Additional information has been requested.

Other Meds: Doxycycline

Lab Data: magnetic resonance imaging, 15?Aug08; Two small lesions at the anterior and posterior horn; CSF oligoclonal band profile, 15?Aug08, results not available; cerebrospinal fluid total protein test, 15?Aug08, normal; cerebrospinal fluid analysis

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 325159-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	06-Feb-2008	21-Apr-2008	75	16-Sep-2008	17-Sep-2008	FR	WAES0809USA01242	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1475F	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Central nervous system lesion, Demyelination, Dysaesthesia, Hypoaesthesia, Neurological symptom

Symptom Text: Information has been received from the health authority (reference number 89029) concerning a 23 year old female with thyroiditis, celiac disease and allergic rhinitis who on 06-FEB-2008 was vaccinated IM with a first dose of GARDASIL (batch # NF35170/lot #1475F), and on 16-APR-2008 was vaccinated IM with a second dose of GARDASIL (batch # NF35170/lot #1475F). On 21-APR-2008, five days after the second dose she presented with neurologic symptoms consistent in dysaesthesia and hypoasthesia of the lower right limb that lead to hospitalization for a suspected central nervous system inflammatory disease. On 13-MAY-2008, a magnetic resonance imaging (MRI) with gadolinium revealed disseminated hyperintense demyelination lesions of the brain and of the spinal cord. On 19-JUN-2008 cerebrospinal fluid examination showed positive anti IgG oligloconal bands. On 19-JUN-2008, a new MRI with T2-fluid attenuated inversion recovery (FLAIR) revealed a slight increase on the number of the disseminated hyperintense demyelinating lesions. From 24-JUN-2008 to 27-JUN-2008 the patient was treated with high dose of E.V. corticosteroid with an improvement of the symptoms. The diagnosis suspected was of an acute disseminated encephalomyelitis (ADEM) or a multiple sclerosis (MS). Follow up information of this case is pending. Additional information is expected.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 13May08, (MRI with glandolinium)-disseminated hyperintense demyelinating lesions of the brain and spinal cord; magnetic resonance imaging, (MRI with FLAIR) - slight increase on the no. of the disseminated hyperin

History:

Prex Illness: Thyroiditis; Coeliac disease; Rhinitis allergic

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325160-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Sep-2008	17-Sep-2008	--	WAES0809USA00783	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Fall, Syncope

Symptom Text: Information has been received from a nurse concerning a female who on an unspecified date, was vaccinated with the first dose of GARDASIL. The nurse reported that the patient was getting HPV vaccine, and fainted and fell into a full blown seizure. The patient was monitored at the office, recovered, and was sent home. Upon internal review, fell into a full blown seizure was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325161-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	27-Jun-2008	28-Jul-2008	31	16-Sep-2008	17-Sep-2008	FR	WAES0809USA00533	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	IPV	SANOFI PASTEUR	NULL		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Muscle spasms, Pharyngitis, Urticaria

Symptom Text: Information has been received from local Health Authorities (reference number DJ20080735) concerning a 23 year old female patient with no relevant medical history reported who on 27-JUN-2008 was vaccinated with GARDASIL injection (batch number not reported). Secondary suspect therapy on the same day included REPEVAX injection (batch number not reported). Other concomitant therapy included "HOLGYEME". On 28-JUL-2008 the patient experienced an urticaria of unknown aetilogy and a pharyngitis. She was prescribed corrective treatment with XYZALL from 28-JUL-2008 to 31-JUL-2008 and with paracetamol. On 31-JUL-2008 the patient suffered from cramps in lower extremities mainly nocturnal with progressive intensity. She consulted the physician on duty at the hospital on 01-AUG-2008. XYZALL which was suspected was stopped and cramps disappeared 2 to 3 days later. At the time of reporting the outcome for urticaria and pharyngitis was not specified. The events of urticaria, muscle spasms and pharyngitis required hospitalization. Additional information is not expected. Other business partners included are: E2008-08268.

Other Meds: cyproterone acetate/ethinyl estradiol, Unk - Unk

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325162-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Oct-2007	23-Oct-2007	0	16-Sep-2008	17-Sep-2008	FR	WAES0809USA00532	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dermographism, Incorrect route of drug administration, Rash, Skin lesion, Urticaria

Symptom Text: Information has been received from the health authority concerning a 14 year old female with a personal and family history of asthma and atopy, who on 23-OCT-2007 was vaccinated subcutaneously with the first dose of GARDASIL. The second and third doses were administered on 08-JAN-2008 and 13-JUN-2008, respectively. In early December 2007, approximately 5 to 6 weeks after the first injection, the patient experienced rash of urticaria on the back of her hands. Flares of urticaria were recurring everyday with no identified eliciting factor and despite treatment with ATARAX, XYZALL and POLARMINE for one month followed by corticotherapy with SOLUPRED for 15 days. In April 2008, an unspecified examination showed isolated dermographism and the patient was hospitalized. Biological tests were normal. No hepatic or autoimmune thyroid impairment was found. All serologies were negative for Hepatitis A virus (HAV), Hepatitis B virus (HBV) and Epstein Barr virus (EBV). toxoplasmosis, tomocara, antistreptokinase, antistreptolysin-O and hydatidosis. Flares subsequently regressed on antihistamines alone. However, on 14-JUN-2008, the day after the third injection , cutaneous lesions recurred then resolved on H1 antihistamines. Subsequently, the patient recovered from chronic urticaria on H1 antihistamines. Other business partner numbers include: E20080823 and MA20081479. Additional information is not expected.

Other Meds: Unknown

Lab Data: dermatological examination, isolated dermographism; diagnostic laboratory test, see narrative; clinical serology test, see narrative

History:

Prex Illness: Asthma; Atopy

Prex Vax Illns:

Vaers Id: 325167-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-May-2007	06-Aug-2007	76	16-Sep-2008	17-Sep-2008	FR	WAES0806USA08904	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1518F	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myalgia, Sensation of heaviness, Vaccine positive rechallenge

Symptom Text: Initial and follow-up information has been received from a paediatrician concerning a 17 year old female who on 22-MAY-2007 was vaccinated with the first dose of GARDASIL (lot # 654884/0902F, batch # NE24240) IM into the upper arm. No adverse effects occurred. On 23-JUL-2007 she was vaccinated with the second dose of GARDASIL (lot # 1518F, batch # NF23330) IM into the upper arm. She developed muscle pain in the arms and legs, in particular during exertion (walking upstairs, doing sports) approximately 14 days post vaccination. Despite ongoing adverse events she was vaccinated with a third dose of GARDASIL (lot # 0276U, batch # NF58550) IM into the upper arm on 23-NOV-2007. She developed increased muscle pain since the third dose of vaccination. Concomitant therapy included hormonal contraceptives. The adverse events were ongoing, but less intense. She still complained of pain and a feeling of heaviness in the lower legs in particular when under stress or physical exertion. Laboratory tests on blood count, borreliosis complement fixation reaction, serum creatine kinase test, serum aspartate aminotransferase test and serum C-reactive protein test showed normal results (date not reported). Laboratory findings on 24-JUN-2008 revealed that antistreptolysin was negative, and C-reactive protein was 0.20 mg/dl, and borrelia spp. IgG and IgM (serum) were negative, and there was no indication for a borrelia infection. The reporter assessed the case as serious as an other important medical event. Other business partner numbers included: E2008-05780. Additional information has been requested.

Other Meds: Hormonal contraceptives (unspecified), unk, unk

Lab Data: Diagnostic laboratory test, 24Jun08, no indication for a borrelia infection; Diagnostic laboratory test, borreliosis complement fixation reaction showed normal results; Serum B.burgdorferi Western blot IgG Ab, 24Jun08, negative; Serum B.bur

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325168-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
31.0	F	01-Jan-2008	01-Jan-2008	0	16-Sep-2008	17-Sep-2008	FR	WAES0809USA00101	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diplopia, Dizziness, Hypoaesthesia, Inappropriate schedule of drug administration, Paralysis, Vertigo, Visual disturbance

Symptom Text: Information has been received from a 31 year old female consumer who in January 2008, was vaccinated with a third dose of GARDASIL. One to two weeks post-vaccination, she developed dizziness, double vision, numbness and paralysis. On 06-MAR-2008 she was admitted to a neurological department of a hospital. An infection was excluded in hospital. Dizziness and double vision were ongoing at the time of reporting. The outcome of numbness and paralysis was not reported. The first dose of GARDASIL was administered in July 2007, and the second dose of GARDASIL was in October 2007 and were well tolerated. The family physician was contacted and confirmed the events of the patient. A doctor's report was sent indicating that the patient was hospitalized from 06-MAR-2008 to 08-MAR-2008. At the end of January 2008 the patient developed continuous vestibular vertigo with abnormal vision (rotating colored circles). She was referred to the ophthalmologist and the examination showed no pathologies. Approximately 14 days prior to hospitalization the patient experienced blurred vision and a few days prior she complained of weakness of both hands with mild hypoaesthesia. A Cranial MRI from 27-FEB-2008 and cerebro spinal fluid on 06-MAR-2008 showed normal results and an infectious genesis of the symptoms was ruled out. There was no indication of a chronic inflammatory CNS disease. Borrelia IgM was negative. The abnormal vision resolved in an unspecified time. Vestibular vertigo and blurred vision were ongoing. The outcome of hypoaesthesia and weakness was not reported. The patient had had a history of borreliosis in 2006, and since then recurrent arthralgia. Other business partner numbers included E2008-08099. Additional information has been requested.

Other Meds: Unknown

Lab Data: ophthalmological exam, ??Jan08, no pathologies; magnetic resonance imaging, 27Feb08, normal; serum B. burgdorferi Western blot IgM Ab, 06?Mar08, negative; cerebrospinal fluid culture, 06Mar08, normal

History: Infection

Prex Illness: Arthralgia

Prex Vax Illns:

Vaers Id: 325169-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	15-Aug-2008	27-Aug-2008	12	16-Sep-2008	17-Sep-2008	TX	WAES0809USA00483	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Dyspnoea

Symptom Text: Information has been received from a physician concerning a 20 year old female with endometriosis who on 15-AUG-2008 was vaccinated with the first dose of GARDASIL. Concomitant suspect therapy included LUPRON DEPOT administered on 26-AUG-2008 (indication not reported). Other concomitant therapy included meningococcal vaccine (unspecified). On approximately 27-AUG-2008, "about 12 days after initial dose of GARDASIL vaccine" the patient experienced abdominal pain and shortness of breath. On 02-SEP-2008 "last night" the patient visited hospital emergency room (ER) and was administered medication for abdominal pain. Lab studies were performed with no results reported. The patient was discharged from the emergency room. The ER physician felt that the patient's visit was "probably related to patient's condition of endometriosis and LUPRON DEPOT vaccine." The reporting physician was not the physician of record when the patient received the initial dose of HPV vaccine, as the patient was relocated due to hurricane. At the time of this report, the patient's abdominal pain and shortness of breath persisted. It was reported that the patient planned to received the next scheduled HPV vaccine and was scheduled to see the physician on 03-SEP-2008. The patient's abdominal pain was considered to be an other important medical event since the event required pain medication in the ER. Additional information has been requested.

Other Meds: LUPRON DEPOT

Lab Data: Unknown

History:

Prex Illness: Endometriosis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325170-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	08-Oct-2007	Unknown		16-Sep-2008	17-Sep-2008	IN	WAES0808USA04883	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0388U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Idiopathic thrombocytopenic purpura, Injection site pain

Symptom Text: Initial and follow-up information has been received from a physician concerning a female patient who on 08-OCT-2007, was vaccinated with her first dose of GARDASIL (Lot # 657622/0388U). On 07-DEC-2007, was vaccinated with her second dose of GARDASIL (Lot # 659435/1265U). On 23-JUN-2008, was vaccinated with her third dose of GARDASIL (Lot # 660393/0067X). After receiving the vaccine "the patient experienced numbness at injection site. The physician stated that she may have thrombocytopenia, she required platelets." The patient sought unspecified medical attention. In follow-up, the nurse reported that the patient had a concurrent condition of Idiopathic thrombocytopenic purpura (ITP). The nurse stated that the patient's mother inquired if the GARDASIL vaccinations had anything to do with the problems her daughter was experiencing with ITP. The nurse stated that the patient made a general statement that the injection was painful and the patient did not complain of injection numbness. Upon internal review, thrombocytopenia was determined to be an Other Important Medical Event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325173-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Sep-2008	17-Sep-2008	FR	WAES0809USA00102	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epilepsy

Symptom Text: Information has been received from a gynaecologist concerning a female who was vaccinated with a second dose of GARDASIL. Subsequently the patient developed epileptic seizure. At the time of report, she was under medication (not otherwise specified). The company was contacted to enquire whether the third dose could be given. Epileptic seizure was considered to be an other important medical event. Other business partner numbers included E2008-08137. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325174-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jul-2008	02-Jul-2008	1	16-Sep-2008	17-Sep-2008	FR	WAES0807USA05884	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Neck pain

Symptom Text: Initial and follow up information has been received from Health Authority (HA ref. 082692) concerning a 16 year old female patient who on 01-JUL-2008 was vaccinated with GARDASIL (lot no., batch no., route, injection site not reported). The day after vaccination (on 02-JUL-2008) the patient developed headache, slight pain in the neck and dizziness. There was no nausea or vomiting. She visited open health care center and after two hours of observation she was better and could return home. The outcome was recovered. Headache, slight pain in the neck and dizziness were considered to be other important medical events. Other business partner numbers include E2008-07077. The case was closed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325176-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
54.0	M	Unknown	06-Aug-2008		16-Sep-2008	22-Sep-2008	--		22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0755U		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diarrhoea

Symptom Text: Patient developed grade 2 diarrhea one day after 3rd vaccination. Possibly related to Gardasil and unexpected. Patient has recent history of diarrhea unrelated to vaccine.

Other Meds: Ritonavir

Lab Data:

History: HIV infection

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325187-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	10-Sep-2008	10-Sep-2008	0	16-Sep-2008	25-Sep-2008	MA		25-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0510X	1	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0572X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2728AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction

Symptom Text: Immediately after immunizations, patient stated she was dizzy and light headed. Had patient lay down and monitor vital signs - stable. Observed in office for 15 minutes by LPN and physician. Patient left office with no further complications.

Other Meds: None

Lab Data: None

History: Penicillin/Amoxicillin

Prex Illness: None

Prex Vax Illns:

Vaers Id: **325188-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Sep-2008	10-Sep-2008	0	16-Sep-2008	25-Sep-2008	MA		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient was given GARDASIL; kept in exam room for observation, approximately 1 1/2 minutes after vaccine was given. Patient was found laying down on exam table, stating she thought she fainted. Vital signs were monitored - stable. Observed in office by MA and physician; was not allowed to drive home from office.

Other Meds: None

Lab Data: None

History: Recurrent strep pharyngitis

Prex Illness: Possible urinary tract infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325192-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-Sep-2008	10-Sep-2008	1	16-Sep-2008	25-Sep-2008	IN		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Face oedema

Symptom Text: 9-9-08 HPV given in right arm and facial edema started 9-10-08

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325197-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Sep-2008	04-Sep-2008	0	16-Sep-2008	25-Sep-2008	IA		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2441AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2966AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0951X	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0843X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Heart rate decreased, Syncope

Symptom Text: Patient fainted after receiving vaccines. Was on exam table at time of incident it was assisted to supine it immediately regained consciousness vs: HR at 1225 54; HR at 1238 - 80

Other Meds: none

Lab Data: none

History: NKDA

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325234-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Sep-2008	11-Sep-2008	0	16-Sep-2008	24-Sep-2008	PA		24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Loss of consciousness

Symptom Text: PATIENT RECEIVED THE VACCINE AND APPROXIMATELY ONE MINUTE LATER SHE FELL TO THE FLOOR FROM THE EXAM TABLE. PATIENT STATES SHE BEGAN TO FEEL DIZZY AND EVERYTHING WENT BLACK. NEXT THING SHE REMEMBERS IS WAKING UP ON THE FLOOR.

Other Meds:

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **325241-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Aug-2008	16-Aug-2008	2	16-Sep-2008	24-Sep-2008	WA		24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2573AA	0	Left arm	Intramuscular	
	MMR	MERCK & CO. INC.	0346X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1968U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: joint pains

Other Meds:

Lab Data: CMP (CO 20 mmol/L, calcium 8.7 mg/dl, protein 8.5 g/dL, albumin 3.4 g/dl, ALP 46 U/L), CBC (11.4 g/dl, RDW 16.2%), ANA c reflex, RF, ESR (23 mm/h).

History:

Prex Illness: runny nose.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325252-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Sep-2008	16-Sep-2008	1	16-Sep-2008	24-Sep-2008	CA		24-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2563AA	0	Left arm	Intramuscular	
MMR	MERCK & CO. INC.	0665X	1	Right arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0133X	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB245AA	1	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B020AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0272X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Immunisation reaction, Oedema peripheral, Pain in extremity

Symptom Text: Administered vaccine (Varicella, MCV4, & Tdap) to her left arm on 9/15/08 in the morning. Pt returned to clinic 9/16/08 in the afternoon c/o moderate reaction from vaccine: left arm painful, red, and swollen. Patient denies fever. Patient afebrile at the time of visit. Instructed patient to apply cold compress to affected area and take tylenol or advil for pain if not contraindicated. patient and mother vervalized understandin.

Other Meds: NONE

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **325256-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		16-Sep-2008	24-Sep-2008	--		24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	??????	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Gardasil shot given at approx 9:00am. Instant numbness in harm.....lasting all day. Leg numbness strated at around 9:00pm on same day. Hopefully things will be better in the morning.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325262-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Sep-2008	10-Sep-2008	0	16-Sep-2008	25-Sep-2008	PA		26-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB245AA		Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0843X		Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2731AA		Left arm	Unknown	
VARCEL	MERCK & CO. INC.	0432X	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure normal, Dizziness, Loss of consciousness, Syncope

Symptom Text: Pt had 4 ordered vaccines, then c/o dizziness and then passed out in the exam table. Dr. aware. Pt monitored BP remained stable and was last documented as 130/87 prior to being D/C'd by Dr to go home w/mother. Syncopal episode lasted approximately 5 seconds.

Other Meds:

Lab Data:

History: Mood D/O

Prex Illness:

Prex Vax Illns:

Vaers Id: 325265-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Sep-2008	15-Sep-2008	0	16-Sep-2008	25-Sep-2008	TX		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Left arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	500557P	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Hypoaesthesia facial, Pain, Throat tightness, Wheezing

Symptom Text: 1 hr after receiving FLUMIST/ pt developed facial numbness, chest and throat tightness with pain and wheezing

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **325272-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	--	WAES0807USA03408	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia, Swelling face

Symptom Text: Information has been received from a female with allergies who on unspecified dates was vaccinated with two doses of GARDASIL (lot # not reported). The consumer reported that "I'm having a fever and some swelling around the face but I think it maybe just my allergies". The consumer also reported that "I will have my third dose of GARDASIL next week". No further information was provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

Vaers Id: **325273-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jul-2008	01-Jul-2008	0	18-Aug-2008	17-Sep-2008	CT	WAES0807USA03505	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a patient female who in July 2008 was vaccinated with GARDASIL vaccine 0.5 mL IM. The physician reported that the patient fainted "last week" in July 2008 after receiving GARDASIL vaccine. The patient sought medical attention; she was seen in the physician office. ("AE occurred in the office"). There was no product quality complaint. No lab diagnostics were performed. On unspecified date the patient recovered. Additional information has been requested. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325274-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Jul-2008	11-Jul-2008	0	18-Aug-2008	17-Sep-2008	CT	WAES0807USA03506	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Loss of consciousness, Vomiting

Symptom Text: Information has been received from a nurse concerning a 15 year old female who was vaccinated with the third dose of GARDASIL vaccine 0.5 mL (Lot # 660393/0067X). The nurse reported that they kept the patient for approximately 10-15 minutes after administration and then on her way out, as she was passing the receptionist desk; she passed out and bumped her head. When she come to; she vomited. She was take to the ER, but the physician's office had not heard any follow up on her condition as of the time of the report. Additional information has been requested. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325275-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Jan-2008	01-Feb-2008	2	18-Aug-2008	17-Sep-2008	NC	WAES0807USA03551	12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Dyspareunia, Menometrorrhagia, Menorrhagia, Nausea, Oral contraception, Pelvic pain, Polyp, Proctalgia, Thrombosis, Uterine dilation and curettage

Symptom Text: Information has been received from a female concerning her 17 year old granddaughter who on unspecified dates was vaccinated with the complete series of GARDASIL. About 7 months ago (in approximately 2008), the patient started to experience blood clots and severe pain on the lower part of her stomach on both sides and still hasn't recovered. The patient was not hospitalized. It was unspecified if the patient sought medical attention. This is one of three reports from the same source. (WAES: 0807USA03323 and 0807USA03552). Additional information has been requested. 10/30/08-records received-on 1/30/08-received 3rd Gardasil injection. Depoprovera given. 3/5/08-C/O continuous bleeding on Depo, has been getting Depo for 3 years but just started bleeding everyday in the last two month. 3/28/08-C/O nausea, difficulty eating, low abdominal cramping heavy bleeding but no clots. Started birth control early March. 4/25/08-RLQ pain radiating to rectal area bleeding after intercourse. Now on Orhto EVRA patch and continues with Depoprovera. 6/19/08-Menometrorrhagia. Patient requests a D&C. 7/15/08-Post D&C now C/O pelvic pain and heavy bleeding. Polyp removed. 7/18/08-passed large clot and bleeding heavy again. Declines depo provera and mirena.

Other Meds: Unknown

Lab Data: Unknown 10/30/2008-records received-7/15/08-Post D&C now C/O pelvic pain and heavy bleeding. Ultrasound normal.

History: Unknown 10/30/08-records received-PMH:ADHD. Benign tumor removed on both ovaries. has been getting Depo for 3 years

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325276-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	--	WAES0807USA03870	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lactose intolerance

Symptom Text: Information has been received from a nurse practitioner concerning one of three girls in the same family who "a few months ago" in 2008, were vaccinated with GARDASIL. Subsequently the patient became lactose intolerant after receiving GARDASIL. It was not specified whether the patient sought medical attention. The patient's lactose intolerance persisted. Additional information has been received from the nurse who called to confirm the information. She will complete the form and send it back to Merck. Follow up information was received which reported that the three girls in the same family became lactose intolerant after receiving GARDASIL. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325277-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	01-Feb-2008		18-Aug-2008	17-Sep-2008	--	WAES0807USA03552	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Cyst, Endometriosis, Thrombosis

Symptom Text: Information has been received from a female concerning her 17 year old granddaughter who on unspecified dates was vaccinated with the complete series of GARDASIL. "Six months ago" (in approximately February 2008), the patient experienced severe pain on the lower part of her stomach. The patient was diagnosed of endometriosis and cyst that needed to be dissolved. The patient was not admitted to hospital but was brought to emergency room three times. The patient was still having big blood clots. This is one of three reports from the same source (WAES: 0807USA03323 and 0807USA3551). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325278-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	--	WAES0807USA03871	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lactose intolerance

Symptom Text: Information has been received from a nurse practitioner concerning one of three girls in the same family who "a few months ago" in 2008, were vaccinated with GARDASIL. Subsequently, the patient became lactose intolerant after receiving GARDASIL. It was not specified whether the patient sought medical attention. The patient's lactose intolerance persisted. Additional information has been requested. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325279-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	17-Jul-2008	Unknown		18-Aug-2008	17-Sep-2008	NY	WAES0807USA03872	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Feeling abnormal, Gaze palsy, Pallor, Syncope, Tremor, Unresponsive to stimuli

Symptom Text: Information has been received from a licensed practical nurse (L.P.N.) concerning a 20 year old female with no medical history or drug allergies who on 17-JUL-2008 was vaccinated with the first dose of GARDASIL. Concomitant therapy included NUVARING. Subsequently the patient felt weird, the patient then became pale and fainted. The reporter stated that the patient's eyes rolled back, she was unresponsive and her arms and legs were shaking. The patient was sent to the emergency room but it was unknown what the patient was diagnosed with. On an unspecified date, the patient recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: NUVARING

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325280-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	--	WAES0807USA03875	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye infection, Scar, Visual acuity reduced

Symptom Text: Information has been received from a consumer concerning her daughter a 21 year old female with penicillin allergy and sulfonamide allergy and no other medical history who in May 2008, was vaccinated with a first dose of GARDASIL. Concomitant therapy included a birth control medicine (name not provided). One week after receiving GARDASIL, the patient developed a bad eye infection in her left eye. The patient's vision with this eye had become worse and had a scar on this eye. Unspecified medical attention was sought. The patient was noted to be recovering. No product quality complaint was involved. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History:

Prex Illness: Penicillin allergy; Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325281-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	--	WAES0807USA03877	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Angioedema, Urticaria

Symptom Text: Information has been received from a nurse concerning a 26 year old female who was vaccinated with the second dose of GARDASIL. Subsequently the patient developed angioendemic urticaria. At the time of this report, the outcome was unknown. No product quality complaint was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325282-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	--	WAES0807USA03878	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal behaviour, Feeling abnormal

Symptom Text: Information has been received from a healthcare worker concerning a 23 year old female who on unspecified dates, was vaccinated with three doses of GARDASIL. After the first dose, the patient felt strange. After the second dose, the patient felt weird. After the third dose, the patient was curled up in a ball. Subsequently on an unspecified date, the patient recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325283-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Jun-2008	07-Jul-2008	11	18-Aug-2008	17-Sep-2008	MO	WAES0807USA03904	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Palpitations

Symptom Text: Information has been received from a registered nurse (R.N.) concerning her 14 year old daughter with adverse drug reaction to pertussis vaccine (caused muscle rigidity) who on 26-JUN-2008 was vaccinated intramuscularly with her first 0.5 ml dose of GARDASIL. Concomitant therapy included unspecified birth control medication. On 07-JUL-2008 the patient started to experience intermittent episodes of heart palpitations. The episodes of palpitation lasted from several minutes to a few hours and resolved without treatment. On 12-JUL-2008 the patient was evaluated in a local emergency room. A complete blood count was normal. A 24 hours Holter monitoring was performed (results pending). At the time of the report, the patient was still experiencing 1-2 episodes of heart palpitations per day. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Holter monitoring, 7/12/08 - results; complete blood cell, 07/12/08 - normal

History: Adverse drug reaction

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325284-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Jun-2008	25-Jun-2008	0	18-Aug-2008	17-Sep-2008	PA	WAES0807USA03985	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Hypoaesthesia, Rash

Symptom Text: Information has been received from a health professional concerning a 16 year old female patient with a history of absence seizure free for 2 years-off divalproex sodium (DEPAKOTE for 2 years) who on 25-JUN-2008 at 10:00 am was vaccinated intramuscularly in the right arm with a first dose of GARDASIL (Lot #658222/0927U). On 25-JUN-2008 the patient went to bed and woke up four times that evening complaining of numbness in the left arm and weakness. She developed a rash on both arms from wrist to elbows the next day on 26-JUN-2008. The numbness and weakness resolved the next morning. At the time of reporting, the outcome of the rash on both arms from wrist to elbows was unknown. It was not specified if there was an illness at the time of vaccination. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Absence seizure

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325285-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	11-Jul-2008	11-Jul-2008	0	18-Aug-2008	17-Sep-2008	--	WAES0807USA04026	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site pain, Injection site reaction, Injection site swelling

Symptom Text: Information has been received from a registered nurse concerning a female who on 11-JUL-2008 was vaccinated with the first dose of GARDASIL. Subsequently the patient developed an injection site reaction. The patient developed arm soreness and injection site reaction. The patient developed arm soreness and hardened raised area the size of a walnut at the injection site. The vaccine was provided at the patient's primary care physician's office, not at this clinic. At the time of the report, the patient was recovering from the symptoms. No further information is available.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325286-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Mar-2008	01-Mar-2008	0	18-Aug-2008	17-Sep-2008	FL	WAES0807USA04035	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling, Urticaria

Symptom Text: Information has been received from a consumer concerning her daughter, an 18 year old female with penicillin allergy who on an unspecified dates was vaccinated with the first and second doses of GARDASIL. The patient did not experience any adverse symptoms after the first and second dose of GARDASIL. In March 2008, was vaccinated with the third dose of GARDASIL, intramuscular, in the left upper arm. There was no concomitant medication. In March 2008, since the patient received the third dose of GARDASIL she developed redness, swelling and tenderness at the injection site of the left upper arm within hours of receiving it. The injection site reaction resolved in a few days without treatment. Since then, the patient has experienced intermittent episodes of widespread hives. The patient was examined by her primary care physician, as well as an allergist, who both prescribed antihistamines and a short-course of unspecified steroids. Contact information for the primary care physician and allergist were not provided. The allergist performed allergy testing, which was negative. The patient continues to experience the episodes of hives. The patient is scheduled to be evaluated by a dermatologist on 21-JUL-2008. No further information available at this time. Additional information has been requested.

Other Meds: None

Lab Data: allergy test, ?/?/08, Negative

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **325287-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-Jul-2008	11-Jul-2008	0	18-Aug-2008	17-Sep-2008	NC	WAES0807USA03559	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a 17 year old female with unknown allergies who 11-JUL-2008 was vaccinated with a first dose of GARDASIL (lot# not reported). Within "24 to 36 hours," the mother of the patient called, because the patient developed rashes on her tongue and on her forearm. The patient was seen by a physician. No further information was available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325288-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	--	WAES0807USA04055	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female who was vaccinated with a dose of GARDASIL. The nurse practitioner reported that "a month or two after receiving a dose of GARDASIL" the patient had developed warts on her face, which were predominately on her lips. No lab diagnostics were performed. The nurse practitioner did not know if the patient is going to receive any more doses of GARDASIL because she had not heard back from the patient as of yet. There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325289-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Apr-2008	26-Apr-2008	0	18-Aug-2008	17-Sep-2008	IL	WAES0807USA04060	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lip swelling, Pruritus, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 26-APR-2008 and 15-JUL-2008 was vaccinated with a first and second doses of GARDASIL, respectively. On the same day of vaccinations were administered, the patient developed swollen lips and "itchy hands". The patient was seen by a physician. The outcomes were not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325290-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	19-Oct-2007	01-Dec-2007	43	18-Aug-2008	17-Sep-2008	NJ	WAES0807USA03573	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	0	Right leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Asthenia, Ear pain, Fatigue, Gluten free diet, Hypersensitivity, Oral contraception, Stomach discomfort, Urticaria, Weight decreased

Symptom Text: Information has been received from a physician concerning a 20 year old female with allergic reaction to doxycycline, who on 19-OCT-2007 was vaccinated with the first dose of GARDASIL. On 14-DEC-2007, the patient was vaccined with the second dose of GARDASIL IM. There was no concomitant medication. In December 2007, the patient developed an allergy to gluten. On 24-DEC-2007, the patient developed hives that resolved on its own. She had seen a hematologist/oncologist, endocrinologist, and Gastroenterologist. The physician mentioned that the specialist were not able to determine a cause for the gluten allergy. The patient had significant abdominal pain, upset stomach, weakness and fatigue. She had a 10-15 weight loss. In October 2007, she weighed 115 lbs and on March 18 2008, she weighed 101 lbs. Testing for Celiac disease were negative. Immunoglobulin A (IgA) was low positive in March, 2008. Repeated testing for Celiac disease in March 2008 was negative. Subsequently, the patient recovered from the adverse events. The patient sought medical attention. Additional information has been requested. 10/07/08-records received-Yasmin OCP. Placed on gluten free diet now feels great and has energy, and gaining weight. 10/7/07 first Gardasil vaccination given. Right ear pain and weight loss.

Other Meds: None

Lab Data: diagnostic laboratory, Testing for Celiac disease: Negative; diagnostic laboratory, 03/??/08, Testing for Celiac disease: Negative; serum immunoglobulin A, 03/??/08, low positive 10/7/08-records received-Ultrasound abdomen negative. Upper

History: 10/7/08-records received-office visit 6/13/07-C/O weight loss, tired, abdominal pain and diarrhea.

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325291-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	30-Jun-2008	30-Jun-2008	0	18-Aug-2008	17-Sep-2008	NY	WAES0807USA04061	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Rash erythematous, Rash papular, Skin warm

Symptom Text: Information has been received from a physician concerning a 11 year old female with a history of blood in urine -cause unknown who on 30-JUN-2008 was vaccinated intramuscularly with 0.5 ml first dose of GARDASIL in her arm (not specified). There was no concomitant medication. On 30-JUn-2008, within one minute of vaccination, the patient developed a red, raised and warm rash on her left arm, and spread to her face, trunk and other limbs in physician's office. No laboratory diagnostics studies were performed. The patient was treated with BENADRYL. On 30-JUN-2008 the patient recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Blood urine present

Prex Illness:

Prex Vax Illns:

Vaers Id: **325292-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	TX	WAES0807USA04062	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site reaction

Symptom Text: Information has been received from a nurse practitioner concerning a 12-13 year old female who on an unspecified date was vaccinated with a dose of GARDASIL. Subsequently the patient developed an indentation at the injection site growing from quarter size to a half dollar size. Unspecified medical attention was sought. At the time of the report, the patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325293-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	17-Jul-2008	17-Jul-2008	0	18-Aug-2008	17-Sep-2008	--	WAES0807USA03580	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: Information has been received from a nurse practitioner concerning a patient, an office staff member, who in approximately 2007 was vaccinated with the first and second dose of GARDASIL. The nurse practitioner reported that the patient was in the office on 17-JUL-2008 for the 3rd dose of GARDASIL. No adverse effect was reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325294-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Jul-2008	12-Jul-2008	1	17-Sep-2008	26-Sep-2008	--	WAES0807USA03588	26-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia, Rash generalised

Symptom Text: Information has been received from a registered nurse concerning a 11 year old female who on 11-JUL-2008 was vaccinated with a dose of GARDASIL and MENACTRA. On 12-JUL-2008, the patient experienced fever and rash all over her body. The patient was also given a TB test the date prior to getting GARDASIL, on 10-JUL-2008. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325295-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Jul-2008	21-Jul-2008	0	18-Aug-2008	17-Sep-2008	--	WAES0807USA04067	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Malaise, Paraesthesia, Syncope

Symptom Text: Information has been received from a pharmacist concerning her 12 year old daughter with no pertinent medical history or allergies who on 21-JUL-2008 was vaccinated intramuscularly with 0.5 ml first dose of GARDASIL in her left upper arm. There was no concomitant medication. A few minutes after vaccination, the patient experienced faint. No laboratory diagnostics studies were performed. The patient recovered while in the office. Since returning home from the office, the patient had complained of malaise and tingling of the left arm "from shoulder to fingertips". There was no problem with movement of the arm. At the time of report, the patient's malaise and tingling of the left arm persisted. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **325296-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	TX	WAES0807USA03592	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Vaginal haemorrhage

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with GARDASIL. Subsequently the patient developed vaginal bleeding. The number of vaccinations was not known. The timing of the incident or whether it was resolved was not known. No additional information is available. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325297-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	25-Sep-2008	--	WAES0807USA03596	25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Contraception

Symptom Text: Information has been received from a nurse practitioner concerning a female who was vaccinated with the first dose of GARDASIL IM and recently received the second dose of GARDASIL. The patient was also started on a new birth control pill, YAZ when the first dose of GARDASIL was given. After the first dose of GARDASIL, the patient experienced abdominal pain. The patient has had abdominal pain since the first dose of GARDASIL. At the time of the reporting, the patient had not recovered. Additional information has been requested.

Other Meds: YAZ

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325298-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	11-Jul-2008	11-Jul-2008	0	18-Aug-2008	17-Sep-2008	--	WAES0807USA04078	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site mass

Symptom Text: Information has been received from a nurse concerning a female in her 20's who on 11-JUL-2008 was vaccinated with the first dose of GARDASIL. Subsequently, the patient experienced a "hard lump", a size of a walnut at the injection site. The patient was not vaccinated in the reporter's office. The patient sought medical attention by contacting the nurse. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325299-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	IL	WAES0807USA04079	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cyanosis, Loss of consciousness, Pallor

Symptom Text: Information has been received from a physician concerning a 16 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL. After receiving GARDASIL the patient passed out, her lips went blue and she was very pale. The physician reported that the patient had passed out for about two to three minutes and then she was fine and left the office. The physician was unsure if the patient was going to receive any additional doses of GARDASIL because of the fainting. The patient sought physician's medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325300-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	--	WAES0807USA04081	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depression

Symptom Text: Information has been received from a physician assistant concerning his niece who was vaccinated with GARDASIL. Subsequently the patient experienced depression. It was unspecified if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325301-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	CA	WAES0807USA04274	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the first dose of GARDASIL (dose and route not reported) and experienced "more than syncope", but passed out for several minutes. The patient was sent for computed axial tomography (CAT) scans (no results provided); she seemed to recover completely. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325302-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	MI	WAES0807USA04339	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Palpitations

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female who in July 2008, was vaccinated with a 0.5 ml dose of GARDASIL intramuscularly into the deltoid (lot number not reported). It was unspecified if this was the patient's first dose or a subsequent dose. Subsequently, also reported as about a week ago, the patient experienced heart palpitations and chest pain. The patient's mother called the office and the reporter instructed the patient to go to the emergency room. It was reported that the office had checked with the hospital but it did not appear that the patient went to the emergency room. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325303-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	09-Jun-2008	09-Jun-2008	0	18-Aug-2008	17-Sep-2008	--	WAES0807USA04344	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain

Symptom Text: Information has been received from a registered nurse concerning a female who on 23-JAN-2008 was vaccinated with a first dose of GARDASIL (lot number, injection site and route not reported). On 09-JUN-2008 the patient was vaccinated with a second dose of GARDASIL (lot number, injection site and route not reported). Subsequently the patient experienced pain and redness at the injection site. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325304-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	21-Jul-2008	21-Jul-2008	0	18-Aug-2008	17-Sep-2008	WI	WAES0807USA04346	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Presyncope

Symptom Text: Information has been received from a physician concerning a 24 year old female who on 21-JUL-2008 was vaccinated with a first 0.5 ml dose of GARDASIL (lot number, injection site and route not reported). On 21-JUL-2008 after the vaccination, the patient nearly experienced syncope. The physician reported that the patient experienced symptoms of syncope but did not lose consciousness. Unspecified medical attention was sought. Subsequently, the patient recovered from symptoms of syncope. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325305-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	CT	WAES0807USA03224	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Muscle spasms, Rash

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female, who, on an unspecified date was vaccinated IM in the deltoid with a 0.5mL dose of GARDASIL. The patient was at the office for pelvic pain when she was vaccinated. Subsequently, post vaccination the patient experienced cramping in both legs and developed red spots over her face. The patient called the office. At the time of the report, the patient had not recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pelvic pain

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325306-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	10-Jul-2008	Unknown		18-Aug-2008	17-Sep-2008	--	WAES0807USA04364	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site cellulitis, Pain in extremity

Symptom Text: Information has been received from a nurse practitioner concerning a 24 year old female who on 10-JUL-2008 was vaccinated with the second dose of GARDASIL (lot# not reported). Concomitant therapy included LEXAPRO and ampicillin. The patient experienced cellulitis at the injection site. The patient had a sore arm for about 5 days. The patient recovered from cellulitis at the injection site. The patient sought medical attention. Additional information has been requested.

Other Meds: ampicillin, LEXAPRO

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325307-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	PA	WAES0807USA04365	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Menorrhagia

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a first dose of GARDASIL 0.5 mL (lot # not reported). The patient said her next menstrual cycle was very heavy and thought it was related to the GARDASIL. Medical attention was sought by the patient. The physician also reported that the patient was vaccinated with a second dose of GARDASIL. There was no further information. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325308-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	14-Jul-2008	14-Jul-2008	0	18-Aug-2008	17-Sep-2008	--	WAES0807USA04366	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a consumer concerning her 9 year old daughter with low blood pressure, low heart rate and environmental allergies to rag weed and mildew, who on 14-JUL-2008 was vaccinated with the first dose of GARDASIL, (lot #660553/0070X), 0.5 ml, intramuscularly (IM). There was no concomitant medication. It was reported that following the vaccination the daughter fainted. She was taken to the emergency room and all tests (types not specified) were negative. She was discharged home after four hours. No treatment or outcome information was provided. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory, 07/14/08, negative

History:

Prex Illness: Low blood pressure; Heart rate low; Environmental allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325309-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	CA	WAES0807USA04367	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a physician concerning a 12 or 13 year old female who approximately 2 months ago (approximately May 2008), was vaccinated with GARDASIL (lot # not reported) and developed alopecia. There were no other concomitant medications or no other vaccines. The patient's alopecia resolved two weeks after the onset. The patient sought unspecified medical attention. No other information was available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325310-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	21-May-2008	08-Jul-2008	48	18-Aug-2008	17-Sep-2008	MA	WAES0807USA04380	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Neck pain

Symptom Text: Information has been received from a drug representative and her 25 year old female friend who on 21-MAY-2008 was vaccinated with a third dose of GARDASIL 0.5 ml IM. Approximately beginning on 08-JUL-2008 the patient experienced neck pain and back (also reported as spine) pain with no cause or injury. The patient's neck pain and back pain persisted. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325312-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	25-Sep-2008	--	WAES0807USA03663	25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a nurse practitioner in physician's office concerning a female who was vaccinated with GARDASIL IM, no Lot number was provided. Nurse practitioner reported that a patient experienced a widely disseminated rash all over her body 4 weeks after receiving the vaccine. No further information was provided. At the time of the report the patient symptoms were resolved. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325313-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	KY	WAES0807USA03668	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lip swelling

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with the first dose of GARDASIL vaccine. After receiving her first dose she experienced swollen lips. At the time of the report, on an unknown date the patient recovered from swollen lips. The physician did not provide any details of the case. The patient sought medical attention, not specified. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325314-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	22-Jan-2007	22-Jan-2007	0	18-Aug-2008	17-Sep-2008	CA	WAES0807USA03672	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0961F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a 29 year old female consumer with no pertinent medical history, no family history of alopecia and no allergies who on 22-JAN-2007 was vaccinated with the first dose of GARDASIL (lot#654389/0961F) 0.5ml IM. On an unspecified date the patient was vaccinated with the second dose of GARDASIL (lot#657617/0384F) 0.5ml IM. On 16-JUL-2007 the patient was vaccinated with the third dose of GARDASIL (lot#658222/0927U) 0.5ml IM> There was no concomitant medication. By March 2007, the patient experienced severe hair loss after the first dose and the patient's hair began as a small bald spot. There was a patch of hair missing and the area was completely slick. The patient saw a dermatologist who said it was not caused by vaccine but instead from alopecia. After the third dose the patient's entire crown of her head was bald and slick. The tests performed on the patient which all came up as negative for lupus, thyroid problems and heavy metal. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory - lupus negative; diagnostic laboratory - thyroid problem negative; diagnostic laboratory - heavy metal negative

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325315-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Apr-2008	25-Apr-2008	1	18-Aug-2008	17-Sep-2008	--	WAES0807USA03674	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: Information has been received from a physician assistant concerning a 15 year old female patient with latex allergy who on 24-APR-2008, was vaccinated with the first dose of GARDASIL 0.5ml, I.M. There was no concomitant medication. On 25-APR-2008, the patient experienced vomiting for 2 to 3 days after administration of her first dose of GARDASIL. On 27-APR-2008, the recovered from vomiting for 2 to 3 days after administration of her first dose. The patient sought for medical attention at the time physician's office. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Latex allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325316-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-Nov-2007	Unknown		17-Sep-2008	25-Sep-2008	MO	WAES0807USA03678	25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise

Symptom Text: Information has been received from an office manager concerning a 12 year old female patient who on an unspecified date was vaccinated with the first dose of GARDASIL. On 14-NOV-2007, was vaccinated with the second dose of GARDASIL and is sick. Specific symptoms unspecified. Patient contacted the office by phone and is coming into the office tomorrow (18-JUL-2008). At the time of reporting the patient had not recovered. The patient's sibling also had an adverse experienced after vaccination with GARDASIL. (WAES # 0807USA03685).

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325317-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Mar-2008	01-Mar-2008	0	17-Sep-2008	25-Sep-2008	MA	WAES0807USA03683	25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contraception, Dizziness, Headache

Symptom Text: Information has been received from an office manager concerning a 20 year old female who was vaccinated with the first and second dose of GARDASIL and did not have any problems. In March 2008, the patient was vaccinated with the third dose of GARDASIL. Concomitant medication included birth control (unspecified). Following the third dose of GARDASIL, the patient experienced continued constant dizziness and headache. The time development of the dizziness and headache were unspecified. The patient went to her primary physician (name unspecified) for treatment of the dizziness and headaches. At the time of reporting, the patient had not yet recovered. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325318-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	14-Nov-2007	14-Nov-2007	0	18-Aug-2008	17-Sep-2008	MO	WAES0807USA03685	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Malaise

Symptom Text: Information has been received from an office manager on 17-JUL-2008 concerning a 9 year old female patient who on an unspecified date was vaccinated with the first dose of GARDASIL and on 14-NOV-2007 was vaccinated with the second dose of GARDASIL and "is sick". Specific symptoms unspecified. The patient sought medical attention, by phone and was coming into the office on 18-JUL-2008. At the time of the report the patient was not recovered. The patient's sibling with the same initials also had an adverse experience after vaccination with GARDASIL. (WAES # 0807USA03678). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325319-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	01-Jul-2008		18-Aug-2008	17-Sep-2008	--	WAES0807USA03691	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a female who an unspecified date was vaccinated with a dose of GARDASIL. The nurse reported that the patient "recently fainted some time after receiving GARDASIL". The patient saw the doctor. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325320-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	27-Dec-2007	17-Jul-2008	203	18-Aug-2008	17-Sep-2008	MN	WAES0807USA03698	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a certified medical assistant concerning a female who on 20-DEC-2007 was vaccinated with the first dose of GARDASIL (lot# 659441/1446U) IM. On 17-JUL-2008 the patient was vaccinated with the second dose of GARDASIL (lot# 659964/1978U) IM. Concomitant therapy included WELLBUTRIN and oral birth control. On 17-JUL-2008 the patient experienced pain at injection site after the vaccination. The patient sought medical attention in office. Additional information has been requested.

Other Meds: WELLBUTRIN; hormonal contraceptives

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325321-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	OH	WAES0807USA03710	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who was vaccinated IM with a 0.5 mL dose of GARDASIL (lot # not provided). Concomitant therapies included hepatitis B virus vaccine (manufacturer unknown, lot # not provided) and TDAP (manufacturer unknown, lot # not provided). Subsequently, 2-3 days after the vaccines, the patient experienced stomach pain, nausea and vomiting. The patient sought unspecified medical attention. The patient recovered on an unspecified date. Additional information has been requested. This is one of two reports from the same source (WAES0807USA05655).

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325322-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Feb-2008	13-Feb-2008	0	18-Aug-2008	17-Sep-2008	KS	WAES0807USA03717	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Skin papilloma

Symptom Text: Information has been received from a physician assistant concerning a 14 year old female with attention deficit/hyperactivity disorder and no known allergies, who on 30-Aug-2007 and 13-Feb-2008 was vaccinated with first and second doses, respectively, of GARDASIL (lot #s not provided) and now has warts. Concomitant therapy included FOCALIN 30 mg morning, and RESPERDAL (reported as "RESPIDERAL") 20mg morning. Unspecified medical attention was sought. It was reported that on 16-Jul-2008 (date reported as "yesterday") the patient was seen by a physician assistant and she had 15 warts on her left hand, 7 warts on her right hand and 1 wart on her left foot. It was reported that the patient had never had any warts before, and will be seen for follow up visit. At the time of this report the patient had not recovered from her experience. No other information available. Additional information has been requested.

Other Meds: Focalin mg; Risperdal mg

Lab Data:

History:

Prex Illness: Attention deficit/hyperactivity disorder

Prex Vax Illns:

Vaers Id: **325323-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	19-Mar-2007	01-May-2007	43	18-Aug-2008	17-Sep-2008	NY	WAES0807USA03718	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Musculoskeletal pain, Pain

Symptom Text: Information has been received from a physician concerning a female who on 04-Oct-2008, 08-Dec-2006 and 19-Mar-2007 was vaccinated with first (lot# 653937/0637F), second (lot# 654389/0961F) and third (lot#657617/0384U) doses, respectively, of GARDASIL. Concomitant therapy included "experimental medication for plantar warts" (therapy unspecified). Physician reported that on 21-Jul-2007, the patient had reported that she had pain in the shoulder, hip, knee, and in general on and off since May 2007, 2 months after she had her 3rd dose of GARDASIL. Unspecified medical attention was sought by seeing her doctor. It was reported that on unspecified date the patient "saw her pediatrician, orthopedist, and rheumatologist. No additional information available. Additional information has been requested.

Other Meds: therapy unspecified

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325324-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	17-Sep-2008	MI	WAES0807USA03731	17-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female (demographics not provided), who on unspecified dates was vaccinated with first and second doses, respectively, of GARDASIL (lot# unspecified). It was reported that the patient fainted after receiving the second dose of GARDASIL. It was mentioned that the patient also fainted after the first dose as well. Unspecified medical attention was sought. It was also reported that the patient had recovered from her experience. No further information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 325325-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	09-Sep-2008	09-Sep-2008	0	17-Sep-2008	18-Sep-2008	--	WAES0809USA01701	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Cold sweat, Convulsion, Malaise, Muscle rigidity, Pallor

Symptom Text: Information has been received from a nurse practitioner concerning a female in her early 20's who on 09-SEP-2008 was vaccinated with the first dose of GARDASIL and experienced a vaso vascular episode or seizure following administration of vaccine. There was no concomitant medication. The patient received the vaccination and stated that she did not feel well. The patient was assisted to a chair and laid her head back against the wall. The patient called a nurse and had placed her head on the desk. Effort was made to have the patient sit up and placed her between her knees. She became rigid and made snorting noises. The patient was lowered to the floor and woke up in a few seconds. She was pale and clammy, blood pressure was 108/72. Patient was treated with an ice pack to the back of the neck. Within 15 minutes the patient reported feeling better and went home. the events were considered to be disabling. Additional information has been requested.

Other Meds: None

Lab Data: blood pressure, 09/09/08, 108/7

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325326-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	18-Sep-2008	--	WAES0809USA01598	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Leukaemia, Malaise

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (lot number, injection site and route not reported). The patient "not long after began to not feel well". The patient was then diagnosed with leukemia. The physician heard this information from another source. The physician is not the patient's physician. The physician also mentioned that the patient and her parents will be moving soon. Unspecified medical attention was sought. The patient's outcome was unspecified. Upon internal review, leukemia is considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325327-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	25-May-2008	09-Aug-2008	76	17-Sep-2008	18-Sep-2008	FR	WAES0809USA01629	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Facial paresis

Symptom Text: Information has been received from a hospital neurologist concerning a 13 year old female patient who on 25-MAY-2008 was vaccinated with GARDASIL (lot#, site and route not reported). On 09-AUG-2008 the patient developed right facial paresis. On an unspecified day the patient was hospitalized. Infectious serology (Borrelia, enteroviruses) was negative. After 14 days the patient was completely recovered. Other business partner numbers included: E2008-08440. No further information is available.

Other Meds: Unknown

Lab Data: enterovirus PCR, Negative; serum Borrelia burgdorferi antibody test, Negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325328-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	02-Apr-2008	04-Apr-2008	2	17-Sep-2008	18-Sep-2008	NY	WAES0809USA01640	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	1	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Hypersensitivity

Symptom Text: Information has been received from a 19 year old female patient, who on 30-JAN-2008, was vaccinated with the first dose of GARDASIL. On 02-APR-2008, the patient was vaccinated with the second dose of GARDASIL ((Lot # 655327/1287U). Concomitant therapy included birth control pills. The consumer reported that after received the second dose of GARDASIL and within 24 hours on 04-APR-2008 she was admitted to the ER. The consumer reported that the hospital releasing statement was that she had an allergic reaction. She complained that she couldn't walk. She was given BENADRYL in the hospital I.V. At the time of the report the patient had recovered. Not being able to walk was considered disabling. Additional information is expected.

Other Meds: Hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325329-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Jun-2008	Unknown		17-Sep-2008	18-Sep-2008	NY	WAES0807USA00383	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alkalosis, Drug exposure during pregnancy, Premature labour, Renal failure, Toxoplasmosis

Symptom Text: Information has been received through the Merck pregnancy registry from a physician concerning a 17 year old female with a history of a pap smear on 01-DEC-2006 that was positive for HPV and showed ASCUS, and a colposcopy on 11-JAN-2007 which showed LGSIL, who on approximately 03-JUN-2008 was vaccinated with a first dose of GARDASIL (route and administrating site not reported) at her primary care provider's office. The patient found out she was pregnant about 3 or 4 weeks after receiving the GARDASIL. The patient has a follow up exam scheduled with the physician. The patient sought medical attention by calling the office. The patient's last menstrual period was approximately 21-JAN-2008. The estimated due date is 24-OCT-2008. An ultrasound test perform on 11-JUN-2008 indicated a SIUP at 20 weeks and 3 days. On 26-JUN-2008 a pap smear was negative for HPV. Follow-up information was received from a registered nurse indicating that on 26-JUN-2008 a toxoplasma IgG and IgM was performed with a positive result. Spiramycin was used from 18-JUL-2008 to 11-AUG-2008 for the treatment of toxoplasmosis. The patient's complications during pregnancy included renal failure and alkalosis. On 26-AUG-2008 the patient gave birth prematurely at 31 weeks. The birth weight of the female infant was 1630 gm. Upon internal review the premature birth and the mother's renal failure were determined to be other important medical events. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, 06/11/08, pregnant: SIUP 20w 3d; cervix HPV DNA assay, 06/26/08, negative; serum Toxoplasma IgG Ab, 06/26/08, positive; serum Toxoplasma IgM Ab, 06/26/08, positive

History: Atypical squamous cells of undetermined significance; Papilloma viral infection; Low grade squamous intraepithelial lesion

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325330-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Aug-2008	01-Aug-2008	0	17-Sep-2008	18-Sep-2008	FR	WAES0809ISR00017	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a health professional concerning an approximately 24 year old female who in approximately August 2008, was vaccinated with GARDASIL second dose. In approximately August 2008, the patient experienced syncope and seizure for a few seconds. Subsequently, the patient recovered from syncope and seizure. The reporter felt that syncope and seizure were possibly related to therapy with GARDASIL second dose. Upon internal review seizure was considered an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325331-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Jun-2008	14-Aug-2008	57	17-Sep-2008	18-Sep-2008	FR	WAES0809USA01522	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1524U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Brain oedema, Cerebral haemorrhage, Cerebral infarction, Headache, Meningeal disorder, Pyrexia, Thrombophlebitis, Visual disturbance, Vomiting

Symptom Text: Information has been received from a health authority concerning a 14 year old female non smoker patient who had menorrhagia and hypertrichosis which was treated with MINERVA 35 since beginning of June, 2008 till August, 2008 and familial hypertrichosis (not ovarian, not adrenal) treated with ALDACTONE 25 mg/day since 04-SEP-2006. Patient had a history of viral meningitis at the age of six. On 18-JUN-2008 the patient was vaccinated with a first dose of GARDASIL, (batch number not reported). On 14-AUG-2008 the patient was vaccinated with a second dose of GARDASIL (batch # NH27440) lot # 1524U. Concomitant suspect therapy included MINERVA 35. Concomitant therapy included ALDACTONE TABLETS. On 14-AUG-2008 she suffered from important cephalgia. On 15-AUG-2008 she developed vomiting with improvement on 16-AUG-2008. Since 17-AUG-2008 she had fever at 38.5 C with cephalgia and vomiting persisting until 19-AUG-2008, the day she consulted emergencies at hospital: Laboratory result showed serum C-reactive protein test at 19 mg/L, cerebrospinal fluid test normal (clear, 2 leukocytes < mega-element/L, GR<100 mega-element/L, cervicospinal fluid proteins at 0.22 g/L (N:0.2-0.4), glycorrhachia at 3.1 mmol/L (N:2.3-4), PCR herpes simplex and enteroviruses negative, and computed axial tomography scan normal. Diagnosis was a meningeal syndrome. She was treated with PROFENID and DAFALGAN. On 20-AUG-2008 there was no improvement therefore she was hospitalized in neuropediatrics via emergencies. An enocephalic magnetic resonance imaging performed on 25-AUG-2008 put in relief a thrombophlebitis of anterior part of superior longitudinal sinus, of bilateral cortical fronto-parietal veins and of lateral sinus and left signoid. There was also a left tempro-occipital congestive edema with some hemorrhagic spots of corticosubcortical junction. CT scan performed on 27-AUG-2008 showed a regression of thrombus of superior longitudinal sinus and of left lateral sinus. Left retro-insular temporal venous infarct without any hemorrh

Other Meds: Aldactone tablets 04Sep06 - unk

Lab Data: Diagnostic laboratory test, 07Jun08, Biological examination was normal; Computed axial tomography, 19Aug08, normal; Diagnostic laboratory test, 19Aug08, PCR Herpes simplex test negative; Brain imaging, 25Aug08, see narrative; Computed axial

History: Meningitis viral

Prex Illness: Non-smoker; Menorrhagia; Hypertrichosis

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325332-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Oct-2007	14-Mar-2008	161	17-Sep-2008	18-Sep-2008	--	WAES0809USA01412	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a certified medical assistant for the pregnancy registry for GARDASIL, concerning a 16 year old female who on 27-JUL-2007 was vaccinated with the first dose of GARDASIL, 0.5 mL, I.M. and on 05-OCT-2007 with the second dose of GARDASIL. On 14-MAR-2008, the patient was scheduled to receive a third dose of the series, but the patient had a positive pregnancy test and the third dose was not given. On 17-MAR-2008, the patient had a miscarriage of the pregnancy. The reporter stated that the patient has since become pregnant again. On an unspecified date, positive pregnancy test since having miscarriage was performed (WAES # 0809USA01854). The patient sought unspecified medical attention. Upon internal review, miscarriage of the pregnancy was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: beta-human chorionic, 03/14/08, positive; beta-human chorionic, ?/?/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325333-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	08-Sep-2008	08-Sep-2008	0	17-Sep-2008	18-Sep-2008	FR	WAES0809AUS00035	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0055X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactic reaction, Anxiety, Feeling hot, Headache, Pharyngolaryngeal pain, Pruritus, Rash, Viral infection

Symptom Text: Information has been received from the NSW via the agency concerning a school girl with asthma and penicillin allergy who on 08-SEP-2008 was vaccinated with the third dose of GARDASIL (Lot # 659659/0055x, Batch # K3031, Expiry date 06-AUG-2010). On 08-SEP-2008 the patient experienced anaphylactic reaction described as pruritus, feeling hot, rash, feeling of impending doom. It was reported that the student was treated at the school, then by the paramedics and was treated with 0.5 mL 1:1000 adrenaline. The patient recovered en route to the emergency room where she was also treated with prednisone but not admitted overnight. The patient was followed up around 09-SEP-2008 or 10-SEP-2008 and was still recovered however she had a sore throat and head. The patient's physician considered that her subsequent sore throat and head were the result of a coincidental virus. The agency considered that anaphylactic reaction was related to therapy with GARDASIL. Upon internal medical review (epinephrine) adrenaline administration in the emergency room within 24 hours of vaccination was considered an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Asthma; Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325334-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	08-Sep-2008	08-Sep-2008	0	17-Sep-2008	18-Sep-2008	FR	WAES0809AUS00038	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0055X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactic reaction, Chest discomfort, Mass, Pain, Rash

Symptom Text: Information has been received from the NSW Department of Health via the agency concerning a school girl who on 08-SEP-2008 was vaccinated with the third dose of GARDASIL (Lot # 659659/0055X, Batch # K3031, Expiry date 06-AUG-2010). On 08-SEP-2008 the patient experienced anaphylactic reaction described as rash, chest tightness, painful lump on chest. It was reported that the student was treated at the school, then by the paramedics and was treated with 0.5 mL 1:1000 adrenaline. Subsequently, the patient recovered from anaphylactic reaction en route to the emergency room but was not admitted overnight. The patient was followed up around 09-SEP-2008 or 10-SEP-2008 and had a rash and chest tightness. The patient was returned to the hospital emergency room and was treated with VENTOLIN, phenergan and TELFAST. The agency considered that anaphylactic reaction was related to therapy with GARDASIL. Upon internal medical review (epinephrine) adrenaline administration in the emergency room within 24 hours of vaccination was considered an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325335-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	08-Sep-2008	08-Sep-2008	0	17-Sep-2008	18-Sep-2008	FR	WAES0809AUS00039	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0055X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactic reaction, Dizziness, Dyspnoea, Pharyngeal oedema, Swollen tongue, Vomiting

Symptom Text: Information has been received from the NSW Department of Health via the agency concerning a school girl who on 08-SEP-2008 was vaccinated with the third dose of GARDASIL (Lot # 659659/0055X, Batch # K3031, Expiry date 06-AUG-2010). On 08-SEP-2008 the patient experienced anaphylactic reaction described as felt faint, vomiting, throat swelling, tongue swelling and breathing difficulty. It was reported that the student was treated at the school, then by the paramedics and was treated with 0.5 mL 1:1000 adrenaline en route to the emergency room where she was also treated with prednisone but not admitted overnight. The patient was followed up around 09-SEP-2008 or 10-SEP-2008 and had recovered. The agency considered that anaphylactic reaction was related to therapy with GARDASIL. Upon internal medical review (epinephrine) adrenaline administration in the emergency room within 24 hours of vaccination was considered an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325348-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Nov-2007	08-Nov-2007	0	17-Sep-2008	18-Sep-2008	FR	WAES0809USA01892	18-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0278U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a gynecologist, concerning a 17 year old female patient who on 08-NOV-2007 was vaccinated with the first dose of GARDASIL (Lot # 0278U and Batch #NF56940) IM into the deltoid muscle. The patient forgot to take contraceptives. Date of last menstrual period was unknown. On 19-NOV-2007, the patient was in gestation week 8. The pregnancy was timely and without pathologies. An intended abortion by the patient after required consultation was performed (exact date not reported). Upon internal review, elective termination of pregnancy was considered a medically significant event. CASE CLOSED. Other business partner numbers included: E2008-08332. No further information is available.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Contraception

Prex Vax Illns:

Vaers Id: **325355-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	28-Aug-2008	28-Aug-2008	0	17-Sep-2008	25-Sep-2008	OR	OR200827	26-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB245AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0328X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0570X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Discomfort, Injection site erythema, Injection site induration, Injection site pruritus, Oedema peripheral, Pain in extremity

Symptom Text: Child began to c/o (L) arm pain (back of arm) prior to going to bed last night. This a.m. Mom states child cont to c/o discomfort and mom notes that the area is reddened approx. SL of a "coffee cup" area is also "hard" to touch and she c/o itching. Mom advised re apply ice, Give TYLENOL or ibuprofen and option of topical or oral BENADRYL. TC to mom 09/0508. Mom states she applied ice intermittently and gave TYLENOL and BENADRYL PO. As well as applied topical BENADRYL for c/o itching "through Sunday" erythema was a 3" area with swelling to elbow. The swelling resolved Sun eve but she cont. to have firmness at the inj site.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325358-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Sep-2008	08-Sep-2008	0	17-Sep-2008	25-Sep-2008	IN		25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye rolling, Muscle twitching, Physical examination normal, Pruritus, Tremor

Symptom Text: Pt's mom reported itching 1 hr after vaccines. Gave Benadryl. Pt's boyfriend states she started twitching/shaking head & neck & eyes rolled back in her head. 9/22/08-records received-9/9/08-Seen in office day after C/O itching, twitching and shaking head and neck. Eyes rolled. PE grossly WNL.

Other Meds: Benadryl Prilosec

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325360-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Sep-2008	12-Sep-2008	0	17-Sep-2008	25-Sep-2008	WI		26-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0952X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2688AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breath sounds abnormal, Loss of consciousness, Nausea, Syncope vasovagal

Symptom Text: None stated

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 325363-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	12-Jun-2008	21-Aug-2008	70	17-Sep-2008	22-Sep-2008	--		16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Confusional state, Convulsion, Cyanosis, Dizziness, Dyskinesia, Fatigue, Feeling abnormal, Gaze palsy, Grand mal convulsion, Headache, Insomnia, Myalgia, Postictal state, Stress

Symptom Text: Patient received first dose of GARDASIL vaccine on 06/12/2008. Per Clinic note: "HLD is a 24-year-old woman who experienced what has been described as a grand mal seizure at about 3 p.m. on 08/21/2008. This was a seizure that was witnessed by a friend and afterwards she was evaluated at the Emergency Room. Patient states that on that day of the seizure, she had been feeling kind of dizzy and out of it all day. She had never experienced that exact feeling before. HLD has been taking XANAX at a dose of 1.5 mg nightly for two or three years for anxiety. The day before the seizure, she had missed her evening dose of XANAX. In addition she had very little, if any, sleep that night before the seizure and she reported feeling also somewhat stressed out on the 08/21/2008. The witness describes the seizure as HLD getting a strange look on her face and gazing around the room randomly for about 30 seconds, after which HLD's eyes rolled back in her head and she fell to the floor and had what were described as flailing movements of her arms and her legs for about 2 to 3 minutes with some turning blue towards the end. Afterwards, she was confused, did not know where she was, or what was going on. In the Emergency Room, she did have a CT scan that showed no evidence of trauma or bleeding or midline shift but that there was an old lacune in the left inferior BG. She had postictal confusion, lasting for a few hours. She did have quite a severe headache and received narcotics in the Emergency Department which may have contributed to some difficulty in clearing of her mentation. She also had muscle soreness for about three days afterwards. During this seizure, she did not bite her tongue. She did not have any bowel or bladder incontinence. At the time of her evaluation in the Emergency Department, the seizure was attributed possibly to withdrawal from XANAX compounded by a sleep deprivation and stress. She has had no further events since the time of her Emergency Department visit. CT scan did not show a cause for seizures but did s

Other Meds: Alprazolam 0.5mg po at bedtime as needed. -08/14/2007-present. CHANTIX Starting Month Pack 0.5mg x 11 doses, then 1mg x 42 doses. -06/12/2008-071/2/2008- Hydrocodone/Acetaminophen 5/500mg 1 tab every 8 hours as needed for pain -07/16/2008-0

Lab Data: CT showed old lacune left inferior basal ganglia. CBC and CMP are within normal limits. Electroencephlaogram-EEG-from 09/02/2008 reports no focal swelling or background asymmetries seen. No epileptiform asymmetries seen. EEG normal. Labs a

History: Past Medical History: Depression, anxiety, dysmenorrhea, nicotine dependence, visual impairment, patellofemoral syndrome; Allergies: none; Social alcohol use 1-2 drinks per week. PMH: depression, anxiety

Prex Illness:

Prex Vax Illns:

Vaers Id: **325371-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jul-2008	17-Jul-2008	1	18-Aug-2008	30-Sep-2008	NJ	WAES0807USA03757	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Injection site bruising, Injection site pain, Joint stiffness, Pain in extremity, Paraesthesia, Pyrexia, Tonsillitis

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female, with environmental allergies and no pertinent medical history, who on 23-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine and on 16-JUL-2008 was vaccinated with the second dose of GARDASIL vaccine (Lot No. 660557/0072X). There was no concomitant medication. On 17-JUL-2008, the patient developed right and sometimes left leg pain and fever. She also had soreness and bruising at the injection site and some tingling of her hands. She had a sore throat when vaccinated. She has been prescribed ADVIL and will see her primary physician. At the time of the reporting the patient has not recovered. The patient sought medical attention, phone call. Additional information has been requested. 9/26/08 Reviewed OB/GYN medical records of 5/23-8/11/08. FINAL DX: none provided Records reveal patient in good health on 5/23/08, day of HPV #1, Lot 1968U. Received HPV #2, Lot 0072X on 7/16/08 & had sore throat prior to vax. Experienced joint pain & stiffness, fever x 4 days. Seen by PCP 7/18 & dx w/tonsillitis. Had sore throat x 1 wk. Joint pain & stiffness resolved.

Other Meds: None

Lab Data: None

History:

Prex Illness: Sore throat; Environmental allergy

Prex Vax Illns:

Vaers Id: **325372-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	10-Jan-2007	Unknown		17-Sep-2008	26-Sep-2008	KY	WAES0807USA03770	26-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anogenital warts, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a registered nurse concerning a 25 year old female, with no drug reaction/allergies, and with normal PAP smear, who on 10-JAN-2007 was vaccinated with the first dose of GARDASIL (lot number unknown) IM 0.5 mL, and late on 21-MAY-2007 was vaccinated with the second dose of GARDASIL (Lot number 655324/0088U) IM 0.5 mL. Concomitant therapy included unspecified birth control pills. In the morning of 18-JUL-2008, the patient was in the office and mentioned to the physician she had genital warts. The patient had a PAP smear done (results unknown). The physician treated her for condyloma and will be back to the office later on 18-JUL-2008, possibly to receive the third dose of GARDASIL. At the time of the report the patient had not recovered. The patient sought medical attention, phone office and visited office. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325373-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	30-Sep-2008	--	WAES0807USA03776	30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a consumer concerning her daughter who on an unspecified date was vaccinated with GARDASIL vaccine (yeast) and her last PAP smear test came up positive for Human papillomavirus (HPV). It was unknown if the patient sought medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Pap test - positive for HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325374-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	26-Sep-2008	KY	WAES0807USA03783	26-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lip swelling, Rash

Symptom Text: Information has been received from a physician who heard that a female who was vaccinated with the first dose of GARDASIL for prevention of HPV, at her physician's office experienced swelling of the lips and rash. The patient's symptoms resolved. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325375-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
49.0	F	01-Nov-2007	Unknown		18-Aug-2008	30-Sep-2008	--	WAES0807USA03793	30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Inappropriate schedule of drug administration, Neck pain

Symptom Text: Information has been received from a 49 year old female registered dietician who in November 2007 was vaccinated with the first dose of GARDASIL vaccine. The second and third dose of GARADSIL vaccine were administered on unknown dates. She reported the the sternoclavicular pain started after the first dose and after the third dose, the pain went into her neck. The patient spoke to a physician. At time of report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325379-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	29-Aug-2008	01-Sep-2008	3	17-Sep-2008	26-Sep-2008	IN		29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypokinesia, Muscular weakness, Musculoskeletal stiffness, Sensory loss

Symptom Text: Pt. complained of left arm weakness 3 days after HPV vaccine injected. Had initial stiffness for 2 days after vaccine. No local reaction, no fever. Patient reported one episode of complete loss of sensation and motor function after sleeping on left arm which resolved with reintroduction of circulation. Patient states that episode occured during first week following vaccine, patient not able to give exact date.

Other Meds: Lexapro, Buspar, Yasmin

Lab Data:

History: Allergic to bees

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325382-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Sep-2008	12-Sep-2008	1	17-Sep-2008	26-Sep-2008	OH		29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Headache

Symptom Text: Headaches: Patient has a history of migraine headaches(first seen 2005 for recurrent HA), mother feels that intensity and frequency of headaches have increased since gardisil vaccine was given. Severe headache within 24 hours of 3rd dose.Patient was assymptomatic at time of visit.

Other Meds: Apri (oral contraceptives)

Lab Data: none

History: migraines/mixed type headaches, dymennorhea, premenstrual mood disorder, asthma, allergies

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325391-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Sep-2008	17-Sep-2008	0	17-Sep-2008	26-Sep-2008	NE		29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B028AA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle twitching, Pallor, Syncope

Symptom Text: Approx 3-4 minutes after receiving a HPV #2 and Tdap she fainted and twitching of facial muscles and extention of arms and legs for less than 5 seconds. After episode was over and she set up she was oriented x 4, pale, Vital Signs within Normal limits. Observed for 30 minutes with V.S. done every 10 minutes. V.S. remained WNL. Mom was presented and escorted daughter home with instructions to take to ER if condition changed.

Other Meds: NONE

Lab Data: None

History: NONE

Prex Illness: NONE

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325394-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Sep-2006	18-Sep-2007	366	18-Sep-2008	29-Sep-2008	MI		29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Injection site pruritus, Rash macular

Symptom Text: red splotches and itching at injection site

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns: red splotches at site~HPV (Gardasil)~2~13~In Sibling1

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325404-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Sep-2008	17-Sep-2008	0	17-Sep-2008	26-Sep-2008	CT		29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Head injury, Joint injury, Syncope

Symptom Text: Within 5min. of HPV vaccine the patient became dizzy and had syncope. She fell down and hit her head and right elbow on a table and chair respectively. We give her milk and she rested for 10 more minutes.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325405-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Sep-2008	14-Sep-2008	6	17-Sep-2008	26-Sep-2008	GA		26-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2899AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2638AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1061U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Woke up with hives Sunday 9/14/08, covering most of body. immunized 9/8/08

Other Meds: Ortho Evra

Lab Data: None

History: No known allergies. Patient denies a family history of asthma; familial congenital defects; hay fever

Prex Illness: Urticaria

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325414-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Sep-2007	01-Sep-2007	0	18-Aug-2008	30-Sep-2008	CA	WAES0807USA03254	30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a nurse concerning a 23 year old female who in September 2007, was vaccinated with the first dose of GARDASIL vaccine (yeast) (Lot No 0250X). Concomitant therapy included (LOESTRIN). In September 2007, the patient experienced pain in arm for 4 months. The patient sought unspecified medical attention. On an unspecified date in January 2008, the patient recovered. Since she had pain for four months she did not get the second dose of GARDASIL vaccine (yeast) until 14-JUL-2008. No AE reported after the second dose. Additional information has been requested.

Other Meds: LOESTRIN

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325415-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	30-Jun-2008	14-Jul-2008	14	18-Aug-2008	30-Sep-2008	KS	WAES0807USA04383	30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Rash

Symptom Text: Information has been received from a 25 year old female with allergies to sulfa, erythromycin and augmentin and Crohn's disease who on 30-JUN-2008 was vaccinated intramuscularly with a first dose of GARDASIL vaccine (yeast). Concomitant therapy included (ZOFRAN), (NEXIUM) and mercaptopurine, "2 weeks after shot", on approximately 14-JUL-2008 the patient developed "a rash and intense itching" (starting around the midline and now on her chest and legs). The patient visited her doctor and dermatologist. She got cortisone (manufacturer unspecified) at the emergency room (ER) and came back for a second shot of cortisone since the rash spread. A biopsy of the rash on the stomach was taken but result was not provided yet. The patient's rash and intense itching persisted and she did not know if she would have the second dose on 03-SEP-2008. Additional information has been requested.

Other Meds: NEXIUM, mercaptopurine, ZOFRAN

Lab Data: Unknown

History:

Prex Illness: Crohn's disease, Sulfonamide allergy, Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **325416-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Jul-2008	22-Jul-2008	0	18-Aug-2008	30-Sep-2008	FL	WAES0807USA04389	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cold sweat, Feeling abnormal, Hyperhidrosis, Injection site pain, Panic attack, Visual disturbance

Symptom Text: Information has been received from a nurse concerning a 14 year old female with no pertinent medical history and no known drug reactions/allergies who on 22-JUL-2008 was vaccinated intramuscularly with the 0.5 mL first dose of GARDASIL vaccine (Lot# 660393/0067X). There was no concomitant medication. Less than 5 minutes after vaccination, the patient complained that the injection site was painful and said "I don't feel good." The nurse had the patient sit down and the patient seemed to have a panic attack. The patient said that she was seeing stars. The patient laid down and she was diaphoretic and clammy. The patient stayed in the office for about a half-hour and was given water and a lollipop. The patient's blood pressure was checked three times and she was fine. Subsequently, the patient recovered from the events. This one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325417-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		18-Aug-2008	01-Oct-2008	--	WAES0807USA04407	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Genital lesion

Symptom Text: Information has been received from a consumer concerning his over 18 year old daughter who on an unspecified date was vaccinated with the first dose of GARDASIL vaccine. The patient had bumps on her genitals after receiving the first dose. The patient got tests (including a pap smear) to see if the bumps on her genitals were genital warts (no results reported). The outcome was unknown. It was unknown if the patient sought medical attention or not. No further information is available.

Other Meds: Unknown

Lab Data: Pap test

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325418-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	19-Jun-2008	19-Jun-2008	0	18-Aug-2008	30-Sep-2008	--	WAES0807USA00958	30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dermatitis contact, Urticaria

Symptom Text: Information has been received from a nurse concerning a 13 year old female who on 19-JUN-2008 was vaccinated with GARDASIL vaccine (yeast) and varicella virus vaccine live (MSD).Shortly thereafter the patient developed hives, contact dermatitis and pseudo-seizure activity. As of 03-JUL-2008, pseudo-seizure activity persisted. The outcome of hives and contact dermatitis was not reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325419-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Jul-2008	18-Jul-2007	-365	18-Aug-2008	01-Oct-2008	MI	WAES0807USA04409	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Dyspnoea

Symptom Text: Information has been received from a certified medical assistant concerning a 16 year old female with epilepsy as a child (no treatment at present) and depression and no history of drug reactions/allergies, who on 17-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (Lot No. 654272/0073X) 0.5 mL, IM. Concomitant therapy included ZOLOFT. The next day, on 18-JUL-2007, the patient called to the office stating that she was having shortness of breathe and chest pain. The patient was advised to go to the local emergency room for evaluation. The medical assistant reported that the patient was never seen at the emergency room and has not returned the phone calls that the office has placed to her home. At the time of reporting, the outcome was unknown. Additional information has been requested.

Other Meds: ZOLOFT

Lab Data: None

History:

Prex Illness: Epilepsy; Depression

Prex Vax Illns:

Vaers Id: **325420-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
30.0	F	01-Nov-2007	01-May-2008	182	18-Aug-2008	30-Sep-2008	--	WAES0807USA01035	30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Inappropriate schedule of drug administration, Myalgia

Symptom Text: Information has been received from a 30 year old female with no relevant medical history or allergies who in November 2007, was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). On unspecified dates the patient was vaccinated with a second and third dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). Concomitant therapy included hormonal contraceptives (unspecified). In May 2008, also reported as after receiving the third dose, the patient experienced muscle pain and weakness. The patient sought unspecified medical attention. The patient's muscle pain and weakness persisted. No further information is available.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **325421-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	02-Jul-2008	02-Jul-2008	0	18-Aug-2008	01-Oct-2008	--	WAES0807USA01054	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a physician concerning a female (age not reported) who on 02-JUL-2008 was vaccinated with a dose of GARDASIL vaccine (lot not reported). On 02-JUL-2008 after vaccination, the patient experienced pain in her legs. The patient's outcome was reported as recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325422-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		18-Aug-2008	01-Oct-2008	CA	WAES0807USA04412	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Vaginal haemorrhage

Symptom Text: Information has been received from a physician concerning her 17 year old female daughter, with no pertinent medical history and no drug reaction/allergies, who on unspecified dates was vaccinated with the first, second and third dose of GARDASIL vaccine INJ. There was no concomitant medication. After receiving the third dose of GARDASIL vaccine, in June 2008, the patient was experiencing continuous bleeding of the vagina. At the time of reporting the patient had not recovered. The patient sought medical attention unspecified. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325423-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	30-Jun-2008	02-Jul-2008	2	18-Aug-2008	30-Sep-2008	--	WAES0807USA01081	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site vesicles, No reaction on previous exposure to drug

Symptom Text: Information has been received from a physician concerning a 24 year old female who on 30-JUN-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast) (lot not reported). On 02-JUL-2008 the patient experienced blisters and itching with redness at the injection site after the second dose of GARDASIL vaccine (yeast). No reaction was reported with the first dose of GARDASIL vaccine (yeast). The patient's status was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325424-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Jul-2008	03-Jul-2008	2	18-Aug-2008	01-Oct-2008	--	WAES0807USA01093	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pruritus, Injection site vesicles, Injection site warmth

Symptom Text: Information has been received from a nurse practitioner concerning a 24 year old female with attention deficit/hyperactivity disorder and a history of allergic reaction to antibiotics (tetracycline) who on 01-JUL-2008 was vaccinated IM in her left deltoid muscle with the second 0.5 mL dose of GARDASIL vaccine (lot 660393/0067X). Concomitant therapy included ADDERALL TABLETS and ORTHO TRI-CYCLEN LO. On 03-Jul-2008, the patient experienced injection site blisters, itching and warmth. The patient received the first dose of GARDASIL vaccine (lot 659653/1448U) on an unspecified date. At the time of the report the patient was recovering. Additional information has been requested.

Other Meds: ADDERALL TABLETS; ORTHO TRI-CYCLEN LO

Lab Data: None

History: Allergic reaction to antibiotics

Prex Illness: Attention deficit/hyperactivity disorder

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325425-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		18-Aug-2008	01-Oct-2008	--	WAES0807USA01118	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning two patients who were vaccinated with a dose of GARDASIL vaccine (lot not reported) and fainted after receiving the vaccine. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325426-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jul-2008	02-Jul-2008	0	18-Aug-2008	30-Sep-2008	--	WAES0807USA01121	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gait disturbance, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 17 year old female with Turner's syndrome and attention deficit/hyperactivity disorder who on 02-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 0250X). On approximately 02-JUL-2008 the patient experienced pain in both legs and difficulty walking. The patient's mother took her daughter to the clinic because the doctor's office was closed. The clinic told the mother that her child experienced a rare reaction to the vaccine. The mother reported that her daughter was 80 % improved. Patient is recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Turner's syndrome, Attention deficit/hyperactivity disorder

Prex Vax Illns:

Vaers Id: **325427-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Apr-2008	04-Jul-2008	94	18-Aug-2008	01-Oct-2008	--	WAES0807USA01125	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Drug exposure during pregnancy, Headache

Symptom Text: Information has been received from the Pregnancy Registry for GARDASIL vaccine from a physician concerning a 16 year old female with a history of asthma and allergic reaction to antibiotics who in April 2008, was vaccinated with the first dose of GARDASIL vaccine (lot not reported). Concomitant therapy included albuterol, ADVAIR, and TYLENOL. In April 2008, "the next day after her second dose," the patient experienced headache and dizziness. She recovered after 1-2 days. The patient found out "last Friday or Saturday" that she was "about 4 weeks pregnant (estimated LMP of 05-JUN-2008). A pregnancy test given before the administration of the vaccine did not show pregnancy. The patient's status was not reported. Additional information has been requested.

Other Meds: TYLENOL; albuterol; ADVAIR

Lab Data: serum beta- human - positive

History:

Prex Illness: Pregnancy NOS (LMP - 06/05/2008); Asthma; Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325428-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Feb-2008	01-Jul-2008	151	18-Aug-2008	01-Oct-2008	IN	WAES0807USA04413	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a nurse concerning her 21 year old daughter who in July 2007, was vaccinated with GARDASIL vaccine. On February 2008, the patient had completed the GARDASIL series. Concomitant therapy included ORTHO TRI-CYCLEN LO. On 01-JUL-2008, the patient had her first abnormal PAP test. Further analysis of the sample will be available on or after 18-AUG-2008. The patient sought medical attention. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: Pap test 07/01/08 - abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325429-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	17-Jul-2008	22-Jul-2008	5	18-Aug-2008	30-Sep-2008	PA	WAES0807USA04420	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nasopharyngitis, Pharyngolaryngeal pain, Pyrexia

Symptom Text: Information has been received from a nurse concerning a 23 year old female who on 17-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast), 0.5 mL, IM. On 22-JUL-2008, the patient called the office to report common cold symptoms including a high fever and sore throat. At the time of reporting, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325430-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	09-Dec-2008	IL	WAES0807USA01164	09-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Dyspnoea, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a pharmacist concerning her daughter with seasonal allergies and a facial tick that has worsened over the past year who between may and June 2007 was vaccinated 0.5ml, IM with a dose of GARDASIL. In may 2008 the patient was vaccinated 0.5ml, IM with a 2nd dose of GARDASIL. There was no concomitant medication. In spring 2008, the patient began developing chest pain and shortness of breath. It first occurred after running a 400 meter race at a track meet. On an unspecified date, the patient had an Echocardiogram and Electrocardiogram and the results were inconclusive. On an unspecified date, the patient had the echocardiogram repeated and believed the results showed "some type of mitral valve or injection fraction problems. "The patient outcome was not reported. The patient sought unspecified medical attention during an office visit. Additional information has been requested.

Other Meds: None

Lab Data: Echocardiography incon, Electrocardiogram incon, Echocardiography - mitral valve or ejection fraction problems

History: Seasonal allergy; Facial spasm

Prex Illness:

Prex Vax Illns:

Vaers Id: **325431-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	30-Sep-2008	CA	WAES0807USA04430	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a dose of GARDASIL vaccine (yeast) then fainted. The physician reported that they followed the procedure for when a patient faints and then the patient came to and was fine. The patient is not going to continue the rest of the series. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325432-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	Unknown	Unknown		18-Aug-2008	30-Sep-2008	--	WAES0807USA01188	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Vaccine positive rechallenge, Vaginal haemorrhage

Symptom Text: Information has been received from a 24 year old female health professional with a urinary tract infection who on an unspecified date was vaccinated with a 1st dose of GARDASIL vaccine (yeast) (lot# not reported). Concomitant therapy included cephalexin (KEFLEX). Subsequently the patient bled for 3 weeks after dose 1 and "was not on her period". On an unspecified date the patient was vaccinated with a 2nd dose of GARDASIL vaccine (yeast) (lot# not reported). After dose 2, the patient immediately started to bled and has been bleeding for 1 week. The patient sought unspecified medical attention. The patient has not recovered from the bleeding. Additional information has been requested.

Other Meds: KEFLEX

Lab Data: Unknown

History:

Prex Illness: Urinary tract infection

Prex Vax Illns:

Vaers Id: **325433-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jul-2008	01-Jul-2008	0	18-Aug-2008	30-Sep-2008	IL	WAES0807USA01189	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning a 16 year old female who in July 2008 (reported as "last week), was vaccinated 0.5 mL, IM, with GARDASIL vaccine (yeast) (lot# and dose not reported). Concomitant medication included carbetapentane tannate (+) diphenhydramine tannate (+) phenylephrine tannate (D-TANN CT). In July 2008, the patient experienced syncope after her vaccination. Subsequently, the patient recovered on the same day of the vaccination from syncope. The patient sought unspecified medical attention. It was also reported that the "patient experienced syncope after all immunizations." Additional information has been requested.

Other Meds: D-TANN CT

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: syncope~HPV (Gardasil)~1~0~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325434-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	01-Oct-2008	AZ	WAES0807USA04431	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a medical assistant concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL vaccine (yeast) (lot # not provided) and fainted in their office. The reporter did not elaborate whether the patient received GARDASIL vaccine (yeast) or not. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325435-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		18-Aug-2008	01-Oct-2008	AR	WAES0807USA04433	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Skin laceration, Syncope

Symptom Text: Information has been received from a physician concerning a 17 year old female who on an unspecified dates was vaccinated with the first and second doses of GARDASIL vaccine (yeast). On an unspecified date, the patient was vaccinated with a third dose of GARDASIL vaccine (yeast), 0.5 mL, IM, then fainted. The patient also received a laceration on head as result of her fall. The patient sought medical attention. At time of reporting, the patient had recovered. Additional information is not expected as the physician requested not to be contacted.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325436-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	28-Apr-2008		18-Aug-2008	01-Oct-2008	NJ	WAES0807USA01196	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dizziness, Nausea

Symptom Text: Information has been received from a female consumer who on 28-APR-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot# not provided). On 23-JUN-2008 the patient received the second dose of GARDASIL vaccine (yeast) (lot# not provided). The patient reported that she continuously had nausea and dizziness a few days after the injection. She had pain in her stomach for about 15 minutes. The patient's outcome was not known. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325437-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	01-Oct-2008	AR	WAES0807USA04435	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal stiffness, Pain in extremity

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated IM with GARDASIL vaccine (yeast) and developed arm pain with stiffness. The physician advised that symptoms resolved on their own and patient had full range of motion when she returned to her office. Additional information is not expected as the physician requested not to be contacted.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325438-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	01-Oct-2008	NJ	WAES0807USA04441	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a female who on an unknown date was vaccinated with GARDASIL vaccine (yeast). On an unspecified date the patient developed hives. The physician did discontinue the series. Subsequently, the patient recovered. The patient sought medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325439-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
30.0	F	01-Nov-2007	01-Nov-2007	0	18-Aug-2008	01-Oct-2008	--	WAES0807USA01259	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Pain, Tremor

Symptom Text: Information has been received from a 30 year old female consumer who sometime in November 2007, was vaccinated with a third dose of GARDASIL vaccine (yeast). Concomitant therapy included hormonal contraceptives (unspecified). Two and a half week post vaccination of dose 3, the patient experienced shakiness and achiness especially in her legs. The patient sought unspecified medical attention. At the time of reporting the patient had not recovered from shakiness and achiness especially in legs. Additional information is not expected,

Other Meds: hormonal contraceptives

Lab Data: diagnostic laboratory - results not reported

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **325440-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Feb-2007	01-Feb-2007	0	18-Aug-2008	01-Oct-2008	OR	WAES0807USA01263	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hyperhidrosis, Nausea, Oedema peripheral, Pallor, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning her 18 year old daughter with a history of asthma and allergy to cefixime (SUPRAX) and cefaclor (CECLOR) who in February 2007, was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot number not provided). On unspecified dates the patient receive the second and third dose of GARDASIL vaccine (yeast) (lot number not provided). Concomitant therapy included albuterol. The caller reported that her daughter's arm swelled up and she experienced severe sweating, paleness, nausea and a fever approximately 1 1/2 hours after receiving her first dose of GARDASIL vaccine (yeast). These symptoms lasted for 24-30 hours. She experienced these same symptoms after her second dose of GARDASIL vaccine (yeast) however they took less than 1 1/2 hours to appear and lasted for 24 hours. These same symptoms appeared quickly after the third dose and lasted 12-15 hours. Unspecified medical attention was sought with several physicians. On an unspecified date the patient recovered. Additional information has been requested.

Other Meds: albuterol

Lab Data: None

History:

Prex Illness: Asthma, Hypersensitivity, Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325441-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	01-Oct-2008	--	WAES0807USA04516	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Information has been received from a registered nurse concerning an unspecified number of female patients who on unspecified dates were vaccinated with a dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). Subsequently the patients experienced pain after vaccination. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this reports. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325442-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	01-Oct-2008	--	WAES0807USA04517	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Depression, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer reading on the internet concerning a female who on an unspecified date was vaccinated with the first dose of GARDASIL vaccine (yeast). The patient was vaccinated with the second dose of GARDASIL vaccine (yeast) on an unspecified date. The patient became depressed after receiving the first dose and recovered shortly afterward. After receiving her second dose she became even more depressed. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325443-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		18-Aug-2008	01-Oct-2008	--	WAES0807USA01267	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	TTOX	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a licensed practical nurse concerning a 13 year old female who on an unspecified date was vaccinated IM with the first 0.5 ml dose of GARDASIL vaccine (yeast). Concomitant therapy included varicella virus vaccine live (VARIVAX), tetanus toxoid (unspecified, manufacturer unknown) meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA) (Sanofi Pasteur). The patient experienced syncope soon after vaccination. Unspecified medical attention was sought at the office. She recovered on the same day as vaccination at the office and was released. Additional information has been requested. No further information is available.

Other Meds:

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325444-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
37.0	F	01-Apr-2008	01-Apr-2008	0	18-Aug-2008	01-Oct-2008	--	WAES0807USA01268	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Inappropriate schedule of drug administration, Scar, Vaccine positive rechallenge

Symptom Text: Information has been received from a 37 year old female consumer with no medical history and an allergy to penicillin who in October 2007, was vaccinated with the first dose of GARDASIL vaccine (yeast) in her left arm "in the muscle". In December 2007 the patient was vaccinated with the second dose of GARDASIL vaccine (yeast) given in the same spot on her left arm. In April 2008, the patient was vaccinated with the third dose of GARDASIL vaccine (yeast) on the back side of her right arm. There was no concomitant medication. A few days after (also reported as a few weeks after) the first dose a red mark appeared that looked like a pimple at first. The red mark was still there when she went back for her second dose. After the second dose the red spot became worse. The patient did not have any red marks after the third dose. At time of reporting, the mark on the patient's left arm was still there, looks like a scar, but has gotten fainter. Unspecified medical attention was sought. Patient outcome was recovering. No further information was available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **325445-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-May-2007	01-Jun-2007	31	18-Aug-2008	01-Oct-2008	MD	WAES0807USA01272	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Rash

Symptom Text: Information has been received from a consumer concerning her 19 year old daughter who on an unspecified date in January 2007, was vaccinated with her first dose of GGARDASIL vaccine (yeast) (Lot #, site, and route not reported). There was no concomitant medication. On an unspecified date in May 2007, the patient was vaccinated with her third dose of GARDASIL vaccine (yeast) (Lot #, site, and route not reported). No information was provided regarding the second vaccination with GARDASIL vaccine (yeast). On an unspecified date in June 2007, the patient experienced a red rash in her hip area going up to her breast area. The patient has been having this rash on and off since June 2007. The patient has sought unspecified medical by visiting "a couple of doctors and dermatologists and no one can determine the cause." As of the time of this report, the red rash was persisted. No additional information is available. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **325446-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	01-Oct-2008	NY	WAES0807USA01276	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information has been received from a nurse concerning a female who on an unspecified date was vaccinated with GARDASIL vaccine (yeast) (Lot #, site, route and dose # not reported). On an unspecified date, the patient had "warts on her hands" after getting GARDASIL vaccine (yeast). The patient sought unspecified medical attention by calling the nurse. The patient outcome was not reported. No additional information was reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325447-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	01-Oct-2008	--	WAES0807USA01280	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling

Symptom Text: Information has been received from a mother concerning her daughter who was vaccinated with GARDASIL vaccine (yeast) (Lot# not reported). Subsequently the patient experienced pain at injection site and swelling at injection site. The patient's outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325448-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		18-Aug-2008	01-Oct-2008	--	WAES0807USA01284	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mood altered

Symptom Text: Information has been received from a licensed visiting nurse that a registered nurse observed 2 patients who experienced a mood change after vaccination with GARDASIL vaccine (yeast) (Lot number not reported). The registered nurse reported that the patients had also received other vaccinations at the time of vaccination, but the specific other vaccines are unspecified. Attempts are being made to obtain additional information on a multi-patient report. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325449-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	01-Oct-2008	MN	WAES0807USA01286	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a female who was vaccinated on unspecified dates with all three doses of GARDASIL vaccine (yeast) (lot #'s not reported). Subsequently the patient was diagnosed with being high risk for HPV. The patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325450-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Jun-2008	04-Jul-2008	4	18-Aug-2008	01-Oct-2008	IN	WAES0807USA01288	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a mother concerning her 12 year old daughter who on 30-JUN-2008 was vaccinated with GARDASIL vaccine (yeast) (Lot# not reported). There was no concomitant medication. On 04-JUL-2008 the patient experienced hair loss. The patient's hair loss persisted. Laboratory tests performed including thyroid test, joint test and autoimmune test were reported as "fine" (dates Unspecified). The patient's outcome was unknown. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **325451-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		18-Aug-2008	01-Oct-2008	OH	WAES0807USA01290	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a physician concerning a very few patients who were vaccinated with GARDASIL vaccine (yeast) (Lot# not reported). Subsequently the patients experienced sore arms after vaccination. The patients' outcome were unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325452-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	M	Unknown	Unknown		18-Aug-2008	01-Oct-2008	CA	WAES0807USA01291	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site induration, Injection site mass, Injection site reaction, Injection site swelling

Symptom Text: Information has been received from an office manager within the office concerning a male who was vaccinated SQ with a dose of GARDASIL vaccine (yeast). Subsequently the patient experienced, injection site reaction. The patient also experienced swelling at the injection site which formed a hard ball. The patient sought unspecified medical attention. The patient's outcome is unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325453-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.8	M	19-Jun-2008	19-Jun-2008	0	18-Aug-2008	01-Oct-2008	MD	WAES0807USA01296	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crying, Cyanosis, Rash, Wrong drug administered

Symptom Text: Information has been received from a consumer concerning her 10 month old male baby with no pertinent medical history, drug reactions or allergies who on 19-JUN-2008 was accidentally vaccinated with a dose of GARDASIL vaccine (yeast). There was no concomitant medication. A nurse at the office accidently mixed up the vials and the mother received diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid which was meant for her baby and her baby received the third dose of GARDASIL vaccine (yeast) that was meant for her. A couple of days later, on 21-JUN-2008 the baby broke out in a rash and had been constantly been crying. "2-3 days after receiving GARDASIL vaccine (yeast)", the baby experienced purple lips. At the time of the report, the baby had not recovered from the events. No medical attention was sought. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325454-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	01-Oct-2008	NY	WAES0807USA01298	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL vaccine (yeast). On an unspecified date the patient fainted after receiving the dose of GARDASIL vaccine (yeast). The patient was seen by the physician. Patient outcome was recovered on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325455-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	06-Sep-2007	06-Sep-2007	0	18-Aug-2008	01-Oct-2008	--	WAES0807USA01317	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Rash

Symptom Text: Information has been received from a nurse practitioner concerning a 19 year old female with no medical history who on 06-SEP-2007 was vaccinated IM in the deltoid with the first dose of the GARDASIL vaccine (yeast). On 19-NOV-2007 the patient was vaccinated in the upper thigh with the second dose of GARDASIL vaccine (yeast). In March 2008, the patient was vaccinated with the third dose of GARDASIL vaccine (yeast). After the first dose the patient was unable to lift her arm and had to go to the neurologist. A month later she developed a rash on her neck. A month after the second dose the patient broke out in rash on her lower body underneath the skin that looked like "bug bites". The patient has been experiencing rashes since the third dose. The rash clears out then comes back again. The patient was seen by multiple specialists and blood work was done that came back abnormal and the nurse asked the patient to call her with the outcomes of the blood work. The patient outcome was not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory - abnor - blood work

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325456-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	01-Oct-2008	--	WAES0807USA01327	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Neuralgia

Symptom Text: Information has been received from a physician concerning a female (age not reported) who was vaccinated with a dose of GARDASIL vaccine (yeast) (lot not reported) and who developed redness and neuralgia in her arm after vaccination. The patient's status was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: neurological examination - results not provided

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325457-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	01-Oct-2008	--	WAES0807USA01343	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Guillain-Barre syndrome

Symptom Text: Information has been received from a physician concerning one of his family friends, a teenage female who was vaccinated with a dose of GARDASIL vaccine (yeast). Subsequently the patient experienced Guillain-Barre syndrome. At the time of the report, it was unknown if the patient had recovered from the event. Unspecified medical attention was sought. Upon internal review, Guillain-Barre syndrome was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325458-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	01-Oct-2008	FL	WAES0807USA04537	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a physician concerning a female teenager patient who on an unknown date was vaccinated with the first dose GARDASIL vaccine (yeast). The physician reported that after the patient received the first dose GARDASIL vaccine (yeast) she contacted him to say that she hadn't had her period. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325459-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	22-Jul-2008	22-Jul-2008	0	18-Aug-2008	02-Oct-2008	NC	WAES0807USA04542	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breast haemorrhage, Nipple disorder, Vomiting

Symptom Text: Information has been received from a physician concerning a female who on 22-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). The same day, the patient's mother called the office to report that her daughter was experiencing vomiting and her nipples were cracked and bleeding. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325460-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	02-Oct-2008	NJ	WAES0807USA04543	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Musculoskeletal pain, Pain in extremity

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with GARDASIL vaccine (yeast) (exact dose and dates of dose were not known) and three weeks after the dose, the patient developed musculoskeletal pain in her legs. The patient has been sent to two neurologists and a conclusive diagnosis has not been obtained. No additional information is available. The patient sought medical attention, office visit. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325461-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	12-Mar-2008	21-Apr-2008	40	18-Aug-2008	02-Oct-2008	--	WAES0807USA04555	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Clumsiness, Dizziness, Vaginal infection

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female patient who on 07-JAN-2008, was vaccinated with the first dose of GARDASIL vaccine (yeast) route intramuscular (lot# 654539/0890F), on 12-MAR-2008, was vaccinated with the second dose of GARDASIL vaccine (yeast) route intramuscular (lot# 655604/0052X). Concomitant therapy included hormonal contraceptives (unspecified). On 21-APR-2008, the patient experienced dizziness, lightheadedness and clumsiness. She had blood work for a Complete Blood Count, Thyroid and glucose, which were all normal. On 23-JUL-2008, the patient called the office and stated her symptoms were continuing. She was referred to an otolaryngologist and a neurologist. The patient sought medical attention in the office. Additional information has been requested. 9/30/08 Reviewed PCP medical records of 3/12-9/23/08. FINAL DX: none provided Records reveal patient experienced vaginitis on 3/12/08. Dizziness 7/23 & referred to ENT & Neuro. 9/23/08 doing well w/occasional dizziness. Office does not have ENT/Neuro consult contact info. Unable to reach patient or parent despite multiple attempts.

Other Meds:

Lab Data: serum glucose - ?/?/08 - Normal, serum TSH - ?/?/08 - Normal, complete blood cell - /?/?08 - Normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **325462-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Jul-2008	Unknown		18-Sep-2008	26-Sep-2008	--	WAES0807USA04570	29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Rash

Symptom Text: Information has been received from a medical assistant a concerning a 15 year old female who on 14-JAN-2008, was vaccinated with the first dose of GARDASIL, on 12-MAR-2008 with the second of GARDASIL and on 14-JUL-2008 with the third dose of GARDASIL. In July 2008, the patient had rash and bumps on her legs and chest and left side of body. The patient's rash then went away but she developed achy joints. These adverse events occurred after the third dose of GARDASIL in July 2008. No adverse reactions were reported after the first or second dose of GARDASIL was given. At time of reporting, the patient was not yet recovered from achy joints. No other information available from medical assistant. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: No adverse reactions were reported after the first or second dose of GARDASIL was given.

Prex Illness:

Prex Vax Illns:

Vaers Id: **325463-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Feb-2008	25-Jun-2008	128	18-Aug-2008	02-Oct-2008	--	WAES0807USA04572	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female with no pertinent medical history who on 23-JUL-2007 was vaccinated with the first dose of GARDASIL vaccine (yeast). On 10-OCT-2007 the patient was vaccinated with the second dose of GARDASIL vaccine (yeast). On 18-FEB-2008 the patient was vaccinated with the third dose of GARDASIL vaccine (yeast). There was no concomitant medication. On 25-JUN-2008 the patient experienced alopecia. At the time of this report, the patient's alopecia persisted. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **325464-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	23-Jul-2008		18-Aug-2008	02-Oct-2008	MO	WAES0807USA04577	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a 21 year old female who on an unspecified date was vaccinated with the first dose of GARDASIL vaccine (yeast) and fainted. It was mentioned that on 23-JUL-2008, after the second dose of GARDASIL vaccine (yeast), injection route, the patient faint as well. All boxes refer to second dose. The patient sought medical attention. No further information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325465-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	02-Oct-2008	--	WAES0807USA04590	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling

Symptom Text: Information has been received from a licensed practical nurse concerning a female who was vaccinated with GARDASIL vaccine (yeast) 0.5 mL, intramuscular. The nurse reported that she heard that the patient developed some injection site swelling after vaccination with GARDASIL vaccine (yeast). It is unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325466-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-May-2007	Unknown		18-Aug-2008	02-Oct-2008	IL	WAES0807USA04596	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Hypoaesthesia, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered nurse concerning a female patient with no known drug allergies and no pertinent medical history, who on 30-MAY-2007 was vaccinated with the first dose of GARDASIL vaccine (yeast) 0.5 mL. On 31-JUL-2007, she received the second dose of GARDASIL vaccine (yeast) 0.5 mL. On 01-DEC-2007, she received the third dose of GARDASIL vaccine (yeast) 0.5 mL. The nurse reported that the patient developed numbness on her right arm and right leg after receiving the vaccinations. The numbness got worse each time she had the vaccinations. She also complained of headaches, so she took some ibuprofen (MOTRIN). The patient saw the physician. Labs diagnostics studies included computerized axial tomography scan and magnetic resonance imaging (MRI), with no date or information reported about the results. At time of reporting, the patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: computerized axial tomography scan, magnetic resonance imaging (MRI)

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325467-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Jul-2008	14-Jul-2008	0	18-Aug-2008	02-Oct-2008	IN	WAES0807USA04605	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gait disturbance, Lymphadenopathy, Pain in extremity

Symptom Text: Information has been received from a physician concerning an 18 year old female no known allergies or pertinent medical history who on 14-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). There was no concomitant medication. The physician reported that the patient was given GARDASIL vaccine (yeast) in the hip and later developed pain in her right leg. Patient also had difficulty walking and thought she had an enlarged lymph node. The patient sought unspecified medical attention. No lab diagnostics were performed. There was no product quality complaint. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **325468-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jan-2008	01-Jan-2008	0	18-Aug-2008	02-Oct-2008	AL	WAES0807USA04606	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Pain

Symptom Text: Information has been received from a physician concerning a 14 year old female who "six months ago" in approximately January 2008, was vaccinated with the second dose of GARDASIL vaccine (yeast). The physician reported that "six months ago" in approximately January 2008, the patient experienced joint aches and pains persisting for the past 6 months. The patient sought medical attentions, he was seen in the physician office. There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325469-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	02-Oct-2008	NH	WAES0807USA04625	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a registered nurse concerning a female who on unspecified dates, was vaccinated with two doses of GARDASIL vaccine (yeast) from another unspecified provider. The nurse reported that recently the patient underwent a Papanicolaou test (PAP smear) that was positive. At the time of the report the patient had not recovered. The patient sought medical attention with an office visit. No further information is available.

Other Meds: Unknown

Lab Data: Pap test - positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325470-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	02-Oct-2008	NJ	WAES0807USA04631	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a physician concerning a female who on unspecified dates was vaccinated with 2 doses GARDASIL vaccine (yeast) and experienced upper leg ache. The patient contacted the physician. At the time of reporting, the outcome of the patient was unknown. There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325471-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Jul-2008	02-Jul-2008	0	18-Aug-2008	02-Oct-2008	ID	WAES0807USA04638	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Hypersensitivity, Rash pruritic, Skin burning sensation

Symptom Text: Information has been received from a physician and a registered nurse concerning a 13 year old female with no medical history and no known allergies, who on 02-JUL-2008 was vaccinated intramuscularly with 0.5 ml of a first dose of GARDASIL vaccine (yeast) (Lot # 660555/0279X). Concomitant vaccination included diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid. On 02-JUL-2008, the patient experienced an allergic reaction after receiving her first and only dose of GARDASIL vaccine (yeast). She developed a red, flat, itchy rash all over the body. The patient said she felt like her skin was on fire. She was taken to an emergency room and released after she was treated with steroids and BENADRYL. On 03-JUL-2008, the patient recovered. There was no product quality complaint. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 325472-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	17-Jun-2008	17-Jun-2008	0	18-Aug-2008	02-Oct-2008	FL	WAES0807USA04687	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Feeling abnormal, Immediate post-injection reaction, Oral herpes, Pyrexia, Respiratory disorder, Viral upper respiratory tract infection

Symptom Text: Information has been received from a health care worker at a physician's office and from emergency room (ER) records (patient education materials) concerning a 24 year old white female student who on 17-JUN-2008 was vaccinated into left deltoid with a first dose of GARDASIL vaccine (yeast) (lot # 660553/0070X). There was no illness at the time of vaccination. The health care worker reported that on 23-JUN-2008, the patient called the office and complained of nasal and above upper mouth lip sores since receiving the GARDASIL vaccine (yeast) (also reported as "immediately post injection"). The patient also reported that she had been febrile and feeling worse everyday. She was asked about having a history of herpes and denied having a history of herpes. She was asked to stop by the office for an evaluation. The reporter stated that when the patient visited the office and visual exam was done, she had sores that looked 100% herpetic. She was reassured that the outbreak was not due to GARDASIL vaccine (yeast), and she was sent to the emergency room for a second opinion and documentation of incident. The patient education materials from the emergency room for the patient, referred to the patient's injury and illness as viral respiratory illness, "she had an upper respiratory illness caused by a virus". Home care education for the viral respiratory illness included : rest for severe symptoms, avoid exposure to cigarette smoke, TYLENOL or ADVIL or MOTRIN for fever, muscle aching, headache. Also to avoid dehydration by drinking 6-8 glasses of fluids daily, and to return promptly or contact physician if any cough with lots of colored sputum occurs (mucus or blood), chest pain, shortness of breath, wheezing, or having trouble breathing, severe headache, face, neck or ear pain and any fever over 1200.4 degrees F (38.0 degrees) for more than three days. The education materials also noted the patient's cold sore-herpes labials, HSV; type 1. Home care information for the cold sore included: the patient's use of TYLENOL or ADVIL

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325473-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.9	F	01-Mar-2008	01-Jul-2008	122	18-Sep-2008	19-Sep-2008	PA	WAES0809USA02010	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	HPV4

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Condition aggravated, Convulsion

Symptom Text: Information has been received from a physician concerning a female with a history of seizures who on an unspecified date was vaccinated with the second dose of GARDASIL. Subsequently, "a couple months later", the patient experienced a seizure. On an unspecified date, the patient recovered from seizure. The patient sought unspecified medical attention. Seizure was considered to be immediately life-threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Convulsion PMH: Seizures, last on 1998. HPV #3 given 10/1/08, no seizure activity followed.

Prex Illness:

Prex Vax Illns:

Vaers Id: **325474-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
34.0	F	13-May-2008	18-Jul-2008	66	18-Sep-2008	19-Sep-2008	FR	WAES0806USA08885	19-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1208U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a physician, concerning a 34 year old female patient, with no previous medical history reported, who on 13-MAY-2008 received the third dose of GARDASIL (Lot # 1208U and batch # NH13360). One week after vaccination the patient started a pregnancy. She was vaccinated at 3 weeks of amenorrhea as the starting date of her last menstruation periods was 21-APR-2008. No adverse reaction was reported. Follow-up information was received from a physician, through the Sanofi Pasteur MSD GARDASIL pregnancy registry, which reported that this is a case of pregnancy. This is also a case of misuse, ie vaccine administered beyond recommended age. Follow-up information was received from a physician, through the Sanofi Pasteur MSD GARDASIL pregnancy questionnaire, which reported that the case was upgraded to serious on 18-JUL-2008, the patient experienced a spontaneous abortion. Spontaneous abortion was considered to be an other important medical event. Other business partner numbers included: E2008-05313. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 21Apr08)

Prex Vax Illns:

Vaers Id: 325475-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	07-Aug-2007	01-Nov-2007	86	18-Sep-2008	19-Sep-2008	AZ	WAES0801USA02528	19-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature rupture of membranes, Suppressed lactation

Symptom Text: Initial and follow up information has been received for the Pregnancy Registry for GARDASIL from an office medical assistant and nurse practitioner concerning a 23 year old female with a history of migraine headaches and HPV and no previous pregnancies who on 11-JUN-2007 was vaccinated with her first dose of GARDASIL (lot #657868/0523U). On 07-AUG-2007 the patient received her second dose of GARDASIL (lot# 658554/0928U). On 20-DEC-2007 the patient came in the office for her third dose of GARDASIL (lot# 659441/1446U). The patient did receive the third dose that day, but during conversation she mentioned she had been spotting and had stopped taking her birth control. The office medical assistant reported that later on that day, they had found out that the patient was pregnant. The patient's last menstrual period was 01-NOV-2007 (previously reported as 03-DEC-2007) and estimated date of delivery by ultrasound was 20-AUG-2008. An ultrasound was performed that showed 5 weeks gestation. No adverse event was involved that time. Medical attention was sought, by a physician. Follow-up information was received. On 14-JUL-2008 the patient experienced premature rupture of membranes and delivered a normal, healthy male baby weighing 5 pounds 10 ounces at 34 weeks. There were no congenital anomalies. The infant with apgar scores of 6.8 was in NICU for breathing. Meconium stained membranes were noted on placenta pathology. Concomitant therapy included UNISOM for insomnia and ZANTAC for heartburn. The patient also noticed decreased milk production during breast feeding. Upon internal review, in NICU for breathing was determined to be an other important medical event. Follow-up information was received from a physician who reported that the mother was not a patient of his and the baby's name was a name unknown to him. Additional information has been requested.

Other Meds: UNISOM; ZANTAC

Lab Data: ultrasound, 12/20/07 - 5 weeks gestation; diagnostic pathological - meconium stained placenta; Apgar score, 6.8

History:

Prex Illness: Pregnancy NOS (LMP = 11/1/2007); Migraine; Papilloma viral infection; Insomnia; Heartburn

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325483-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	01-Nov-2007	01-Dec-2007	30	18-Sep-2008	19-Sep-2008	FR	WAES0809USA01800	19-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Aphthous stomatitis, Arthralgia, Behcets syndrome, Inappropriate schedule of drug administration, Pericarditis, Uveitis

Symptom Text: Information has been received from a infectiologist concerning a 29 year old female with HLA B51 positive who in November 2007, was vaccinated with GARDASIL via intramuscular route. Three weeks later, the patient developed aphtha, polyarthralgia and pericarditis and was hospitalized. She was hospitalised and Behcet's disease diagnosed. Corticotherapy and treatment with colchicine were implemented. In hospital, the patient was diagnosed with uveitis. At the time of reporting, she was recovering. Other business partner numbers include E2008-08498. Further information is expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: HLA marker study positive

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 325485-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Jul-2008	30-Jul-2008	21	18-Sep-2008	26-Sep-2008	KS		29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts, Skin lesion

Symptom Text: Patient had normal pelvic exam (per Dr Ob/Gyn) in July 08 and was started on GARDASIL vaccine. About 3 weeks after 1st shot, she developed lesions on her perineum. She denied new sexual partner or any known exposure to HPV/genital warts. 7-10-08 <- Presented to Gyn clinic with 6 genital warts 2-4mm in size on right upper labia majora. Triacetic Acid applied. Aldora Topical 3-4 days after (TCA) burning - resolves. Above treatment started 9-10-08.

Other Meds: LoDural; Esomeprazol Magnesium Trihydrate

Lab Data: None

History: None Known

Prex Illness: None Known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325487-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Sep-2008	11-Sep-2008	1	18-Sep-2008	26-Sep-2008	MA		26-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2542AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0185E	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Vomiting

Symptom Text: Gardasil and Menactra given 9/10/08 - On 9/11/08 patient reports headache and vomiting.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325504-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	23-Jul-2008	24-Jul-2008	1	18-Aug-2008	02-Oct-2008	--	WAES0807USA04762	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness, Myalgia

Symptom Text: Information has been received from a nurse practitioner (NP) concerning a 22 year old female with drug allergy to levofloxacine (LEVAQUIN) and no pertinent medical history who on 28-MAY-2008 and 23-JUL-2008, was vaccinated intramuscularly with her first and second 0.5 ml doses, respectively, of GARDASIL vaccine (yeast) (Lot # of the second dose: 659964/1978U). Concomitant therapy included ethinyl estradiol (+) etonogestrel (NUVARING) and escitalopram oxalate (LEXAPRO). On 24-JUL-2008 the patient experienced flu-like symptoms and muscle pain. At the time of the report, the patient's flu-like symptoms and muscle pain persisted. The patient sought medical attention by calling office. Additional information has been requested.

Other Meds: LEXAPRO, NUVARING

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325505-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	24-Jul-2008	24-Jul-2008	0	18-Aug-2008	02-Oct-2008	SC	WAES0807USA04793	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysphagia, Hypoaesthesia, Injection site pain, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 21 year old female who on 24-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). Subsequently on 24-JUL-2008 the patient experienced pain at the injection site, numbness, tingling and difficulty swallowing. Outcome of the adverse event were not reported. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325506-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jul-2008	01-Jul-2008	0	18-Aug-2008	02-Oct-2008	--	WAES0807USA04796	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Myalgia, Pruritus

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female with asthma and mitral valve prolapse and no known drug reactions/allergies who on 01-JUL-2008 was vaccinated intramuscularly with the 0.5 ml first dose of GARDASIL vaccine (yeast) (LOT # 660389/1968U). Concomitant therapy included FLONASE, albuterol and montelukast sodium (MSD). Several hours after the vaccination, the patient developed itching on her chest and chest pain. Several hours after onset, the patient recovered from itching on her chest and chest pain. The symptoms resolved without any treatment. On 30-JUL-2008, the nurse practitioner reported that the patient saw a cardiologist and the physician felt that it was just a muscular pain. Additional information has been requested.

Other Meds: albuterol, FLONASE, SINGULAIR

Lab Data: None

History:

Prex Illness: Asthma, Mitral valve prolapse

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325507-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		18-Aug-2008	02-Oct-2008	GA	WAES0807USA04797	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Flushing, Hypoaesthesia oral

Symptom Text: Information has been received from a licensed practical nurse concerning a 17 year old female who on an unspecified date was vaccinated with the second dose of GARDASIL vaccine (yeast). The nurse reported that 36 hours after receiving the second dose of GARDASIL vaccine, the patient developed flushing and numbness of the lips. The patient was given BENADRYL and the flushing and numbness went away within 30 minutes. At the time of the report, the patient had recovered. The patient sought medical attention calling the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325508-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		18-Aug-2008	02-Oct-2008	--	WAES0807USA04798	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Menstrual disorder

Symptom Text: Information has been received from a registered nurse (RN) concerning her 17 year old daughter who on an unspecified date was vaccinated with 0.5 ml first dose of GARDASIL vaccine (yeast). Subsequently the patient experienced a premature menstrual cycle and extreme pain at the injection site. Subsequently, the patient recovered. On an unspecified date, the patient was vaccinated with 0.5 ml second dose of GARDASIL vaccine (yeast). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325509-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Jul-2008	23-Jul-2008	0	18-Sep-2008	20-Oct-2008	NJ	WAES0807USA04800	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	660620/0571X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Headache, Loss of consciousness

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a 14 year old female with no pertinent medical history or allergies who on 23-JUL-2008 was vaccinated intramuscularly with 0.5ml Hp, rll , 6, 16, 18, VLP vaccine (yeast) (lot#660620/051X).Concomitant therapy included hepatitis A vaccine (inactive) (HAVRIX) and diphtheria toxoid (+) pertussis acelluar vaccine (unspecified) (+) tetanus toxoid. On 23-JUL-2008, 5 minutes after vaccination, the patient walked out the office's door, passed out. Fell backwards and hit her head. The patient was revived and taken into the office, where she almost passed out again. The patient had headache and studies were performed. After resting for 45-minutes, the patient recovered.

Other Meds: Diphtheria Toxoid, Pertussis Haverix

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325510-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	24-Jul-2008	24-Jul-2008	0	18-Aug-2008	02-Oct-2008	IL	WAES0807USA04801	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site irritation

Symptom Text: Information has been received from a registered nurse concerning a 23 year old female with no known pertinent medical history or drug reactions/allergies who on 20-SEP-2007 was vaccinated with a first dose of GARDASIL vaccine (yeast) 0.5 ml IM (lot# 654539/0742U). Concomitant therapy included drospirenone (+) ethinyl estradiol (YAZ), LEXAPRO and CONCERTA. On 24-JUL-2008 the patient was vaccinated with a second dose of GARDASIL vaccine (yeast) 0.5 ml IM (lot# 660620/0571X). The patient experienced burning at the injection with the second dose of GARDASIL vaccine (yeast). The patient sought medical attention in the office. Additional information has been requested. This is one of several reports from the same source.

Other Meds: YAZ, LEXAPRO, CONCERTA

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325511-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	23-Jul-2008		18-Aug-2008	02-Oct-2008	--	WAES0807USA04810	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Pain

Symptom Text: Information has been received from a nurse practitioner concerning a female who on an unspecified date was vaccinated with a second dose of GARDASIL vaccine (yeast) 0.5 ml IM. On 23-JUL-2008 the patient experienced a temperature and body aches. The patient's temperature and body aches persisted. The patient did not seek medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325512-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Jul-2008	21-Jul-2008	3	18-Aug-2008	02-Oct-2008	MA	WAES0807USA04813	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0187U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pyrexia, Vomiting

Symptom Text: Information has been received from a physician concerning a healthy 14 year old female with no known pertinent medical history, who on 18-JUL-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast) (Lot # 656049/0187U). There was no concomitant medication. The physician reported that on 21-JUL-2008, the patient experienced nausea, vomiting, dizziness and fever. The patient sought medical attention at the physician's office. At the time of the report the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325513-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		18-Aug-2008	02-Oct-2008	WA	WAES0807USA04825	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who on an unspecified date was vaccinated with the first and second dose of GARDASIL vaccine (yeast). The mother's patient informed the physician that her daughter was more tired now than she had been in the past. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325514-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	04-Jun-2008	04-Jun-2008	0	18-Aug-2008	02-Oct-2008	--	WAES0807USA04832	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Pruritus, Pyrexia, Rash maculo-papular

Symptom Text: Information has been received from a physician concerning to his r 21 year old daughter with penicillin allergy and seasonal allergy who on 04-JUN-2008 was vaccinated with the third dose of GARDASIL vaccine (yeast) 0.5 ml intramuscular. The patient did not experienced any adverse event after the first and second dose of GARDASIL vaccine (yeast) (one of the two doses was given in November 2007). On 04-JUN-2008 the patient experienced low-grade fever and headache which lasted one day. On 07-JUN-2008, the patient experienced rash maculo-papular distributed on her face, chest and upper thighs and was slightly itchy. The patient was evaluated by a dermatologist and was prescribed topical steroids cream and course of oral steroids (name unspecified). The rash improved slightly at first but then increased to include the patient's shoulders and back. The patient was scheduled for another office visit with the dermatologist the week of 28-JUL-2008. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy, Seasonal allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325515-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		18-Aug-2008	03-Oct-2008	NJ	WAES0807USA04835	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 17 year old female who was vaccinated with a dose of GARDASIL vaccine (yeast). Physician reported the patient had upper leg thigh aches and pains in both legs post vaccination with GARDASIL vaccine (yeast). The patient has had 2 doses of GARDASIL vaccine (yeast). The physician did not provide any other information. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325516-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	10-Jul-2008	10-Jul-2008	0	18-Aug-2008	03-Oct-2008	MI	WAES0807USA04846	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who on 10-JUL-2008 was vaccinated with the first dose of GARDASILL vaccine (yeast) 0.5 mL, IM, and fainted twice after receiving the dose. Subsequently, the patient recovered from fainted twice after received GARDASIL vaccine (yeast). The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 325517-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jun-2007	Unknown		18-Aug-2008	03-Oct-2008	TX	WAES0807USA04913	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter who in January 2007 was vaccinated with the first dose of GARDASIL vaccine (yeast) and in June 2007 was vaccinated with the third dose of GARDASIL vaccine (yeast) (time of the second dose was not reported). The patient switched physicians and was told that her pap smear last year came back abnormal. Outcome of the abnormal pap smear was not reported. The patient sought medical attention with a physician office visit. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear - ?/?/07 - abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325518-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	20-Mar-2008	Unknown		18-Aug-2008	03-Oct-2008	NY	WAES0807USA05035	24-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye disorder, Photopsia

Symptom Text: Information has been received from a office manager concerning a 22 or 23 year old female who on 20-MAR-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) (route and administration site not reported). Subsequently the patient developed white blinking light syndrome which was confirmed by an ophthalmologist. On an unspecified date recently the patient was vaccinated with a second dose of GARDASIL vaccine (yeast). The patient's outcome was unknown. The patient was to follow up with the ophthalmologist. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown HPV#2 given 6/3/08, lot # 0152X, IM, RA

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325519-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	04-Jan-2008	23-Jul-2008	201	18-Aug-2008	03-Oct-2008	--	WAES0807USA05038	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Calcinosis, Haematoma

Symptom Text: Information has been received from a physician's assistant concerning an 18 year old female who on 23-JUL-2007 was vaccinated with a first dose of GARDASIL vaccine (yeast) 0.5 ml IM. On 04-JAN-2008 the patient was vaccinated with a third of GARDASIL vaccine (yeast) 0.5 ml IM. Concomitant therapy included hormonal contraceptives (unspecified) and metronidazole. On 23-JUL-2008 the patient developed calcified hematoma on her left arm that was discovered after her third dose of GARDASIL vaccine (yeast). The patient's calcified hematoma persisted. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: hormonal contraceptives, metronidazole

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325520-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	01-Jun-2008	01-Jun-2008	0	18-Aug-2008	03-Oct-2008	NJ	WAES0807USA05048	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bladder pain, Dysuria, Hypertonic bladder, Inappropriate schedule of drug administration, Pollakiuria

Symptom Text: Information has been received from a consumer concerning his daughter a 27 year old female with no pertinent medical history and no allergies who in January 2008, was vaccinated with the first dose of GARDASIL vaccine (yeast). In March 2008 the patient was vaccinated with the second dose of GARDASIL vaccine (yeast). In early June 2008, the patient was vaccinated with the third dose of GARDASIL vaccine (yeast). There was no concomitant medication. Middle to late in June 2008, the patient began to experienced a burning sensation in the area of her bladder when urinating and she had a more frequent need to urinate than usual. Originally her physician treated this as an urinary tract infection and more recently she was diagnosed as having an overactive bladder. Blood tests and urine sample tests were performed. At the time of this report there was slight improvement. No further information is available.

Other Meds: None

Lab Data: diagnostic laboratory - blood test, urinalysis

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325521-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	07-Jul-2008	09-Jul-2008	2	18-Aug-2008	03-Oct-2008	TX	WAES0807USA05054	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Myalgia

Symptom Text: Information has been received from a medical assistant concerning a 27 year old female, with unremarkable medical history and no known drug reactions/allergies, who on 06-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) and on 07-JUL-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast), 0.5 mL, IM. Concomitant therapy included hormonal contraceptives (unspecified). On 09-JUL-2008, the patient experienced deep muscle aches in arms and legs. Patient will not receive her final dose of GARDASIL vaccine (yeast) in future. There wasn't any adverse event after first dose of GARDASIL vaccine (yeast). Therapy with GARDASIL vaccine (yeast) was discontinued. The patient sought unspecified medical attention. The patient's deep muscle aches in arms and legs persisted. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325522-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Mar-2008	Unknown		18-Aug-2008	03-Oct-2008	--	WAES0807USA05076	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Coxsackie viral infection, Skin lesion

Symptom Text: Information has been received from a certified nurse midwife concerning an 18 year old female with asthma and no known drug reactions/allergies, who on 11-JAN-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) 0.5 mL, IM, and on 11-MAR-2008 with the second dose. Concomitant therapy included DEPO-PROVERA and an unspecified inhaler. On 12-MAR-2008, the patient was diagnosed with Coxsackie virus. The patient was evaluated and treated, by her unspecified primary care physician, with folic acid, thiamine, and unspecified steroids. The first course of treatment was completed after one month. On an unknown date, the patient experienced a recurrence of the lesions and a second course of the same treatment was prescribed. The patient sought medical attention by a phone call. The patient's Coxsackie virus persisted. Additional information has been requested.

Other Meds: therapy unspecified, DEPO-PROVERA

Lab Data: None

History:

Prex Illness: Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325523-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	03-Oct-2008	--	WAES0807USA05104	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Stomatitis

Symptom Text: Information has been received from a nurse concerning a female patient who on an unspecified date, was vaccinated with the first dose of GARDASIL vaccine (yeast). On an unspecified date, was vaccinated with the second dose of GARDASIL vaccine (yeast) 0.5 ml, IM. A day after vaccine was received, the patient experienced sores in her mouth after second dose. The patient's sores in her mouth persisted. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325524-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Jul-2008	22-Jul-2008	0	18-Aug-2008	03-Oct-2008	LA	WAES0807USA05111	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Thrombocytopenia

Symptom Text: Information has been received from a physician concerning a 14 year old female patient who on 20-MAY-2008, was vaccinated with the first dose of GARDASIL vaccine (yeast) and the second dose of GARDASIL vaccine (yeast) was given on 22-JUL-2008. The patient had a lesion removed from her scalp (the lesion was present prior to starting of the HPV vaccine series). When the plastic surgeon requested to have additional margins of the lesion area of the scalp removed he performed a complete blood count on 22-JUL-2008 that showed a platelet count of 40.000. A diagnosis of thrombocytopenia was given. A repeat complete blood count was performed on 24-JUL-2008, and that showed a platelet count of 42.000. The physician mentioned that he spoke with the pathologist performing the complete blood count/manual smear review and was told that the smear was normal. The patient's thrombocytopenia persisted. Additional information has been requested.

Other Meds: None

Lab Data: platelet count - 07/22/08 - 40.00, platelet count - 07/24/08 - 42.00

History:

Prex Illness: Skin lesion

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325528-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	24-Jul-2008	Unknown		18-Sep-2008	26-Sep-2008	NJ		06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	2050X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood test, Computerised tomogram, Convulsion, Dizziness, Electrocardiogram ambulatory, Feeling hot, Lethargy, Nuclear magnetic resonance imaging, Palpitations, Pharyngolaryngeal pain, Pruritus, Rash erythematous, Rash macular, Syncope, Tinnitus

Symptom Text: See attached (pg 2) Consult re: reaction to GARDASIL; 1st GARDASIL given 7/24/08. Saw PCP - Dr around 8-1-08 for physical. At that time patient complained of sore throat and ringing in the ears. Started Z-Pack 8.4.08 x 5days; Saw Dr on 8/28/08 for "red bumps" on left side of body; was put on Medrol dose pack x 5days. Complained of heart palpitations, dizziness; 9/4/08 - Saw Dr. complained itchy blotches on body. Put on Ativan; Saw Dr 9/11/08 for blood work. ER 9/12/08, Fri evening dinner at dinner patient, felt dizzy warm lethargic, fainted and convulsions; had once; CT scan, MRI; Prone to fainting; Started Holter monitor 9/16/08 by Dr x 24 hours; now; Meds: Yaz, Ativan 0.5mg PRN, Xyzal -> Allergies. Blood work -> Allergy to Shellfish

Other Meds: Yasmin

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325539-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Sep-2008	17-Sep-2008	0	18-Sep-2008	29-Sep-2008	PA		29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2726AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0788X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0571X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Chest pain, Dyspnoea, Vomiting

Symptom Text: Chest pain and tightness, Shortness of breath, vomiting.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325542-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	18-Sep-2008	18-Sep-2008	0	18-Sep-2008	29-Sep-2008	CO		29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2609AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1968U	0	Left arm	Intramuscular	
	HEP	MERCK & CO. INC.	1884U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Back pain, Dizziness, Pallor

Symptom Text: pt started to feel faint and light headed. Became pale in face. After 5-10 mins, pt started to have lower back pain then began to wrap around to her stomache area. Also, had stomache cramping. Didn't start to feel better until 30mins post injection reaction time.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **325562-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Aug-2008	Unknown		18-Sep-2008	26-Sep-2008	CO		29-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B027AA		Unknown	Intramuscular	
VARCEL	MERCK & CO. INC.	1994U		Unknown	Subcutaneously	
MNQ	SANOFI PASTEUR	U243AA		Unknown	Intramuscular	
HEPA	MERCK & CO. INC.	AHAVB243AA		Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	05224		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pregnancy test positive

Symptom Text: Well child visit 8/27/08. Reported positive pregnancy test via mother 9/8/08.

Other Meds:

Lab Data: N/A

History: Allergic rhinitis

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325575-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	16-Jun-2008	16-Jun-2008	0	18-Aug-2008	03-Oct-2008	OH	WAES0807USA05154	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash macular

Symptom Text: Information has been received from a physician concerning a 20 year old female who on 16-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) in the upper left deltoid. After vaccination, she was asked to sit for 15 minutes before leaving the office, 10 minutes later, the patient experienced red blotches on her right and left thighs. She did not feel pain. The symptoms cleared and she called the office to set up an appointment for her second dose. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325576-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
3.0	F	22-Jul-2008	22-Jul-2008	0	18-Aug-2008	03-Oct-2008	NC	WAES0807USA05156	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Wrong drug administered

Symptom Text: Information has been received from a patient's mother concerning a 36 month old female who on 22-JUL-2008 was vaccinated with GARDASIL vaccine (yeast) by a human mistake. Concomitant therapy also given on 22-JUL-2008, included hepatitis A virus vaccine (unspecified) (manufacturer unknown). On 22-JUL-2008, the child seemed more tired than usual after the vaccination. The mother called the physician. At the time of reporting, the child was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 325577-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	08-Aug-2007	15-Sep-2007	38	18-Aug-2008	09-Oct-2008	PA	WAES0807USA05184	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Balance disorder, Benign intracranial hypertension, Diplopia, Eye pain, Headache, Myopia, Neck pain, Optic nerve disorder, Pain, Pruritus, Strabismus, Vision blurred, Visual disturbance

Symptom Text: Information has been received from health professional concerning an 11 year old female with nearsightedness and drug allergies to ZITROMAX, sulfamethoxazole, plus BACTRIM, and sulfa, who on 06-JUN-2007, 08-AUG-2007 and 08-NOV-2007 was vaccinated into the right arm with the first, second and third doses of GARDASIL (Lot# first dose 657737/0522U, second dose lot#658222/0927U and third dose lot#659435/1265U). On 15-SEP-2007 the patient experienced headaches and was diagnosed with pseudotumor cerebri by neurologist and neuro-ophthalmologist. On 10-OCT_2007 she was seen by a neuro-ophthalmologist who felt that she had mild myopia on the right eye, intermittent exotropia and mild elevation of the optic nerves nasally, right side worse than left. Venous pulsations were not noted. The physician indicated that she needed studies to rule out an intracranial cause of the elevation of her optic nerves and it was suspected that she might most likely have pseudotumor cerebral. On 15-OCT-2007 she had a magnetic resonance venography (MRV) which was also normal. On 19-October-2007 the patient saw a neurologist who reported tha the patient is an 11-year-old young lady sent for evaluation of probable pseudotumor cerebri (PTC). Her problems began about 1 month ago (mid September), when she had suden onset of horizontal double vision and she noted that her eyes were turning in. She stated the two images are side-by-side. She was seen by her family doctor and then and ophthalmologist. A few days later she developed headaches. She describes her headaches as fluctuating, sharp pain at the top and back of her head. She also experienced pain in her neck. The pain was more severe in the morning and at about noon each day. When the pain gets worse, her eyes get a bit blurry and hurt. Her vision might also darken slightly. She sometimes felt somewhat unsteady and weak with a headache. She was taking over-the-counter medication without improvement of the heacaches. At times she felt some achiness of her body. She injured her wrist in March

Other Meds: None

Lab Data: Magnetic resonance, 10/15/2007, Orbits and brain: Normal; diagnostic radiology, 10/18/2007, Magnetic resonance venography: Normal; Blood pressure, 10/19/2007, 112/6 mmHg, Brain: normal; physical examination, 10/19/2007, within normal limits

History:

Prex Illness: Nearsighted; Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325578-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	15-Jul-2008	15-Jul-2008	0	18-Aug-2008	03-Oct-2008	MO	WAES0807USA05197	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a physician concerning a 19 year old female with a history of fainting when receiving injections who on 15-JUL-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast). On 15-JUL-2008 the patient fainted immediately after the vaccination. No treatment required. On 15-JUL-2008 the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Syncope

Prex Illness:

Prex Vax Illns:

Vaers Id: **325579-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Jun-2008	22-Jun-2008	0	18-Aug-2008	03-Oct-2008	AZ	WAES0807USA05214	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	NULL		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0928U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 22-JUN-2008 was vaccinated intramuscularly with 0.5 ml first dose of GARDASIL vaccine (yeast) (lot #658554/0928U). On 22-JUN-2008, the same office visit, the patient also received varicella virus vaccine live (Oka/Merck) in her right arm. On 22-JUN-2008, "30 minutes after leaving office", the patient experienced "shooting pain down her left arm down to her left calf all the way to her big toe". The patient called the physician and was advised to rest. At the time of the report, no outcome was reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325580-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		18-Aug-2008	03-Oct-2008	KS	WAES0807USA05264	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mood altered

Symptom Text: Information has been received from a physician (a counselor reported it to the physician) concerning unspecified number of patients who were vaccinated with a dose of GARDASIL vaccine (yeast). Subsequently the patients experienced moodiness. The counselor stated that she felt mood problems were probably related to the vaccination as she had seen similar reactions in other clinics. This is one of several reports from the same source. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325581-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Jun-2007	27-Jun-2007	0	19-Sep-2008	22-Sep-2008	--	WAES0708USA04445	22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received through Merck pregnancy registry from a nurse midwife concerning an underweight 20 year old female with a history of LGSIL, biopsy, colposcopy, and 1 previous pregnancy with an elective termination, who on 27-JUN-2007 was vaccinated with the first dose of GARDASIL. Concomitant therapy included 150 mg DEPO-PROVERA, and prenatal vitamins 200 mg. It was reported that the patient was found to be pregnant and at the time of reporting the patient was about 14 weeks pregnant (last menstrual period was approximately 15-MAY-2007 and her estimated delivery date was 20-FEB-2008. Unknown medical attention was sought. No product quality complaint was involved. Follow-up information was received from a certified nurse midwife and from pediatric medical records indicating that on 19-FEB-2008, at 39 weeks and 6 days the patient delivered a 6 pound 7 ounce female infant with an apgar score of 9/9. The infant was reported to be normal with no congenital anomalies and no complications. It was reported that a neonatal prenatal ultrasound showed in utero hydrocephalus. Both lateral ventricles were dilated and there was some dilation in the third ventricle. A late repeat ultrasound (on 14-NOV-2007 and 27-DEC-2007) showed resolution. Additional information has been received from a physician via pediatric medical record concerning a 10 week old female. On 05-MAR-2008 the patient was seen at the office for her 2 week visit. It was reported that the child's growth and development were normal. On 28-APR-2008 the patient was seen at the office for her 2 month visit. It was reported that the child was well, with normal growth and development. The patient presented to the office with a dysconjugate gaze in which the patient's pupil's were not responding, and the patient could not "track." Inutero hydrocephalus was seen on an ultrasound. A late ultrasound showed resolution, therefore a repeat ultrasound was scheduled. The patient was referred to another physician to be examined. The patient was instructed to follo

Other Meds: DEPO-PROVERA; Vitamins (unspecified) 200 mg

Lab Data: Ultrasound, 02/01/07, 5 pounds 6 ounces afi 13.4; Colposcopy, 04/??/07, colposcopy and biopsy - LGSIL; Ultrasound, 08/15/07, positive - 13 week estimated delivery date 2/20/08; Ultrasound, 10/17/07, level II ultrasound 22 week normal echo s

History: Biopsy; Colposcopy; Low grade squamous intraepithelial lesion; Termination of pregnancy - elective

Prex Illness: Pregnancy NOS (LMP = 5/15/2007); Low weight

Prex Vax Illns:

Vaers Id: **325582-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-Sep-2008	22-Sep-2008	--	WAES0809USA02382	22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse practitioner concerning a female child who was vaccinated with GARDASIL. The patient had seizure after the vaccination. The patient sought medical attention. Upon internal review, seizure was determined to be an other important medical event. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325583-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Apr-2008	08-Apr-2008	7	19-Sep-2008	22-Sep-2008	FR	WAES0809USA02143	22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug eruption, Pruritus, Rash generalised, Rash maculo-papular, Skin exfoliation

Symptom Text: Information has been received from a physician concerning a female patient (age unknown) was vaccinated with a dose of GARDASIL (lot number, injection site and route not reported). After vaccination the patient developed an exanthema. The outcome was not reported. Follow-up information was received. Upon receipt of new information this case was upgraded due to hospitalization. The hospital report was sent via the dermatologist: The 14-year old female patient was vaccinated with a third dose of GARDASIL (lot number, site and route not reported) on 01-APR-2008. One week after the vaccination, the patient experienced generalized exanthema with pruritus. It started from the injected arm and extended over the whole body. She was hospitalized on 13-APR-2008. Routine laboratory without pathological findings. Drug eruption was diagnosed. Dermatological examination showed a maculopapulous exanthema with mild desquamation. Local treatment included a mixture of topic betamethasone in zinc oxide lotion (lotio alba 1:1). The pruritus was treated with FENISTIL drops as needed. Under this therapy systems improved notedly and the patient was discharged recovered on 18-APR-2008. The physician assessed the eruption as probably caused by the vaccine. Tinea pedis of the left foot has been observed for several weeks prior to reporting date and has been treated with LAMISIL CREME. Other business partner numbers included: E2008-07977. No further information. The file is closed.

Other Meds: LAMISIL, Unk - Unk

Lab Data: dermatological examination, a maculopapulous exanthema with mild desquamation; diagnostic laboratory test, without pathological findings

History:

Prex Illness: Tinea pedis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325584-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		19-Sep-2008	22-Sep-2008	--	WAES0809USA02083	22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Autism

Symptom Text: Information has been received from a nurse midwife which reported that "a mother of one of her patients said she read somewhere" concerning a 17 year old female who on an unspecified date was vaccinated with a dose of GARDASIL. Subsequently the patient developed autism. It was unknown if the patient sought any medical attention. The outcome of the patient was unknown. Upon internal review, autism was determined to be an other important medical events. Attempts are being made to verify the existence of an identifiable patient and reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325585-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Dec-2007	01-Jan-2008	31	19-Sep-2008	22-Sep-2008	NY	WAES0809USA01973	22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Autoimmune disorder, Headache, Malaise, Myalgia, Systemic lupus erythematosus

Symptom Text: Information has been received from a consumer concerning her daughter a 17 year old female who on an unspecified dates was vaccinated with the first and second doses of GARDASIL. In December 2008, the patient was vaccinated with a third dose of GARDASIL. Around January 2008, the patient developed headaches and muscle aches. She has a pending diagnosis of lupus. The patient has been in and out school due to sickness and autoimmune systems issues. Upon internal review, lupus was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325586-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-Sep-2008	22-Sep-2008	NC	WAES0809USA01947	22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Cerebrovascular accident, Intensive care

Symptom Text: Information has been received from a physician concerning a female who on an unspecified dates was vaccinated with the first, second and a third dose of GARDASIL. The patient told physician that a friend experienced a stroke after receiving the third dose of GARDASIL. The friend was admitted to the hospital (intensive care unit) twice and is currently hospitalized. Stroke were considered to be immediately life-threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325587-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	16-Jan-2008	29-Apr-2008	104	19-Sep-2008	22-Sep-2008	NY	WAES0809USA01812	22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a physician, for the pregnancy registry for GARDASIL, concerning a 20 year old female with a history of 1 pregnancy and 1 elective termination who on 16-NOV-2007, 16-JAN-2008 and 03-SEP-2008 was vaccinated with a first, second and third doses, respectively, of GARDASIL (Lot # of the first dose 658222/0927U, Lot # of the third dose 660557/0072X). Concomitant therapy included ORTHO TRI-CYCLEN. Subsequently the patient became pregnant. Her LMP was 29-APR-2008. Estimated conception date was 13-MAY-2008. Estimated delivery date was 03-FEB-2009. On 16-JUN-2008 the patient had an elective termination. The products of conception were not examined. It was unknown if the fetus was normal. There was no complication during pregnancy. There were no concurrent medical conditions. Upon internal review, "elective termination" was determined to be an other important medical event. No further information is available.

Other Meds: ORTHO TRI-CYCLEN

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 4/29/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325588-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-Jul-2008	10-Jul-2008	3	19-Sep-2008	22-Sep-2008	FR	WAES0809USA01803	22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1113U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Complicated migraine

Symptom Text: Information has been received from an Authority Health (reference number PEI2008013601) concerning a 12 year old female with a history of Euthyroid Goitre and neurodermatitis who on 07-JUL-2008, was vaccinated with her first dose of GARDASIL (Lot 113U & Batch NH10090) IM into the left upper arm. On 10-JUL-2008, symptoms (not specified) started. The patient was hospitalized (dates of hospitalization were not reported). Electroencephalography (EEG) showed abnormal results and a follow-up EEG was normal. Cranial Magnetic Resonance Imaging (MRI) showed normal results. No therapy was performed. On 11-JUL-2008, the patient recovered from complicated migraine. Encephalitis was ruled out. In August 2008 diagnosis of complicated migraine was established by a neuropaediatrician who didn't see a causal relation to the vaccine. File Closed. Other business partner numbers included: E2008-08390. No additional information is available.

Other Meds: Unknown

Lab Data: electroencephalography, abnormal and epilepsy was suspected; magnetic resonance imaging, normal; electroencephalography, normal

History: Euthyroid goitre; Neurodermatitis

Prex Illness:

Prex Vax Illns:

Vaers Id: 325589-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Apr-2008	20-May-2008	49	19-Sep-2008	22-Sep-2008	FR	WAES0809USA01801	21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bicytopenia, Fatigue, Idiopathic thrombocytopenic purpura, Incorrect route of drug administration, Iron deficiency anaemia, Microcytic anaemia, Pallor, Thrombocytopenia

Symptom Text: Information has been received from a local health authority agency (reference number TO20080960) concerning a 16 year old female with house dust allergy and a history of surgical procedure repeated (4 times) for tumefaction of her left index who in February 2008, was vaccinated with her first dose of GARDASIL (Batch & Lot not reported) and in April 2008, was vaccinated with her second dose of GARDASIL (Batch & Lot not reported) both via subcutaneous route instead of intramuscular route. Concomitant therapy included ethinyl estradiol (+) levonorgestrel, daily (manufacturer unknown). On 20-MAY-2008, the patient experienced thrombocytopenia with bicytopenia and anaemia leading to her hospitalization from 20-MAY-2008 to 21-MAY-2008. At the time of reporting the patient was recovering. Clinical examination showed no tumorous syndrome, no peripheral adenopathy and no hepatosplenomegaly. The patient had fatigue and pallor. In May 2008, biological work-up revealed: blood hemoglobin test 6 g/dl, microcytic with mean corpuscular volume at 70, sideropenic, ferritin at 2 ug/l, serum haptoglobin test 0.82 g/l, sideropenic anaemia linked to important menstrual flows corrected with TARDYFERON, thrombocytopenia at 1700 /mm3, leukocytes 6500 /mm3, with polynuclear neutrophilic leukocytes at 3800, blood lymphocyte count 2300, 1 % basophilic leukocyte, 2 % eosinophilic leukocyte and 3 % monocyte, reticulocyte count 5100, serum C-reactive protein test 3.2, sedimentation rate 46, protein electrophoresis with no particularity, no monoclonal anomaly, Hepatitis B and C, HIV, Toxoplasmosis and Herpes simplex were all negative, cytomegalovirus Epstein Barr virus and mumps serologies were in favour of a past infection, hepatitis E serology was positive with IgG and IgM but polymerase chain reaction: negative, there were anti-platelets auto-antibodies in the blood serum. Non mediated aetologies eliminated. Central origin excluded due to the presence of numerous megakaryocytes in the cervical spinal cord. As to the peripheral origin, the hem

Other Meds: ethinyl estradiol (+) levonorgestrel, Unk - Unk

Lab Data: diagnostic laboratory test, ??May08, Toxoplasmosis: negative; diagnostic laboratory test, ??May08, Herpes simplex serologies: negative; diagnostic laboratory test, ??May08, HIV: negative; diagnostic laboratory test, ??May08, cytomegalovirus

History: Surgical procedure repeated; Swelling

Prex Illness: House dust allergy

Prex Vax Illns:

Vaers Id: 325590-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Mar-2008	01-Mar-2008	0	19-Sep-2008	22-Sep-2008	KY	WAES0809USA01791	12-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Alopecia, Arthralgia, Atrioventricular block, Chills, Malaise, Nausea, Pyrexia, Urticaria, Weight increased

Symptom Text: Information has been received from a consumer concerning her 18 year old daughter with no pertinent medical history or drug reactions/allergies, who about six months ago (approximately in March 2008) was vaccinated with the first dose of GARDASIL. There was no concomitant medication. Reporter's daughter developed a fever, chills, nausea, hives, and became seriously ill after getting the first dose of GARDASIL. Patient has been hospitalized 4 times since then. Lab diagnostics studies performed included numerous tests. Therapy with GARDASIL was discontinued. At time of report, the patient had not recovered. Additional information has been requested. 1/7/09-records received for DOS 5/23-5/26/08-Admitted with C/O pain unable to get out of bed without any discomfort. History of polyarthralgia admitted for increased symptoms. first degree heart block. 11/2/08 C/O hair loss, weight gain.

Other Meds: None

Lab Data: diagnostic laboratory, numerous tests 1/7/09-records received-Workups for arthritis negative. Complement levels normal, rheumatoid factor normal, CRP increased.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **325591-1 (S)** **Related reports:** 325591-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Mar-2007	01-Apr-2007	12	19-Sep-2008	22-Sep-2008	--	WAES0809USA01747	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688F	0	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, SERIOUS

MedDRA PT Amenorrhoea, Amnesia, Bruxism, Chest pain, Convulsion, Costochondritis, Eye movement disorder, Loss of consciousness, Memory impairment, Muscle twitching, Presyncope, Somnolence, Syncope vasovagal, Unresponsive to stimuli

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter who was vaccinated with the three doses of GARDASIL in 2007 (March, April and September). In March 2007 she started to have seizures. She had a total of 7 seizures in 2007. She had no history of seizures prior to receiving GARDASIL. Her daughter had another seizure last month (August 2008). She has been taking unspecified medication for her seizures. The patient sought medical attention at the emergency room. The patient's mother also indicated that the patient was hospitalized. Patient's mother stated: "My daughter started having seizures when she received GARDASIL and I don't know why. She has never had seizures before and I told the doctor the only thing that was different was she received GARDASIL". "I don't know how to tell my daughter that this was because of GARDASIL". "She can't get her driver's license because of her seizures". "She's now taking a medication for her seizures which would cause birth defects if she tries to have children in the future". Additional information is not expected. 10/23/2008 10/23/2008 PCP records received. WCC 3/20/08 with normal exam except c/o heavy periods and passing large clots. Seen for hospital f/u after 3 episode of vasovagal syncope. 2nd HPV dose given 34 days after 1st. Another syncopal episode reported by mom. Seen 6/19/07 for Amenorrhea x 3 months. Seen 6/25/07 with c/o intermittent mid-sternal chest pain x 2 weeks. Assessment costochondritis. Syncopal episode with head twitching, amnesia and post-episode grogginess. Referred to Neurology. Neurology records received beginning 8/8/2007 to 8/27/2008 with DX: Seizures. Pt initially presented to neurologist after several episodes of passing out. First 2 likely episodes likely syncope, the 3rd episode of unresponsiveness more likely seizure or psuedoseizure. After several more, started on Trileptal. No episodes until 8/5/08 but mother reports forgetfulness, and grades have dropped. No menses x 3 months. Obn 8/5/08 pt found unrespo

Other Meds: [therapy unspecified]

Lab Data: Unknown. Labs and Diagnostics: EKG in SR with 1st' AV block. 24 hr EEG WNL. Holter monitor WNL. Urine drug screen (+) for tricyclic anti-depressants which pt denies.

History: Unknown. PMH: 1 syncopal episode 8/06 with brain CT and Echo WNL

Prex Illness:

Prex Vax Illns:

Vaers Id: **325591-2** **Related reports:** 325591-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Mar-2007	01-Apr-2007	12	09-Oct-2008	29-Dec-2008	MI		29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688F	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion

Symptom Text: My daughter have experience seizures 8 times since have taken the shot, GARDASIL.

Other Meds: Seizures meds, FOLIC ACID

Lab Data:

History: Seizure on medication

Prex Illness:

Prex Vax Illns:

Vaers Id: 325592-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	21-Aug-2008	21-Aug-2008	0	19-Sep-2008	22-Sep-2008	--	WAES0809USA01423	22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Bradycardia, Dyspnoea, Hyperhidrosis, Immediate post-injection reaction, Inappropriate schedule of drug administration, Malaise, Nausea, Pallor, Syncope vasovagal

Symptom Text: Information has been received from a physician assistant concerning a 22 year old female with allergy to CECLOR, who on 16-AUG-2007 was vaccinated intramuscularly with a first dose of GARDASIL (Lot # reported as "9725103") 0.5 ml, on 21-NOV-2007 was vaccinated intramuscularly with a second dose of GARDASIL (Lot # 654539/0742U) 0.5 ml and on 21-AUG-2008 was vaccinated intramuscularly in the left deltoid with a third dose of GARDASIL (Lot # 655604/0052X) 0.5 ml. There was no concomitant medication. The physician assistant (P.A) reported that the patient experienced a vasovagal attack after getting the third dose of GARDASIL on 21-AUG-2008. Immediately after vaccination, the P.A reported that the patient stated that she was not feeling well and was having difficulty breathing. She became pale, nauseous, very sweaty, and had bradycardia. She was laid completely flat. She did not lose conscious nor did she vomit. The patient was given ammonia inhalant and recovered in about 15-20 minutes. It was reported by the P.A that the events were considered to be serious as life threatening as the patient was having difficulty breathing. The patient remained recovered. The P.A reported that the events were "directly related" to GARDASIL. There was no product quality complaint. A Lot check has been requested. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325593-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Oct-2007	01-Oct-2007	0	19-Sep-2008	22-Sep-2008	--	WAES0802USA02656	22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Death neonatal, Drug exposure during pregnancy, Premature baby, Suicide attempt

Symptom Text: Information has been received from Merck pregnancy registry through a 15 year old female consumer with cardiac murmur, asthma, and an allergic reaction to Penicillin, Augmentin, and c-Chlor who in October 2007, was vaccinated with the first dose of GARDASIL (lot# not provided). At the time of reporting the patient was approximately 16 weeks pregnant. No adverse side effects were reported. Unknown medical attention was sought. An ultrasound showed that the baby was okay at this point. The patient's outcome is unknown. No product quality complaint was involved. Follow-up information was received from the patient's mother which reported that in March 2008, the patient gave birth to a female baby at 23 weeks. The baby was born alive, her organs were well developed and had a strong heart beat. The baby weighed 11lb 8oz. Eight hours after birth, the baby died. According to the patient's mother, the doctors could do nothing for it because the baby was too premature. The patient's mother reported that the patient had even attempted suicide. Upon internal review, premature baby, birth weight low and suicide attempt were considered to be other important medical events. Additional information is not expected.

Other Meds: None

Lab Data: ultrasound - baby is normal at this point; complete blood cell

History:

Prex Illness: Pregnancy NOS (LMP = 10/21/2007); Cardiac murmur; Asthma; Penicillin allergy; Allergic reaction to antibiotics; Hypersensitivity

Prex Vax Illns:

Vaers Id: **325599-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Jun-2008	23-Jun-2008	0	19-Sep-2008	22-Sep-2008	FR	WAES0809USA02280	22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Angioedema, Eye swelling, Lacrimation increased, Rhinorrhoea

Symptom Text: Information was received from an HCP on 01-SEP-2008 (local reference # BGAR2008106) concerning a 16-year-old female, with a medical history of hay fever (her family also has it), who on 23-JUN-2008 was vaccinated via intramuscular route into her left deltoid with a first dose of GARDASIL (lot number not reported). One and half hour after the administration, she experienced Quincke's oedema with manifestations of running nose, tearing eyes and swollen eyes. The events lasted a few days. The patient started a treatment on 23-JUN-2008 to treat the adverse events (end date of treatment unknown), including CETIRIZIN 10 mg (2 tablet/day, oral, 3 days) and MEDROL 32 mg (1 tablet/day, oral, descending scheme 32-16-8-4 mg). Subsequently she recovered from the adverse events. The reporter considered the events as medically significant. Other business partner numbers included: E200808241. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Hay fever

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325600-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-Sep-2008	22-Sep-2008	--	WAES0809USA02159	22-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse practitioner concerning a female child who was vaccinated with GARDASIL. The patient had seizure after the vaccination. The patient sought medical attention. Upon internal review, seizure was determined to be an other important medical event. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325601-1 (S)** **Related reports:** 325601-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Aug-2007	18-Aug-2007	1	19-Sep-2008	25-Sep-2008	WA		07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B015AA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0171U	0	Right arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Electrolyte imbalance, Headache, Hypoaesthesia, Liver function test abnormal, Myalgia, Neck pain, Pain, Pancytopenia, Pyrexia, Screaming, Tremor, Viral infection, White blood cell count decreased

Symptom Text: Severe neck pain, headache so bad she held her head screaming in pain, drop in white blood cell count to 1000, very high fever, uncontrollable shaking, hurting from head to toe, numbness in arms. 10/6/2008 MR received for DOS 8/21-26/2007 with D/C DX: Viral Syndrome. Pt presented with onset of severe headache, myalgias, arthralgias, and fever beginning on 8/18/07. Seen in local ER for meningitis w/u which was (-). Found to be pancytopenic so admitted for further w/u. Severe H/A tx with IV and po pain meds. Fevers up to 103 with ID w/u all (-), so abx d/c after cx (-). Pancytopenia improving. Had some electrolyte imbalances to be f/u as outpt. LFTs abnormal to f/u as outpt.

Other Meds: Prozac

Lab Data: Every test came back negative, (i.e. meningitis, West Nile, mono, etc.). Labs and Diagnostics: CSF cx (-). Blood cx (-). Head CT (-). Sinus X-ray (-). CRP 15.3. ESR 9-13. SGOT 92. SGTP 104. Total protein 5.0Albumin 2.6. Ca++ 6.4 wi

History: PMH: depression, anxiety

Prex Illness: None

Prex Vax Illns:

Vaers Id: **325601-2 (S)** **Related reports:** 325601-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Aug-2007	18-Aug-2007	1	28-Oct-2008	29-Oct-2008	--	WAES0810USA03693	04-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B015AA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0171U	0	Right arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Electrolyte imbalance, Headache, Hypoaesthesia, Myalgia, Neck pain, Pain, Pancytopenia, Pyrexia, Screaming, Tremor, Viral infection

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 16 year old female patient with depression and anxiety, who on 17-AUG-2007, was vaccinated with her first dose of GARDASIL (Lot # 655620/0171U) into her right arm and INFANRIX (Lot # AC52B015AA) into the left arm. Concomitant therapy included PROZAC. The patient experienced severe neck pain, headache so bad she held her head screaming in pain, drop in white blood cell count to 1000, very high fever, uncontrollable shaking, hurting from head to toe and numbness in arms. MR received for date of service 21-AUG-2007 to 26-AUG-2007 with discharge diagnosis with viral syndrome. The patient presented with onset of severe headaches, myalgias, arthralgias and fever beginning on 18-AUG-2007. Seen in local ER for meningitis which work up was negative. Found to be pancytopenic so admitted for further work up. Severe headache treatment with intravenous and oral pain medicaments. Fevers up to 103 with infectious disease work up all negative. Pancytopenia improving. Had some electrolyte imbalances to be follow-up as output. Every test came back negative (meningitis, West Nile, mono etc.) Labs and diagnostics: cerebrospinal fluid (CSF): negative, Blood: negative, Head computed axial tomography: negative, Sinux x-ray: negative. Serum C-reactive protein test: 15.3. Erythrocyte sedimentation rate: 9-13; (SGOT): 92. SGPT 104. Total protein 5.0. Albumin 2.6. Serum Calcium 6.4 wi. The original reporting source was not provided. VAERS ID #: 325601. No further information is available.

Other Meds: PROZAC

Lab Data: diagnostic laboratory, cerebrospinal fluid: negative; diagnostic laboratory, meningitis: negative; diagnostic laboratory, West Nile: negative; head computed axial, negative; X-ray, sinux: negative; serum C-reactive, 15.3; erythrocyte, 9-13;

History:

Prex Illness: Depression; Anxiety

Prex Vax Illns:

Vaers Id: **325604-1 (S)** **Related reports:** 325604-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Jun-2008	01-Sep-2008	75	19-Sep-2008	24-Sep-2008	MO		22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Asthenia, Asthma, Ataxia, Back pain, Dysarthria, Endotracheal intubation, Facial palsy, Foot deformity, Gait disturbance, Headache, Hypoaesthesia, Intensive care, Joint swelling, Liver function test abnormal, Lumbar puncture, Mental disorder, Muscular weakness, Oedema peripheral, Pain in extremity, Paraesthesia, Tongue paralysis

Symptom Text: Muscle weakness, trouble walking, psychiatric changes - starting early September. 9/30/08 Reviewed hospital medical records of 9/21-9/22/08. FINAL DX: facial palsy, weakness, slurred speech Records reveal patient had asthma exacerbation requiring intubation & ICU stay shortly s/p HPV injection. While in ICU began having thigh & back pain & weakness which progressed over 3 wks until unable to walk. Developed slurred speech, HA & tongue deviation. Had been seen in other hospitals & w/u WNL. 10/21/08 Reviewed hospital records of 9/12-9/17/2008, ER records of 9/5-6/08. FINAL DX: no d/c summary available Records reveal patient experienced asthma exacerbation & hospitalized 8/08 in PICU. Developed leg pain, toes pointing in w/walking, tingling in toes, numbness in forearms that resolved. Seen by PCP & labs revealed elevated LFTs. Leg pain progressed & had difficulty walking, HA, back pain. Seen in ER 9/6/08. admitted 9/9/08 for evaluation of possible GBS. CSF & EMG were WNL & developed n/v s/p spinal tap. Had missed several weeks of school. Neuro eval WNL. 10/7/08 Reviewed hospital medical records of 9/9-9/12/2008. FINAL DX: LE pain & weakness; elevated liver enzymes Records reveal patient experienced pain in back & extremities, ataxia, swelling of feet/ankles, numbness/tingling left arm, unable to walk, drug induced HA & skin rash(tegretol). Neuro consult done. Transferred per parental request.

Other Meds: None at time of vaccination

Lab Data: MRI, EMG, LP-normal, working with psychiatry 9/5 labs: WBC 21.0(H), 9/6 labs: potassium 3.2(L), calcium 8.2(L), total protein 5.4(L), ALT 68(H), x-ray of spine WNL. 9/12 LABS: MRI, LP, EMG/NCS. AST/ALT 103/185(H). CK 40(L). ESR 1

History: None PMH: GERD, scoliosis, asthma, learning disability, sensorineural hearing loss, hearing aids, allergy: toradol (itchy rash). Birth twin, sibling expired. Frequent bronchitis & pneumonia but no hospital admissions until 8/08. Parents smoke, 4 kittens in home & several outside dogs, ovarian cyst, fx right ankle x 2 yr ago.

Prex Illness: None

Prex Vax Illns: ~HPV (Gardasil)~UN~0~In Sibling

Vaers Id: **325604-2 (S)** **Related reports:** 325604-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Jun-2008	01-Sep-2008	75	28-Oct-2008	29-Oct-2008	--	WAES0810USA03692	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Gait disturbance, Mental disorder

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 15 year old female patient with no medical history reported and no known drug allergies, who on 18-JUN-2008, was vaccinated with her first dose of GARDASIL (Lot # 658554/0928U) into her left arm IM. No concomitant therapy at time of vaccination. The patient experienced weakness, trouble walking, psychiatric changes starting early September. Labs and diagnostics: Magnetic Resonance Imaging (MRI), Electromyogram (EMG), LP- normal and working with psychiatry. The listing indicated that one or more of the events required hospitalization. The original reporting source was not provided. VAERS ID #: 325604. No further information is available.

Other Meds: Unknown

Lab Data: diagnostic laboratory, LP-normal; electromyography, normal; magnetic resonance, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325632-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Sep-2008	05-Sep-2008	3	19-Sep-2008	29-Sep-2008	NH		08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Dizziness, Headache, Lumbar puncture, Malaise, Nausea, Presyncope, Pyrexia, Tunnel vision, Vertigo, Vomiting

Symptom Text: Pt developed malaise 4 days after HPV#1 vaccine. Five days after, pt developed high fever (Tmax 102.6), headache, and dizziness & vertigo. Pt described "tunnel vision" & bilateral hip pains. 10/3/08 Reviewed ER records of 9/8-9/9/2008. FINAL DX: Fever, HA Records reveal patient seen 9/8/08 after experienced malaise, low grade fever, nausea, 1 episode emesis, vertigo beginning approx 2 days s/p vaccination. D/c to home & returned to ER on 9/9/08 after being seen by PCP for fever & HA, ill appearing, dizzy, brief episode of tunnel vision, near-syncope. LP done. D/C to home

Other Meds: None.

Lab Data: Strep & CSF Cxs NEG. EEE/StLouis/WNV CSF IgMs NEG. EBV titers NEG. CBC:4.5> 13.3/39< 206 (81N 11L 7M). CSF: 0 WBC, 0 RBC, glu 64, prot 15. LABS: CBC, UA WNL. CSF tests all WNL. CSF,throat c/s neg. Mono test neg.

History: Remote PMH asthma & allergic rhinitis. PMH: heart murmur

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325633-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	07-Aug-2008	21-Aug-2008	14	19-Sep-2008	29-Sep-2008	SC	SC0809	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	N188U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Headache, Myalgia

Symptom Text: 9/10/08 presented to office with joint pain (knees, ankles, elbows, wrists) and headaches X 3 weeks. 9/25/2008 Office notes received from PCP for OV 9/10/2008 for pt c/o joint pain x~3 weeks. Pain in all joints all over. Also c/o headache x 6 days. PE (+) for joint tenderness. DX: Arthragia/myalgia.

Other Meds:

Lab Data: CBC, ANA, Rheumatoid Factor, Sed Rate allWNL. Labs and Diagnostics: RF (-). ANA (-). Chem WNL. CBCWNL.

History: PMH: none noted

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325637-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Sep-2008	17-Sep-2008	0	19-Sep-2008	29-Sep-2008	NM		29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Hyperhidrosis, Pallor, Unresponsive to stimuli

Symptom Text: Adminis. Lt deltoid IM within 2-10 seconds pt unresponsive-eyes closed and arms legs extended with faint jerking of legs-pt open eyes within 20 seconds, but continued to be very slow to respond pale and skin moist this gradually improved over the next hour.

Other Meds:

Lab Data: Seen same day within 1.5 hours at the emergency room where a further EEG and neurologist cosult is pending.

History: No none previous allergies, defects or medical conditions

Prex Illness: No known illness

Prex Vax Illns:

Vaers Id: 325642-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	29-Aug-2008	29-Aug-2008	0	19-Sep-2008	29-Sep-2008	WI		29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	4	Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Musculoskeletal pain

Symptom Text: COMPLAINED OF A SORNESS TO SCAPULAR AREA ON LEFT SIDE OF BACK AND SHOULDER WITHIN 8 HOURS OF VACCINE, LASTING ABOUT 2 DAYS

Other Meds: SKELAXIN, LEXOPRO, LOESTREN-24, MVI

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325650-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-May-2008	29-Jun-2008	48	19-Sep-2008	29-Sep-2008	TX		29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: 7/29/2008 Mother called to report that pt. has been having hair loss since she received the 2nd dose of HPV vaccine. She reported that she really noticed it 4 weeks prior(6/29/2008). Pt. has several small areas where it is bald on her scalp. Referred to PCP

Other Meds: NONE

Lab Data:

History: NO KNOWN

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325656-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Aug-2008	15-Aug-2008	1	19-Sep-2008	29-Sep-2008	TX		29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	C2774AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0070X	0	Right arm	Unknown	
	MEN	UNKNOWN MANUFACTURER	42624AA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Rash, Urticaria

Symptom Text: 08/15/2008 2:20 pm Mom reported after child received immunization on 8/14/08 at 9 pm. She first had pruritus on the neck, back and posterior side of bilateral palm then broke out in hives. She gave benadryl and problem resolved. on 08/18/08 9 am followup with Mom stated child broke out in rash seen at children med. center ER on 08/15/08 at 7 pm treated problem resolved.

Other Meds:

Lab Data:

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: 325661-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-Sep-2008	13-Sep-2008	9	19-Sep-2008	29-Sep-2008	IL		29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0245U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Blister, Erythema, Headache, Induration, Myalgia, Rash pustular

Symptom Text: Erythema, Induration-approx 12mm in diameter, vesical/pustule approx 2mm in diameter, arthralgia,myalgia, headache.

Other Meds: none

Lab Data:

History: none

Prex Illness: no

Prex Vax Illns:

Vaers Id: **325671-1 (S)** **Related reports:** 325671-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Sep-2007	01-Jan-2008	108	19-Sep-2008	24-Sep-2008	FL		11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1111	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Convulsion, Diplopia, Disturbance in attention, Dizziness, Drooling, Extrasystoles, Fatigue, Gaze palsy, Headache, Hyporeflexia, Migraine, Musculoskeletal stiffness, Nausea, Palpitations, Phonophobia, Photophobia, Postictal state, Status migrainosus, Tremor, Vomiting

Symptom Text: PT HAD THE SECOND GARDASIL INJECTION IN SEPT '07. AND THE FOLLOWING MONTH SHE STARTED HAVING HEADACHES, ABOUT 3XS A WEEK. THEN IT GRADUALLY INCREASED SOME WORSE THAN OTHERS. FINALLY ON JANUARY 1 '08, SHE HAD A SEVERE MIGRAINE. THAT INCAPACITATED HER FOR AN ENTIRE 2 DAYS. THE PAIN WENT ON FOR A WEEK THEN SHE BEGAN TO GET HEART PALPS. THEN AFTER GIVING HER MEDICINE FOR THE MIGRAINE. SHE HAD A SEIZURE ONE NIGHT. SHE WAS TAKEN TO THE E.R. BY AMBULANCE AND WAS ADMITTED FOR A DAY AND A HALF. IN ORDER TO GET CONTROL OF THE HEAD PAIN WHICH BY THIS TIME HAD BEEN CONSTANT FOR ABOUT 3WKS. FINALLY THE HOSPITAL WAS ABLE TO GET RID OF THE HEADACHE. BUT THE SAME DAY SHE WAS RELEASED WE HAD TO RETURN BECAUSE THE PAIN RETURNED WORSE. SHE WAS GIVEN PAIN MEDS I.V. AND SENT HOME. WE TRIED VARIOUS MIGRAINE MEDS AND NOTHING WORKED FOR LONG. THEN WE SAW A NEUROLOGIST WHO TREATED HER FOR ABOUT 2MNTHS. SHE HAD A COUPLE MORE SEIZURES BETWEEN THAT TIME, AND THE NEUROLOGIST ADMITTED HER AGAIN. TO START THE I.V. PAIN MED. SHE WAS ADMITTED FOR 2DYS THEN. FINALLY HAD SOME RELIEF FOR THE FIRST TIME IN A MNTH SINCE THE LAST ADMISSION. THAT LASTED 2DYS AND THEN THE PAIN RETURNED. AND HER SEIZURES INCREASED. SHE MISSED A LOT OF SCHOOL, WAS NOT ABLE TO PLAY OR CONCENTRATE. SHE LIVED IN CONSTANT FEAR OF FALLING OUT AND HAVING INCREASED HEART PALPS. SHE HAD BOUTS OF BIGEMENY ALSO. THIS HAS GONE ON SINCE THE 2ND SHOT OF THAT GARDASIL. SHE HAS NEVER TAKEN MORE THAN TYLENOL FOR PAIN ALL HER LIFE. VERY ACTIVE, FUN KID. BUT FOR MONTHS SHE HAD BEEN STRUGGLING WITH THIS. I FOLLOWED THE REPORTS ON THIS DRUG WHICH LEAD ME TO CONTACT SOMEONE ABOUT THIS. THEN DIFFERENT PEOPLE I SPEAK WITH IN DR OFFICES HAVE HAD FAMILY MEMBERS ALSO HAVE BAD REACTIONS, ALSO THE MORNING NEWS CLIP ABOUT HOW SOME OTHER YOUNG GIRLS HAD BAD REACTIONS. NOW SHE IS GETTING BETTER (PROBALLY BECAUSE SHE DID NOT HAVE THE 3RD INJECTION). BUT EVEN NOW THINGS ARE HARD FOR HER. SHE HAS REALLY BAD MIGRAINES NOW WHICH WAS NEVER AN ISSUE, AND SHE GETS TIRED EASIER NOW, MUCH EASIER. I WOULD

Other Meds:

Lab Data: Labs and Diagnostics: MRI/MRA WNL. Head CT (-). CSF with 100% monos, CSF glucose low at 44. All bacterial, fungal and viral tests (-). ANA (+). AST 73/ALT 72 increased on 2/5/08. CBC with WBC 3.35. EBV IgG titre (+). Labs and Diagnosti

History: NONE. PMH: T&A age 7

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325671-2 (S)** **Related reports:** 325671-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jul-2007	01-Jul-2007	0	07-Oct-2008	08-Oct-2008	FL	WAES0810USA00204	11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Computerised tomogram, Convulsion, Dizziness, Extrasystoles, Lumbar puncture, Migraine, Nuclear magnetic resonance imaging

Symptom Text: Information has been received from a consumer concerning his 15 year old daughter with no pertinent medical history or allergies who in July 2007 and on an unspecified date was vaccinated intramuscularly with a 0.5 ml first and second doses of GARDASIL (lot #658094/0524U, 658563/1063U), respectively. There was no concomitant medication. The patient experienced bigeminy after receiving GARDASIL. "Two months after the second dose", the patient developed severe migraines, dizziness and seizures. The patient had been hospitalized twice because of the migraines. The patient stayed in the hospital for 1 and 1/2 days for the first stay and 2 days for the second stay. During the hospital stay, the patient received "intravenous dihydroergotamine mesylate". "Spinal tap, MRI, CT scan" were performed but no results provided. The patient had also been seen by a neurologist. At the time of this report, the patient was recovering. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 325672-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Jan-2008	09-Jun-2008	154	20-Sep-2008	30-Sep-2008	MA		14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	C2863AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1062U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Dizziness, Headache, Menstruation irregular, Odynophagia, Sinusitis, Temporomandibular joint syndrome, Toothache, Upper respiratory tract congestion, Vaginal discharge, Vaginal infection, Weight decreased

Symptom Text: Severe joint pain, knee's, elbow, TMJ, missed periods. Pt has seen an oral surgeon and is now being treated by a TMJ specialist as well as a Rheumatologist to try to figure out what is going on. All these issues started after the vaccinations began. 9/29/2008 PCP records received from 1/7/2008 to present. 16 yr WCC with normal exam 1/7/08. Seen 3/21/08 for URI sx, head pressure, tooth pain, feeling faint, and vaginal d/c. Assessment: vaginitis. sinusitis. Seen 6/23/08 for c/o knee pain R>L x 2 weeks with no injury. PE WNL. F/U 8/8/08 with joint pain in elbows, knees and cracking shoulder. Hurts to swallow. Diminished energy over past few months. Weight loss. Assess: Wt loss, joint aches and pains, increasing over past 2-3 months. ? rheum issue or r/t Topamax. Will refer to Rheum.

Other Meds:

Lab Data: second vaccination 03/21/08. third vaccination 06/25/08. Labs and Diagnostics: ANA (+), Lyme (-), RF (-), UC(+) for gram+ flora. Vaginal cx with normal genital flora.

History: PMH: OCD

Prex Illness: pain at injection site

Prex Vax Illns:

Vaers Id: **325673-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
1.2	F	17-Sep-2008	18-Sep-2008	1	20-Sep-2008	30-Sep-2008	OR		30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2660BA		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0572X		Unknown	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB297CA		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Skin warm

Symptom Text: Large area of red, warm, swollen from Axilla to elbow beginning day after injection and worsening following day. 9/19/08 Seen by Dr. TX. Ice, advil, Benadryl Much better after Doctor visit and TX.9/20/08

Other Meds: None

Lab Data: none

History: None

Prex Illness: None

Prex Vax Illns: Swollen Neck Nodes~Measles + Mumps + Rubella (MMR II)~2~2~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325681-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	26-Aug-2008	26-Aug-2008	0	19-Sep-2008	29-Sep-2008	CA	CA080015	29-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U264AA		Right arm	Unknown	
HPV4	MERCK & CO. INC.	0072X		Left arm	Unknown	
VARCEL	MERCK & CO. INC.	1801U		Left arm	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB284		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Loss of consciousness, Oxygen supplementation, Syncope, Urinary incontinence

Symptom Text: Symptoms = Fainting, urination, short of breath. Signs = None; Time cause= 4:15 pm 30 minutes after doses given. Please see attached !!; On Tuesday August 26, 2008 we had a 18 year-old female patient who came in with mother for vaccines, that were in need promptly requested by school. Patient information, Vaccine Questioner, and VFC application were given to the patient due to the fact that it was the patients first time at the facility. After the patient had concluded inputting here information she was registered in LINK. Patient at the moment was due for a total of 4 vaccines which are as follows: Varicella, HPV, Meningococcal, and Hepatitis A. The patients mother was then informed that the subsequent vaccines mentioned were due along with HPV, but that GARDASIL was not needed by School system. After the mom was informed about GARDASIL and what it prevents, mother agreed to render that vaccine along with the other three. The patient was then taken to the triage room and vitaled. The temperature recorded at the time was 97.9 Oral-temperature. Routing slip from LINK was then given to P.A.C to approve all vaccines that were in need. After approval all four vaccines were administered. Patient was advised by Medical Assistant to have a seat in the waiting room, while vaccine card was being printed. While the patient was seated at the waiting area she collapse while being seated. The patient was unconscious and ammonia was passed by nasal area. The patient gained conscience, but immediately went unconscious again. While patient collapsed again she urinated at the same time. Ammonia was passed for the second time and gained permanently. Oxygen tank was then put on the patient to help the oxygen flow. Paramedics were called and arrived 5 minutes later at the scene. Paramedics vitaled the patient and recommended for her to go with them. patient was adamant and denied the advice and she signed the AMA for the paramedics. The patient left 5 minutes after the paramedics were gone. Patient was called the following day of th

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325682-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	09-Sep-2008	09-Sep-2008	0	19-Sep-2008	29-Sep-2008	CA		29-Sep-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2604AA	1	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0928U	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1807U	1	Left arm	Subcutaneously	
TDAP	SANOFI PASTEUR	AC52B018BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient with syncopy response to injected about 3-4 second and recovered without complication. Observed 30 min after response.

Other Meds:

Lab Data:

History: None

Prex Illness: last 3-4 second

Prex Vax Illns:

Vaers Id: **325686-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Aug-2008	Unknown		19-Sep-2008	29-Sep-2008	MN		30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Left arm	Intramuscular	
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	AHABB116AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2618AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: None Stated.

Other Meds:

Lab Data:

History: Migraines

Prex Illness: Radius fx which occurred 2-3 weeks before 8-6-08

Prex Vax Illns:

Vaers Id: **325687-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	20-Aug-2008	Unknown		19-Sep-2008	29-Sep-2008	MN		30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	AHABB23AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: None Stated.

Other Meds: none

Lab Data:

History: none reported by patient or parent/ or physician

Prex Illness: none reported

Prex Vax Illns:

Vaers Id: **325695-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	03-Oct-2008	TX	WAES0807USA05336	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with GARDASIL vaccine (yeast) and MENACTRA vaccine (dip toxoid) on the same office visit and had fainting and dyskineteic movements after receiving GARDASIL vaccine (yeast) and MENACTRA vaccine (dip toxoid). "She was in the ER for 18 hours." The patient saw the doctor. No further information is available.

Other Meds: MENACTRA

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325696-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	07-Jul-2008	07-Jul-2008	0	18-Aug-2008	03-Oct-2008	NJ	WAES0807USA05346	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Information has been received from a physician concerning a 21 year old female with a history of fainting during medical procedures who on approximately 07-JUL-2008, reported as "3 weeks ago", was vaccinated 0.5mL, IM with a 1st dose of GARDASIL vaccine (yeast) (lot# not reported). It was reported that the patient fainted as soon as the needle was withdrawn from her arm and was unconscious for approximately 2 minutes. It was reported that the nurse moved the patient's feet up and eventually the patient was conscious. The patient sought medical attention from the physician in the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Syncope

Prex Illness:

Prex Vax Illns:

Vaers Id: **325697-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	28-Mar-2008	28-Mar-2008	0	18-Aug-2008	06-Oct-2008	MA	WAES0807USA05360	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Nausea

Symptom Text: Information has been received from a registered nurse considering a 23 year old female with no known drug allergies and no previous medical history who on 28-JAN-2008 was vaccinated IM in the deltoid with her first dose of GARDASIL vaccine (yeast) (lot#659657/1487U) 0.5 ml. There was no concomitant medication. The patient received her second dose of GARDASIL vaccine (yeast) (lot# 659182/1757U, site not reported) on 28-MAR-2008. Subsequently she "passed out" and felt nauseous after the second dose. The patient did not seek treatment for her symptoms and recovered on an unspecified date. No further information was available Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325698-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	07-Jul-2008	Unknown		18-Aug-2008	06-Oct-2008	MD	WAES0807USA05381	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 26 year old female with no medical history or no known drug allergies, who on 02-JAN-2008 was vaccinated IM with a first dose of GARDASIL vaccine (yeast) (Lot# 660393/0067X). Concomitant therapy included ACETEXA. On 07-Jul-2008 the patient received the second dose of GARDASIL vaccine (yeast). Within a few hours of vaccination the patient experienced redness, pain and swelling at the injection site. The patient also mentioned after she received the second dose, that she did have a similar reaction after the first dose. Medical attention was not sought. On an unspecified date the patient was recovered. Additional information has been requested.

Other Meds: ACETEXA

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **325699-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Mar-2008	01-Mar-2008	0	18-Aug-2008	06-Oct-2008	NY	WAES0807USA05508	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Information has been received from a physician concerning an 18 year old female who in March 2008, was vaccinated with the third dose of GARDASIL vaccine (yeast), IM. It was reported that the patient experienced joint pain after receiving the third dose of GARDASIL vaccine (yeast). The patient sought medical attention. No additional information available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325700-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	08-Jun-2008	09-Jun-2008	1	18-Aug-2008	06-Oct-2008	--	WAES0807USA05510	04-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia, Postpartum state

Symptom Text: Information has been received from an office secretary concerning a 23 year old female neighbor who on approximately 08-JUN-2008, was vaccinated with the first dose of GARDASIL vaccine (yeast). The office secretary stated that on approximately 09-JUN-2008, the patient experienced tingling in her hands and toes, the day after receiving her first dose of HPV vaccine, postpartum 3 weeks ago. The patient's tingling in her hands and feet persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Delivery

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325701-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	21-Jul-2008	21-Jul-2008	0	18-Aug-2008	06-Oct-2008	--	WAES0807USA05511	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Oral herpes, Pruritus, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female patient with a history of her first abnormal PAP Low Grade Squamous Intraepithelial Lesion (LGSIL) (18-MAR-2008) and cervical intraepithelial neoplasia (CIN 1) after colposcopy (02-MAY-2008), who on 14-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 660393/0067X) IM and on 21-JUL-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast) (lot # 660553/0070X) IM. Concomitant therapy included drospirenone (+) ethinyl estradiol (YAZ). The nurse practitioner reported that on 14-MAY-2008 and on 21-JUL-2008, the patient experienced itching, redness, swelling on left palm after received the first and second dose of HPV vaccine. On 15-MAY-2008, the patient was seen by her family physician who did not know patient had just received HPV vaccine and diagnosed patient with a cold sore and patient was treated with VALTREX 1gm for 1 dose. On 16-MAY-2008, the patient recovered from her first episode of itching, redness, swelling on left palm and swelling on left palm. On 21-JUL-2008, after the second dose of HPV vaccine, the patient developed itching, redness, and swelling of the left palm that evening. On 23-JUL-2008, antibody titers were done which showed IgM not detected IgG titer for Herpes simplex 1 was positive. On 26-JUL-2008, the patient recovered from her second episode of itching, redness, swelling on left palm. The NP was unsure if she would give the patient the third dose of HPV vaccine. Additional information has been requested.

Other Meds:

Lab Data: colposcopy - 05/02/08 - CIN 1, serum Herpes simplex - 07/23/08 - not detected, Pap test - 03/18/08 - Abnormal, serum Herpes simplex - 07/23/08 - Positive

History: Cervical dysplasia, Papanicolaou smear abnormal

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325702-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Mar-2008	01-May-2008	61	18-Aug-2008	25-Sep-2008	OH	WAES0807USA05512	25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nodule

Symptom Text: Information has been received from a nurse concerning a 15 year old female patient who in March 2008, was vaccinated with the second dose of GARDASIL. In May 2008, the patient called and told that she experienced knot on her upper right arm. According to the nurse, it was documented in their file that second dose of GARDASIL was given on left arm of the patient. At the time of the report, the patient was not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325703-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	16-Jun-2008	17-Jun-2008	1	18-Aug-2008	06-Oct-2008	--	WAES0807USA05513	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Injection site reaction, Paraesthesia

Symptom Text: Information has been received from a physician's assistant concerning a female patient who on 16-JUN-2008 was vaccinated with a dose of GARDASIL vaccine (yeast). On 17-JUN-2008 the patient experienced shortness of breath and tingling in the arm were the vaccination had been given. The patient was then sent to the emergency room to be evaluated. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325704-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		18-Aug-2008	06-Oct-2008	TN	WAES0807USA05514	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia

Symptom Text: Information has been received from a physician concerning a 20 year old female who was vaccinated with the all three doses of GARDASIL vaccine (yeast). The patient reported that after receiving the third dose of GARDASIL vaccine (yeast) experienced decreased in energy level. The patient receive all three doses in anther physician's office, the reporting physician's office, the reporting physician in the case did not administer the of GARDASIL vaccine (yeast). The physician was performing blood tests. Additional information has been requested.

Other Meds: Unknown

Lab Data: Blood tests

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325705-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	24-Jun-2008	24-Jun-2008	0	18-Aug-2008	06-Oct-2008	--	WAES0807USA05522	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 12 year old female who on 24-JUN-2008 was vaccinated intramuscularly with her first 0.5 ml dose of GARDASIL vaccine (yeast) (Lot #660555/0279X). Concomitant therapy included meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA). On 24-JUN-2008, after receiving the first dose GARDASIL vaccine (yeast), the patient fainted. On the same day the patient recovered from the same event. Unspecified medical attention was sought. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325706-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	22-Jul-2008	22-Jul-2008	0	18-Aug-2008	06-Oct-2008	--	WAES0807USA05527	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female patient who in May 2008, was vaccinated with a first dose of GARDASIL vaccine (yeast) and approximately on 22-JUL-2008 was vaccinated with a second dose of GARDASIL vaccine (yeast). Concomitant medication was not reported. The nurse practitioner reported that the patient developed a red itchy area at the right wrist the evening she received GARDASIL vaccine (yeast). This occurred after both the first and second doses. Both doses were administered in the right arm. The saw her primary care physician after the first accident and he prescribed VALTREX for her and the symptoms resolved. After the second incident the patient saw the reporting nurse practitioner. No treatment was ordered. The nurse practitioner did perform a blood test for Herpes Simplex Virus 1 that was positive. The patient recovered on an unspecified date. There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory - 07/22?/08 - herpes simplex virus-1 (HS V-1) : positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325707-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	06-Oct-2008	CA	WAES0807USA05534	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a dose of GARDASIL vaccine (yeast) then fainted. The physician reported that they followed the procedure for when a patient faints and then the patient came to and was fine. The patient is not going to continue the rest of the series. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325708-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	06-Oct-2008	CA	WAES0807USA05535	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a dose of GARDASIL vaccine (yeast) then fainted. The physician reported that they followed the procedure for when a patient faints and then the patient came to and was fine. The patient is not going to continue the rest of the series. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325709-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	06-Oct-2008	NM	WAES0807USA05539	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a certified medical assistant concerning a female patient who was vaccinated with the first dose of GARSASIL vaccine (yeast) 0.5ml intramuscularly. The medical assistant reported that the patient fainted after receiving HPV vaccine. At the time of the report the patient had fully recovered. It is unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325710-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		18-Aug-2008	06-Oct-2008	TN	WAES0807USA05543	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Swelling

Symptom Text: Information has been received from a physician concerning a 16 year old female who was vaccinated IM with GARDASIL vaccine (yeast) 0.5 ml. The physician reported that a patient developed redness and swelling from the right side of her face to her wrist after she received GARDASIL vaccine (yeast). The patient sought unspecified medical attention. There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325711-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	24-Jul-2008	24-Jul-2008	0	18-Aug-2008	06-Oct-2008	--	WAES0807USA05552	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	DTAP MEN VARCEL

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cold sweat, Decreased activity, Dizziness, Dizziness postural, Fatigue, Feeling abnormal, Feeling hot, Immediate post-injection reaction, Increased appetite, Injection site erythema, Injection site induration, Injection site swelling, Injection site warmth, Malaise, Menstruation delayed, Muscular weakness, Paraesthesia, Rash generalised, Sensation of heaviness, Syncope

Symptom Text: Information has been received from the patient's mother concerning a 13 year old female with no known medical history and no known drug reactions/allergies, who on 24-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). There was no concomitant medication. On 24-JUL-2008, minutes after injection, the patient fainted and had sweating, tingling and heavy and weak limbs and had the same symptoms on 27-JUL-2008. Patient also reported feeling tired and her "feeling weird". The patient sought doctor medical attention. The patient was recovering from the adverse events. Additional information has been requested. 10/1/08 Reviewed PCP medical records of 7/12-9/23/2008. FINAL DX:Records reveal patient experienced usual state of good health on 7/12 when received Varivax, Menactra & TDaP. Parent called PCP 7/14 w/local varicella reaction of red, swollen, warm & indurated injection site. RTC 7/24 for HPV #1. Dizzy & fainted in office immediately after injection. Observed & released. Parent called office 7/29 after fainted again on 7/27 after having tingling in hands & cold sweat. RTC 9/24 w/rash all over body, malaise, extreme fatigue, continued dizziness when standing, increased appetite, activities decreased, tingling hands, feeling hot, periods infrequent

Other Meds: None

Lab Data: None 10/1/08-records received-LABS: CBC, TSH, CMP, mono test all pending

History: None 10/1/08-records received- PMH: vegetarian. Family hx: thyroid disorders.

Prex Illness:

Prex Vax Illns:

Vaers Id: 325712-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Jul-2008	15-Jul-2008	0	18-Aug-2008	06-Oct-2008	NY	WAES0807USA05554	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 16 year old female who on approximately 15-JUL-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast), 0.5 mL, injection. On approximately 15-JUL-2008, the patient fainted after getting second dose of GARDASIL vaccine (yeast). It was unknown when patient was administered with first dose. The patient sought unspecified medical attention. On an unspecified date, the patient recovered from fainted. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325713-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Apr-2008	04-Apr-2008	0	18-Aug-2008	06-Oct-2008	TN	WAES0807USA05569	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysmenorrhoea, Musculoskeletal pain, Pain in extremity, Vaccine positive rechallenge

Symptom Text: Information has been received from a mother concerning her daughter, with no pertinent medical history and no drug reaction/allergies, who on 04-APR-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) 0.5mL IM, and on 03-APR-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast) 0.5mL IM. There was no concomitant medication. The mother stated that each time her daughter was given GARDASIL vaccine (yeast), she had pain in the back of her shoulder of the arm she got the shot in and it "went down her arm" and she had menstrual cramps. Each time the AE started the day she got the vaccination and she recovered after 2 days. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 325714-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	18-Jul-2008	18-Jul-2008	0	18-Aug-2008	06-Oct-2008	KS	WAES0807USA05587	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial bones fracture, Fall, Syncope

Symptom Text: Information has been received from a nurse concerning a 22 year old female with no known drug allergies and no pertinent medical history, who on 18-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 660557/0072X) 0.5 mL, IM into her right deltoid. There was no concomitant therapy. The patient was sitting on the exam table and after GARDASIL vaccine (yeast) was administered, she fainted and fell forward onto the floor and broke her nose. She was taken to the emergency room (ER) but was admitted. The patient told the nurse she is not afraid of needles, injections or blood being drawn, but never had an experience like this. At the time of reporting, the patient was recovering. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325715-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	06-Oct-2008	--	WAES0807USA05606	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Palpitations, Syncope

Symptom Text: Information has been received from a registered nurse reporting that she heard of a patient that experienced lightheadedness, palpitations and fainting after receiving GARDASIL vaccine (yeast). The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325716-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		18-Aug-2008	06-Oct-2008	TX	WAES0807USA05631	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning about 5 patients who on unspecified dates, were vaccinated with GARDASIL vaccine (yeast) and meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA). Subsequently, the patients experienced syncope and saw the physician. The outcome of the event was not reported. No further information is available.

Other Meds: MENACTRA

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325717-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Aug-2008	30-Sep-2008	--	WAES0807USA05655	30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information was also received from a nurse at this practice concerning a different patient who fainted after receiving GARDASIL vaccine (lot # not provided). No additional information was available. This is one of two reports from the same source (WAES# 0807USA03710) Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325718-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	28-Jul-2008	29-Jul-2008	1	18-Aug-2008	06-Oct-2008	--	WAES0807USA05681	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Injection site discomfort, Nausea, Photophobia

Symptom Text: Information has been received from a physician concerning her 20 year old with Gilbert's syndrome, CECLOR and BACTRIM allergies and a history of tonsillectomy (June 2008) and wisdom teeth removal (07-JUL-2008), who at the end of May 2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) and on 28-JUL-2008 was vaccinated with a second dose of GARDASIL vaccine (yeast) 0.5 ml intramuscularly. Concomitant therapy included YAZ. After vaccination with the first dose of GARDASIL vaccine (yeast), the only complaint the patient had was injection site discomfort. The patient developed a severe headache after her second dose of GARDASIL vaccine (yeast). A dull headache began on 29-JUL-2008 around 10:30 pm after she returned home from working at the movie theater. The headache was at the back of her head and radiated to the top. On 30-JUL-2008, she awoke with a severe headache at the back of neck and to the left side of the head. She also had nausea and light sensitivity. The patient stated that "it is the worst headache ever". The patient sought medical attention. There was no product quality complaint. Additional information has been requested.

Other Meds: YAZ

Lab Data: None

History: Tonsillectomy, Wisdom teeth removal

Prex Illness: Gilbert's syndrome, Allergic reaction to antibiotics, Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325719-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-Mar-2008	08-Mar-2008	0	18-Aug-2008	07-Oct-2008	--	WAES0807USA05685	17-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Headache, Malaise, Onychoclasis, Photophobia, Tremor

Symptom Text: Information has been received from a pharmacist concerning a 12 year old female with graves' disease and no known allergies, who on 05-SEP-2007 was vaccinated with a first dose of GARDASIL vaccine (yeast) 0.5 ml intramuscularly. On 06-NOV-2007 and on 08-MAR-2008 was vaccinated with a second and a third dose of GARDASIL vaccine (yeast) respectively. There was no concomitant medication prior to vaccination with GARDASIL vaccine (yeast). The pharmacist mentioned that the patient had experienced headaches since the first dose of GARDASIL vaccine (yeast). She had already completed the series. The headaches had persisted since September 2007, the degrees of the pain changed from dull to severe pain, but had never fully resolved. The patient had been seen by a neurologist. Scans of her head were performed and all results were negative. The pharmacist mentioned that the neurologist believed that the headaches are "tension headaches". The patient had been on several medications and pain medications without relief. Her endocrinologist took her off all the medications and prescribed her a muscle relaxer at bed time. This also did not seem to provide the patient with relief. The patient sought medical attention. She contacted the pharmacist. There was no product quality complaint. Additional information has been requested. 10/1/08 Reviewed PCP medical records of 8/11-9/2/08. FINAL DX: Records reveal patient experienced chronic HAs. 10/17/08-records received for DOS 2/5-10/6/08-follow-up visits for Grave's disease diagnosed 1/8/07. Visit on 2/5/08-headache waxes and wanes began in early September 2007-occurring daily ever since. Visit on 5/6/08- C/O feeling tired and malaise worse in morning. Intermittent headache per another physician they are tension headaches. Intermittent tremor. Brittle nails. Visit 10/6/08-Continues with headaches for last 13 months. No longer feeling tired or malaise. 11/6/08-records received-DOS 1/2/08-C/O continued headaches since 11/7/07-CT scan of head and sinuses normal. Some sensitivity t

Other Meds: None

Lab Data: diagnostic laboratory - Head scan with dye: negative, diagnostic laboratory - Head scan without dye: negative

History: 10/01/08-records received-PMH: Graves disease.

Prex Illness: Graves' disease

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325720-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Oct-2007	Unknown		18-Aug-2008	07-Oct-2008	TN	WAES0807USA05686	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1236U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Hypertension

Symptom Text: Information has been received from a licensed practical nurse (LPN), for the Pregnancy Registry for GARDASIL vaccine (yeast), concerning a 15 year old female with no drug allergies who on 25-JUL-2007 was the first dose of vaccinated with GARDASIL vaccine (yeast) (lot # 658490/0802U) and on 27-OCT-2007 was the second dose of vaccinated with GARDASIL vaccine (yeast) (lot # 658282/1263U). At week 37 of pregnancy, the patient developed slight hypertension. The patient delivered a healthy baby on 28-JUN-2008. At the time of this report, the outcome of slight hypertension was unknown. The patient was seen in office. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Pregnancy NOS (LMP = 9/22/2007)

Prex Illness:

Prex Vax Illns:

Vaers Id: **325721-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	07-Oct-2008	LA	WAES0807USA05687	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Information has been received from a patient's parents concerning an adolescent female who on an unspecified date was vaccinated with a dose of GARDASIL vaccine (yeast) (route and administration site not reported). Subsequently the patient experienced arthralgia. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325722-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Jan-2006	01-Mar-2007	424	18-Aug-2008	07-Oct-2008	--	WAES0807USA05690	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Information has been received from a parent concerning her 19 year old daughter with sulfonamide allergy who in November 2006, was vaccinated intramuscularly with a first dose of GARDASIL vaccine (yeast) (lot # not reported). There was no concomitant medication. The parent reported that since March 2007, her daughter has been experiencing severe hip pain after the second dose of GARDASIL vaccine (yeast) 0.5 mg. On an unspecified date she underwent an MRI (results not reported). At the time of the report, the patient had not recovered. The parent reported that her daughter has received all three GARDASIL vaccines (yeast), and that therapy was stopped in January 2007. No further information was provided. Additional information has been requested.

Other Meds: None

Lab Data: magnetic resonance - Results not reported

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **325723-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	07-Oct-2008	IL	WAES0807USA05698	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with GARDASIL vaccine (yeast) (lot # not reported). Subsequently the patient had an abnormal pap after receiving GARDASIL vaccine (yeast). The patient was seen in the physician's office. No other information was available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test - Abnormal pap

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325724-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	01-Mar-2008		18-Aug-2008	07-Oct-2008	--	WAES0807USA05708	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Liver function test abnormal

Symptom Text: Information has been received from a nurse practitioner (NP) concerning a 17 year old female who was vaccinated with GARDASIL vaccine (yeast), In approximately March 2008, "about 5 months ago", the patient's liver specific protein profile was 2.5 times above normal after she received the first dose. It was noted that the latter profile was a liver profile lab report. Liver specific protein profiles also remained at same level after the second dose as well. Recently liver specific protein profiles were closed to normal. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory - LSP profile was 2.5 times above normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325725-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		22-Sep-2008	23-Sep-2008	AL	WAES0809USA01796	23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Cerebrovascular accident, Encephalitis, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 13 year old female who on an unknown date was vaccinated with GARDASIL. The first dose was received at another clinic but it was not sure about the second dose. The physician reported that the patient had cerebritis and inflammation of the brain after each GARDASIL shot. It was reported that the doctors concurred that the patient had a stroke. The patient was hospitalized (duration unspecified) and cerebritis and inflammation of the brain and stroke were considered to be immediately life-threatening. The outcome was not reported. The patient sought medical attention, "saw doctor and hospital". Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325729-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-Feb-2008	01-Mar-2008	11	22-Sep-2008	23-Sep-2008	FR	WAES0806USA00251	23-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0311U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Iron deficiency, Loss of consciousness, Malaise, Pain, Vaccine positive rechallenge

Symptom Text: Information has been received from a pharmacist concerning a 14 year old female who on 19-FEB-2008 she was vaccinated with the second dose of GARDASIL (lot no. not reported). Since MAR-2008 the patient experienced frequent pain not otherwise specified, regular loss consciousness and fit coughing. Medical work-up not specified were normal. The patient had not recovered. Follow up information has been received on 08-SEP-2008 reported that the patient was vaccinated with the first dose GARDASIL (lot no. 1358F, batch no. NG01510) IM in the right arm on 19-DEC-2007. On 19-FEB-2008 she was vaccinated with the second dose of GARDASIL (lot no. 0311U, batch no. NG14100) IM in the right arm. Unexpected pain appeared several times after the second dose of GARDASIL. It was localized on different part of the body and lasted 2 to 10 minutes each. Regular loss of consciousness reported as malaise occurred in MAR-2008 associated to an important iron deficiency. On 24-JUN-2008 she received the third dose of GARDASIL (lot no. 1201U, batch no. NG41880) IM in the left arm and pain did not change. At the time of reporting the patient had recovered with sequelae: pain was still occurring. She had concomitant treatment of BI-PROFENID since 11-MAR-2008 and of TARDYFERON since 20-MAR-2008 during 2 months. Pain, malaise, iron deficiency and coughing were considered to be other important medical events. The case was closed. Other business partner numbers include E2008-04899. No further information is available.

Other Meds: BI-PROFENID, 11Mar08; TARDYFERON, 20Mar08

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325736-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-Dec-2007	22-Jan-2008	42	22-Sep-2008	30-Sep-2008	TX		29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Bronchitis, Cough, Headache, Loss of consciousness, Neurological examination normal, Ophthalmological examination normal, Orthostatic hypotension, Pharyngitis, Pharyngolaryngeal pain, Presyncope, Pyrexia, Rales, Rhonchi, Upper respiratory tract congestion, Visual disturbance

Symptom Text: Patient had multiple "black out" episodes without loss of consciousness. Evaluated by cardiology and neurology without being given a diagnosis. Treated as orthostatic hypotension. First episode 1 1/2 months after 3rd Gardasil. 9/30/08 Reviewed PCP medical records of 12/11/07-5/15/2008. Records reveal patient experienced low grade temp w/cough & congestion x 1 week on 12/11/07. Exam revealed rhonchi/rales & sore throat. Dx w/bronchitis & possible pneumonia. Tx w/antibiotics. RTC 1/22/08, had seen eye surgeon day before due to having trouble w/vision & black out spells. Dx w/near syncope. Referred for EKG/EEG. RTC 5/15/08 w/sore throat, fever, HA x 2 days. Dx w/pharyngitis. 10/7/08 Reviewed hospital lab reports of 2/14-3/4/2008. 10/24/08 Reviewed cardiac consultant records of 5/14- FINAL DX: none provided Records reveal patient experienced recurrent pre syncope attacks w/blackouts since 9/2007. Neuro & ophtho consults had been done & were WNL.

Other Meds: Z pack

Lab Data: Normal brain MRI, Chiori one malformation, normal EKG and Echo, normal EEG. LABS: CBC WNL. Rapid strep (-). MRA circle of Willis WNL.

History: Chiari one malformation PMH: bronchiolitis, vaginitis, pharyngitis, OM. Family hx epilepsy..

Prex Illness: Bronchitis; Afebrile

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325738-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	06-Sep-2008	07-Sep-2008	1	22-Sep-2008	02-Oct-2008	VA		02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye swelling, Rash

Symptom Text: Rash on face, swelling of bilateral eyes

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **325741-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Sep-2008	Unknown		22-Sep-2008	02-Oct-2008	FL		02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB377AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	
	MMR	MERCK & CO. INC.	16700	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2665AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Expired drug administered

Symptom Text: No adverse/reactions, no treatment *Expired hepatitis B vaccine*

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325745-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	11-Sep-2008	11-Sep-2008	0	22-Sep-2008	02-Oct-2008	CA		02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1764U	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Rash

Symptom Text: Client was given HPV and varicella vaccines. Approximately 15 minutes later - Mother described her daughter as "felt dizzy, then fell to her knees". Client was noted to have diffuse pink, flat, pinpoint spots on several areas over arms and upper torso, including but not limited to injection sites. No urticaria or edema noted. Vital signs slight elevated. All symptoms resolved within 30 minutes.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325747-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Nov-2007	15-Sep-2008	313	22-Sep-2008	02-Oct-2008	NH		02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Paraesthesia

Symptom Text: Patient reported at a well visit on 9/15/08 that she has had tingling and skin color change (pale) since her 2nd Gardasil - she also plays volleyball.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **325772-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Aug-2008	18-Aug-2008	7	22-Sep-2008	02-Oct-2008	FL		02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives 1 wk out of shot

Other Meds:

Lab Data:

History: seasonal allergies

Prex Illness: ear lobe irritation from earrings

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325783-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	15-Sep-2008	15-Sep-2008	0	22-Sep-2008	02-Oct-2008	MO		02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Constant headache for 24 hours

Other Meds: Yasmin, Flonase, Claratin

Lab Data: N/A

History: Seasonal Allergies

Prex Illness: None

Prex Vax Illns: 103 degree temperature~HPV (Gardasil)~2~19~In Patient

Vaers Id: **325784-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	18-Sep-2008	18-Sep-2008	0	22-Sep-2008	02-Oct-2008	NY		02-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0279X	2	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB294BA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0788X	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site erythema, Injection site urticaria, Local reaction, Rash macular, Swelling, Urticaria

Symptom Text: On day of vaccination, 9/18/08; immediately post vaccination with varivax to the right arm-deltoid area ; developed redness/ "splotchy: hive like reaction localized to varivax injection site.Patient noted today that 1-2 days later (9/19 - 9/20/08), increased swelling- per mother "like giant hive" and developed hives on that right arm and on back. Seen today 9/22/08 and symptoms have resolved other than localized reaction still around sit of varivax injection. Per mother, much better today than past two days.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325804-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-Sep-2008	12-Sep-2008	1	22-Sep-2008	02-Oct-2008	NJ		02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C2826AA	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2565AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Tenderness

Symptom Text: (+) red, swollen tender about 4x5 cm on (R) arm.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325807-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Sep-2008	22-Sep-2008	0	22-Sep-2008	30-Sep-2008	FL		30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blindness, Dizziness, Vision blurred

Symptom Text: Pt developed blurry vision in (R) eye, loss of vision in (R) eye temporarily. Pt also c/o dizziness 3 min after vaccine.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 325821-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Apr-2008	01-Apr-2008	0	23-Sep-2008	24-Sep-2008	MD	WAES0809USA03000	24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a 16 year old female who in the beginning of April 2008 was vaccinated with the first dose of GARDASIL. It was reported that the patient experienced seizure, no time frame provided, and was hospitalized for a week to 10 days. As of 16-SEP-2008, the outcome was unknown. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: Convulsion~HPV (Gardasil)~1~16~In Sibling

Vaers Id: 325822-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	26-Oct-2007	10-Dec-2007	45	23-Sep-2008	24-Sep-2008	FR	WAES0809USA02790	24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Multiple sclerosis, Paraesthesia, Steroid therapy

Symptom Text: Information has been received from a general practitioner concerning a 20 year old female who was well tolerated with the previous vaccinations (hepatitis A, hepatitis B, typhoidis, meningo) and was in good health when vaccinated with GARDASIL. On 17-AUG-2007 the patient was vaccinated with the first dose of GARDASIL. The patient was well tolerated with the first dose and had no adverse effect. On 26-OCT-2007 the patient was vaccinated with the second dose of GARDASIL (batch number not reported). On 10-DEC-2007 the patient presented with paraesthesia of one arm. She was hospitalized. In January 2008, a magnetic resonance imaging performed showed plaques. The patient was treated with a bolus of corticosteroids. 3 to 4 months later she presented with new manifestations (not described). On 18-JUN-2008 another magnetic resonance imaging performed showed hypersignals. Diagnosis was multiple sclerosis. The patient was treated again with a bolus of corticosteroids. Results of the lumbar puncture were not provided. The patient was also prescribed interferon. At the time of reporting this treatment was on going and the patient had not recovered. Other business partner numbers include E2008-08603. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, ??Jan08, Comment: plaques; magnetic resonance imaging, 18Jun08, Comment: hypersignals - diagnosis was multiple sclerosis

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325823-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Aug-2008	05-Sep-2008	9	23-Sep-2008	24-Sep-2008	FR	WAES0809USA02789	24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Headache, Pyrexia

Symptom Text: Information has been received from a health care professional concerning a 15 year old female with no previous medical history who on 27-AUG-2008 was vaccinated with the first dose of GARDASIL (lot number, route and site of administration unknown). The patient experienced headache, fever and stomach ache and was hospitalized on 05-SEP-2008 until 14-SEP-2008. The results of lab tests showed that cytomegalovirus was negative and viral meningitis was negative. The patient fully recovered. Other business partner numbers include E2008-08644. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, Comment: viral meningitis - negative; cytomegalovirus antigen, Comment: negative

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325824-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	24-Jul-2008	24-Jul-2008	0	23-Sep-2008	25-Sep-2008	NJ	WAES0809USA02639	25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Pharyngitis, Rash, Syncope, Weight increased

Symptom Text: Information has been received from a physician concerning a 23 year old female with a history of endometriosis who on 24-JUL-2008 was vaccinated with the first dose of GARDASIL. Concomitant therapy included ALLEGRA-D and YAZ. The patient developed pharyngitis followed by a rash after receiving her first dose of GARDASIL. The patient was treated by her family physician (not this physician) with steroids. After this treatment the patient experienced weight gain, syncope and possible seizure. The patient was evaluated in an emergency room for syncope and possible seizure. A complete blood cell count (CBC) and blood chemistry panel were performed and the results were within normal limits. At the time of reporting the patient continued to experience some lightheadedness and her weight was still greater than it was prior to receiving GARDASIL. The pharyngitis and rash had been resolved. Upon internal review possible seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: YAZ; ALLEGRA-D

Lab Data: complete blood cell - within normal limits; partial blood chemistry - within normal limits

History: Endometriosis

Prex Illness:

Prex Vax Illns:

Vaers Id: 325825-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Apr-2008	01-Apr-2008	0	23-Sep-2008	24-Sep-2008	MD	WAES0809USA02455	24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a 16 year old female who in the beginning of April 2008 was vaccinated with the first dose of GARDASIL. It was reported that the patient experienced seizure, no time frame provided, and was hospitalized for a week to 10 days. As of 16-SEP-2008, the outcome was unknown. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: Convulsion~HPV (Gardasil)~1~16~In Sibling

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325826-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-Jul-2008	01-Aug-2008	4	23-Sep-2008	25-Sep-2008	FR	WAES0809USA02183	25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Crohns disease

Symptom Text: Information has been received from a physician concerning a 13 year old female who on 29-JAN-2008 was vaccinated with the first dose of GARDASIL IM. On approximately 29-MAR-2008 the patient was vaccinated with the second dose of GARDASIL. On 28-JUL-2008 the patient was vaccinated with the third dose of GARDASIL IM. There was no previous exposure to GARDASIL or related drug. In August 2008 the patient developed Crohn's disease and was hospitalized. The patient was administered cortisone and mesalamine since then. The patient recovered from Crohn's disease. The disease is considered in remission. The reporter felt that Crohn's disease was not related to therapy with GARDASIL. No further information is available.

Other Meds: cortisone; mesalamine

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325827-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Sep-2007	12-Aug-2008	321	23-Sep-2008	24-Sep-2008	IN	WAES0809USA02151	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	2	Unknown	Unknown	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Grand mal convulsion, Myoclonic epilepsy, Neurological examination, Tongue biting

Symptom Text: Information has been received from a physician concerning a 14 year old female who in September 2007, was injected with her third dose of GARDASIL (lot number and site not reported). The patient completed all three doses of GARDASIL last year. The patient now has been experiencing seizures. There is no further information was provided. Upon internal review seizures were considered an other important event. Unspecified medical attention was sought. Additional information has been requested. 12/02/08 Reviewed ER medical records of 08/12/2008. FINAL DX: juvenile myoclonic epilepsy Records reveal patient experienced 2-3 min of generalized tonic-clonic seizure activity & bit her tongue. Neuro consult done. Tx w/antiseizure meds & d/c to home for neuro f/u as outpatient.

Other Meds: Unknown

Lab Data: Unknown LABS: CBC, chemistry WNL. EEG abnormal. Brain MRI WNL.

History: Unknown PMH: seizure at 6 yo & on anticonvulsant x 1 year.

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325828-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	31-Jul-2008	30-Aug-2008	30	23-Sep-2008	24-Sep-2008	NJ	WAES0809USA01576	24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse for the Pregnancy Registry for GARDASIL concerning a 22 year old female who on 31-JUL-2008 was vaccinated with the first dose of GARDASIL (lot# 0250X) I.M. in a deltoid. The patient's pregnancy was terminated on 30-AUG-2008 or 31-AUG-2008. The patient's LMP was 23-JUL-2008 and EDD 29-APR-2009. No adverse symptoms. The lab test performed was urine pregnancy. Upon internal review, the patient's pregnancy was terminated was considered an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: urine beta-human - pregnancy

History:

Prex Illness: Pregnancy NOS (LMP = 7/23/2008)

Prex Vax Illns:

Vaers Id: **325829-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-Feb-2008	Unknown		23-Sep-2008	24-Sep-2008	FR	WAES0802USA06344	24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Complication of pregnancy, Drug exposure during pregnancy, Foetal disorder, Premature labour, Threatened labour

Symptom Text: This is a case of pregnancy follow-up initially reported on 22-Feb-2008 by a general practitioner through the Sanofi Pasteur MSD pregnancy registry. A 14 year old female patient started a spontaneous pregnancy before receiving the first dose of GARDASIL (batch number not reported) on 19-FEB-2008. Beta-human chorionic gonadotropin level was positive 3 days after vaccination. Before vaccination, the patient claimed that she never had sexual relations. Further information is expected. Follow-up information received on 23-Apr-2008 through initial pregnancy follow-up form: Patient's pregnancy was reported as spontaneous. Her last menstrual period date was unknown (estimated to be 18-Nov-2007). Estimated conception date was on 01-Dec-2007. Estimated delivery date was on 26-Aug-2008. She never had a pregnancy before. An echography performed on 28-Feb-2008 defined her term as 15 weeks of amenorrhea. Follow-up information was reported by the general practitioner on 11-SEP-2008: The patient's weight was reported as 38 kg (previously 63 kg). She had no family history of congenital anomaly or genetic issue. No abnormal examinations, no infections or diseases were observed during pregnancy. However the patient experienced complications during her pregnancy, with a threatened premature labour. The foetus had acute foetal distress. Products of conception were examined, however the result was not described. On 06-AUG-2008 the patient gave birth to a baby boy via cesarean section at 37 weeks of amenorrhea. The baby's weight was 2.6 kg, his Apgar score was 9 at 1 and 5 minutes. The baby was found with hydrocephaly. The outcome was not reported. Follow-up information was reported by the physician on 16-SEP-2008: Prenatal ultrasounds were normal. The baby presented with hydrocephaly, cortical atrophy and respiratory distress. He recovered from respiratory distress after one day. The events were reported as other important medical events. Other business partner numbers include E2008-01516 and E2008-08541.

Other Meds: Unknown

Lab Data: ultrasound, 28Feb08, Comment: 15 weeks of amenorrhea; ultrasound, Comment: prenatal ultrasounds: normal; Apgar score, 06Aug01, Comment: 9 at the 1 minutes; Apgar score, 06Aug01, Comment: 9 at the 5 minutes; serum beta-human chorionic gonado

History:

Prex Illness: Pregnancy NOS (LMP = 18Nov07)

Prex Vax Illns:

Vaers Id: **325830-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	08-Nov-2007	16-Dec-2007	38	23-Sep-2008	25-Sep-2008	--	WAES0802USA05591	25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Congenital anomaly, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received from a 25 year old female consumer with allergy to PERCOCET, for the Pregnancy Registry for GARDASIL, who on 08-NOV-2007 was vaccinated with the first 0.5 ml dose of GARDASIL. On 08-JAN-2008 the patient was vaccinated with the second dose of GARDASIL. As of 25-FEB-2008, the patient reported that she was 10 weeks pregnant. The patient reported in follow-up that on 16-SEP-2008 she delivered a healthy 8 pounds 13 ounces boy. The baby had a complete unilateral cleft lip and palate, which was diagnosed prenatally on ultrasound. The patient reported that she was prepared for this finding and she had already scheduled follow-up for the baby for surgery (dates not provided). The patient reported that both she and the baby were doing well, no problems for herself. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound - diagnosed prenatally that the baby had a complete unilateral cleft lip and palate; beta-human chorionic - positive

History:

Prex Illness: Pregnancy NOS (LMP = 12/16/2007); Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325831-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	15-Feb-2008	15-Feb-2008	0	23-Sep-2008	24-Sep-2008	--	WAES0802USA04467	24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a 23 year old female with a shellfish allergy who on 15-FEB-2008 was vaccinated with the first dose of GARDASIL. The patient found out on 19-FEB-2008 that she was pregnant. Her LMP is estimated as 19-JAN-2008. Follow up information has been received from a 23 year old female that reported that in March 2008, she had a miscarriage. She said she was fine now, and doing well. Upon internal review miscarriage was determined to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 1/19/2008); Shellfish allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325843-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	12-Sep-2008	15-Sep-2008	3	23-Sep-2008	30-Sep-2008	IL		30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Haematoma, Injection site bruising, Injection site haematoma, Injection site pain, Injection site swelling

Symptom Text: Pt. had 3 cm raised area at injection site slightly tender to touch, minimal bruising appears to be hematoma.

Other Meds: NUVA RING

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **325847-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	15-Sep-2008	15-Sep-2008	0	23-Sep-2008	24-Sep-2008	IA		24-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Disorientation, Headache, Sensory loss, Vision blurred, Visual disturbance

Symptom Text: Headache and blurred vision including flashes of light around 8:00 pm. Loss of sensation in right hand in conjunction with previous symptoms around 10:00 pm. Slight disorientation as well. Aside from headache, symptoms cleared between 10:20 and 10:30pm.

Other Meds: ortho-tri-cyclen lo

Lab Data:

History: allergy to sulfa

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325852-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	27-Aug-2008	27-Aug-2008	0	23-Sep-2008	30-Sep-2008	IL		01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt. was walking down hallway after receiving the Gardasil vaccine. Pt fainted for about 5 seconds, was conscious and able to answer questions. Pt was guided to floor by a nurse after attended to by RNs and MDs. Pt left ambulatory

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325858-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	24-Apr-2008	25-Apr-2008	1	23-Sep-2008	03-Oct-2008	FL		03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Patient states a rash. Started the day after her 2nd Gardasil injection. Rash on neck down to lower abdomen. States she has not changed detergents/soaps/lotion and denies sun exposure. Patient reported this on 4/29/08.

Other Meds: Ortho Tri-Cyclen W

Lab Data: No

History: N/A

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325880-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Sep-2008	23-Sep-2008	1	23-Sep-2008	03-Oct-2008	MI		03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2644AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0930U	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB244BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives located on arms, neck and trunk. Parents gave oral benadryl and put anti itch cream on hives

Other Meds: Caritin 10mg

Lab Data: None completed

History: allergic rhinitis

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325894-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Sep-2008	19-Sep-2008	3	23-Sep-2008	03-Oct-2008	PA		03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pain, Swelling

Symptom Text: SWELLING, PAINFUL, RED

Other Meds: NO

Lab Data: NONE

History: NO

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325907-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Sep-2008	22-Sep-2008	0	23-Sep-2008	02-Oct-2008	GA		02-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0229X	0	Left leg	Intramuscular	
FLU	SANOFI PASTEUR	U2762AA	3	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB289AP	1	Left arm	Unknown	
TDAP	SANOFI PASTEUR	C2998BA		Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0273X	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Heart rate decreased, Injection site pain, Muscle spasms, Pallor, Syncope

Symptom Text: Cramping at site of HPV vaccine then fainting. Pale, low pulse. Alert by time we entered room less than 1 minute. Able to walk out of office in 10 minutes, alert, good color, good pulse and blood pressure.

Other Meds: Advil

Lab Data: None

History: History asthma

Prex Illness: None - well child check

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325912-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	04-Sep-2008	08-Sep-2008	4	23-Sep-2008	02-Oct-2008	UT		02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2965AA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2669AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0570X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister, Pruritus, Rash papular

Symptom Text: 4 day after HPV #1 Developed itchy arm a 1.5 cm ring of papules with slight blistering arm itching- no rash in center of >1 cm- Fanning gradually over 2 weeks.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **325921-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Dec-2007	01-Feb-2008	62	18-Aug-2008	07-Oct-2008	--	WAES0807USA01350	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea, Fatigue, Pyrexia, Vein disorder, Weight decreased

Symptom Text: Information has been received from a nurse concerning a 17 year old female patient with an allergy to BIAXIN who in June 2007 was vaccinated IM with a first dose of 0.5 mL GARDASIL vaccine (yeast) (lot # 655503/0012U), in August 2007 was vaccinated with a second dose of GARDASIL vaccine (yeast) (lot # 658282/0929U), and in December 2007, was vaccinated with a third dose of GARDASIL vaccine (yeast) (lot # 659055/1522U). There was no concomitant medication. It was reported that the patient experienced weight loss, fever, fatigue, and bulging veins. The patient has had a 20 pound weight loss between March 2008 and May 2008. The patient sought medical attention by phone and office visit. The patient was in the office on 05-MAY-2008 because of a "fever for the past 2 days and off and on diarrhea in February and March 2008. "Laboratory diagnostic studies performed were complete metabolic panel, CBC, sed rate, mono spot, EBV titers, thyroid, and urinalysis. All tests were normal except one of the tests showed patient had "MONO" in the past. Subsequently, the patient recovered on an unknown date. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory - mono spot "had MONO in the past", diagnostic urinalysis - normal, diagnostic laboratory - complete metabolic panel was normal, complete blood cell - normal, Epstein-Barr virus - normal, thyroid function test - normal

History: Allergic reaction to antibiotics

Prex Illness:

Prex Vax Illns:

Vaers Id: **325922-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	17-Jun-2008	Unknown		18-Aug-2008	07-Oct-2008	--	WAES0807USA01351	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy, Muscular weakness, Musculoskeletal pain, Neck mass

Symptom Text: Information has been received from a nurse concerning a 23 year old female patient who in April 2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot # not provided) and on 17-Jun-2008 was vaccinated with a second dose of GARDASIL vaccine (yeast) (lot # not provided). After the second dose the patient developed left arm weakness, pain at the back of the shoulder, swollen glands and a lump on the neck. At the time of reporting, the patient sought medical attention at the office on 07-Jul-2008 for these symptoms. The patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325923-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Jan-2008	01-Mar-2008	60	24-Sep-2008	03-Oct-2008	--	WAES0807USA01357	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Headache, Immune system disorder, Menstruation irregular, Urticaria

Symptom Text: Information has been received from a consumer concerning her 20 year old daughter with allergies to dander, dust and cigarette smoke who on an unspecified date in July 2007, was vaccinated with her first dose of GARDASIL (Lot #, site and route dose of GARDASIL (Lot #, site and route not reported). In the middle of August 2007, the patient was vaccinated with her second dose of GARDASIL (Lot #, site and route not reported). On an unspecified date in January 2008, the patient was vaccinated with her third dose of GARDASIL (Lot #, site and route not reported). Concomitant therapy included montelukast sodium (MSD) and ADVAIR (taken as needed). On an unspecified date, while the patient was in college, she had "blood work done" (not otherwise specified). When the patient came home in May 2008, "she had a complete panel" and the physician told her "her immune system was out of whack". In March 2008, the patient experienced minor hair loss. In May 2008, the patient experienced major hair loss where her hair would "fall out on its own without even having to touch it, when she shakes her head, washing her hair and touching her hair as well". The patient has experienced really bad headaches "Where she cannot move" (not further specified). The patient already had dander allergies, but when they flared up it would come out as a sinus problem, but lately the allergies have come out in the form of hives (not further specified). Her menstrual period was irregular, but now it is back to normal (not further specified). The patient has seen a dermatologist who has her "not washing her hair, increase her protein and is using ROGAINE". The dermatologist gave the patient a B-12 shot, and "now the patient's food intake is being monitored". The patient is going to see her primary care physician. The patient's hair loss has persisted. No further AE information was provided. Additional information has been requested.

Other Meds: ADVAIR; SINGULAIR

Lab Data: diagnostic laboratory, 05/07; hematology

History:

Prex Illness: Allergy to animal dander; House dust allergy; Hypersensitivity; Sinus

Prex Vax Illns:

Vaers Id: **325924-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	07-Jul-2008	07-Jul-2008	0	18-Aug-2008	07-Oct-2008	--	WAES0807USA01365	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a registered nurse concerning a 22 year old female who on 07-JUL-2008 was vaccinated intramuscularly in the left deltoid with her third dose of GARDASIL vaccine (yeast) (Lot # r660555/0279X). No information was provided related to the first and second dose of GARDASIL vaccine (yeast). On 07-JUL-2008 the patient began to feel faint about 15 minutes after the injection. The patient was brought back in the office, given some juice and laid down until she was feeling better. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325925-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Apr-2008	Unknown		18-Aug-2008	07-Oct-2008	PA	WAES0807USA01371	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a nurse concerning a female who in April 2008, was vaccinated with her second dose of GARDASIL vaccine (yeast) (lot# unknown, route and site not reported). Subsequently the patient experienced bumps on her hips. The patient had heard the news media about all the adverse events experienced with GARDASIL vaccine and called the doctor's office to report the bumps on her hips.. The patient's bumps on her hips persisted. No other information was available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325926-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	07-Oct-2008	TX	WAES0807USA01374	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Oedema peripheral

Symptom Text: Information has been received from a health professional concerning a female who was vaccinated on an unspecified on an unspecified date with a dose of GARDASIL vaccine (yeast) (lot# not reported). Subsequently on an unspecified date the patient experienced pain at the injection site and swelling of the arm. The patient's outcome was not reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325927-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	08-Jul-2008	08-Jul-2008	0	18-Aug-2008	07-Oct-2008	CT	WAES0807USA01376	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a nurse concerning a 19 year old female who on 08-JUL-2008 was vaccinated intramuscularly in the left deltoid with her first dose of GARDASIL vaccine (yeast) (lot# 660555/0279X). On 08-JUL-2008 the patient fainted almost immediately after receiving her first dose, The nurse reported that they gave the patient some juice and had her lie down until th symptoms resolved. It was noted that the patient had not eaten much prior to receiving the vaccine. The patient sought unspecified medical attention on an unspecified date and the patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325928-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jul-2007	01-Jul-2007	0	18-Aug-2008	07-Oct-2008	FL	WAES0807USA01392	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Menstruation delayed, Weight increased

Symptom Text: Information has been received from a physician concerning a female who in approximately July 2007 was vaccinated with her first dose of GARDASIL vaccine (yeast) (lot# not reported) and she was late getting her menstrual cycle. Subsequently the patient also gained 30 pounds since getting the vaccine. The patient sought medical attention since getting the vaccine. The patient sought medical attention on an unspecified date with an office visit, The patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325929-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Apr-2008	08-Jun-2008	58	18-Aug-2008	07-Oct-2008	NJ	WAES0807USA01496	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 15 year old female who was vaccinated with a first dose of GARDASIL vaccine (yeast) (date not reported). On 11-APR-2008 the patient was vaccinated with a second dose 0.5 ml dose GARDASIL vaccine (yeast). On 08-JUN-2008, for the past month, the patient has experienced right foot pain and parasthesia. At the time of the report the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325930-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	05-May-2008	05-May-2008	0	18-Aug-2008	08-Oct-2008	--	WAES0807USA01506	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness

Symptom Text: Information has been received from a consumer who on 05-MAY-2008 was vaccinated with the third dose of GARDASIL vaccine (yeast) (Lot number not reported) and experienced flu like symptoms. Consumer declined to provide any additional information. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325931-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	04-Jun-2008	Unknown		18-Aug-2008	08-Oct-2008	NY	WAES0807USA01509	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a healthcare worker concerning a female patient who on approximately 04-JUN-2008 was vaccinated with the third dose of GARDASIL vaccine (yeast) (Lot number not reported) and broke out in hives on an unspecified date. Healthcare worker also states when the patient goes in a cold pool, she breaks out in hives. Patient sought unspecified medical attention by calling physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325932-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	08-Oct-2008	--	WAES0807USA01514	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass

Symptom Text: Information has been received from a physician assistant concerning a female patient who was vaccinated with a dose of GARDASIL vaccine (yeast) (lot # not provided). Subsequently the patient developed a small lump on the arm of the injection site. The patient sought unspecified medical attention. The patient recovered on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325933-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	08-Oct-2008	SC	WAES0807USA01518	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Peroneal nerve palsy

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASSIL vaccine (yeast). Subsequently the patient experienced drop foot. The patient sought unspecified medical attention. At the time of the report the outcome was unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325934-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-May-2008	09-Jun-2008	31	18-Aug-2008	08-Oct-2008	--	WAES0807USA01520	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Emotional disorder, Insomnia, Syncope

Symptom Text: Information has been received from a consumer concerning her 13 year old daughter who on approximately 09-MAY-2008 was vaccinated with her first dose of GARDASIL vaccine (yeast) (lot# not reported). On approximately 09-JUN-2008 the patient experienced a fainting spell 1 month after receiving the vaccine. The mother feels this was due to lack of sleep and also looking at pictures of burn victims in health class. Subsequently, the patient recovered from the fainting spell. No additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325936-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		18-Aug-2008	08-Oct-2008	PA	WAES0807USA01533	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Initial and follow up information has been received from a nurse practitioner (NP) concerning an 17 year old white female student with no known drug allergies who was vaccinated with a first and a second dose of GARDASIL vaccine (yeast). Subsequently, the patient experienced nausea and vomiting respectively. There was no illness at the time of vaccination. Twenty four to forty eight hours after vaccine, the patient recovered from nausea and vomiting. No product quality complaint was involved. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325937-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	08-Oct-2008	--	WAES0807USA01538	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a nurse practitioner concerning a female who on an unspecified date was vaccinated with a second dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). Subsequently the patient developed hives. The patient sought unspecified medical attention. The patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325938-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	07-Jul-2008	08-Jul-2008	1	18-Aug-2008	08-Oct-2008	--	WAES0807USA01541	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash macular, Skin discolouration

Symptom Text: Information has been received from a 22 year old female with allergic reaction to erythromycin who on 07-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot number was not available). Concomitant therapy included hormonal contraceptives (unspecified). On 08-JUL-2008 the patient experienced a rash of brown spots on her hands and arms. The patient's a rash of brown spots on her hands and arm persisted. Medical attention was sought via physician and nurse. No product quality complaint was involved. No further information is available.

Other Meds: hormonal contraceptives

Lab Data: None

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **325939-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Jun-2008	18-Jun-2008	17	18-Aug-2008	08-Oct-2008	VT	WAES0807USA01544	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a 20 year old female with anxiety disorder and a history of papanicolaou smear abnormal and positive for HPV that resolved with no treatment and no drug allergies who in June 2008, was vaccinated with the third dose of GARDASIL vaccine (yeast). Concomitant therapy included PROZAC. On 18-JUN-2008, the patient had a Papanicolaou (PAP) that was positive for HPV. Medical attention was sought via office visit. No product quality complaint was involved. Additional information has been requested.

Other Meds: PROZAC

Lab Data: Pap test - 06/18/08 - positive for HPV

History: Papanicolaou smear abnormal, Papilloma viral infection

Prex Illness: Anxiety disorder

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325940-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-May-2008	01-May-2008	0	18-Aug-2008	08-Oct-2008	PA	WAES0807USA01545	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope vasovagal

Symptom Text: Information has been received from a physician concerning an 18 year old female with no pertinent medical history, drug reactions or allergies who in May 2008, was vaccinated intramuscularly with a first dose of GARDASIL vaccine (yeast). There was no concomitant medication. The patient passed out within 5 minutes of receiving the first dose of GARDASIL vaccine (yeast) at the office. She was sent by ambulance to the hospital and was diagnosed with vasovagal. The patient recovered on the same day. This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325941-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-May-2008	01-May-2008	0	18-Aug-2008	08-Oct-2008	MD	WAES0807USA01556	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a nurse concerning a 21 year old female with no pertinent medical history or history of drug reactions or allergies who in May 2008, was vaccinated intramuscularly with a 0.5 ml dose of GARDASIL vaccine (yeast) (lot no 660389/1968U). Concomitant therapy included LOESTRIN. The nurse reported that the patient was having amenorrhea. The patient's last menstrual period was April 2008. The patient took a few home pregnancy tests and was not pregnant. At the time of this report, the patient's amenorrhea persisted. The patient contacted the office to seek unspecified medical attention. Additional information has been requested.

Other Meds: LOESTRIN

Lab Data: beta-human chorionic - negative

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **325942-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	20-May-2008	Unknown		18-Aug-2008	08-Oct-2008	OH	WAES0807USA01579	18-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site discomfort, Injection site pain

Symptom Text: Information has been received from a registered nurse concerning a female who on 20-MAY-2008 was vaccinated with a 0.5 ml dose of GARDASIL vaccine (yeast) IM into the deltoid (lot number not reported). Concomitant therapy included DEPO-PROVERA. Subsequently the patient experienced pain and discomfort of the vaccinated arm. The patient was seen in the physician's office. The patient's pain and discomfort of the vaccinated arm persisted. Additional information has been requested. This is in follow-up to report(s) previously submitted on 6/14/2008. Information has been received from a registered nurse concerning a female who on 20-MAY-2008 was vaccinated with a 0.5 ml dose of GARDASIL IM into the deltoid (lot number not reported). Concomitant therapy included DEPO-PROVERA. Subsequently the patient experienced pain and discomfort of the vaccinated arm. The patient was seen in the physician's office. The patient's pain and discomfortof the vaccinated arm persisted. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325943-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-May-2008	01-May-2008	0	18-Aug-2008	08-Oct-2008	NJ	WAES0807USA01596	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hepatitis C positive

Symptom Text: Information has been received from a patient's mother concerning a 22 year old female patient with no pertinent medical history and no allergies who in approximately May 2008, was vaccinated with the second dose of GARDASIL vaccine (yeast) 0.5ml IM. There was no concomitant medication. In May 2008, the patient tested hepatitis C positive two weeks after receiving her second dose. The patient sought medical attention, Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory - 05/??/08 - hepatitis C positive

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325944-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		18-Aug-2008	08-Oct-2008	NC	WAES0807USA01602	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female who was vaccinated with GARDASIL vaccine (yeast) 0.5ml IM. Concomitant therapy included hormonal contraceptives (unspecified). The patient developed dizziness since vaccination. The patient had completed the series (dates of vaccination not known at this time). It was not clear at what point in the series that the dizziness began, "but it has been a while". The patient sought medical attention in office. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325945-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	07-Feb-2008	07-Feb-2008	0	18-Aug-2008	08-Oct-2008	TX	WAES0807USA01613	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0929U	0	Unknown	Intramuscular	
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Inappropriate schedule of drug administration, Pallor

Symptom Text: Information has been received from a physician concerning a 12 year old female who on 07-FEB-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 658282/0929U) 0.5ml IM at the same office visit. Concomitant therapy included diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid, MENACTRA vaccine (dip toxoid) and varicella virus vaccine live (MSD). On 07-FEB-2008 the patient experienced pale and weak. Therapy with human papillomavirus vaccine was discontinued. The patient's mother took her to the emergency room. On an unspecified date the patient recovered from pale and weak. Additional information has been requested.

Other Meds: MENACTRA

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325946-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	09-Jul-2008	09-Jul-2008	0	18-Aug-2008	09-Oct-2008	OH	WAES0807USA01618	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Cold sweat, Dizziness, Feeling abnormal, Feeling hot, Pallor, Pulse pressure decreased, Syncope vasovagal

Symptom Text: Information has been received from a certified registered nurse practitioner concerning a 22 year old white female with an allergy to amoxicillin, azithromycin (Zpack) and seasonal allergies and no known illness at time of vaccination who on /1968U), IM, left 09-JUL-2008 at 11:00 AM was vaccinated with first dose of GARDASIL vaccine (yeast) (Lot# 660389/1968U) (Dose not reported). Concomitant therapy included YASMIN. On 09-JUL-2008, the patient received her first dose of GARDASIL vaccine (yeast) and at 11:10 AM she became "light headed, hot, felt funny, stomach ache, cool, pale, clammy skin, faint pulse". The nurse could not get her blood pressure and the office had to call 911 to send her to hospital via squad. Approximately 1 hour later on the same day, the patient called the office back and said she was feeling fine and was released from hospital and that it was a Vaso Vagal reaction. The patient recovered from the Vaso Vagal reaction. Additional information is not expected.

Other Meds: YASMIN

Lab Data: Unknown

History:

Prex Illness: Contraception, Penicillin allergy, Seasonal allergy, Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **325947-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	25-Jun-2008	Unknown		18-Aug-2008	09-Oct-2008	--	WAES0807USA01632	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a registered nurse concerning a female who on approximately 25-JUN-2008, also reported as within the past two weeks, was vaccinated with a first dose of GARDASIL vaccine (yeast) by intramuscular injection (lot number and injection site not reported). Subsequently the patient developed hives that she gets off and on. Unspecified medical attention was sought. The patient's hives persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325948-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	09-Oct-2008	LA	WAES0807USA01633	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). A couple days after vaccination the patient fainted. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325949-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		18-Aug-2008	09-Oct-2008	NY	WAES0807USA01635	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oral contraception, Skin papilloma

Symptom Text: Information has been received from a consumer concerning her daughter, a 25 year old female with no known drug reactions/allergies and a history of migraine who in 2007 was vaccinated with a total of three 0.5 ml doses of GARDASIL vaccine (yeast) (exact time of each dose not reported). Concomitant therapy included birth control pills. In 2008, a "couple months ago" the patient experienced wart like growths on her fingers. Biopsy was done and no result was provided. The patient's wart like growths persisted. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Migraine

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325950-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	09-Oct-2008	--	WAES0807USA01640	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Vomiting

Symptom Text: Information has been received from a nurse concerning her daughter, a female patient who on an unspecified date was vaccinated with a second dose of GARDASIL vaccine (yeast) (route and administrating site not reported). The patient experienced terrible vomiting and diarrhea. The physician mentioned that it could have been the flu that was going around. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325951-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Apr-2008	24-Jun-2008	84	18-Aug-2008	09-Oct-2008	LA	WAES0807USA01647	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Gastroenteritis, Nausea, Neck pain, Vomiting

Symptom Text: Information has been received from a physician concerning a 16 year old female with a history of rheumatoid arthritis who on 21-SEP-2007 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot# 656372/0243U) (route and administrating site not reported), and a dose of MENACTRA vaccine (dip toxoid). On 21-NOV-2007 the patient was vaccinated with a second dose of GARDASIL vaccine (yeast) (lot# 657737/0522U) (route and administrating site not reported). On 05-DEC-2007 the patient had to see a rheumatologist for neck and hip pain. On 01-APR-2008 the patient was vaccinated with a third dose of GARDASIL vaccine (yeast) (lot# 659962/1740U) (route and administrating site not reported) and after that the patient experienced nausea and vomiting and was diagnosed with gastroenteritis. On 24-JUN-2008 the patient started experiencing abdominal pain and was referred to another physician who prescribed omeprazole (MSD) which did not help and switched to REGLAN. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Rheumatoid arthritis

Prex Illness:

Prex Vax Illns:

Vaers Id: **325952-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	09-Oct-2008	--	WAES0807USA01654	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from a health department coordinator concerning a female who was vaccinated with a dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). Subsequently the patient experienced tingling and numbness in the arm. The patient sought unspecified medical attention. Subsequently, the patient recovered from tingling and numbness in the arm. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325957-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	01-May-2007	01-Jul-2007	61	24-Sep-2008	25-Sep-2008	--	WAES0809USA02640	25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Convulsion, Nervous system disorder, Pyrexia, Rash, Renal failure, Speech disorder, Systemic lupus erythematosus

Symptom Text: Information has been received from a physician concerning a 10 year old female with CYTOXAN allergy who in May 2007 was vaccinated with the first dose of GARDASIL. In July or August of 2007, the patient was vaccinated with the second dose of GARDASIL. There was no concomitant medication. The patient has not yet received the third dose. The patient first experienced high fever and rash in July 2007. The patient was diagnosed with lupus. She then progressed to having seizures and kidney insufficiency. The patient lost all neurological functions including the ability to walk and talk considered to be disabling. She was hospitalized from 23-NOV-2007 to 30-JAN-2008 until there was some improvement. The patient was given oxygen while in the hospital. The patient still can not walk but able to recover her speech. The patient was considered to be recovering from lupus, seizures and renal insufficiency. Seizures were considered to be immediately life-threatening. Lupus, seizures, loss of ability to walk and talk and kidney insufficiency were considered to be an other important medical events and disabling by the physician. Additional information has been requested.

Other Meds: None

Lab Data: lupus anticoagulant, 07?/??/08, positive

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: 325958-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Sep-2007	13-Sep-2007	7	24-Sep-2008	25-Sep-2008	IL	WAES0809USA02424	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Daydreaming, Ear pain, Epilepsy, Fatigue, Feeling abnormal, Grand mal convulsion, Headache, Loss of consciousness, Memory impairment, Mental status changes, Paraesthesia, Thinking abnormal, Tongue biting

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with allergy to DPT and pertussis shot, and no pertinent medical history who on 21-JUN-2007 was vaccinated with the first dose of GARDASIL. On 06-SEP-2007, the patient received the second dose of GARDASIL and within a week later, approximately on 13-SEP-2007, she started to feel like she's not herself and she felt tired all the time. Patient's mother reported that she feels like she was in a cloud and she has been day dreaming. Patient was brought to her family doctor and had a cat scan, blood test and sleep study and it was determined that she had seizures activity. Patient is currently on seizures medication and the symptoms started to improve. Third dose of GARDASIL was given on 03-JAN-2008. Lot numbers were not available. There was no concomitant medication. Upon internal review, seizures activity was considered to be an other important medical event. Additional information has been requested. 10/1/08 Reviewed PCP medical records of 12/27/07-8/28/08 which include Neuro consult of 1/21/08 FINAL DX: epilepsy Records reveal patient experienced black out spells often after a nap, pain behind left ear, tingling in head & becomes briefly unaware w/different thinking & forgetfulness when resolves. Referred to Neuro for altered mental status & possible seizures. Had generalized tonic-clonic seizure & bit tongue 4/2008. Neuro consult 1/21/08

Other Meds: None

Lab Data: computed axial, seizures activity; sleep study, seizures activity; diagnostic laboratory, blood test LABS: sleep study WNL. EEG abnormal. CT head WNL. CBC & chemistry WNL. GTT abnormal.

History: PMH: mild acne, enlarged tonsils, loud snoring. Vaccine reaction @ 5 mo w/allergy to DPT.

Prex Illness: Allergy to vaccine

Prex Vax Illns:

Vaers Id: **325959-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	06-Aug-2008	06-Aug-2008	0	24-Sep-2008	25-Sep-2008	--	WAES0809USA02628	01-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Convulsion

Symptom Text: Information has been received from a 23 year old female with possible penicillin allergy who on approximately 06-AUG-2008 (about six weeks ago) was vaccinated with the second dose of GARDASIL. There was no concomitant medication. The patient reported that since second dose was given on approximately 06-AUG-2008, she had 3 cases of seizures (last episode happened about a week ago, approximately 10-SEP-2008). She mentioned that she only had one incident of seizure activity prior to GARDASIL. The patient stated that she also was experiencing joint pain in her hip as well. At time of reporting, the patient had not recovered. Laboratory tests and studies performed included electroencephalography, cat scan and blood work with unknown results. The patient sought unspecified medical attention. Upon internal review, episodes of seizures were considered to be other important medical events. Additional information is not expected.

Other Meds: None

Lab Data: electroencephalography; computed axial; diagnostic laboratory, blood work

History:

Prex Illness: Penicillin allergy; Convulsion

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325960-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Sep-2008	16-Sep-2008	0	24-Sep-2008	25-Sep-2008	MD	WAES0809USA02684	25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 13 year old female who on 16-SEP-2008 was vaccinated intramuscularly with the 0.5 ml third dose of GARDASIL. Three hours after the vaccination, the patient fainted and possibly had a seizure. At the time of the report, the patient was recovering from the symptoms. The patient was seen by the physician. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325961-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		24-Sep-2008	25-Sep-2008	PA	WAES0809USA03241	25-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Malaise

Symptom Text: Information has been received from a physician concerning a female patient who on an unknown date, was vaccinated with her first dose of GARDASIL and after vaccination had to go to the hospital (duration not specified). On an unknown date, was vaccinated with her second dose of GARDASIL and became sick. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 325965-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-May-2007	14-Jun-2008	408	24-Sep-2008	29-Sep-2008	--		15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0962F	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Autoimmune hepatitis, Coagulopathy, Encephalopathy, Fluid overload, Hepatic failure, Injection site pain, Jaundice, Ocular icterus, Oedema peripheral, Peripheral vascular disorder, Portal hypertension, Splenomegaly

Symptom Text: Last year in January 2007 my child was given the H.P.V vaccine and after the 1st dose, her legs and feet started swelling up. I took her to the doctor and they said that she had a problem with her Blood Circulating and they gave her a script for some Peg Hoes Stocking to help support her Blood to circulate. She also had pain at the injection site too. Well her legs swelled up a total of three time's last year and I also took her to our physician and they ran blood work and they gave us the same answer as the Emergency Room When took her. My child got all Three doses of the H.P.V Vaccine. Her last Dose was in 08-10-07 and this year in June of 2008 her feet and legs swelled up again and they diagnosed her with Liver Failure caused by a very rare disease called Autoimmune Hepatitis. 10/6/08-records received-presented to liver transplant clinic on 7/15/08-History ESLD and autoimmune hepatitis. Hospitalized 6/24-6/25/08 for coagulopathy and volume overload at which time diagnosed with autoimmune hepatitis type 1, cirrhosis and EBV hepatitis, portal hypertension. Lower extremity edema, jaundice and encephalopathy. Over past year or two has had some lower extremity edema and some significant fatigue. PE: scleral icterus, abdomen obese, splenomegaly.

Other Meds:

Lab Data: 10/6/08-records received-Liver panel elevated.

History: 10/6/08-records received-PMH:end stage liver disease secondary to autoimmune hepatitis and EBV hepatitis. Increasing fatigue and weight gain over last several years, leg swelling and yellowing of eyes.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325966-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	08-Sep-2008	08-Sep-2008	0	24-Sep-2008	06-Oct-2008	NC	NC08099	06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Pain in extremity

Symptom Text: Received telephone call from patient's mother 4:30 pm 9/08/08. Reports patient received #3 HPV injection this am at 8:30 am - since receiving injection, patient with complaints of feeling "light headed, dizzy and tired". Also complaints of pain to arm - Enc M.D. follow up: immediately.

Other Meds: Unknown

Lab Data: N/A

History: Gallbladder surgery 3 months

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325969-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Feb-2008	16-Feb-2008	3	18-Aug-2008	09-Oct-2008	CT	WAES0807USA01660	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Rash, Urticaria

Symptom Text: Information has been received from a health professional concerning a 17 year old female who on 13-FEB-2008 was vaccinated with a dose of GARDASIL vaccine (yeast) 0.5 ml in her left deltoid (lot# 655327/1287U0. Concomitant therapy included CELEXA and minocycline. On approximately 16-FEB-2008 the patient experienced dizziness and was taken by ambulance to the emergency room. It was unspecified if the patient was admitted to the hospital or just treated and released by the emergency room. It was determined in the emergency room that the patient had a "probable allergic reaction" to GARDASIL vaccine (yeast), which also included a rash and hives. The patient was treated with BENADRYL. Additional information has been requested.

Other Meds: CELEXA, minocycline

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325970-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	08-Jul-2008	08-Jul-2008	0	15-Aug-2008	30-Sep-2008	NY	WAES0807USA01675	30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pain, Rash

Symptom Text: Information has been received from a physician concerning a 14 year old female with no pertinent medical history and no history of drug reactions or allergies who on 08-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine. There was no concomitant medication. Subsequently, the patient had nausea and aches overnight and then developed a bilateral rash from her knees down to her feet. The physician stated there was no fever and the rash was fading on the day of the report. It was unspecified if the patient sought medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325971-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	25-Jun-2008	25-Jun-2008	0	18-Aug-2008	09-Oct-2008	OH	WAES0807USA01676	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning a 26 year old female who on approximately 25-JUN-2008 was vaccinated with a dose of GARDASIL vaccine (yeast). After receiving GARDASIL vaccine (yeast), the patient left the office and went to work. It was reported that on approximately 25-JUN-2008 the patient was on her feet all night at work, had an alcoholic beverage after work and when she was going home that night she had felt dizzy. The dizziness had lasted until the morning and got better on her own. Unspecified medical attention was sought. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325972-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Mar-2008	04-Mar-2008	0	18-Aug-2008	09-Oct-2008	TX	WAES0807USA01677	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1459U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 04-MAR-2008 was vaccinated intramuscularly with a first 0.5 ml dose of GARDASIL (Lot#655670/1459U). Concomitant therapy included hepatitis B virus vaccine (manufacture unknown). On 04-MAR-2008, after receiving GARDASIL, the patient fainted. EPIPEN was used to revive the patient. Subsequently, the patient recovered from the event. The patient decided to discontinue the dosing schedule of GARDASIL. The reporting physician considered syncope to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325973-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Jun-2008	03-Jun-2008	0	18-Aug-2008	09-Oct-2008	TX	WAES0807USA01681	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Pallor, Vomiting

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 03-JUN-2008 was vaccinated with a first 0.5 ml dose of GARDASIL vaccine (yeast) (lot number 659180/1758U) (injection site and route not reported). On the same day of vaccination the patient became pale, weak and vomited when she went to her car from the office. She did not faint or become dizzy. The patient was seen in the office. Subsequently, the patient recovered from the events. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325974-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	10-Jul-2008	10-Jul-2008	0	18-Aug-2008	09-Oct-2008	FL	WAES0807USA01766	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event

Symptom Text: Information has been received from a licensed practical nurse concerning a 23 year old female who on 07-MAY-2008 was vaccinated with her first dose of GARDASIL vaccine (yeast) (Lot# 659964/1978U) and on 10-JUL-2008 was vaccinated with her second dose of GARDASIL vaccine (yeast) (Lot# 660391/0063X). There was no concomitant medication. On 10-JUL-2008 the nurse reported that the patient was presenting with an abnormal tuberculosis test (TB).The nurse states that the TB test had a ring around the puncture. The TB test was conducted 2 days ago but the results were read today. At the time of reporting the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: tuberculin skin test - 07/08/08 - abnormal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 325975-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jul-2008	02-Jul-2008	0	18-Aug-2008	09-Oct-2008	IN	WAES0807USA01770	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Contraception, Fatigue, Nausea, Vaccine positive rechallenge

Symptom Text: Information has been received from a mother concerning her 17 year old daughter who with an allergy to "Zithromax", on 02-JUL-2008 was vaccinated with her third dose of GARDASIL vaccine (yeast) (Lot# not reported). Concomitant therapy included hormonal contraceptives (unspecified). The mother reported that the patient was always tired after receiving the first and second doses of GARDASIL vaccine (yeast) (Lot# not reported). On 02-JUL-2008 reported as "within a day or so" the patient experienced tiredness, nausea and chills. At the time of reporting, the patient had not recovered. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **325976-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	09-Oct-2008	PA	WAES0807USA01780	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: Information has been received from a physician concerning a female who was vaccinated intramuscularly with her first dose of GARDASIL vaccine (yeast) (Lot# not reported). The patient fainted 10 minutes after the first dose. It was reported that the patient hit her head "pretty hard" and stayed in the office until recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325977-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		18-Aug-2008	14-Oct-2008	--	WAES0807USA01784	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning to his 14 year old niece with peanut and other allergies as well (unspecified) who was vaccinated with GARDASIL. Subsequently the patient experienced hives that last for weeks after vaccination. The patient was also given other unspecified vaccines at that time. The patient was now recovered. Additional information is not expected.

Other Meds: [therapy unspecified]

Lab Data: Unknown

History:

Prex Illness: Peanut allergy; Hypersensitivity

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325978-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jul-2008	01-Jul-2008	0	18-Aug-2008	09-Oct-2008	CT	WAES0807USA01789	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a patient female who in July 2008 was vaccinated with GARDASIL vaccine (yeast) 0.5ml IM. The physician reported that the patient fainted "last week" in July 2008 after receiving GARDASIL vaccine (yeast). The patient sought medical attention, she was seen in the physician office. ("AE occurred in the office"). There was no product quality complaint. No lab diagnostics were performed. On unspecified date the patient recovered. Additional information has been requested. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325979-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Jul-2008	11-Jul-2008	0	18-Aug-2008	14-Oct-2008	CT	WAES0807USA01792	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Haematoma, Head injury, Immediate post-injection reaction, Nausea, Syncope, Tenderness, Vomiting

Symptom Text: Initial and follow-up information has been received from a physician concerning a 15 year old female who on 11-JUL-2008, was vaccinated with a third dose 0.5ml of GARDASIL (lot# 660393/0067X) intramuscularly in the left arm. On 11-JUL-2008 the physician reported the patient fainted approximately 3 minutes after receiving GARDASIL at the physician's office. The patient hit her head. The patient was also dizzy, nauseous and began vomiting. The patient was sent to the emergency room. On 11-JUL-2008 the patient was recovered. Medical records were received. A 15 year old female who was sent to the emergency room by her pediatrician's office for evaluation of a head injury, status post a brief syncopal event after receiving her third GARDASIL injection in the office. The patient stated she received a third GARDASIL injection in the office and approximately 30 seconds later, she had a witnessed syncopal event for a "couple of seconds". Her mom and her sister were there, as well as the pediatrician staff. The patient struck the back of her head on the floor below and since that time, vomited once and had been extremely dizzy and complained. The patient denied any history of previous head injury or concussion. There was no abrasion or laceration noted to the scalp. The incident occurred approximately 30 minutes to 45 minutes prior to arrival in the emergency department. A physical examination was performed and the vital signs were stable and the patient was afebrile. The patient appeared nontoxic in no extremis. The patient's head revealed a mild posterior scalp hematoma with tenderness to palpation in the occipital region. A CT scan was performed of the head and was negative for acute pathology per the radiologist's interpretation. The emergency room physician reported "given the fact that this did occur directly after an injection this might be vasovagal in nature". This was discussed with the patient and her mother and no further diagnostic work-up was indicated at the time. The patient was discharg

Other Meds: Unknown

Lab Data: physical examination, 07/11/2008, see narrative; computed axial, 07/11/2008, negative; vital sign, 07/11/2008, stable, afebrile

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325980-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Jul-2008	10-Jul-2008	0	18-Aug-2008	13-Oct-2008	CO	WAES0807USA01806	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness, Suture insertion, Syncope, Wound

Symptom Text: Information has been received from a registered nurse, a physician and a certified medical; assistant concerning a 15 year old female who in July 2007, was vaccinated intramuscularly with a first dose, of GARDASIL vaccine (yeast) (lot # not reported). On 10-JUL-2008 the patient received meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA) first; then she received a second dose of GARDASIL vaccine (yeast) 0.5mL intramuscularly (lot # 659964/1978U), and lastly she received varicella virus vaccine live (VARIVAX) (MSD). The patient fainted after the injections. The patient was talking when she passed out, fell and hit her chin on the side of the exam table. She required 8 stitches that were completed in the physician's office. The patient returned to the office in about 1-2 hours and the physician stated "she was fine and smiling". The registered nurse considered stitches in chin to be an other important medial event but the physician and the medical assistant did not consider it to be an other important medical event. No additional information was available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325981-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		18-Aug-2008	13-Oct-2008	--	WAES0807USA01807	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Information has been received from a office administrator concerning her daughter, a 20 year old female who on an unknown date, was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # not available). The patient experienced dizziness and nausea the same day after receiving GARDASIL vaccine (yeast). The patient did not seek medical attention. Patient recovered the following day. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325982-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	08-Jul-2008	08-Jul-2008	0	18-Aug-2008	13-Oct-2008	--	WAES0807USA01811	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a 26 year old female who on an unknown date was vaccinated with the first dose of GARDASIL vaccine (yeast) and on 08-JUL-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast), 0.5 mL, IM. On 08-JUL-2008, the patient fainted after receiving the second dose of GARDASIL vaccine (yeast). On 08-JUL-2008, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325983-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	10-Jul-2008	10-Jul-2008	0	18-Aug-2008	13-Oct-2008	--	WAES0807USA01824	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, Syncope

Symptom Text: Information has been received from the mother of a 12 year old female patient, who on 07-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). On 10-JUL-2008, the patient received the second dose of GARDASIL vaccine (yeast). The consumer reported that about three minutes after receiving the second dose of GARDASIL vaccine (yeast), her daughter felt nauseous and fainted. About 15 minutes later she came to and went home. The consumer reported that when her daughter got home she laid down for about an hour and she was doing better. The consumer also reported that her daughter did eat breakfast that morning before getting GARDASIL vaccine (yeast). The patient sought unspecified medical attention. At the time of the report the patient was recovering. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325984-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		18-Aug-2008	13-Oct-2008	--	WAES0807USA01840	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaccine positive rechallenge, Weight increased

Symptom Text: Information has been received from a mother concerning her 21 year old daughter who on unknown dates was vaccinated with the first and second doses of GARDASIL vaccine (yeast). The patient's mother reported that her daughter gained 20 pounds after her 1st and 2nd doses of GARDASIL vaccine (yeast). It is unknown if the patient sought medical attention. Caller did not have time to fill out an AE report and will call back. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325985-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		18-Aug-2008	13-Oct-2008	--	WAES0807USA01845	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 12 or 13 year old female who was vaccinated with GARDASIL vaccine (yeast). At the same time, the patient was vaccinated with hepatitis A virus vaccine inactivated (manufacturer unknown) and meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA) as GARDASIL vaccine (yeast). The physician reported that the patient had a fainted from a dose of GARDASIL vaccine (yeast). The patient was fine in a few seconds. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325986-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	13-Oct-2008	--	WAES0807USA01868	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Headache, Heart rate increased

Symptom Text: Information has been received from a consumer concerning her daughter who was vaccinated with GARDASIL vaccine (yeast). The patient's mother reported that her daughter. Subsequently she experienced shortness of breath, rapid heart beat, dizziness and headaches. Outcome was not reported. Additional information is not expedited.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325987-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jul-2007	01-Jul-2007	0	18-Aug-2008	13-Oct-2008	FL	WAES0807USA01869	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a physician concerning a female who in approximately July 2007 was vaccinated with her first dose of GARDASIL vaccine (yeast) (lot# not reported) and she was late getting her menstrual cycle. The patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325988-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	26-Jun-2008	30-Jun-2008	4	18-Aug-2008	13-Oct-2008	NJ	WAES0807USA01872	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Rash papular, Urticaria

Symptom Text: Information has been received from a nurse concerning a 22 year old female patient with penicillin, amoxicillin and erythromycin allergies who on 26-JUN-2008 was vaccinated with GARDASIL vaccine (yeast) (Lot # 660553/0070X), 0.5 mL, IM. On 30-JUN-2008, the patient developed "red welts" on her abdominal and trunk area. On 10-JUL-2008, the patient had dry, small raised, red bumps on her abdominal area and upper back. The patient was recovering from "red welts" on her abdominal and trunk area and dry, small raised, red bumps on her abdominal area and upper back. The patient sought medical attention at the physician's office. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy, Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **325989-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Nov-2007	01-Apr-2008	140	18-Aug-2008	13-Oct-2008	--	WAES0807USA01904	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Headache, Hypoaesthesia, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 13-NOV-2007 was vaccinated with the first dose of GARDASIL vaccine (yeast) (Lot # 659180/1758U, route and site of administration not reported) and on 11-APR-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast) (Lot # 659435/1265U, route and site of administration not reported). The physician reported that the patient had numbness in her top right foot, headaches and severe abdominal pain with her first and second doses of GARDASIL vaccine (yeast). She will not receive dose 3. She reported this to the physician on 08-JUL-2008 after her mom saw "news reports of GARDASIL vaccine (yeast) problems." No additional AE information reported. At the time of the report, it was unknown if the patient had recovered from the numbness in her top right foot, headaches and severe abdominal pain. The patient sought medical attention, was seen by physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **325990-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	13-Oct-2008	TX	WAES0807USA01906	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Oedema peripheral

Symptom Text: Information has been received from a health professional concerning a female who was vaccinated on an unspecified date with a dose of GARDASIL vaccine (yeast) (lot# not reported). Subsequently on an unspecified date the patient experienced pain at the injection site and swelling of the arm. The patient's outcome was not reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325991-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	13-Oct-2008	TX	WAES0807USA01907	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Oedema peripheral

Symptom Text: Information has been received from a health professional concerning a female who was vaccinated on an unspecified date with a dose of GARDASIL vaccine (yeast) (lot# not reported). Subsequently on an unspecified date the patient experienced pain at the injection site and swelling of the arm. The patient's outcome was not reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325992-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-May-2008	02-May-2008	1	18-Aug-2008	13-Oct-2008	PA	WAES0807USA01949	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning a female with no pertinent medical history, drug reactions or allergies who in a late afternoon of May 2008, was vaccinated intramuscularly with a first dose of GARDASIL vaccine (yeast). There was no concomitant medication. The next morning after the vaccination, the patient felt dizzy and faint like. On the same day the patient recovered. The patient sought medical attention by contacting office. This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **325993-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Jul-2008	03-Jul-2008	0	18-Aug-2008	13-Oct-2008	PA	WAES0807USA02112	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness

Symptom Text: Initial and follow-up information has been received from a physician concerning a 16 year old white, 119 pound, 65 inch, female with pertinent medical history reported as none, with no illness at time of vaccination, except complaints of hunger, who on 03-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 660389/1968U), 0.5 ml. It was reported that immediately when the needle was withdrawn the patient passed out. She was caught by the physician, her feet were elevated, cool compresses were applied, and smelling salts were used. The event lasted 15-30 seconds. After a "T & R" popsicle she was observed for 20 minutes and had no further sequelae. The patient was reported as recovered on 03-JUL-2008. This is one of two patients from the same source. No additional information is expected.

Other Meds: Unknown

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **325994-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		18-Aug-2008	13-Oct-2008	PA	WAES0807USA02140	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with GARDASIL vaccine (yeast) (Lot# not reported). The patient fainted. It was reported that the patient recovered with no problems. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **325995-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Jul-2008	11-Jul-2008	0	18-Aug-2008	13-Oct-2008	CT	WAES0807USA02148	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Gaze palsy, Head injury, Vomiting

Symptom Text: Information has been received from a nurse concerning a 15 year old female with a history of vasovagal reaction who on 11-JUL-2008 was vaccinated with the third dose of GARDASIL vaccine (yeast). On 11-JUL-2008 "within the last hour" the patient fell down and hit her head at the front of the office. The patient was vomiting and her eyes rolled back. The patient was sent to emergency room. It was unknown if the patient had any problems with the first dose or the second dose of GARDASIL vaccine (yeast). The patient's outcome was unknown. Patient sought medical attention in the office and emergency room. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Vasovagal reaction

Prex Illness:

Prex Vax Illns:

Vaers Id: **325996-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	16-Oct-2007	Unknown		18-Aug-2008	13-Oct-2008	NY	WAES0807USA02150	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Heart rate decreased, Muscular weakness, Myalgia, Paraesthesia, Syncope, Urticaria

Symptom Text: Information has been received from a physician concerning a 25 year old female who on 14-AUG-2007 was vaccinated with the first dose of GARDASIL vaccine (yeast). On 16-OCT-2007 the patient was vaccinated with the second dose of GARDASIL vaccine (yeast) and on 19-FEB-2008 was vaccinated with the third dose of GARDASIL vaccine (yeast). Between the second dose and the third dose, the patient had a decrease in pulse, fainting spells, hives, tingling in her fingers, and aches and weakness in her muscles. A "whole workup" was done and no result was provided. The patient's symptoms persisted. The patient sought medical attention in the physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326001-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Sep-2007	08-Sep-2007	0	24-Sep-2008	06-Oct-2008	AL	AL0824	06-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB223AA	0	Left arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB529AA	1	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1448U	1	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2567AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Chills, Feeling hot, Neck pain, Pain in extremity

Symptom Text: Pt. o.k. at Family planning appt. Immunizations below given with problems. Patient called 9/10/08 c/o joints hurting, rt.elbow, lt.knee, rt. foot & neck. Advised try advil and better that pm to 9/11/08 am. Pt. states thinks had fever night of 9/08/08 some shivers but none since. Better today 9/11/08

Other Meds: none

Lab Data: None

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326013-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	31-Jul-2008	31-Jul-2008	0	24-Sep-2008	06-Oct-2008	MA		07-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Headache, Hypoaesthesia facial, Immediate post-injection reaction, Malaise, Menorrhagia, Muscle twitching, Musculoskeletal pain, Neck pain, Thyroid neoplasm, Vaccine positive rechallenge

Symptom Text: About 4 weeks after receiving 2nd Gardasil shot, had sudden periods of severe dizziness, extreme fatigue, and malaise followed by muscle twitches and headaches. All blood tests, chest x-ray and head MRI came back normal. Immediately after 3rd Gardasil shot, experienced facial numbness for 10 hrs. Also experienced recurring periods of dizziness, fatigue, and malaise with continued muscle twitches. Blood tests continue to be normal. Affects seemed to improve about 1.5 months after 3rd shot, but relapse of symptoms occurred within 2 weeks and symptoms persist. Only treatment so far is vestibular physical therapy to try and relieve dizziness. 1/6/09-records received-office visit 7/31/08-C/O hypertension, bruit thyroid gland. Seen on 8/24/08 C/O 2 weeks of intermittent neck and bilateral shoulder pain. 9/4/08-Last few month C/O heavy menstrual cycles. 11/11/08-Continues to C/O heavy period. assessment menorrhagia.

Other Meds: None

Lab Data: Blood tests such as BMP and CBC are all normal. Chest x-ray and head MRI are normal. 1/6/09-records received-Pelvic US normal-

History: Mild hypertension 1/6/09-records received-Six year history of hypertension possibley mild renal artery stenosis. Five years ago had shortness of breath, headache and abdominal pain.

Prex Illness: None

Prex Vax Illns: About 4 weeks after receiving 2nd Gardasil shot, had sudden periods of severe dizziness, extreme fatigue, and malaise followed b

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326019-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	02-Apr-2008	04-Apr-2008	2	25-Sep-2008	30-Sep-2008	CA		30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	1	Left arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Epilepsy, Grand mal convulsion, Partial seizures, Vaccine positive rechallenge

Symptom Text: Two days after first vaccination, experienced first grand mal seizure. Second HPV vaccine two months later, second grand mal seizure within 4 days after vacinnation. Since the second vaccine and seizure, two more grand mal seizures and several partial seizures. At least 4 ER visits via ambulance due to seizures. Abnormal MRI. Course of anti-seizure medication begun. Currently being followed by neurologist. Diagnosis of epilepsy. No prior history of epilepsy or seizures. No family history of epilepsy.

Other Meds: Advair, Loestrin

Lab Data: EEG, Two MRI's, Numerous Doctor's Visits, Emergency Room Visits, Laboratory Tests.

History: Asthma,controlled with medication

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326031-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	02-Jul-2008	02-Jul-2008	0	24-Sep-2008	06-Oct-2008	GA		06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea

Symptom Text: Nausea

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326050-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Jul-2007	01-Oct-2007	92	18-Aug-2008	13-Oct-2008	IL	WAES0807USA02523	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information has been received from a consumer concerning her daughter with a history of attention deficit/hyperactivity disorder and no drug reactions/allergies who in July 2007 and in January 2008, was vaccinated with first and third doses, respectively, of GARDASIL vaccine (yeast) (lot#s unspecified). Concomitant therapy included CONCERTA. Date and lot # of the second dose was unspecified. It was reported that in October 2007, the patient developed warts on her hands and fingers. It was also reported that the warts were treated and disappeared, but returned four times worse in March 2008. Unspecified medical attention was sought. At the time of this report, the patient's warts persisted. Additional information has been requested.

Other Meds: Concerta

Lab Data:

History:

Prex Illness: Attention deficit/hyperactivity disorder

Prex Vax Illns:

Vaers Id: **326051-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-May-2008	Unknown		18-Aug-2008	13-Oct-2008	--	WAES0807USA02528	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymph node pain

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female who on 13-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot not reported). Subsequently the patient experienced tenderness near her inguinal lymph nodes. On 14-JUL-2008 the patient was vaccinated with the second dose of GARDASIL vaccine (yeast) (lot not reported). On an unspecified date, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: hematology - results not provided

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326052-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	07-Jul-2008	07-Jul-2008	0	18-Aug-2008	13-Oct-2008	GA	WAES0807USA02537	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Information has been received from a practice manager concerning a 20 year old female who on approximately 07-JUL-2008 (reported as "last week") was vaccinated intramuscularly with first 0.5 ml dose of GARDASIL vaccine (yeast) (lot# unspecified). It was reported that the patient has been experiencing nausea and vomiting and that the symptoms lasted through the weekend and up to and including today, 14-Jul-2008. Unspecified medical attention was sought. It was reported that the physician will be prescribing a suppository (unspecified brand) for her symptoms. No other details. At the time of this report the patient's nausea and vomiting persisted. No other details available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326053-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	14-Oct-2008	--	WAES0807USA02541	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a female who on unspecified dates was vaccinated with first and second doses, respectively, of GARDASIL vaccine (yeast) (lot#s not reported). Nurse reported that the patient fainted shortly after receiving her second dose of GARDASIL vaccine (yeast). Nurse reported that she gave the patient something to drink and then the patient "was fine". It was also reported that the patient had not eaten anything for several hours prior to her office visit. Unspecified medical attention was sought. No further information was provided. Additional information is not expected.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326054-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	12-Jun-2008	12-Jun-2008	0	18-Aug-2008	14-Oct-2008	--	WAES0807USA02542	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Stress, Weight decreased, Wrong drug administered

Symptom Text: Initial and follow up information has been received from consumer, a 19 year old pregnant female, and her aunt, for the Pregnancy Registry for GARDASIL vaccine (yeast), who on 12-JUN-2008 was vaccinated (route unknown) "by accident" with the first 0.5 mL dose of GARDASIL vaccine (yeast) (Lot # unknown). No medical history and or drug reaction/allergies were reported. It was reported that the patient was supposed to receive an unknown vaccine for "negative blood". The patients LMP was reported as "18-MAR-2008". The aunt reported that the patient has lost ten pounds since the vaccination, probably due to stress. The aunt also reported that the patient is taking prenatal vitamins (unspecified). This is a consolidation of two reports concerning the same patient. No further information is available.

Other Meds: None

Lab Data: beta-human chorionic - positive

History: LMP = 3/18/2008

Prex Illness: Pregnancy NOS

Prex Vax Illns:

Vaers Id: **326055-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	26-Jun-2008	28-Jun-2008	2	18-Aug-2008	14-Oct-2008	--	WAES0807USA02656	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Bruxism, Dyspnoea, Fatigue, Feeling hot, Migraine, Restlessness

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female who on 26-JUN-2008 was vaccinated with a dose of GARDASIL vaccine (yeast) lot not reported. On 28-JUN-2008 the patient experienced restlessness, tiredness, shortness of breath, migraines, wrist soreness, teeth grinding, hot face, ankle soreness and knee soreness. The patient was treated with ibuprofen and referred to her physician. The outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326056-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	18-Jun-2008	14-Jul-2008	26	18-Aug-2008	14-Oct-2008	--	WAES0807USA02659	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling

Symptom Text: Information has been received from a 23 year old female who on 18-JUN-2008 was vaccinated with the thirds dose of GARDASIL vaccine (yeast) (lot not reported). Concomitant therapy included hormonal contraceptives (unspecified). "A month after vaccination" the patient experienced pain and swelling at the injection site. The patient's pain and swelling at the injection site persisted. No further information is available.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326057-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	09-Jul-2008	09-Jul-2008	0	18-Aug-2008	14-Oct-2008	--	WAES0807USA02662	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Injection site erythema, Urticaria

Symptom Text: Information has been received from a physician concerning a female (age not reported) who on 09-JUL-2008 was vaccinated with the first 0.5 mL dose of GARDASIL vaccine (yeast) (lot not reported). "Soon after receiving the second dose of the vaccine the patient experienced injection site red welt and ongoing headache that will not go away. The patient's injection site red welt and ongoing headache that will not go away persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326058-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Aug-2007	Unknown		18-Aug-2008	14-Oct-2008	--	WAES0807USA02770	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Ataxia, Dysarthria, Extensor plantar response, Hyperreflexia, Speech disorder

Symptom Text: Information has been received from a physician concerning an 18 year old female with histiocytosis X and severe scoliosis and a history of iron deficiency secondary to dysfunctional uterine bleeding who in August 2007, was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). On an unspecified date, the patient was vaccinated with a second dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). In March 2008, the patient was vaccinated with a third dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). About the time she started the vaccination, the patient was very ataxic. At the time of reporting, the patient's speech was slurred and slow, and was hyper reflexic with present Babinskis bilaterally. The patient was seen by a neurologist, but had no diagnosis. The patient had scheduled for second opinion neurologist. Additional information has been requested.

Other Meds: Unknown

Lab Data: neurological examination - hyper reflexic with Babinskis bilaterally

History: Histiocytosis, Scoliosis, Dysfunctional uterine bleeding, Iron deficiency, Surgery

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326059-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Jun-2008	01-Jun-2008	0	18-Aug-2008	14-Oct-2008	--	WAES0807USA02773	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Cataplexy, Hypersomnia, Narcolepsy

Symptom Text: Information has been received from a physician concerning a 12 year old white female patient who in June 2008 was vaccinated with the third dose of GARDASIL vaccine (yeast). In June 2008, the patient shortly (within days) began to have decrease energy and had several episodes of cataplexy. Her energy continued to decline. Sleeping longer and longer, her blood work was normal (including Lyme) and finally the patient was sent to a neurologist who specializes in sleep disorders, he immediately suspected narcolepsy and it was confirmed on a sleep study-polysomnogram. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory - blood work normal, sleep study - narcolepsy, Lyme disease assay - normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326060-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		18-Aug-2008	14-Oct-2008	CA	WAES0807USA02776	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ataxia, Peripheral motor neuropathy

Symptom Text: Information has been received from a physician concerning a 13 year old female who was vaccinated with a dose of GARDASIL vaccine (yeast). Subsequently the patient experienced progressive ataxia and motor neuropathy. At the time of this report, the outcome was unknown. The reporter felt that progressive ataxia and motor neuropathy were plausibly related to therapy with GARDASIL vaccine (yeast). This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326061-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	Unknown	Unknown		18-Aug-2008	14-Oct-2008	--	WAES0807USA02777	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ataxia, Peripheral motor neuropathy

Symptom Text: Information has been received from a physician concerning a 24 year old female who on an unspecified date was vaccinated with GARDASIL vaccine (yeast). Shortly after receiving GARDASIL vaccine (yeast) the patient experienced progressive ataxia and motor neuropath. It was reported that the patient was being worked up right now for progressive ataxia and motor neuropathy. One of the pediatric rheumatologists who had been heavily involved did believe there was a very plausible link. This is one of two reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326062-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	01-Jun-2008	01-Jun-2008	0	18-Aug-2008	14-Oct-2008	MI	WAES0807USA02807	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Vomiting

Symptom Text: Information has been received from a medical assistant concerning a 10 or 11 year old female who in June 2008, was vaccinated with a first dose of GARDASIL vaccine (yeast) by intramuscular injection (lot number and injection site not reported). Immediately after administration, the patient experienced vomiting. Subsequently, the patient recovered from vomiting. The patient did not seek any medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326063-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-Feb-2008	19-Feb-2008	0	18-Aug-2008	14-Oct-2008	--	WAES0807USA02831	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Bronchitis, Injection site pain, Joint sprain, Mononucleosis heterophile test positive, Nausea

Symptom Text: Information has been received from a registered office nurse manager and a consumer concerning her 12 year old daughter who on 19-FEB-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 660387/1967U) intramuscularly in her right deltoid. The patient's mother reported that her medical doctor noted she was in good physical condition at the time the vaccine was administered. She also reported that the patient's vaccine site was extremely tender and sore for a complete week after she received the vaccination. Within a few days of receiving the vaccine, in February 2008, the patient began complaining of persistent stomach cramps and nausea. The nurse office manager reported that the patient developed stomach cramps and nausea after the vaccination. According to the nurse, the patient was treated as the physician's office as follows: on 07-MAR-2008 for a diagnosis of bronchitis (treatment unspecified) on 23-APR-2008, for symptoms of a left ankle sprain (treatment unspecified), on 15-MAY-2008 for symptoms of stomachache. On 16-MAY-2008, an ultrasound of the liver, kidney, pelvis and spleen were performed and the results were within the normal range. On 23-MAY-2008, upper gastrointestinal air contrast, hematology test, routine immunology test, blood chemistry test were performed and the results reported to be within the normal range except for serum Epstein-Barr virus antibody test positive for EBV IgG, EBV IgM and EBV nuclear antigen. Results suggested recovery or reactivation. The provider will recommend a gastrointestinal consult. No other symptoms or treatment noted. The patient's mother reported that the patient's stomach cramps and nausea continued until the time of this report despite a series of medical testing. The outcome of the patient's bronchitis, L ankle sprain and positive mononucleosis test was unknown. The patient sought medical attention.. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound - 05/16/08 - performed for kidney, spleen, pelvis and live. Results reported to be in normal range, upper GI series x-ray - 05/23/08 - within normal range, serum Epstein-Barr virus - 05/23/08 - positive for EBV IgG, EBV IgM and E

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326064-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Feb-2008	27-May-2008	90	18-Aug-2008	14-Oct-2008	NY	WAES0807USA02837	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea

Symptom Text: Information has been received from a mother concerning her 16 year old daughter with no known drug allergies and asthma, who on 14-AUG-2007 was vaccinated with the first dose of GARDASIL vaccine (yeast) (Lot # not reported). On 17-OCT-2007, the patient was vaccinated with the second dose of GARDASIL vaccine (yeast) (Lot # not reported). On 27-FEB-2008, the patient received the third dose of GARDASIL vaccine (yeast) (Lot # not reported), 0.5 mL by injection. There was no concomitant therapy. The mother reported that on approximately 27-MAY-2008, three months after receiving the third dose of GARDASIL vaccine (yeast), her daughter experienced severe chronic diarrhea which had been occurring for the next two months. The patient sought medical attention. A colonoscopy, blood work, and stool sampling were performed (dates and results not reported). At the time of the report the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326065-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Jul-2008	07-Jul-2008	0	18-Sep-2008	20-Oct-2008	MA	WAES0807USA02838	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	660393/0067X	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Musculoskeletal stiffness, Syncope

Symptom Text: Information has been received from a nurse concerning a 16 year old female who on 07-JUL-2008 was vaccinated with the first dose of HPV rtl, 6,11,16,18, VLP vaccine (yeast) (lot#660393/0067X). Concomitant therapy included diphtheria toxoid (+) pertussis cellular vaccine (unspecified) (+) tetanus toxoid and Meninggococcal ACYW Conjugation vaccine (Dip toxoid) (Menactra). On 07-JUL-2008 the patient fainted post vaccination and her arms got stiff as well. Subsequently, the patient recovered the same day. Medical attention was sought from physician. No product quality complaint was involved. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326066-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Sep-2008	20-Oct-2008	WA	WAES0807USA02849	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope Information has been received from a nurse concerning 5-10 female patients who were vaccinated with a dose of HPV rll 6 11 16 18 VLP vaccine (yeast) (lot number, injection site and route not reported). Subsequently the patients fainted. Some fainted after the first dose, other after the second and third dose of vaccine. Several times the patient had left the office but fainted in the elevator. Subsequently, the patients all recovered from the events. Attempts are being made to obtain additional identifying information to distinguish the individual patience mentioned in this reports. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326067-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Jul-2008	14-Jul-2008	0	18-Aug-2008	14-Oct-2008	--	WAES0807USA02854	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Myalgia, Photophobia

Symptom Text: Information has been received from a nurse practitioner concerning a 12 year old female with seasonal allergies and a history of adenoidectomy and ear tubes who on 14-JUL-2008 was vaccinated with the third dose of GARDASIL vaccine (yeast) (Lot # 0152X). Concomitant therapy included montelukast sodium (MSD), FLONASE and ZYRTEC. On 14-JUL-2008, the patient experienced headaches, muscle aches and light sensitivity. The patient sought medical attention by a phone call to the nurse practitioner. The patient's outcome was not reported. Additional information has been requested.

Other Meds: ZYRTEC, FLONASE, SINGULAIR

Lab Data: Unknown

History: Adenoidectomy, Ear tube insertion

Prex Illness: Seasonal allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326068-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	14-Oct-2008	--	WAES0807USA02870	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Conversion disorder

Symptom Text: Information has been received from a physician concerning her daughter who was vaccinated with a dose of GARDASIL vaccine (yeast) and manifested pseudoseizures. At the time of the report the outcome was unknown. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326070-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	06-May-2008	13-May-2008	7	18-Sep-2008	20-Oct-2008	CA	WAES0807USA02889	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Dizziness, Inappropriate schedule of drug administration, Migraine, Nausea, Vaccine positive rechallenge

Symptom Text: Information has been received from a 31 year old female with no known drug allergies and no pertinent medical history, Who on 05-May-2008 was vaccinated with the first dose of HPV rll, 6, 11, 16, 18, VLP vaccine (yeast) (lot# number not provided, 0.5ml. Concomitant therapy included Sumatriptan (IMITREX) and topiramate (Topamax). On approximately 13-MAY-2008, a week after receiving her first dose. The patient experienced memory loss, dizziness, nausea and migraines. After receiving her second dose of HPV rll, 6, 11, 16, 18, VLP vaccine (yeast) (lot# number not reported) on approximately 08-JUL-2008, all of the symptoms worsened. Every time she ate she felt as if she had to vomit. She had to sit in the dark because of her migraines. The patient sought medical attention. No lab diagnostic studies were preformed. As of the 15-Jul-2008 report date, the patient had not recovered. She is not expected to receive the third dose of HPV rll, 6, 11, 16, 18, VLP vaccine (yeast)

Other Meds: Imitrex (Sumatriptan) Topamax

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326071-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		18-Sep-2008	20-Oct-2008	NJ	WAES0807USA02891	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	658556/106OU		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Urticaria

Symptom Text: Information has been received from a physician concerning a 21 year old female who on an unspecified date was vaccinated with a dose of GARDASIL (Lot#658556/10600) 0.5ml, intramusclar administration. The patient developed hives and joint pain 8-10 hours post vaccination with GARDASIL. The patient sought medical attention and was treated with diphenhydramine hydrochloride (Benadryl) and Corticosteroids.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326072-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	14-Jul-2008	14-Jul-2008	0	18-Aug-2008	14-Oct-2008	--	WAES0807USA02896	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a Nurse Practitioner concerning a female with a history of fainting with drawing of blood and other vaccines, who on 14-JUL-2008 was vaccinated with the the third dose of GARDASIL vaccine (yeast) and fainted in the hallway after walking out of the office. The patient sought medical attention. She sat down and was given orange juice and was fine 5 minutes later. It is unknown if this occurred with the first and second doses of GARDASIL vaccine (yeast). No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Syncope

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326073-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	09-Jul-2008	09-Jul-2008	0	18-Sep-2008	20-Oct-2008	NJ	WAES0807USA02920	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Lymphadenitis, Pyrexia

Symptom Text: Information has been received from a nurse concerning a female who in July 2007, was vaccinated with the first dose of GARDASIL on 09-JUL-2008, the patient was vaccinated with the second dose of GARDASIL it was reported that 24 hours later the patient developed sharp abnormal pain and had a fever of 102.5 on 11-JUL-2008 the patient went to see her physician and she was sent to the Emergency Room. It was reported that the patient was diagnosed of "mesentery "adentite" and was prescribed with a pain medication, and was told that it should be resolved after a week. At the time of this report the patient recovered from a fever of 102.5. But the patient's abdominal pain persisted.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326074-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		18-Aug-2008	14-Oct-2008	NY	WAES0807USA02163	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information has been received from a physician concerning a 14 year old female who was vaccinated with a dose of GARDASIL vaccine (yeast). On an unknown date the patient's mother said that her daughter developed a growth or some type of warts. The patient's outcome was unknown. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326075-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Jul-2008	10-Jul-2008	0	18-Aug-2008	14-Oct-2008	PA	WAES0807USA02172	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Immediate post-injection reaction, Pallor

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 10-JUL-2008 was vaccinated with the first 0.5 ml dose of GARDASIL vaccine (yeast) (lot no. 660389/1968U). On the same date the patient also received meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA) and hepatitis A vaccine (inactive) (HAVRIX). After receiving the first dose the patient immediately became pale, lost her color and her arm felt numb at top of the arm. The patient was recovered after 15 minutes. The patient sought unspecified medical attention in office. This is one of two reports received from the same source. Additional information has been request.

Other Meds:

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326076-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-May-2008	Unknown		18-Aug-2008	14-Oct-2008	TX	WAES0807USA02188	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	0	Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Muscular weakness, Pain in extremity

Symptom Text: Information has been received from a physician concerning an 18 year old female who on 07-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 659055/1522U) and also with varicella virus vaccine live (Oka/Merck) in her arm. Concomitant therapy included meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA). The physician reported that the patient experienced pain and weakness in her arm after receiving GARDASIL vaccine (yeast) (Lot # 659055/1522U) and varicella virus vaccine live (Oka/Merck). The vaccines were administered in the same arm on the same day and the symptoms are being experienced in the same arm that the vaccines were administered. The patient's pain and weakness in her arm persisted. No further information was provided. The patient sought medical attention, seen by the physician. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326077-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	14-Oct-2008	NY	WAES0807USA02190	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female (demographics not provided), who on unspecified dates was vaccinated with first and second doses, respectively, of GARDASIL vaccine (yeast)(Lot #s not provided). It was reported that post vaccination of the second dose of GARDASIL vaccine (yeast) the patient fainted and "almost went into seizure". At the time of this report the outcome was unknown. No further information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326078-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	28-Apr-2008	12-May-2008	14	18-Aug-2008	14-Oct-2008	--	WAES0807USA02194	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a nurse practitioner concerning a female who on 28-APR-2008 was vaccinated with her third dose of GARDASIL vaccine (yeast) (lot# not reported). On 12-MAY-2008 the patient experienced a headache. Subsequently, the patient recovered from the headache. The patient sought unspecified medical attention with a phone call on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 326079-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Sep-2007	01-Sep-2007	0	18-Aug-2008	14-Oct-2008	--	WAES0807USA02205	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abasia, Asthenia, Complex regional pain syndrome, Decreased appetite, Fatigue, Headache, Hypoaesthesia, Irritability, Lyme disease, Pain, Paraesthesia, Tremor

Symptom Text: Information has been received from a 15 year old female patient who reported in September 2007, was vaccinated with the first dose of GARDASIL vaccine (yeast). She reported she received her first dose of HPV vaccine and shortly afterward her hands became numb. A couple of months later her legs and feet became so numb that she could not walk. She decided not to receive the 2nd and 3rd doses". Therapy with human papillomavirus was discontinued. Subsequently, the patient recovered from hands became numb and legs and feet became so numb in the "last week". The patient sought medical attention, several physicians. The laboratory diagnostics studies performed were MRI, unspecified blood test (results not reported). Additional information has been requested. 12/12/2008 Reviewed PCP medical records of 9/5/2007- FINAL DX: borreliosis, fatigue, reflex sympathetic dystrophy Records reveal patient experienced general good health on 9/5/07. RTC 10/26 w/HA, irritability, poor appetite, shaking & generalized aching. Dx w/Lyme's disease. Tx w/antibiotics. RTC 1/3/08 w/paresthesia. ER visits x 2 w/Neuro consults. Tx w/meds. Rheumatology consult done 11/2007 & 3/14/08 & being treated w/meds. RTC 4/17/08 w/continued pain & weakness. Referred to ortho & accupuncture. RTC 6.20 & was improving slowly w/accunpuncture.

Other Meds: Unknown

Lab Data: Unknown LABS: Borrelia (+). (+)ANA. EMG & MRI head/spine WNL.

History: Unknown PMH: alopecia & thelarche 5/2000. Mom w/(+)ANA.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326080-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		18-Aug-2008	14-Oct-2008	NC	WAES0807USA02209	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye irritation, Inappropriate schedule of drug administration, Vision blurred

Symptom Text: Information has been received from a registered nurse concerning a 16 year old female patient who was vaccinated with the first dose of GARDASIL vaccine (yeast) and diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (date not reported). The patient developed burning of the eyes and blurred vision four days after vaccination. The patient was getting over a virus at that time. The patient received the second dose of GARDASIL vaccine (yeast) this week (approximately 07-JUL-2008) and no adverse were not reported. Subsequently, the patient recovered from burning of the eyes and blurred vision. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326081-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jun-2008	20-Jun-2008	4	18-Aug-2008	14-Oct-2008	--	WAES0807USA02210	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning an 18 year old female with chlamydial infection who on approximately 16-JUN-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast). Concomitant therapy included doxycycline. The patient had experienced vomiting and nausea for the last three weeks (from approximately 20-JUN-2008). The patient's vomiting and nausea persisted. No further information is provided. Additional information has been requested.

Other Meds: doxycycline - mg

Lab Data: Unknown

History:

Prex Illness: Chlamydial infection

Prex Vax Illns:

Vaers Id: **326082-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Jun-2007	Unknown		18-Aug-2008	14-Oct-2008	MI	WAES0807USA02213	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Thyroiditis, Weight increased

Symptom Text: Information has been received from a physician concerning an approximately 16 year old female with no pertinent medical history, who on 29-JUN-2007, was vaccinated with the first dose of GARDASIL vaccine (yeast) (Lot # 658100/0525U). On 07-JAN-2008, the patient received the second dose of GARDASIL vaccine (yeast) (Lot # 659439/1267U), and on 03-JUL-2008 the patient received the third dose of GARDASIL vaccine (yeast) (Lot # 660391/0063X). Concomitant therapy included hepatitis A vaccine (inactive) (HAVRIX) and "acne medicines". The physician reported that he saw the patient who had developed thyroiditis after receiving GARDASIL vaccine (yeast), and complained of weight gain and fatigue. A titer test for thyroid was performed, and the patient was found to have antibodies against thyroid. Additional information has been requested.

Other Meds: therapy unspecified

Lab Data: thyroid function test - have antibodies against thyroid

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326083-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-May-2008	21-May-2008	1	18-Aug-2008	15-Oct-2008	--	WAES0807USA02221	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pharyngolaryngeal pain, Pyrexia

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female who on 20-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (Lot # 659964/1978U). On 21-MAY-2008, the patient developed a 102F fever after vaccination and a sore throat. On 22-MAY-2008, patient sought medical attention at the physician's office where a rapid strep test was negative. Treatment was acetaminophen (TYLENOL) and ibuprofen. On an unknown date, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: rapid streptococcus - 05/22/08 - negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326084-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	15-Oct-2008	TX	WAES0807USA02224	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dysgeusia, Nausea

Symptom Text: Information has been received from a physician concerning a female who was vaccinated intramuscularly on an unspecified date with a dose of GARDASIL vaccine (yeast) (lot# not reported). Subsequently the patient experienced nausea, dizziness and an "abnormal taste sensation in her mouth" sometime after the vaccination. The patient sought medical attention by calling the office. The patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326085-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-May-2008	01-May-2008	0	18-Aug-2008	15-Oct-2008	OR	WAES0807USA02227	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a nurse concerning an about 18 year old female who in approximately May 2008 was vaccinated with GARDASIL vaccine (yeast). That same day, the patient developed injection site soreness which was still sore one week after vaccination. The patient sought medical attention by a phone call. The patient outcome was not reported. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326086-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-May-2008	01-May-2008	0	18-Aug-2008	15-Oct-2008	PA	WAES0807USA02232	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information has been received from a mother concerning her 24 year old daughter who in May 2008 was vaccinated with the first dose of GARDASIL vaccine (yeast), injection form, (Lot # was not available). Concomitant therapy included hormonal contraceptives (unspecified). In approximately May 2008, 2 to 3 weeks after receiving the first dose of GARDASIL vaccine (yeast) the patient developed warts on her hand. The patient's warts on hand persisted. The patient sought medical attention of a dermatologist. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326087-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-May-2008	11-May-2008	0	18-Aug-2008	15-Oct-2008	CA	WAES0807USA02233	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Agitation, Blood pressure increased, Dizziness, Syncope, Urinary retention

Symptom Text: Information has been received from a physician concerning a "14 year old" female who on approximately 11-MAY-2008 was vaccinated with her first dose of GARDASIL vaccine (yeast) (lot# not reported). Concomitant therapy included diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid and meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA). On approximately 11-MAY-2008 the patient felt dizzy, agitated, had elevated blood pressure, was holding in urine and fainted. Subsequently, the patient recovered from feeling dizzy, agitated, elevated blood pressure, holding in urine and fainting. The patient sought unspecified medical attention on an unspecified date. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326088-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		18-Aug-2008	15-Oct-2008	NY	WAES0807USA02248	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Movement disorder, Pain in extremity, Pyrexia

Symptom Text: Information has been received from a physician concerning her 14 year old female daughter was vaccinated on an unspecified date with her first dose of GARDASIL vaccine (yeast). A week later she the patient experienced fever of about 103 degrees, had a headache and her left arm had pain and difficulty moving. Subsequently, the patient recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326089-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	15-Oct-2008	FL	WAES0807USA03006	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with the first dose of GARDASIL vaccine (yeast) 0.5ml. Subsequently the patient developed hives. Subsequently, the patient recovered from hives. The patient sought medical attention with a telephone call. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326090-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		18-Aug-2008	15-Oct-2008	TN	WAES0807USA03008	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 17 year old female who was vaccinated with the third dose of GARDASIL vaccine (yeast) (lot#, therapy route and dose not reported). On the same day of vaccination of the third dose, the patient had arm pain and achiness down the length of the arm from the shoulder down to the hand. Which arm unspecified. The patient's arm hurt a couple of days after vaccination then it went away and then came back. The patient did not have any problems with the first and second doses of GARDASIL vaccine (yeast). The patient came into office to seek medical attention. The patient was prescribed unspecified medications for the achiness. As of 15-JUL-2008, the arm pain persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326091-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Jul-2008	15-Jul-2008	0	18-Aug-2008	15-Oct-2008	TX	WAES0807USA03014	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Injection site reaction, Peripheral coldness

Symptom Text: Information has been received from a physician concerning an 11 year old female patient who on 15-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). Concomitant vaccination included meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA) and diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (manufacturer unknown). The physician reported that post-vaccination, the patient complained of headache and that her arm was cold at the injection site. The patient was given ibuprofen (ADVIL) and felt better. The patient was sent home. At the time of the report the patient was recovering. The patient sought medical attention at the physician's office. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326092-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	15-Oct-2008	--	WAES0807USA03015	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician assistant concerning a female patient who on an unspecified date, was vaccinated with a dose of GARDASIL vaccine (yeast), 0.5ml, intramuscularly for HPV prevention. The physician assistant reported that the patient fainted after receiving the vaccine. The patient recovered on the same day of the vaccination. The patient sought unspecified medical attention. Additional information has been requested. \

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326093-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		18-Aug-2008	15-Oct-2008	TN	WAES0807USA03033	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle spasms, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning a 14 year old female patient who was vaccinated with the entire series of GARDASIL vaccine (yeast). The nurse reported that the patient experienced muscle spasms after each of her HPV vaccine doses. It is not known when the spasms began or how long they lasted. At the time of the report the patient had recovered. The patient sought medical attention by phone. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326097-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	26-Mar-2008	Unknown		25-Sep-2008	26-Sep-2008	VA	WAES0809USA03150	26-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from a 24 year old female pharmacy technician with no allergies who on 25-JAN-2008 was vaccinated with the first dose of GARDASIL 0.5 ml (lot no. not reported) and on 26-MAR-2008, with second dose of GARDASIL 0.5 ml, (lot no. not reported). Concomitant therapy included hydrochlorothiazide (manufacturer unknown). On an unspecified date, the patient was diagnosed with multiple sclerosis and was hospitalized from 01-AUG-2008 to 20-AUG-2008. A magnetic resonance imaging (MRI) and a computed axial tomography were performed (results not reported). Additional information has been requested.

Other Meds: Hydrochlorothiazide

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326098-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Sep-2008	03-Sep-2008	0	25-Sep-2008	26-Sep-2008	FR	WAES0809USA02960	26-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1524U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Asthenia, Headache, Heart rate normal, Immediate post-injection reaction, Injection site pain, Loss of consciousness, Malaise, Neurological examination normal, Syncope vasovagal

Symptom Text: Information was received from a paediatrician concerning a 14-year-old female patient, with a history of vagal malaise, including one with loss of consciousness, anxiety and pollen allergy who on 03-SEP-2008 was vaccinated with a first dose of GARDASIL (lot # 1524U, batch # NH38000, route unknown) into her deltoid via intramuscular route. Four hours after the injection, the patient experience violent cephalgia, abdominal pain and vagal malaise. She rapidly recovered. The physician thought that the patient was probably emotional and that could have induced her malaise. Additional information was received from local Health Authorities (reference # BR20080309). According to report, on 03-SEP-2008, ten minutes after vaccination, the patient experienced continuous frontal cephalgia. Four hours later she experienced a vasovagal syncope with loss of consciousness, asthenia, abdominal pain and persisting cephalgia. She also had injection site pain immediately after vaccination. Evolution was favorable with recovering of consciousness, persisting cephalgia which resolved in 20 to 30 minutes after corrective treatment with paracetamol. Neurological examination was normal; blood pressure was at 130/70, pulse rate at 60-65/min, apyrexia, supple painless abdomen. Evolution 3 days later: She had persisting asthenia and injection site pain. The patient's experience was considered serious as an other important medical event. Other business partner numbers included: E200808457. No further information is available. The file is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Malaise; Loss of consciousness

Prex Illness: Pollen allergy; Anxiety

Prex Vax Illns:

Vaers Id: **326099-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Nov-2007	26-Jan-2008	71	25-Sep-2008	26-Sep-2008	AR	WAES0803USA01717	26-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	0	Unknown	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female with a history of excess sweating and no drug reactions/allergies who on 16-Nov-2007 was vaccinated with the first dose of GARDASIL (lot#657617/0384U). Concomitant therapy included a first dose of Tdap and RUBINUL (therapy unspecified). On 22-Feb-2008, the patient was vaccinated intramuscularly with 0.5ml of the second dose of GARDASIL (lot# 657617/0384U) and found out she is pregnant (LMP = 26-JAN-2008). On an unspecified date GC test (gonorrhea and chlamydia test) and PAP test were performed (results pending). Also, on an unspecified date the patient took urine pregnancy test. Unspecified medical attention was sought in the office. Follow-up information was received. On 09-APR-2008 an ultrasound was performed which indicated a 9 weeks 2 days pregnancy. On an unspecified date the female patient experienced spontaneous abortion. The outcome of the spontaneous abortion was unknown. Upon internal review the spontaneous abortion was considered to be an other important medical event. Additional information is not expected.

Other Meds: [therapy unspecified]

Lab Data: ultrasound, 04/09/08, 9 2/7 w lmp; urethral C., results pending; Pap test, results pending; urine beta-human, positive

History: Excess sweating

Prex Illness:

Prex Vax Illns:

Vaers Id: 326100-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Aug-2007	15-Jun-2008	310	25-Sep-2008	26-Sep-2008	FR	WAES0802USA03757	26-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1537F	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cervical incompetence, Drug exposure during pregnancy, Gardnerella infection, Premature labour, Tocolysis

Symptom Text: Information has been received from a physician concerning 16 year old female who on 10-AUG-2007 was vaccinated with the first dose of GARDASIL (lot # 1451F; batch NF42160). It was well tolerated. On 11-OCT-2007, she was vaccinated intramuscularly in the deltoid muscle with her second dose of GARDASIL (lot # 1537F; Batch NF42170). After the second dose the reporter diagnosed pregnancy (duration not reported). At the time of reporting pregnancy was normal. Follow-up information was received from a gynaecologist which reported that the patient was hospitalized on 15-JUN-2008 due to premature labour in the 30th week of pregnancy. Incompetence of cervix and gardnerella infection were diagnosed. The gardnerella infection was treated with Ampicillin and a tocolysis (intravenous route) was given. Under this treatment the premature labour ceased. The patient was discharged on 23-JUN-2008. From 27-JUL-2008 to 31-JUL-2008, the patient was hospitalized again due to imminent premature birth in the 36th week of pregnancy. No labour was observed and the patient was discharged on 31-JUL-2008. On 15-AUG-2008, the patient gave birth to a normal newborn boy. His weight at birth was 3.650 grams and height at birth was 54 cm. The Apgar score was 10/10/10. Postnatal examinations of mother and child showed no pathologies. CASE CLOSED. Upon receipt of new information, this case was upgraded because of hospitalization due to premature labour. Other business partner numbers include: E2008-00789. Additional information is not expected.

Other Meds: Unknown

Lab Data: Gardnerella vaginalis culture, 15Jun08, gardnerella infection

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 326127-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	02-Jun-2008	Unknown		18-Aug-2008	15-Oct-2008	CA	WAES0807USA02252	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Dizziness

Symptom Text: Information has been received from a physician concerning a 24 year old female healthcare worker with dizziness and sleep disorder and a history of pain who on 02-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). Concomitant therapy included ROZEREM. Subsequently, the patient experienced more severe dizziness after her first dose. The patient sought medical attention, saw a physician and had an eye check performed. At the time of reporting, the patient's dizziness persisted. No additional AE information provided. Additional information has been requested.

Other Meds: ROZEREM

Lab Data: ophthalmological exam

History: Pain

Prex Illness: Sleep disorder, Dizziness

Prex Vax Illns:

Vaers Id: **326128-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	01-Aug-2007		18-Aug-2008	15-Oct-2008	--	WAES0807USA02260	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Allergy to metals, Bacterial infection, Dyspnoea, Erythema, Rash generalised, Rash pruritic, Skin irritation

Symptom Text: Information has been received from a 26 year old female with an allergy to TYLENOL who in 2007 was vaccinated with the first dose of GARDASIL vaccine (yeast) prior to a spinal fusion surgery in August 2007. Two weeks after the surgery she broke out in a serious rash all over her body that was red, itchy and oozy. She went back to her surgeon who thought she may have caught a bacterial infection while in the hospital. After the treatment for that, the rash did not go away and patient was thought to have a staph infection. The rash was getting worse and she started having difficulty breathing and had to be taken to ER. It was determined she may have an allergic reaction to the nickel hardware that was placed in her spine. After that she was sent to an allergist who performed some tests, however the patient was taking allergy medication at the time and the test came back inconclusive. She did receive a second and third dose of GARDASIL vaccine (yeast) and was also scheduled for a second spinal fusion to replace the hardware with stainless steel. The patient is still experiencing a rash, that comes and goes depending on whether she puts the cream on it or not. She will bring the package insert for GARDASIL vaccine (yeast) with her to the allergist office to look at the ingredients and perform some tests to see if she could be allergic to any of the components. At time of report, the patient had not recovered from her rash. The outcome of the difficulty breathing, bacterial staph infection and allergic reaction to nickel hardware is unknown. No further information is available.

Other Meds: Unknown

Lab Data: skin biopsy - ?/?/07 - punch hole biopsy inconclusive, diagnostic laboratory - ?/?/07 - touch test for nickel inconclusive

History: Spinal operation, Hospitalization

Prex Illness: Drug hypersensitivity, Spinal disorder

Prex Vax Illns:

Vaers Id: **326129-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	20-Jun-2008	20-Jun-2008	0	18-Aug-2008	15-Oct-2008	--	WAES0807USA02368	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypersomnia

Symptom Text: Information has been received from a consumer, concerning her 19 years old daughter, who was vaccinated with the first dose of GARDASIL vaccine (yeast) (Lot #, site and route of administration not reported) in Jun 2008 (reported as "three weeks ago"). When the patient got the first injection she went home and immediately fell asleep for 15 hours. She was very worried about getting the shot before it happened. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326130-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Mar-2008	Unknown		18-Aug-2008	15-Oct-2008	MI	WAES0807USA02443	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Information has been received from a physician concerning an 18 year old female patient who on 14-JAN-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 659653/1448U) and on 14-MAR-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast) (lot # 660387/1967U). Concomitant therapy included hormonal contraceptives (unspecified). The physician reported that on 2008 the patient developed Bell's palsy after administration of two doses of HPV vaccine. The patient sought medical attention via telephone. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326131-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	09-Jul-2008	11-Jul-2008	2	18-Aug-2008	15-Oct-2008	NC	WAES0807USA02445	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Hypomagnesaemia, Nausea, Viral infection, Vomiting

Symptom Text: Information has been received from a nurse concerning a 19 year old female who on 09-JUL-2008 was vaccinated with 0.5 ml of the first dose of GARDASIL vaccine (yeast) (lot # 660553/0070X) intramuscular. Concomitant therapy included drospirenone (+) ethinyl estradiol (YAZ). The Nurse reported that on 11-JUL-2008, the patient experienced nausea, vomiting, numbness throughout her body after receiving the dose of GARDASIL vaccine. The patient was brought to the emergency room were it was determinate that the symptoms were due to a virus and low magnesium level. Subsequently, the patient recovered from nausea, vomiting, numbness, virus infection and low magnesium level. Additional information has been requested.

Other Meds: YAZ

Lab Data: serum magnesium - 07/11/08 - low

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326132-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-Jun-2008	04-Jul-2008	7	18-Aug-2008	15-Oct-2008	NY	WAES0807USA02449	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Muscular weakness

Symptom Text: Information has been received from a consumer concerning to his daughter who on 27-JUN-2008 was vaccinated with 0.5 ml of GARDASIL vaccine (yeast) (batch and lot numbers not reported) intramuscular. Concomitant therapy included PROZAC and CLONOPIN. About a week after she got the vaccine (on approximately 04-JUL-2008) the patient experienced stomach pain and muscle weakness. The patient had blood work done (results not reported). The patient was recovering from stomach pain and muscle weakness. Additional information has been requested.

Other Meds: CLONOPIN, PROZAC

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326133-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		25-Sep-2008	07-Oct-2008	--	WAES0807USA02455	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site irritation, Injection site pain

Symptom Text: Information has been received from a registered nurse concerning female patients of various ages who were vaccinated with GARDASIL. All her patients who received GARDASIL experienced injection site pain and burning immediately upon injection. This has caused some of the patients to not return for their subsequent doses. The patients recovered while they were in the office. These symptoms occurred with any dose of the series. The patients sought unspecified medical attention. Follow up information was received from the nurse stating that, she was not aware of any specific patients but rather a general statement was made regarding patients experiencing injection site pain and burning. With HIPAA, the nurse would not feel comfortable providing any patient information anyway. As this was a general statement, there will be no patient information coming from this office.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326134-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	15-Oct-2008	--	WAES0807USA02456	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal distension, Condition aggravated, Gastrointestinal disorder

Symptom Text: Information has been received from a registered nurse concerning her daughter with an unspecified gastrointestinal disorder who was vaccinated with GARDASIL vaccine (yeast) (Lot # not reported). The nurse reported that her daughter developed a worsening of a gastrointestinal disorder after receiving GARDASIL vaccine (yeast). The patient experienced increased abdominal bloating. The patient sought medical attention at physician's office. At time of report, the patient's gastrointestinal disorder and increased abdominal bloating persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Gastrointestinal disorder

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326135-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	07-Sep-2007	01-Nov-2007	55	18-Aug-2008	15-Oct-2008	SC	WAES0807USA02461	04-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Arterial bruit, Asthenia, Blood pressure decreased, Dizziness, Electrocardiogram abnormal, Gastritis, Nausea, Presyncope, Syncope, Tuberculin test, Visual disturbance

Symptom Text: Information has been received from a nurse concerning a 20 year old female with a history of cervical dysplasia and abnormal PAP, who in July 2007, was vaccinated with the first dose of GARDASIL vaccine (yeast). In September 2007, she was vaccinated with the second dose of GARDASIL vaccine (yeast) and in January 2008, she was vaccinated with the third dose of GARDASIL vaccine (yeast). The nurse reported that the patient developed persistent dizziness with occasional nausea after receiving the vaccine. The dizziness and nausea began in November 2007. The patient's persistent dizziness and occasional nausea persisted. Additional information has been requested. 10/1/08 Office notes received from PCP. Pt presented 1/3/08 with c/o nausea and dizziness. Nausea began 11/07 and dizziness several weeks ago. Feels like sesation of passing out. Nausea is constant. PE WNL. Assessment: Gastritis, new. Dizziness, new. Nausea, new. Non-specific reaction to Tuberculin skin test w/o active TB, new. Tx with meds. Returned 6/25/08 with c/o worsening dizziness and lightheadedness which is interfering with QOL. Nausea improved. Weakness noted during pre-syncopal spells. Assessment: Dizziness, worsening. Nausea, stable. Plan to refer to cardiology, however office does not have consult name. 10/09/2008 Cardiology consult received for 7/7/2008 with Dx: Abnormal EKG. Dizziness and Giddiness. Syncope/Collapse. Disturbance of Vision. Nausea alone. PE (+) for flow murmur. Referred to ophth for black spots in visual field. Enc to increase salt intake. 11/03/2008 Neurology consult received dated 7/10/08. Pt reports ~6 month hx of dizziness, feeling like pt will faint w/o LOC. Brought on by standing quickly. PE WNL with BP drop from 100/80 to 96/80 with standing.

Other Meds: Unknown

Lab Data: cervical smear. Labs and Diagnostics: Chem, CBC and TSH WNL. EKG abnormal with non-specific ST changes-non acute. Echo with trace tricuspid and mitral regurg. EEG mildly abnormal with L temporal sharp transients. MRI brain WNL.

History: Cervical dysplasia, Papanicolaou smear abnormal. PMH: None. On OCs.

Prex Illness:

Prex Vax Illns:

Vaers Id: **326137-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Jun-2008	02-Jun-2008	0	25-Sep-2008	07-Oct-2008	--	WAES0807USA02478	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness, Insomnia, Muscle spasms, Nausea, Pyrexia

Symptom Text: Information has been received from a consumer concerning her daughter, a 15 year old female with a sulfa allergy and no pertinent medical history, who on 02-JUN-2008 was vaccinated with a dose of GARDASIL. There was no concomitant therapy. The patient developed fever, cramps, nausea and flu-like symptoms the day of vaccination or the day after. She had difficulty sleeping that night. The consumer called the physician. No lab diagnostic studies were performed. The patient took TYLENOL and ADVIL. The symptoms resolved the next day. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326138-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	27-May-2008	27-May-2008	0	18-Aug-2008	15-Oct-2008	--	WAES0807USA02481	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female with no known drug allergies or pertinent medical history who on 27-MAY-2008 was vaccinated IM with the first dose of GARDASIL vaccine (yeast) (lot n. 654272/0073X). Concomitant therapy included an unspecified birth control pill. The patient received the first dose of GARDASIL vaccine (yeast) and immediately fainted. She was unconscious for 5-10 minutes. The patient sought medical attention at the office. No treatment was required and the patient recovered on 27-MAY-2008. Additional information has been requested.

Other Meds: therapy unspecified

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326140-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Jun-2008	07-Jul-2008	7	18-Aug-2008	15-Oct-2008	CA	WAES0807USA02496	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Chest pain, Conjunctival hyperaemia, Cough, Iridocyclitis, Iritis, Myopia, Proteinuria, Respiratory tract congestion, Scoliosis, Seasonal allergy, Sinusitis, Spinal haemangioma, Tubulointerstitial nephritis, Vision blurred, Visual acuity reduced, Wegeners granulomatosis

Symptom Text: Information has been received from a physician concerning a 15 year old female with a cough and history of migraine who on 30-JUN-2008 was vaccinated with the first dose GARDASIL vaccine (yeast) (Lot number 660555/0279X). There was no concomitant medication. On 07-JUL-2008, seven day later, she was diagnosed with iritis. She was seen by an ophthalmologist and received an unnamed treatment. She was also scheduled to see a rheumatologist. She had a cough before receiving GARDASIL vaccine (yeast) and still had the cough. At the time for this reporting, the patient's iritis persisted. Additional information has been requested. 1/12/2009 MR received from 7/10/08-11/25/08 with DX: Chronic anterior uveitis, both eyes, without uveitic complications. Hx of migraine episodes. Sinus disease. Chronic cough. Elevated CRP and ESR. Proteinuria. Pt initially presented 7/10/08 with c/o 1 wk hx of intermittent blurred vision of the L eye and 3 week hx of cough. PE (+) for conjunctival injection with 2+ cells in anterior chamber. Impression: Acute Iritis OS of unknown etiology. Early myopia. F/U 7/16/2008 now bilateral Iritis. Consult 8/19/08 with another ophth. Referred for eval and mgmt of uveitis, both eyes due to little response to previous tx with topical steroid. ? TINU (Tubulo-interstitial nephritis and uveitis) being considered 2' to proteinuria. 2/2/09 MR received from rheumatology and nephrology consults. Seen 7/16/08 with c/o blurry eyes, decreased vision, red eyes, recent chest pain and cough and congestion. PE (+) for mild scoliosis. DX: Iritis. Cough and congestion. Wegener's Granulomatosis. Increased Sed rate, (+) ANA. Mild scoliosis. Proteinuria. F/U visit Dx changed to Likely TINU-Tubulo-interstitial nephritis: mild uveitis and nephritis. Hemangioma T4 spinal vertebra. Sinusitis. Seasonal allergies. Now c/o back pain-lower back and T12 to L1-4. Referred to nephrology for proteinuria. Uveitis slowly improving with steroid drops. Proteinuria resolved.

Other Meds: None

Lab Data: Unknown Labs and Diagnostics: CRP 0.97. ESR 61. ANA 1: 640 speckled. CXR (-). Renal US WNL. CT chest suggestive of hemangioma at T4. Sinus CT (+). IgG high at 2229. urine protein 475. Lyme (-).

History: Migraine PMH: Migraines

Prex Illness: Cough

Prex Vax Illns:

Vaers Id: **326141-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-May-2008	01-May-2008	0	18-Aug-2008	15-Oct-2008	--	WAES0807USA02507	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received from a nurse practitioner concerning a female (age not reported) who in May 2008, was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot not reported). There was no concomitant medication. In May 2008, the patient developed a fever of 102c the day after the first dose of GARDASIL vaccine (yeast). Subsequently, the patient recovered from fever of 102c. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326142-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Feb-2008	29-Feb-2008	1	18-Aug-2008	15-Oct-2008	--	WAES0807USA02512	24-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2540AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1486U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Anorexia, Asthenia, Cough, Dizziness, Hypophagia, Pyrexia, Viral infection, Vomiting

Symptom Text: Information has been received from a physician concerning her daughter (age not reported) who on an unspecified date was vaccinated IM with the first dose of GARDASIL vaccine (yeast) (lot not reported). Her daughter became weak, dizzy and stayed in bed for two days after vaccination. The outcome was not reported. Additional information has been requested. 11/18/08 Reviewed ER medical records of 3/4/2008. FINAL DX: viral syndrome Records reveal patient experiencec felt faint x 1 day, fever, vomiting, cough, loss of appetite, abdominal pain, reduced oral intake. Tx w/IVF & meds, improved & d/c to home, instructed not to go to school next day.

Other Meds: Unknown

Lab Data: Unknown LABS: CBC WNL.

History: Unknown PMH: ADD.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326144-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.1	U	16-Jul-2008	16-Jul-2008	0	18-Aug-2008	15-Oct-2008	DE	WAES0807USA03399	16-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: Information has been received from a registered nurse concerning a 4 week old patient who on 16-JUL-2008 was vaccinated with ROTATEQ vaccine live (human-bovine). There were no adverse events reported. At the time of the report, the patient's status was unknown. There was no product quality complaint involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326149-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.3	F	21-Jul-2008	21-Jul-2008	0	18-Aug-2008	16-Oct-2008	NY	WAES0807USA04114	16-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1887U	0	Unknown	By Mouth	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: Information has been received from a physician concerning a 13 week old female patient who on 21-JUL-2008 was vaccinated orally with a first dose of ROTATEQ vaccine live (human-bovine). There were no adverse effects reported. At the time of the report, the patient's status was unknown. There was no product quality complaint involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326195-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Sep-2008	18-Sep-2008	1	25-Sep-2008	06-Oct-2008	PA		06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN TO ME	0	Left arm	Intramuscular	
	MEN	UNKNOWN MANUFACTURER	UNKNOWN TO ME	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Dysstasia, Eyelid oedema, Pyrexia, Swelling face

Symptom Text: Fever of 105, extreme dizziness to the point of being unable to stand on own, swelling in eyelids and face, and difficulty breathing. Called family doctor to confirm if this was a reaction to the HPV and they said to go to the ER, which we did. Today is one week after injection, and dizziness still occurs. The other symptoms are no longer visible.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **326198-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	31-Jul-2008	31-Jul-2008	0	25-Sep-2008	06-Oct-2008	FL		06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2546AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2491AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0525X	0	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1487U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Head injury, Skin laceration, Swelling, Syncope

Symptom Text: PT ADMIN. HPV VACCINE 15 MIN. AFTER ADMIN. PT FAINTED WHILE STANDING IN CHECK OUT LINE WITH FATHER AND HIT HER HEAD.V/S TAKEN BY NURSING STAFF AND PT WAS ASSESSED BY PHYSICAN LACERATION FOUND ABOVE LEFT BROW.AREA CLEANED AND ICE PACK APPLIED FOR SWELLING.PT D/C @11:35 AM. FATHER ADVISRD IF EPISODE HAPPENS AGAIN TO TAKE PT TO E.R.

Other Meds:

Lab Data: N/A

History: NKDA OR BIRTH DEFECTS

Prex Illness: FAINTING

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326211-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	02-Apr-2008	02-Apr-2008	0	25-Sep-2008	13-Oct-2008	MA		13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	10634	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Pt developed hives 20-30 minutes after receiving GARDASIL, was given BENADRYL & Prednisone.

Other Meds:

Lab Data: Allergy Eval - P

History: RAD, Nuts

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326215-1** **Related reports:** 326215-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Sep-2008	19-Sep-2008	1	25-Sep-2008	29-Sep-2008	WA		09-Dec-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2662AA	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2966A	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0063X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immunisation reaction, Paraesthesia

Symptom Text: Tingling in hands/fingers on side of HPV vaccine noted 24 hours after shot and continued intermittently at least 3 days. No abnormalities on exam. 12/3/08 Office note received from PCP. Pt seen for c/o tingling sensation in R hand/fingers since 1 day after vax. Occurs intermittantly. PE WNL. Normal strength. Impression: May have irritation from vaccine or something else. Resolved by 9/30/08

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326215-2** **Related reports:** 326215-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Sep-2008	19-Sep-2008	11	26-Sep-2008	29-Sep-2008	WA		29-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2966A	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2662AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Tinglin in hands/fingers on side of HPV vaccine noted 24 hrs after shot and continued intermittently at least 3 days. No abnormalities on exam.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 326270-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	28-Dec-2007	16-Jan-2008	19	26-Sep-2008	01-Oct-2008	WI		06-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1210U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Ageusia, Anticoagulant therapy, Bed rest, Central nervous system lesion, Chest pain, Convulsion, Deafness, Hemiparesis, Hypercoagulation, Hypoaesthesia, Hypotonia, Laceration, Limb discomfort, Menstruation irregular, Migraine, Muscle spasms, Muscle tightness, Neurological symptom, Neutropenia, Pain, Paraesthesia, Partial seizures with secondary generalisation, Phantom pain, Phonophobia, Photophobia, Pulmonary embolism, Rash, Sensory loss, Simple partial seizures, Sinusitis, Status epilepticus, Thrombosis, Unresponsive to stimuli, Urticaria, Vena cava filter insertion, Weight decreased

Symptom Text: Seizures - antiseizure medication; Blood clot (left arm) - blood thinner. Extreme pain on left side, felt like a Charlie Horse. Irregular menstrual cycle - Oct '07 - Jan '08. Rashes/hives - ALLEGRA, ZYRTEC, BENADRYL. Brain inflammation. Phantom feeling on left side. Bedrest for 2 months. 10/14/2008 MR received for DOS 1/27-2/20/2008 with D/C DX: Simple partial seizures with capacity for secondary generalization. Epilepsia partialis continua manifested by L chest pain, L neck pressure, and L-sided numbness and paresthesias involving the arm and leg. R parietal cortex lesion. Pulmonary Embolism from probable hypercoagulable state. Sinusitis. Pt presented after transfer from local facility. Has had 5-10 ER visits over the last 11 days for progression of symptoms which began 1/16/2008 with numbness and discomfort which begins in the L arm and progresses to chest and L leg. Symptoms have become more frequent and of increased intensity. On the night prior to admission pt was found unresponsive and gurgling. Seen in local ER and d/c. 2nd episode which involved flailing of all 4 limbs followed by becoming unresponsive and limp. Initial PE (+) for L sided weakness, tongue lac, and subjective decreased sensation of the L arm. Initially had some improvement in seizure activity on anti-convulsants, however pt developed persisitant numbess of the L arm, thorax and L leg and increasing pain in the chest and L neck. PE was dx 2/11 and pt placed on anti-coagulants. IVC filter placed and removed 2/19/08. Symptoms of numbness and pain decreased as seizures under control. D/C home 2/20/08. 2/2/09 MR received from neurology consults dated 5/7/08, 5/9/08 and 11/6/08. DX include Refractory partial epilepsy, R central MRI abnormality, Pulmonary embolism, Coumadin anticoagulation, Urticaria, RUQ abdominal pain, Loss of taste and weight loss, New onset migraine H/A w/out oura, recurrent sinusitis and hx of neutropenia. Hx as above. Still with daily seizures. New onset migraines which began in 7/2008 with phono/photophobia a

Other Meds:

Lab Data: Labs and Diagnostics: EEG c/w epileptic changes. Brain MRI (+) for R parietal cortex abnormality. Cervical MRI WNL. Cerebral angiogram WNL. Chest CT (+) for PE in RLL. Venous dopplars WNL. CSF WNL except CSF lymphocyte percentage 87%,

History: allergies: PCN and idiopathic, take Zyrtec for seasonal allergies. PMH: Idiopathic urticaria. Recurrent sinusitis. Allergy to PCN.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326273-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Sep-2008	24-Sep-2008	0	26-Sep-2008	14-Oct-2008	MD		30-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2730AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0572X		Unknown	Unknown	
	FLUN	MEDIMMUNE VACCINES, INC.	500544P		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Fall, Head injury, Syncope

Symptom Text: Pt received FLUMIST, MENACTRA and GARDASIL, had syncopal event, fell & head injury, and had approx. 15-20 sec generalized seizure.

Other Meds:

Lab Data: Head CT Normal

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326278-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Sep-2008	13-Sep-2008	1	26-Sep-2008	14-Oct-2008	TX		14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Headache, Injection site erythema, Injection site swelling, Injection site warmth, Sinusitis

Symptom Text: Fever for 3-4hrs, injection site was red, swollen and hot the day aftr the shot. Pt complains of headaches moving down her back through her pine. Pt was referred to central Texas Medical Center ER. Pt's mother states that Pt was seen in ER, given ABx for sinus infection, and is feeling better and back in school. 09/18/2008

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326280-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	20-Sep-2008	20-Sep-2008	0	26-Sep-2008	14-Oct-2008	NY		14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury

Symptom Text: Pt. fell to ground, hit back of head, did no lose consciousness. Pt. remained in office, lying down - B/P 100/70 for one hour.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 326281-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Sep-2008	17-Sep-2008	0	26-Sep-2008	14-Oct-2008	WA		14-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB246AA	0	Left arm	Unknown	
MNQ	SANOFI PASTEUR	V2669AA	0	Right arm	Unknown	
TDAP	SANOFI PASTEUR	02966AA	5	Right arm	Unknown	
HPV4	MERCK & CO. INC.	0279X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amnesia, Clonus, Disorientation, Fatigue, Feeling abnormal, Immediate post-injection reaction, Laceration, Musculoskeletal stiffness, Pallor

Symptom Text: Suspected syncope VS seizure. Five minutes after immunization, patient felt odd, then per mom, her legs "flipped out from her body"- mom caught her torso; arms extended and entire body stiffened X seconds. Then, approximately 15 sec of clonic movement of legs. Teeth bit lower lip. Then, big gasp of air, and patient "came to; though pale and slightly disoriented X 5-10 min, and tired for at least several hours after. Amnesia of event. To Emergency Department for evaluation.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326286-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Sep-2008	23-Sep-2008	1	26-Sep-2008	15-Oct-2008	GA		15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2689AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0381X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Headache, Pain, Pruritus, Rash papular

Symptom Text: Red papules on face, headache and body ache with itching within 18 hours of administration of MENACTRA and GARDASIL immunization.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: None~ ()~~0~In Patient|None~ ()~~0~In Sibling|None~ ()~~0~In Sibling

Vaers Id: **326305-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	22-Sep-2008	22-Sep-2008	0	26-Sep-2008	06-Oct-2008	IN		06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2936BA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0070X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Heart rate increased, Myalgia, Nausea, Pyrexia, Retching, Vomiting

Symptom Text: C/o fever,myalgia,nausea & vomiting;dry heaves;CBC & urinalysis WNL;givrn 4 mg Zofran for nausea & Toradol 60mg;Ibuprofen rx 600mg q6-8 hrs prn;advised bland food prn;Temp 99.8;Pulse117;BP 117/79

Other Meds: Allegra q12 hours;Prozac 20mg;Provigil 200mg;Welbutrin SR 100mg

Lab Data: CBC & urinalysis WNL

History: Depression;allergic rhinitis;narcolepsy

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326320-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	11-Sep-2008	11-Sep-2008	0	26-Sep-2008	06-Oct-2008	PA		05-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Dyspnoea, Heart rate increased, Sleep disorder

Symptom Text: I received the guardasil shot and started having rapid heart beats along with sharp pains to the heart. I have trouble sleeping at night because my heart beat so fast and have trouble breathing. I was prescribed Naproxen but it does not help. When I go to sleep, I'm awaken by fast pumping and pain in my chest. I have a hard time catching my breath and this started hours after receiving the shot.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **326337-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	26-Jan-2007	07-Jul-2007	162	28-Sep-2008	08-Oct-2008	MD		08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0187U	0	Gluteous maxima	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Influenza like illness, Nausea, Pain, Pyrexia

Symptom Text: I received Gardasil at approximately 1pm on July 6, 2007. The morning after receiving my first dose of Gardasil I experienced severe flu-like symptoms. I had a fever, the chills, was nauseous, and achy all over. This lasted approximately 24 hours.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326349-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Sep-2008	Unknown		26-Sep-2008	22-Oct-2008	WV		22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	3	Right arm	Intramuscular	HPV4

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Extra dose of HPV vaccine given 4 weeks after third dose.

Other Meds: ORTHO TRI CYCLEN LO

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **326352-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Sep-2008	25-Sep-2008	0	26-Sep-2008	28-Oct-2008	CA		28-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAB297AA	1	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2995BA	5	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2637AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0843X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Syncope, Tremor, Unresponsive to stimuli

Symptom Text: 1740 fainted after giving multiple shots (HPV, MCV4, Hep A & Tdap; becomes pale & non responsive noted with minor shakes lasted few seconds recovered right away. Seen by Dr., monitored closely by Dr., observed for another 10 min, went home in alert, stable condition.

Other Meds: none

Lab Data:

History: none

Prex Illness: a foot corn

Prex Vax Illns:

Vaers Id: **326363-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		02-Sep-2008	02-Oct-2008	MD	WAES0807USA01354	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypersensitivity, Injection site urticaria

Symptom Text: Information has been received from a nurse concerning a female patient, demographics not provided. On an unspecified date the patient received a dose of GARDASIL (unspecified dose and lot# not provided). The nurse reported that on an unspecified date, post vaccination, the patient "had an allergic reaction like hives" at the injection site. No additional AE information was provided. Additional information is not expected. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326364-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		02-Sep-2008	02-Oct-2008	MD	WAES0807USA01353	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Injection site anaesthesia

Symptom Text: Information has been received from a nurse concerning a "few" female patients, demographics not provided, that had complained their arm had gone numb at the injection site where GARDASIL was received (unspecified dose and date of vaccination); however, no additional AE information was provided. Additional information is not expected. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326365-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		02-Sep-2008	02-Oct-2008	MO	WAES0807USA01345	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female, no demographics provided, who was vaccinated with an unspecified dose of GARDASIL (lot# not reported) on an unspecified date and fainted in the elevator post vaccination. The patient sought unspecified medical attention on an unspecified date. The patient's outcome was not reported. Additional information has been requested. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326371-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	01-Jan-2008		18-Aug-2008	17-Oct-2008	--	WAES0807USA03794	17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Infectious mononucleosis, Malaise, Myalgia, Pain in extremity

Symptom Text: Information has been received from a public health nurse concerning her daughter a 19 year old female patient with no known allergies who on last summer (2007), was vaccinated with the first dose of GARDASIL vaccine (yeast). On last fall (2007), was vaccinated with the second dose of GARDASIL vaccine (yeast). In February 2008, was vaccinated with the third dose of GARDASIL vaccine (yeast). In January 2008, the patient was diagnosed with mononucleosis and was treated with (3 MEDROL dose pack). The patient's mononucleosis persisted. Nurse states that her daughter was not on any medication when the third dose of GARDASIL vaccine (yeast) was administered. The patient had muscle aches and pains on both arms and legs, had been tired, fatigued and generally feels unwell. Nurse states she thought these symptoms were lingering due to mononucleosis, but is not sure now. At the time of reporting the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326372-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	17-Oct-2008	--	WAES0807USA03799	17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myalgia

Symptom Text: Information has been received from a mother who called to say her daughter received a dose of GARDASIL vaccine (yeast) a couple of months prior to the 18-JUL-2008 report date, and experienced muscle pain. The patient did not seek medical attention. The mother said she would call back if they found out this was caused by GARDASIL vaccine (yeast). At the time of report, the patient was recovering. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326373-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		18-Aug-2008	17-Oct-2008	OH	WAES0807USA03816	17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning her 16 year old daughter who was vaccinated with the complete series of GARDASIL vaccine (yeast). A week and a half after each dose, the patient started having fainting spells. The patient was rushed to the emergency room about five times. No lab diagnostic studies were performed. It was said she was having these spells for about a year. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326374-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	17-Oct-2008	FL	WAES0807USA03820	17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pallor

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the first dose of GARDASIL vaccine (yeast) injection, Lot # not provided. Subsequently the patient became pale and slumped over for about 10 seconds. The patient did not lose consciousness. No further information was provided. At the time of the report, the patient recovered. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326375-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Dec-2007	14-Dec-2007	0	18-Aug-2008	17-Oct-2008	NC	WAES0807USA03832	17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness, Nausea, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female patient who 14-DEC-2007 and on 07-MAR-2008 was vaccinated with the first and second dose of GARDASIL vaccine (yeast) respectively. There was no concomitant medication. The registered nurse reported that within 24 hours of vaccination with the first dose of GARDASIL vaccine (yeast) on 14-DEC-2007, the patient developed a fever of 101 degrees F, nausea and flu like symptoms. It was unclear how long the fever, nausea and flu like symptoms lasted. The patient recovered. On 07-MAR-2008, the same night after the second vaccination with GARDASIL vaccine (yeast), the patient developed a fever of 102 degrees F, nausea and flu like symptoms that lasted for "several days". On an unspecified date, the patient recovered. It was not specified if the patient sought for medical attention. There was no product quality complaint. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 326376-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	03-Jul-2008	13-Jul-2008	10	18-Aug-2008	17-Oct-2008	CO	WAES0807USA03833	17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Back pain, Dysuria, Fatigue, Headache, Menstruation irregular

Symptom Text: Information has been received from a consumer concerning her 24 year old daughter with sulfonamide allergy and no relevant medical history who on 03-JUL-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). There was no concomitant medication. On 13-JUL-2008 the patient experienced stomach cramps, back pain, extreme fatigue, pain upon urination, headaches and irregular menstrual cycles. Unspecified medical attention was sought. The patient's events persisted. Additional information has been requested.

Other Meds: None

Lab Data: urinalysis - 07/13/08 - negative

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **326377-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Jun-2008	24-Jun-2008	0	18-Aug-2008	17-Oct-2008	NC	WAES0807USA03836	17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a 16 female who on 24-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). There was no concomitant medication. On 24-JUN-2008 the patient experienced faint after vaccination. The patient then revived and then fainted again within a short time while still in office. The patient recovered from faint after vaccination before leaving the office on 24-JUN-2008. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326378-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-May-2008	01-Jun-2008	2	18-Aug-2008	17-Oct-2008	KS	WAES0807USA03846	17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal distension, Amenorrhoea, Anger, Irritability, Mood altered

Symptom Text: Information has been received from a physician concerning a 14 year old white female with menarche in February 2008 and irregular periods. The patient had asthma, acne and mood swings for which she was seen by a counselor prior to vaccination who on 30-MAY-2008 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL vaccine (yeast) (lot no. 659182/1757U). Concomitant therapy included albuterol, benzoyl peroxide (TRIAZ) and RETIN-A MICRO GEL. On approximately 01-JUN-2008 (within the first week after the vaccination) the patient experienced anger outbursts, irritability, moodiness and bloating. The patient stated that she did not have a period in June 2008 but experienced bloating, moodiness and anger outburst off and on. She went on to have a menstrual period on 09-JUL-2008. The physician confirmed that the patient was not pregnant. On 16-JUL-2008, the patient was seen by the physician for the symptoms. The patient was asymptomatic at the visit. The patient was in counseling and the counselor stated that she felt mood problems were probably related to her vaccination. The patient's symptoms were noted to occur "on and off". This is one of several reports from the same source. Additional information has been requested.

Other Meds: albuterol, TRIAZ, RETIN-A MICRO GEL

Lab Data: None

History: Irregular periods

Prex Illness: Mood swings, Acne, Asthma

Prex Vax Illns:

Vaers Id: **326379-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Jul-2008	17-Jul-2008	0	18-Aug-2008	20-Oct-2008	PA	WAES0807USA03852	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0755U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 17-JUL-2008 was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL vaccine (yeast) (lot no. 658219/0755U). After receiving the second dose the patient fainted in the parking lot of the physician's office. The patient was taken back to the office for observation. Subsequently, on the same day, the patient was recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326380-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		18-Aug-2008	20-Oct-2008	NE	WAES0807USA03853	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fungal infection, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning a 22 year old female who on unspecified dates was vaccinated with 2 doses of GARDASIL vaccine (yeast). After the first vaccination, the patient developed yeast infection. After the second vaccination the patient developed another yeast infection. As of 18-JUL-2008, the patient was not recovered. The patient saw a doctor. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326383-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	21-Jun-2007	21-Jun-2007	0	29-Sep-2008	30-Sep-2008	MD	WAES0707USA03061	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received through the Merck Pregnancy Registry from a physician concerning a 24 year old female, with no pertinent medical history, who on 21-JUN-2007 was vaccinated with a first dose of GARDASIL. Subsequently, the patient became pregnant. On an unspecified date the patient was seen in the doctor's office for an obstetrics visit. "The routine obstetrics lab work was taken" (results not reported). Her last menstrual period was 27-MAY-2007 and the estimated date of delivery was 02-MAR-2008. Follow-up information was received via phone call on 22-SEP-2008 from two other health professionals indicating that the baby was born on 28-FEB-2008 by C-section. The baby was born normal and healthy. There were no problems with the mother or the baby. The mother was seen for post partum visit and "everything is just fine". Upon internal review, birth by C-section was determined to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Laboratory test, OB laboratory work

History:

Prex Illness: Pregnancy NOS (LMP = 5/27/2007)

Prex Vax Illns:

Vaers Id: **326384-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Jan-2008	23-Jan-2008	0	29-Sep-2008	30-Sep-2008	--	WAES0802USA03155	30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breech presentation, Caesarean section, Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from Merck pregnancy registry through a health professional concerning a 16 year old female with a medical history of tonsillectomy 4 years ago, and with no allergies, who on 23-JAN-2008 was vaccinated IM with the first dose of GARDASIL (lot# 659657/1487U). Concomitant therapy included Tdap and MMR II (Enders-Edmonston, Jeryl Lynn, Wistar RA 27/3) (MSD). On 28-Feb-2008 it was determined that the patient was pregnant with a LMP of 09-Dec-2007. The patient will be seeing the physician. The patient's outcome is unknown. Follow up information was received from a physician who reported that the patient was taking prenatal vitamins during her pregnancy. On 02-MAY-2008 the patient had ultrasound test for sex of baby and the result indicated within normal limits. On 01-SEP-2008 due to the baby was breech, the patient underwent c-section and delivered a normal, but small male baby whose weight was 4 pounds and 9 ounces and height was 17 inches. Upon internal review, c-section due to breech presentation was determined to be an other important medical event. Additional information is not expected.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 05/02/08, sex of baby: within normal limits

History: Tonsillectomy

Prex Illness:

Prex Vax Illns:

Vaers Id: **326385-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	22-Aug-2008	22-Aug-2008	0	29-Sep-2008	30-Sep-2008	FR	WAES0809HUN00009	30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Asthenia, Convulsion, Fall, Headache, Malaise, Syncope, Vomiting

Symptom Text: Information has been received from a health professional concerning a 22 year old female with a history of migraine who on 22-AUG-2008 was vaccinated with the first dose of GARDASIL, 0.5 ml, IM. Concomitant therapy included JEANINE. On 22-AUG-2008, two minutes after vaccination, patient sat on chair, then felt against the wall and then on floor. After that started short-term "convulses" (5-8 seconds). Then patient opened eyes and did not remember anything, what happened. Five to six hours after vaccination, patient vomited. All day she felt weakness, felt herself ill, had headache. Thee patient recovered from syncope, convulses and vomiting on 22-AUG-2008. Weakness and headache lasted for two more days and resolved on 24-AUG-2008. The reporter felt that syncope, convulses, vomiting and headache, weakness were related to therapy with GARDASIL. Upon internal review, it was determined that "convulses" was serious as an other important medical event. Additional information has been requested.

Other Meds: dienogest (+) ethinyl estradiol, Unk - Unk

Lab Data: Unknown

History: Migraine

Prex Illness:

Prex Vax Illns:

Vaers Id: 326386-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	25-Jan-2008	30-Jan-2008	5	18-Aug-2008	15-Oct-2008	FR	WAES0809ISR00025	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Paraplegia, Sensory loss, Syncope

Symptom Text: Information has been received from a physician concerning a 19 year old female with a history of syncope and sensory loss in lower extremities approximately 3.5 years ago after a 2000 meter run who on 25-NOV-2007 was vaccinated with GARDASIL first dose and no adverse event. On 25-JAN-2008 the patient was vaccinated with GARDASIL second dose. Concomitant therapy included MELIANE. On 30-JAN-2008 the patient experienced loss of feeling in lower extremities and syncope and was hospitalized for 5 days. During hospitalization head computed axial tomography and spinal tap were normal. After 20 hours the patient had gradually gained back feeling in lower extremities. Subsequently, the patient recovered from syncope and loss of feeling in lower extremities. Post hospitalization, magnetic resonance imaging, Holter monitoring and echocardiography were normal. One month since the event, the patient had returned to the military service. Three days later, on approximately 01-MAR-2008 the patient experienced syncope, loss of feeling in lower extremities and paraplegia. Subsequently, the patient recovered from syncope. The patient's paraplegia and loss of feeling in lower extremities persisted. Therapy with GARDASIL was discontinued. Paraplegia were considered to be disabling and other important medical event upon internal review. The details for this event were received from the patient's mother who is also a nurse. Additional information is not expected.

Other Meds: ethinyl estradiol (+) gestodene

Lab Data: spinal tap, 30?Jan08, Normal; head computed axial tomography, 30?Jan08, Normal; magnetic resonance imaging, ??Feb?08, Normal; echocardiography, ??Feb?08, Normal; Holter monitoring, ??Feb?08, Normal

History: Syncope, Sensory loss

Prex Illness:

Prex Vax Illns:

Vaers Id: 326387-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Mar-2008	01-Mar-2008	0	29-Sep-2008	30-Sep-2008	FR	WAES0809POL00020	30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anaphylactic reaction, Asthenia, Chills, Infusion, Injection site reaction, Vaccine positive rechallenge, Vertigo

Symptom Text: Information has been received from a physician concerning a 25 year old female who in January 2008, was vaccinated with the first dose of GARDASIL. In approximately March 2008 the patient was vaccinated with the second dose of GARDASIL. In approximately 5-7 days after vaccination the patient experienced increased temperature, chills, vertigo and weakness and was hospitalized. The patient was treated with infusion fluids and antiallergic drugs. The patient recovered from increased temperature, chills, vertigo and weakness. In August 2008 the patient was vaccinated with the third dose of GARDASIL. In approximately 5-7 days after vaccination the patient experienced anaphylactic symptoms, increased temperature, chills, injection site reaction, weakness and was hospitalized. The patient was treated with infusion fluids and shock-controlling drugs. The patient recovered from anaphylactic symptoms, increased temperature, chills, injection site reaction and weakness. The patient was in good general condition. The reporter felt that vertigo, anaphylactic symptoms, chills, injection site reaction, increased temperature, chills, and weakness were related to therapy with GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: body temp, ??Aug08, increased

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326389-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		29-Sep-2008	30-Sep-2008	FR	WAES0809USA03374	30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Coagulopathy, Epistaxis, Evans syndrome

Symptom Text: Information has been received from a health authority, concerning a female patient (age not reported) who on an unknown date was vaccinated with the second dose of GARDASIL (Batch number not reported). Three months post vaccination, she developed Evan's Syndrome associated with coagulation disorder following chronic epistaxis. At the time of the report, the outcome was not specified. To be noted that the patient received the first dose of GARDASIL (batch not reported) on an unspecified date. The adverse event was considered as other important medical event. Other business partner numbers included: E2008-08679. Additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326390-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Dec-2006	01-Dec-2006	0	29-Sep-2008	30-Sep-2008	NY	WAES0809USA03453	30-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Alopecia, Asthenia, Blindness, Body temperature increased, Cough, Dizziness, Fatigue, Hair disorder, Headache, Heart rate irregular, Immune system disorder, Infection, Malaise, Nasopharyngitis, Oropharyngeal pain, Rhinorrhoea, Sinus headache, Sinusitis, Vision blurred, Visual disturbance, Vomiting

Symptom Text: Information has been received from a 22 year old female who in December 2006, received the second vaccination of GARDASIL (lot # not provided). Concomitant therapy included unspecified vitamins. The patient reported "constant sickness", her "vision was really screwed up," and hair loss and hair change on her 2nd dose of GARDASIL. She "had no side effects on the 1st dose and chose not to have the 3rd dose". The patient reported she "felt fine" after her 2nd shot but the next morning at work her vision "completely went". She felt "like there was a white veil over" her eyes, "like half of 1 of the eyes was working, the other half was gray". She had to be driven home since she could not see. She said she "had a very bad headache". Her gynecologist, did not know the cause of her symptoms. The patient reported she in general does not get very sick, but from her 2nd dose to June 2007, she was "constantly sick with the same cold and infection". The patient believes GARDASIL "knocked" her immune system. She "could not keep anything down for 6 months and had stool samples done last year after the shot". In June 2007, the patient and her hairdresser noticed her "hair part was so wide" and the patient's "hair looked like it was thinning". She visited a dermatologist. She said now her "hair is not as bad as June 2007, maybe because of popping 8-9 vitamins a day" (manufacturer unspecified), but she does "not see a lot of regrowth". She does "not have baldness spots, but it has fallen out more" than she has ever seen. Dr. ran bloodwork less than a week ago. The patient is also concerned about her fertility, but has not reported fertility problems. The patient had no pertinent medical history. At the time of the report, the patient was recovering. Upon internal review, loss of vision was considered to be an other important medical event. Additional information has been requested. 12/26/2008 MR received from PCP. Reported to PCP on 3/2/07 that since receiving HPV vax pt has been having blurry vision and dizziness. Returned 3/

Other Meds: Vitamins (unspecified)

Lab Data: Diagnostic laboratory, 09/12?/08 Labs and Diagnostics: CBC WNL. Gliadin Ab (-). Stool cx, O&P (-)./

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326391-1** **Related reports:** 326391-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Aug-2008	13-Aug-2008	0	29-Sep-2008	30-Sep-2008	CA	WAES0809USA04079	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X		Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B027AA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Bundle branch block right, Dizziness, Loss of consciousness, Malaise, Syncope vasovagal

Symptom Text: Information has been received from a physician concerning a 13 year old female who on 13-AUG-2008 was vaccinated with GARDASIL (lot #659184/0843X) and BOOSTRIX (lot #AC52B027AA) both via IM into her left arm at 2:00 PM. After the vaccination at 2:25 p.m., the patient did not feel good, then she was feeling dizzy. She was talking, but later on was weak, so she was placed on the table to lie down and an ambulance was called. An electrocardiogram (EKG) showed right bundle branch block. Her outcome was not provided. The reporter considered the events to be other important medical events. Additional information has been requested. 10/10/2008 MR received for ER visit 8/13/08 with Dx: Vasovagal syncope. Pt passed out shortly after receiving Gardasil injection. Transported by EMS to ER. Normal exam in ER except EKG showed possible RVH. D/C home.

Other Meds: None

Lab Data: electrocardiogram, 08/13/08, RIGHT BUNDLE BRANCH BLOCK. Labs and diagnostics: UA cloudy (+) for 25-100 epi, 25-100 bacteria, 3+ mucus. UC (+) 90K normal urogenital flora. EKG in NSR with possible RVH.

History: None. PMH: none.

Prex Illness:

Prex Vax Illns:

Vaers Id: **326391-2** **Related reports:** 326391-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Aug-2008	12-Aug-2008	0	17-Sep-2008	23-Oct-2008	CA	WAES0808USA03662	23-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bundle branch block right, Syncope

Symptom Text: Information has been received from a physician, concerning a 13 year old female patient who was vaccinated with 0.5 mL of the first dose of GARDASIL vaccine (yeast) (Lot #659184/0843X). The patient fainted after vaccination. An ambulance was called and the patient was brought to the emergency room where it was determined by electrocardiogram that the patient had a blockage in her right branch. The patient sought medical attention at the office. There was no product quality complaint. Additional information is expected.

Other Meds: Unknown

Lab Data: electrocardiogram - blockage in her right branch

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326392-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		29-Sep-2008	30-Sep-2008	NY	WAES0809USA04134	30-Sep-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a vaccine nurse concerning 6 or 7 kids who were vaccinated with GARDASIL (lot # not provided). Subsequently the patients experienced seizure. The patients sought for unspecified medical attention. Upon internal review, "seizure" was considered to be an other important medical event. Attempts are being made to obtain identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326400-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	25-Sep-2008	25-Sep-2008	0	29-Sep-2008	07-Oct-2008	KY		07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Hearing impaired, Hyperhidrosis, Immediate post-injection reaction, Loss of consciousness, Vision blurred

Symptom Text: Vaccine administered around 11:30 am in (L) arm. Pt immediately felt a little unusual gi upset. Once she got to lobby, she broke out in drenching sweat and sat down and passed out for 5-10 sec. Vision and hearing seemed "fuzzy". Symptoms resolved by 3:30 pm

Other Meds: None

Lab Data: None

History: Penicillin allergy

Prex Illness: None

Prex Vax Illns:

Vaers Id: **326430-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jun-2008	01-Sep-2008	92	29-Sep-2008	06-Oct-2008	NH		06-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN		Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Areflexia, Diplegia, Dysphemia, Muscular weakness, Reflex test abnormal, Speech disorder, Tongue paralysis

Symptom Text: She recieved the Gardasil series, which ended in June of 2008. In the first weeks of September 2008, she began to suffer from her tongue becoming paralyzed. On September 23rd, 2008 she woke up and could no longer walk. Her legs had become so weak and then paralyzed. She was hospitalized and now cannot walk, her arms are now becoming weak, and her speech has slowed and has stuttering.

Other Meds:

Lab Data: Spinal Tap- normal, MRI- normal, ECG- normal, Multiple blood samples-normal, Reflex tests- no reflex in foot Blood pressure- normal

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **326441-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Sep-2008	29-Sep-2008	0	29-Sep-2008	09-Oct-2008	KS		09-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEP	MERCK & CO. INC.	1612U	3	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB243AA	1	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0072X	1	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2774AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Neurological examination normal, Syncope

Symptom Text: Approximately 3-5 minutes postvaccination pt was squatting down near parent when pt stated she was starting to feel light headed then fainted. Legs were elevated and vital signs taken. Pt. revived within 30 - 40 seconds. An ARNP examined pt. who was then able to sit without difficutlies. Neuro check wnl PERRLA. Cranberry juice provided to pt. who had stated she had very little to eat today. Approximately 5-8 minutes post fainting pt. was able to stand without c/o light headedness. Had pt and parent stay 20-25 minutes longer for observation.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **326452-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	03-Mar-2008	Unknown		29-Sep-2008	09-Oct-2008	MI		19-Nov-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TD	SANOFI PASTEUR	U1982DA	1	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1061U	1	Right arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBB448AA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: HPV vaccine given to pg woman (client speaks different language)

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **326455-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	29-Sep-2008	29-Sep-2008	0	29-Sep-2008	09-Oct-2008	IL		09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2788EA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0843X		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness

Symptom Text: Was given 2 injections, within seconds passed out for a brief moment.

Other Meds:

Lab Data:

History: No

Prex Illness:

Prex Vax Illns:

Vaers Id: **326469-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	28-Jul-2008	28-Jul-2008	0	18-Aug-2008	20-Oct-2008	--	WAES0807USA05716	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Dyspnoea, Headache, Vision blurred

Symptom Text: Information has been received from a physician assistant concerning a 19 year old with no pertinent medical history or drug reactions or allergies who on 28-JUL-2008 was vaccinated intramuscularly with the first dose of GARDASIL vaccine (yeast) (lot no. 659184/0843X). Concomitant therapy included an unspecified birth control pill (patient had been on for years). On the same day, a few hours after leaving the office the patient had a significant headache. On 29-JUL-2008, "the following day" the patient experienced weakness, headache, blurred vision, dizziness and shortness of breath during a workout. The patient had always regularly worked out before the vaccination. On 30-JUL-2008, "today", the patient was feeling better but not fully recovered. The patient called the office to seek unspecified medical attention. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326470-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	25-Jul-2008	25-Jul-2008	0	18-Aug-2008	20-Oct-2008	--	WAES0807USA05717	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea

Symptom Text: Information has been received from a nurse concerning a 19 year old female who on 25-JUL-2008 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL vaccine (yeast). The nurse reported that on 30-JUL-2008, "today", the mother called the office and reported that her daughter had been nauseous since receiving the first dose. At the time of this report, the patient was still nauseous. The patient's mother called the office to seek unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326471-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Jul-2008	29-Jul-2008	1	18-Aug-2008	20-Oct-2008	IN	WAES0807USA05728	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Fatigue, Pain, Rash

Symptom Text: Information has been received from a physician concerning an 18 year old female with no relevant medical history or allergies who on 28-JUL-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast). There was no concomitant medication. On 29-JUL-2008, also reported as "24 hours after vaccination" the patient developed fatigue and a rash on the palms of the hands and the soles of the feet. On 30-JUL-2008, the patient sought treatment with an urgent care provider rather than the provider who administered the vaccine. The rash was described as "little reddened spots that were almost raised and similar in look to that of a hands foot and mouth disease rash". The rash was painful and did not itch. The physician planed to prescribe unspecified anti-inflammatory pain medication for the symptoms. At the time of reporting, the patient's events persisted. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326472-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-Jul-2007	27-Jul-2007	0	18-Aug-2008	20-Oct-2008	IL	WAES0807USA05729	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pain in extremity

Symptom Text: Information has been received from an office manager concerning an 18 year old female who on 27-JUL-2007 was vaccinated with the first dose of GARDASIL vaccine (yeast). After receiving the first dose, the patient's arm was sore. On 29-JUL-2008 the patient came back to the office and was vaccinated with the second dose of GARDASIL vaccine (yeast), which was almost a year later. Concomitant therapy included diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid. On the same day, after receiving the second dose, the patient was a little dizzy so she waited for a while until she felt better. The patient was fully recovered on that day. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326473-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	30-Jul-2008	30-Jul-2008	0	18-Aug-2008	20-Oct-2008	NC	WAES0807USA05736	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	3	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Pain in extremity

Symptom Text: Information has been received from a medical assistant concerning an 18 year old female with no pertinent medical history or drug reactions or allergies who on 01-NOV-2006 was vaccinated with the first dose of GARDSIL vaccine (yeast) (lot no. 653978/0955F). On 11-JAN-2007 the patient was vaccinated with the second dose of GARDASIL vaccine (yeast) (lot no. 654389/0961F). On an unspecified date, the patient was vaccinated with the third dose of GARDASIL vaccine (yeast). On 30-JUL-2008 the patient was vaccinated intramuscularly with the fourth 0.5 ml dose of GARDASIL vaccine (yeast) (lot no. 659962/1740U) and experienced a sore arm (which arm unspecified). There was no concomitant medication. It was not documented in the patient's record that a third dose was given however the mother of the patient insist she had received the third dose. At the time of this report, the patient was recovering from a sore arm. The patient sought unspecified medical attention in the office. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326474-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	01-Jan-2008	01-Jan-2008	0	18-Aug-2008	20-Oct-2008	--	WAES0807USA05737	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass

Symptom Text: Information has been received from a physician's assistant concerning a patient who in approximately January 2008, "7 months ago", was vaccinated with the first dose of GARDASIL vaccine (yeast). On the same day, "shortly after the first dose was given", the patient developed a "knot" at the injection site. The patient had since been given the next 2 doses and had not reported any adverse reactions. On an unspecified date the patient recovered from a "knot" at the injection site. The patient contacted the physician's office and sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326475-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Dec-2006	14-Dec-2006	0	18-Aug-2008	20-Oct-2008	GA	WAES0807USA05740	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1424F	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site reaction, Injection site swelling, Injection site warmth

Symptom Text: Information has been received from a bachelor of science in nursing concerning a 16 year old female with no pertinent medical history and codeine allergy who on 14-DEC-2006 was vaccinated with the first dose of GARDASIL vaccine (yeast) 0.5 ml IM (lot # 654885/1424F). Concomitant therapy included SUDAFED and DELSYM. On 14-DEC-2006 the patient experienced injection site reaction, arm red, swollen and warm from shoulder to the elbow for 5 days after the injection. Subsequently, the patient recovered from injection site reaction, arm red, swollen and warm from shoulder to the elbow. The patient did not contact the physician at the time of the events. Additional information has been requested.

Other Meds: DELSYM, SUDAFED

Lab Data: None

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

Vaers Id: 326476-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Jul-2008	29-Jul-2008	0	18-Aug-2008	20-Oct-2008	--	WAES0807USA05748	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling

Symptom Text: Information has been received from a consumer concerning her daughter a 15 year old female who on 29-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). On approximately 29-JUL-2008 the patient experienced a little bit of swelling at the injection site after getting the shot. The patient's a little bit of swelling at the injection site persisted. The patient did not seek medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326477-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	07-May-2008	07-May-2008	0	18-Aug-2008	20-Oct-2008	TN	WAES0807USA05749	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Dizziness, Dyspnoea, Nausea, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered nurse concerning a 21 year old female patient who on 07-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 659182/1757U) 0.5ml intramuscularly. On 14-JUL-2008, the patient was vaccinated with the second dose of GARDASIL vaccine (yeast) (lot # 660389/1968U) 0.5ml intramuscularly. Concomitant therapy included YAZ. The nurse reported that the patient developed dizziness, nausea, some shortness of breath and heaviness in her chest after the first two doses of HPV vaccine. The nurse reported that the symptoms were worse after the second dose. The patient was observed in the office for 20 minutes after the vaccination and then was discharged home when all symptoms resolved. At the time of the report, the patient had recovered. The patient sought medical attention. Additional information has been requested.

Other Meds: YAZ

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326478-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jul-2008	01-Jul-2008	0	18-Aug-2008	20-Oct-2008	MO	WAES0807USA05751	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain, Pain in extremity

Symptom Text: Information has been received from a physician concerning a female patient who in July 2008, was vaccinated with the first dose of GARDASIL vaccine (yeast) for HPV prevention. The physician reported that the patient was experiencing persistent arm pain, "shooting pains in the shoulder" for about a month after receiving her first dose of HPV vaccine in July 2008. At the time of the report, the patient had not recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 326479-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	10-Mar-2008	10-May-2008	61	18-Aug-2008	20-Oct-2008	NY	WAES0807USA05761	03-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Autoimmune disorder, Cough, Fatigue, Gastrointestinal haemorrhage, Haematochezia, Idiopathic thrombocytopenic purpura, Menorrhagia, Menstruation irregular, Nasal congestion, Petechiae, Pharyngolaryngeal pain, Pyrexia, Systemic lupus erythematosus, Weight decreased

Symptom Text: Information has been received from a physician's nurse concerning a 14 year old female who on 10-MAR-2008 was vaccinated with the third dose of GARDASIL vaccine (yeast) (Lot # 659435/1265U). There was no concomitant medication. The reporter heard that the patient was very sick and had an autoimmune disorder. It was unclear if the patient was hospitalized. The physician in the case had not been contacted by the patient's mother at the time of the report. The patient's autoimmune disorder persisted. The patient sought unspecified medical attention. Additional information has been requested. 10/20/08-records received-4/30/08-C/O irregular and excessive menstruation. Pt got her period for first time in December and skipped 3 months until April. Presented to ED on 5/10-5/13/08- DC DX: ITP and GI bleed. C/O feeling tired, weak, fever spiked to 102.2 nasal congestion, cough, sore throat. Petechial rash. Bloody stool 2 days ago. Weight loss.

Other Meds: None

Lab Data: Unknown 10/20/08-records received-ANA positive and positive double stranded DNA and lupus anticoagulant and positive antiphospholipid antibody. Platelets 4.39.

History: Unknown 10/20/08-records received-PMH: bruising and blood in stool.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326480-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-May-2008	Unknown		18-Aug-2008	20-Oct-2008	NY	WAES0807USA05764	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Headache, Loss of consciousness

Symptom Text: Information has been received from a physician concerning a 16 year old female who in May 2008, complete her series of GARDASIL vaccine (yeast). In 2008, the patient experienced chest pain and she also had pressure in her head that caused blacking out. The patient had no problems when the series of GARDASIL vaccine (yeast) was completed. An MRI was performed (results not reported). At the time of this report, the patient was recovering. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: MRI

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326481-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	20-Oct-2008	OH	WAES0807USA05765	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL vaccine (yeast) INJ. After receiving GARDASIL vaccine (yeast), the patient experienced a dizzy episode. At the time of the reporting the patient had recovered. The patient sought unspecified medical attention. No additional information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326482-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	29-Jul-2008	29-Jul-2008	0	18-Aug-2008	20-Oct-2008	CA	WAES0807USA05774	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 12 year old female who on 29-JUL-2008 was vaccinated with a dose of GARDASIL vaccine (yeast) 0.5 ml (route and administration site not reported). Other suspect therapy included varicella virus vaccine live (Oka/Merck) (MSD) (duration and dose not reported) and hepatitis A virus vaccine inactivated (manufacturer unknown). Other concomitant therapy included meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA). After she received the dose of GARDASIL vaccine (yeast), she fainted. It was mentioned that the patient had not eaten most of the day. The patient sought medical attention in the office at time. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326483-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	04-Jan-2008	04-Jan-2008	0	18-Aug-2008	20-Oct-2008	FL	WAES0807USA05782	18-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Joint swelling, Rash, Urticaria, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning a 13 year old female patient who on 04-JAN-2008, was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 657006/0188U) IM, on 19-MAR-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast) (lot # 659657/1487U) IM and on 09-JUL-2008, was vaccinated with the third dose GARDASIL vaccine (yeast) (lot # 660553/0070X) IM. The nurse reported the patient developed hives, arthralgia and swollen knees and ankles after administration of her first dose of HPV vaccine in January-2008. The patient experienced the symptoms intermittently through receiving her HPV vaccine series. Medical attention was sought. The laboratory diagnostics studies performed were sedimentation rate, CBC and rheumatoid factor were negative. The patient's hives and arthralgia and swollen knees and ankles persisted. The patient is being treated with ibuprofen (motrin) and cetirizine (Zyrtec). Additional information has been requested. 10/08/2008 PCP office records received. 13 yr WCC 1/4/08. PE WNL except nevus noted on neck, wart on finger. Seen 5/19/08 for worsening joint pain, constant x 2 weeks-5 months duration. Pain ankles, knees, hips and back. One time ankle swelling. Sent for labs. DX: Joint pain-unspecified. Seen 7/9/08 for spreading rash and joint pain. PE (+) for wheal and flare lesion on knee and shoulder. Pediatric Rheumatology consult 8/21/08 with Impression: Arthralgia associated with mild joint hypermobility. Urticaria. Pt reports transient joint swelling as well. Tx with Aleve.

Other Meds: None

Lab Data: serum rheumatoid factor - ?/?/08 - negative, erythrocyte - ?/?/08 - negative, complete blood cell - ?/?/08 - negative. Labs and Diagnostics: RF (-). ANA (-). Sed rate 4.

History: None. PMH: none

Prex Illness:

Prex Vax Illns:

Vaers Id: **326484-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	20-Oct-2008	WV	WAES0808USA00011	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling abnormal

Symptom Text: Information has been received from a registered nurse concerning a female with a history of seizure who was vaccinated with GARDASIL vaccine (yeast). The registered nurse reported that a patient's family is reporting a patient has been feeling "funny" since she was given GARDASIL vaccine (yeast). The patient was given 2 doses so far but the third dose will not be given due to the patient feeling "funny". The patient sought medical attention, by calling the physician office. There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Convulsion

Prex Illness:

Prex Vax Illns:

Vaers Id: **326485-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	30-Jul-2008	30-Jul-2008	0	18-Aug-2008	20-Oct-2008	VA	WAES0808USA00017	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Eye pain, Pyrexia

Symptom Text: Information has been received from a physician concerning a 13 year old female with no known allergies or pertinent medical history who on 30-JAN-2008 was vaccinated IM with the first dose of GARDASIL vaccine (yeast) 0.5ml, on 28-MAR-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast), on 30-JUL-2008 was vaccinated with the third dose of GARDASIL vaccine (yeast). Concomitant therapy included ACCUTANE. On 30-JUL-2008 the patient developed a high fever, joint pain and eye pain after receiving her third dose of GARDASIL vaccine (yeast). The patient's high fever and joint pain and eye pain persisted. No lab diagnostics were performed. The patient sought medical attention, "phone call and the patient will be seen in the office". There was no product quality complaint. Additional information has been requested.

Other Meds: ACCUTANE

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326486-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jul-2008	01-Jul-2008	0	18-Aug-2008	20-Oct-2008	PA	WAES0808USA00021	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female who in April 2008, was vaccinated with a first dose of GARDASIL vaccine (yeast). No adverse reaction was reported. In July 2008, the patient was vaccinated with a second dose of GARDASIL vaccine (yeast) (lot #660620/0571X). In July 2008, after the vaccination, the patient "held her head and fainted". Medical attention was sought, the patient spoke to medical assistant. At the time of this report, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326487-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	30-Jul-2008	31-Jul-2008	1	18-Aug-2008	20-Oct-2008	KY	WAES0808USA00031	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall

Symptom Text: Information has been received from a nurse concerning a 22 year old female who on 30-JUL-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). According to the nurse, the patient had no symptoms when she left the office after vaccination. On 31-JUL-2008 the patient experienced dizzy and fell in her closet when she woke up at 4:00 AM. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326488-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	30-May-2008	30-May-2008	0	18-Aug-2008	20-Oct-2008	--	WAES0808USA00034	20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Headache, Injection site pain, Pain, Pain in extremity, Similar reaction on previous exposure to drug

Symptom Text: Information has been received from a 26 year old female with an allergy to amoxicillin who on 30-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) 0.5ml and on 30-JUL-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast). After the first dose of vaccination the patient experienced a sore arm, headache and pain at the injection site. The AE went away in one day. After the second dose of the vaccination, the patient experienced the same AE and also burning and sting. After 2 days the patient was still in pain. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326489-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Jun-2008	16-Jun-2008	0	18-Aug-2008	21-Oct-2008	--	WAES0808USA00038	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed, Nausea, Pyrexia

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter who on 16-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). Subsequently the patient experienced nausea and fever. As of 31-JUL-2008 the patient had not gotten her period yet. The patient's nausea and fever persisted. The patient didn't seek medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326490-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	20-May-2008	20-May-2008	0	18-Aug-2008	21-Oct-2008	NJ	WAES0808USA00045	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dermatitis contact, Injection site erythema, Rash pruritic

Symptom Text: Information has been received from a registered pharmacist concerning her 22 year old daughter with a lobster allergy and a history of a tonsillectomy 5 years ago and chickenpox in childhood who on 20-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) 0.5ml IM. Concomitant therapy included YAZ. Subsequently, not long after vaccination, the patient experienced "a little" redness at the injection site which resolved on its own. One week after the vaccination (on approximately 27-MAY-2008) the patient developed a "rash". The patient also developed poison ivy at the time. The "rash" had persisted since that time. The rash looked like tiny hives that itch, no drainage noted. The patient had seen her primary physician and a dermatologist. The patient was prescribed 2 courses of MEDROL dose pack and multiple creams that have been resolved the rash. The rash had completely resolved and then come back again. The location of the rash changed each time it returned. It has been located on her arms, legs, knees, and thighs at different times. The dermatologist stated that it may be caused from a virus or nerves. Additional information has been requested.

Other Meds: YAZ

Lab Data: None

History: Tonsillectomy, Chickenpox

Prex Illness: Seafood allergy

Prex Vax Illns:

Vaers Id: **326491-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Jul-2008	25-Jul-2008	0	18-Aug-2008	21-Oct-2008	MD	WAES0808USA00047	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Injection site pain, Injection site swelling, Pyrexia, Urticaria

Symptom Text: Information has been received from a registered nurse (RN) concerning a 16 year old female with no medical history or no drug allergies who on 25-JUL-2008 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL vaccine (yeast) (lot # 660391/0063X). There was no concomitant medication. On 25-JUL-2008 the patient experienced an allergic reaction. The patient had pain and swelling at injection site. The patient then developed hives and fever. The patient saw the physician to seek medical attention. On an unspecified date, several days later, the patient recovered. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326492-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Jul-2008	29-Jul-2008	0	18-Aug-2008	21-Oct-2008	PA	WAES0808USA00057	21-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Information has been received from a physician concerning a 14 year old female with no relevant medical history and no drug allergy who on 29-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (dose, route and site of administration and lot number not reported). There was no illness at the time of vaccination. The second suspect therapy included varicella virus vaccine live (lot number not reported). Other concomitant therapy included meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA) and hepatitis A vaccine (inactive) (HAVRIX). The patient developed dizziness and nausea while getting into the car to leave the physician's office. The patient sought medical attention and was taken back into the office to observe. Subsequently the symptoms resolved. The patient recovered from dizziness and nausea and was as discharged home. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326493-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-May-2008	Unknown		18-Aug-2008	21-Oct-2008	WV	WAES0808USA00060	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state

Symptom Text: Information has been received from a nurse concerning a 16 year old female with epilepsy and no known allergies who on 28-MAY-2008 was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL vaccine (yeast) (lot no. 659653/1448U). Concomitant therapy included CARBATROL and ASTELIN. A few days after her second vaccination, the patient developed some mental confusion that lasted several days. On an unspecified date, the patient recovered from mental confusion. The patient sought unspecified medical attention at routine office visit. Additional information has been requested.

Other Meds: ASTELIN, CARPATROL

Lab Data: None

History:

Prex Illness: Epilepsy

Prex Vax Illns:

Vaers Id: **326494-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	16-Jun-2008	28-Jul-2008	42	18-Aug-2008	21-Oct-2008	--	WAES0808USA00061	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Visual disturbance

Symptom Text: Information has been received from a nurse practitioner (NP) concerning a female who on 16-JUN-2008 was vaccinated with a dose of GARDASIL vaccine (yeast). "This week", on approximately 28-JUL-2008 the patient went to emergency room with visual disturbances. The patient was not hospitalized. At the time of the report, it was unknown if the patient had recovered from visual disturbances. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326495-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
37.0	F	01-Jul-2008	01-Jul-2008	0	18-Aug-2008	21-Oct-2008	NC	WAES0808USA00066	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injection site mass, Injection site pain

Symptom Text: Information has been received from a physician concerning a 37 year old female healthcare worker who "a couple of weeks ago", in approximately July 2008, was vaccinated with a first dose of GARDASIL vaccine (yeast). Subsequently, the patient developed a tender "knot" at the injection site. At the time of this report, the patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326496-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	21-Oct-2008	TX	WAES0808USA00074	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Tinnitus

Symptom Text: Information has been received from a physician concerning his daughter a female with no pertinent medical history who was vaccinated with GARDASIL vaccine (yeast). Subsequently the patient experienced ringing in her ears after vaccination. On an unspecified date, the patient recovered from ringing in her ears. The reporter felt that ringing in the patient's ears was not related to therapy with GARDASIL vaccine (yeast). The MRI was performed. The patient sought medical attention. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326497-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Aug-2008	21-Oct-2008	--	WAES0808USA00077	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depression, Pyrexia

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with GARDASIL vaccine (yeast). Subsequently the patient experienced fever and depression after vaccination. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326498-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	24-Jul-2008	24-Jul-2008	0	18-Aug-2008	21-Oct-2008	--	WAES0808USA00088	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Nausea, Vomiting

Symptom Text: Information has been received from a medical assistant concerning a 20 year old female who on 24-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). On 24-JUL-2008 the patient experienced nausea, vomiting and tiredness after received the vaccine. The patient's nausea and vomiting and tiredness persisted. No further information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326499-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	25-Jul-2008	26-Jul-2008	1	18-Aug-2008	21-Oct-2008	CA	WAES0808USA00093	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Dyspnoea, Painful respiration, Rash

Symptom Text: Information has been received from a physician assistant concerning a 20 year old white female student patient who on 25-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 660555/0279X) IM in her right arm. Concomitant therapy included YAZ. On 26-JUL-2008, the patient experienced shortness of breath, pain in back lung area with deep breath, rash on lower extremities, after administration of her first dose of GARDASIL vaccine. The patient recovered from shortness of breath, pain upon deep breaths and rash, in less than 48 hours. No further information is available.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326500-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	30-Nov-2007		18-Aug-2008	21-Oct-2008	--	WAES0808USA00130	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Syncope

Symptom Text: Information has been received from a physician concerning a female who on 30-NOV-2007 was vaccinated with the first dose of GARDASIL vaccine (yeast). On 30-NOV-2007, the patient experienced syncopal episode. The patient finish her series and receive her third dose of GARDASIL vaccine, on 21-APR-2008. On approximately 21-JUL-2008 the patient has another dizzy, clammy feeling episode. The grandmother who reported this to the physician mentioned it was her third episode already. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326501-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-May-2008	01-May-2008	0	18-Aug-2008	21-Oct-2008	MI	WAES0808USA00149	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, No reaction on previous exposure to drug

Symptom Text: Information has been received from a registered nurse concerning a female who on unspecified dates was vaccinated with the first and second doses of GARDASIL vaccine (yeast). In May 2008, the patient was vaccinated with a third dose of GARDASIL vaccine (yeast), 0.5 mL, IM, and developed nausea. The patient sought medical attention at the office. At time of reporting, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326502-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	31-Jul-2008	31-Jul-2008	0	18-Aug-2008	21-Oct-2008	OH	WAES0808USA00154	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Immediate post-injection reaction, No reaction on previous exposure to drug, Visual disturbance

Symptom Text: Information has been received from a licensed practical nurse concerning a 13 year old female who on 30-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) IM. On 31-JUL-2008 the patient received the second dose of GARDASIL vaccine (yeast) IM and 5-10 minutes after injection was given, she felt dizzy and fell on ground. She could only see black, but was talking to nurse the entire time. Oxygen was given and patient rested. She was discharged home with her mother. On 31-JUL-2008, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326503-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Jul-2008	30-Jul-2008	0	18-Aug-2008	21-Oct-2008	TX	WAES0808USA00158	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lethargy, Malaise, Syncope

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female who on 30-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). Concomitant vaccination included diphtheria toxoid (+) pertussis acellular 1-component vaccine (+) poliovirus vaccine inactivated (Vero) (+) tetanus toxoid (DTAP-IPV) and meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA). After vaccination, the patient fainted (outcome unknown). Patient's mother called the doctor's office on 31-JUL-2008 stating her daughter was not feeling well, not feeling like herself and was lethargic. At the time of reporting, the patient had not recovered. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326505-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	31-Jul-2008	31-Jul-2008	0	18-Aug-2008	21-Oct-2008	CA	WAES0808USA00239	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female with no pertinent medical history who on 31-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). Concomitant therapy included meningococcal ACYW conj vaccine (dip toxoid) (MENACTRA). The physician reported that on 31-JUL-2008 a patient fainted after she received her first and only dose of GARDASIL vaccine (yeast). The patient woke up after few seconds. Recovered 31-JUL-2008. The patient had not eaten anything prior the vaccination. The patient sought medical attention, she was seen by the physician. There was no product quality complaint. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326506-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		18-Aug-2008	21-Oct-2008	NC	WAES0808USA00248	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a physician concerning a teenage girl believed to be 17 year old who on an unknown date was vaccinated with GARDASIL vaccine (yeast). The physician reported that a patient developed severe headaches after received GARDASIL vaccine (yeast). The patient is currently seeing a neurologist (name unspecified) and taking NEURONTIN for the headaches. There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326507-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	20-May-2008	20-May-2008	0	18-Aug-2008	21-Oct-2008	NJ	WAES0808USA00267	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician's office manager concerning a female who on 20-MAY-2008 was vaccinated intramuscularly with the first dose of GARDASIL vaccine (yeast). There was no concomitant medication. The patient felt dizzy afterwards, however that went away. On 22-JUL-2008 the patient was vaccinated intramuscularly with the second dose of GARDASIL vaccine (yeast) and has been dizzy ever since. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326508-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		18-Aug-2008	21-Oct-2008	--	WAES0808USA01439	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a patient who on an unspecified date was vaccinated with a dose of GARDASIL vaccine (yeast) (lot number not provided) and fainted. The patient outcome was unknown. This is one of the several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326516-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-Jun-2008	01-Aug-2008	56	30-Sep-2008	01-Oct-2008	FR	WAES0809USA04122	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1114U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical conisation, Cervix carcinoma stage 0, Cervix carcinoma stage III

Symptom Text: Information has been received from a gynecologist via Sanofi Pasteur as part of a business agreement concerning a 20 year old female with a history of a normal smear test papanicolaou II (Dec-2007) who on 06-Jun-2008 was vaccinated with the third dose of GARDASIL (lot # 1114U, batch # NH010940)) IM in her deltoid. Concomitant therapy included hormonal contraceptives (unspecified). In August 2008, the patient had a check-up cytology smear test (papanicolaou) showed PAP IVa, highly positive for HPV. In September 2008, the patient underwent conisation resulting in CIN III. On 10-Oct-2007, the patient was vaccinated with the first dose of GARDASIL (LOT# 1518F, batch # NF23330), and on 13-Dec-2007, the second dose of GARDASIL (LOT# 0276U, batch # NF58550). Both vaccinations were given in to the deltoid and well tolerated. The reporter pointed out that smear test papanicolaou had been without pathological findings until Aug-2008. Last smear test had been in Dec-07 which was PAP II. Cervical intraepithelial neoplasia III and papanicolaou smear abnormal, class IVa were considered other important medical events. No further information is available.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Pap test, ??Jul07, Comment: No pathological findings, PAP II; Pap test, ??Aug08, Comment: PAP IV a, highly positive for HPV

History: Papanicolaou smear normal

Prex Illness:

Prex Vax Illns:

Vaers Id: **326517-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-May-2008	29-Jun-2008	59	30-Sep-2008	01-Oct-2008	FR	WAES0809USA03950	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Central nervous system lesion, Facial palsy, Multiple sclerosis

Symptom Text: Information has been received from a health care professional concerning a 19 year old female who was vaccinated with the second dose of GARDASIL (route and lot number not reported) by the end of May-2008. On 29-Jun-2008 the patient presented with facial palsy. Symptoms were not observed by the reporter. MRI on 29-Jun-2008 revealed lesions. The specialist performed another MRI with contrast's product (unspecified date) but there was no contrast uptake for lesions. The specialist evoqued past multiple sclerosis. A MRI was scheduled in Dec-2008. At time of reporting the outcome was not specified. She had received the first dose of GARDASIL in Mar-2008. Upon internal review, multiple sclerosis-like syndrome was determined to be other important medical events. Other business partner numbers included: E2008-08715. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 29Jun08, Comment: revealed lesion

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326518-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	11-Sep-2008	11-Sep-2008	0	30-Sep-2008	01-Oct-2008	FR	WAES0809USA03698	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Fatigue, Syncope, Tooth fracture

Symptom Text: Information has been received from a health professional concerning a 19 year old female who on 11-SEP-2008 at 11 am was vaccinated with the third dose of GARDASIL (batch number and route of administration not reported). Within 3 seconds after injection, the patient experienced very brutal and violent syncope. She fell from the examination table and had fractured her left upper incisor tooth. The event was not a vagal malaise; there was no anticipation sign and it was very sudden. The patient remained distraught for 15 to 20 seconds because of the shock. She was kept under observation for one hour at the physician's office; she was very tired. She could subsequently walk, however she was still very tired. The outcome was not reported. The patient has no adverse effect after 1st and 2nd injections of GARDASIL and no reaction after other vaccines. Patient was rested and coming back from holidays. The reporter considered the adverse events to be other important medical events. Other business partner numbers included: E2008-08537. No further information is available. The case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 326519-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Jan-2007	Unknown		30-Sep-2008	01-Oct-2008	LA	WAES0708USA03487	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood test normal, Cephalo-pelvic disproportion, Culture negative, Delayed delivery, Drug exposure during pregnancy, Laboratory test normal, Umbilical cord around neck

Symptom Text: Information has been received for Pregnancy Registry for GARDASIL from a consumer's mother concerning her 18 year old daughter with no medical history who on 24-JAN-2007 was vaccinated with a first dose of GARDASIL. Concomitant therapy included HEP B (unspecified) and Vitamins (Prenatal DHA). The reporter mentioned that "her daughter received her first injection and found out that she was pregnant 2-3 weeks later." No adverse event reported. It was reported that she had a pregnancy test done. On 27-SEP-2007, the patient delivered a normal, healthy female baby weighing 7 lbs and 6 oz, length 20, apgar score 8/9, head circumference not reported. No congenital anomalies. Complications during pregnancy or labor/delivery included Nuchal cord x 1 and cephalopelvis disproportion (1 CTC/S) failure to progress. Diagnostic test during pregnancy included routine Quad screen, routine labs, culture and biophysical all within normal limits. Upon internal review cephalopelvis disproportion and failure to progress were considered to be an other important medical event. No further information is available.

Other Meds: vitamins (unspecified)

Lab Data: Beta-human chorionic

History:

Prex Illness: Pregnancy NOS (LMP = unknown)

Prex Vax Illns:

Vaers Id: 326520-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	27-Jun-2008	07-Jul-2008	10	30-Sep-2008	01-Oct-2008	AL	WAES0809USA04230	20-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2566AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C2862AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1758U	0	Left arm	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Arthralgia, Back pain, Complex regional pain syndrome, Dyspnoea, Fatigue, Gastrooesophageal reflux disease, Headache, Hypoaesthesia, Hypoaesthesia facial, Joint swelling, Muscle tightness, Nausea, Oropharyngeal pain, Pain, Paraesthesia, Positive Rombergism, Pyrexia, Rash erythematous, Sensory disturbance, Sinus congestion, Sinusitis, Sleep disorder, Tenderness, Throat tightness, Tremor, Viral infection, Vomiting

Symptom Text: Information has been received from a physician concerning a 12 year old female with a history of infectious mononucleosis, who "about two months ago" (approximately in July 2008) was vaccinated with the first dose of GARDASIL, a dose of MENACTRA and another unspecified vaccine. Concomitant therapy included NEURONTIN, ELAVIL, NEXIUM and CLARITIN. The physician stated that "about one week" after receiving vaccination, the patient developed headache, numbness, extremity tingling and pain on the left side of the body. The patient had been unable to attend school for two months because of the adverse symptoms. The patient sought medical attention with an office visit. At time of reporting, the patient had not recovered. Lab tests included a blood work with unknown results. The physician considered the adverse events to be disabling. Additional information has been requested. 12/08/2008 MR received from PCP. Seen 7/14/08 with c/o sore throat, H/A, congestion x 1 week. DX: Sinusitis-tx abx. Seen in ER 7/15/08 with same sx in addition to joint aches. Thought to be viral etiology. Seen 7/16/08 with additional stomach cramping, body aches, and red bumps on back. Worsening H/A. Worsening pain upper L side. Feels like throat is swelling up, migratory joint pain. Tx-Tylenol #3. Still c/o joint pain and difficulty sleeping. Assessment: Joint Pain/Fatigue. ? Viral Syndrome. By 8/26/08 pt worsening sx-H/A and sensory issues on the L side. Been out of school for long time. Referred to Rheumatology and Neurology. 1/5/09 MR received from Immunology and Neurology consults. 8/19/2008 and 8/26/08. Seen for c/o fatigue, H/A, back pain and joint pain. Also with c/o numbness of jaw and extremities, episodes of joint swelling, SOB, muscle tightness and nausea which began several days after receiving Gardasil vax. Now in home school due to intensity of sx. PE (+) for 8/10 H/a, mild (+) Romberg, point tenderness. Returned 9/16/08 for c/o disturbances of skin sensation. DX: Reflex Symphathetic Dystrophy, GER. Episode

Other Meds: ELAVIL; NEXIUM; NEURONTIN; CLARITIN

Lab Data: Laboratory test, blood work. Labs and Diagnostics: AST 45. ALT 86. monospot (-). ESR 27, 51. ANA (-). RF (-). Lyme (-). EBV c/w acute infection. Abd US WNL. CPK 53. EBV (-). MRI brain and C-spine WNL.

History: Infectious mononucleosis. PMH: none. Allergy to sulfa.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326521-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	21-Apr-2008	23-Apr-2008	2	30-Sep-2008	01-Oct-2008	AZ	WAES0809USA04225	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Impaired work ability, Muscle spasms

Symptom Text: Information has been received from a nurse concerning a 22 year old female who on 21-APR-2008 was vaccinated with the first dose of GARDASIL and on 23-APR-2008 developed back spasms. The patient's father called the office stating his daughter was off from work for 1 week due to the back spasms. The patient stated that she was not going to continue the GARDASIL series. At time of report, the patient was not having any problems. Back spasms were considered to be disabling. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326522-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-May-2008	09-Jun-2008	19	30-Sep-2008	01-Oct-2008	FR	WAES0809USA04400	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Encephalitis

Symptom Text: Information has been received from Health Authority concerning a 16 year old female who on 21-MAY-2008 was vaccinated with GARDASIL, 0.5 ml, IM (batch number unknown). On 09-JUN-2008 the patient developed encephalitis. She was hospitalized due to the event from 07-JUL-2008 to 08-JUL-2008. There was an increase of monocytes in liquor and some EEG-changes were noted. At a return visit in September 2008 she was fully clinical recovered from encephalitis. The case was closed. Other business partner numbers included E2008-08847. Health Authority reference number included 083170. Additional information is not expected.

Other Meds: Unknown

Lab Data: Electroencephalography, EEG-change; CSF monocyte count, increase

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326523-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	02-Apr-2008	13-May-2008	41	30-Sep-2008	01-Oct-2008	--	WAES0809USA04198	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Ectopic pregnancy, Haemorrhage, Surgery

Symptom Text: Information has been received from a 24 year old female patient, for the Pregnancy Registry for GARDASIL. The patient with no drug allergy and no other medical history, on 02-APR-2008, was vaccinated with the first dose of GARDASIL. On 06-JUN-2008, the patient received the second dose of GARDASIL. There was no other concomitant medication. On 17-JUN-2008 the patient went to the physician's office because her period is already late. The blood test was implemented and the result showed that she was pregnant and experienced ectopic pregnancy (estimated due date of 17-FEB-2009). On the night of 17-JUN-2008 the patient experienced bleeding and was brought to the hospital and was admitted for 1 day. Subsequently, the patient ended up having a surgery because of the ectopic pregnancy. At the time of this report, the patient is recovering. The patient sought medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Serum beta-human, pregnant and is ectopic pregnancy

History:

Prex Illness: Pregnancy NOS (LMP = 5/13/2008)

Prex Vax Illns:

Vaers Id: 326528-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jun-2008	24-Jun-2008	8	30-Sep-2008	01-Oct-2008	FR	WAES0809USA04258	01-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0466U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hypotonia, Muscle disorder, Paralysis

Symptom Text: Information has been received from a health professional concerning a 14 year old female with no reported relevant history who on 16-JUN-2008 was vaccinated intramuscularly into the upper arm with the first dose of GARDASIL (lot#: 0466U, batch #:NG34890). On 24-JUN-2008, the patient developed a sensation of paralysis and muscular tonus disorder in legs in particular in the thighs and less intensive in arms. The patient was hospitalized for 1 day (exact dates not reported). The patient recovered after 1 day. The reporting physician assessed the causal relation to the vaccine as probable. Other business partner numbers included: E2008-08704. No further information is available. File closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326530-2 (S)** **Related reports:** 326530-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Nov-2007	30-Nov-2007	0	12-Nov-2008	13-Nov-2008	AR	WAES0811USA00735	14-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Back pain, Convulsion, Headache, Hypoaesthesia, Nausea, Neck pain, Vomiting

Symptom Text: Information has been received from a nurse concerning an 18 year old female with an allergy to Ibuprofen who on 30-NOV-2007 was vaccinated with the first dose of GARDASIL IM (Lot#659055/1522U), (site unknown) and on 28-JAN-2008 was vaccinated with the second dose of GARDASIL IM (Lot#659653/1448U), (site unknown). Concomitant therapy included DEPO-PROVERA (indication not specified). In November 2007, after receiving the first dose, the patient experienced nausea, vomiting, neck pain, back pain and headache. In July 2008, the patient began to experience seizures and numbness in various parts of her body. The patient sought medical attention. Laboratory tests performed included: "pregnancy test", "electrolytes", urinalysis and "CBC". The patient was not pregnant and the other test results were unknown. At the time of report on 05-NOV-2008, the patient was not recovered. The physician considered all these events to be significant disability or incapacity. Additional information has been requested.

Other Meds: Doxycycline; DEPO-PROVERA

Lab Data: beta-human chorionic, no pregnant

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326532-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Sep-2008	19-Sep-2008	2	30-Sep-2008	10-Oct-2008	IN		10-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2620AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0955F	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site pain, Injection site swelling, Injection site warmth, Pyrexia

Symptom Text: Marked pain involving entire upper arm where injection was given, swelling and warmth. Patient unable to lift her arm due to pain. Subjective fevers. All occurred within 1-2 hours after vaccines and worsened over 36 hours. Managed with acetaminophen and Ibuprofen.

Other Meds: Ortho-cept

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326534-1** **Related reports:** 326534-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Oct-2007	Unknown		30-Sep-2008	10-Oct-2008	CA		20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Dizziness, Fall, Headache, Syncope vasovagal, Tremor

Symptom Text: Per mom, had intermittent headaches and dizziness for several months. Had a possible seizure, syncope of 9-22-08. Called 911 tonight by ambulance to local hospital. Saw Neurologist 9/23, 24. 10/14/08 Reviewed ER medical records of 9/23/2008. FINAL DX: vasovagal syncope, possible seizure Records reveal patient experienced fall in bedroom after standing from bent over position w/mild shaking, mild abdominal pain. Tx w/IVF & d/c to home.

Other Meds: Unknown

Lab Data: Unknown LABS: EEG, ECG, CT brain, CBC, chemistry, UA all WNL.

History: No chronic major problems.

Prex Illness: None recorded

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326534-2** **Related reports:** 326534-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Oct-2007	01-Jan-2008	68	08-Oct-2008	09-Oct-2008	CA	WAES0810USA00239	10-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Computerised tomogram, Convulsion, Dizziness, Drooling, Electroencephalogram, Headache, Pallor

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 03-MAY-2007 was vaccinated with the first dose of GARDASIL, on 17-JUL-2007 was vaccinated with the second dose of GARDASIL and on 25-OCT-2007 was vaccinated with the third dose of GARDASIL (lot#: 658560/1062U). Two or three months after she received the third dose her mother reported that she had been having seizures at night while she was sleeping. She also began experiencing headaches and dizziness. It was not known if this also occurred after the first two doses. The mother told the physician that the patient's sister went into her room a few times and noticed that she was very pale and had white saliva dripping out of her mouth. She was currently seeing a neurologist but it was not known if she had recovered. Electroencephalogram (EEG) and computed axial tomography (CAT) scan was performed (results not reported). Upon internal review the patient's seizures were determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326536-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Jul-2008	31-Jul-2008	0	30-Sep-2008	10-Oct-2008	CA		10-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	U928U		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2571AA		Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B021AA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Lip swelling, Syncope, Tooth fracture

Symptom Text: Pt fainted after receiving 3 vaccines, TDAP MENACTRA and HPV #1. Pt. refused to lay down or to hold moms hand. She fainted after 5-8 seconds after vaccines were given. Fell hit her forehead, lip was swollen and chipped her tooth was discharged and reviewed by dr at office.

Other Meds: None

Lab Data:

History: pregnancy dx after immunizations.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326545-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Sep-2008	16-Sep-2008	1	30-Sep-2008	10-Oct-2008	NY		10-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling abnormal, Muscle twitching, Peripheral coldness

Symptom Text: Twitching or restless leg movements (muscles) starting at 10:30 PM-12:00 AM (midnight), feet cold, uneasy feeling due to quick onset. Rest, warm milk, camomil tea was given and child did not have any twitching in next AM, just the start of a cold.

Other Meds: None

Lab Data:

History: None

Prex Illness: Mild cold

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326546-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
40.0	F	09-Sep-2008	10-Sep-2008	1	30-Sep-2008	28-Oct-2008	LA		04-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Burning sensation, Hypoaesthesia, Pain, Pain in extremity, Pyrexia

Symptom Text: High fever (100 degrees) on the evening of 9/10/08, which returned to normal by morning. Also on the evening of 9-10-08, my fingertips on my right hand began to hurt (numbness, burning, aching) and have continued to hurt (worse at night). Now being treated with prednisone.

Other Meds: ZENCHENT (birth control pill), after vaccination : metronidazole for 2 days

Lab Data:

History: Mitral valve prolapse

Prex Illness: Trichomoniasis

Prex Vax Illns:

Vaers Id: **326561-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	22-Sep-2008	23-Sep-2008	1	30-Sep-2008	14-Oct-2008	OR		14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0085X	1	Left arm	Subcutaneously	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB246AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Pruritus

Symptom Text: Developed 5cm x 7cm area erythema at injection site w/in 24 hours of vaccine. (+) pruritis.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **326568-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Sep-2008	29-Sep-2008	0	30-Sep-2008	10-Oct-2008	MS		10-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	1	Gluteous maxima	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Laceration, Suture insertion, Syncope, Tooth fracture

Symptom Text: RECEIVED SECOND GAURDASIL INJECTION, AFTER WAITING 15 MINUTES, WALKED TO FRONT TO CHECK OUT, MY DAUGHTER FAINTED, CHIN AND JAW HIT FLOOR FIRST. CAUSING A LACERATION TO HER CHIN THAT REQUIRED 4 STITCHES. broke a tooth

Other Meds: NONE

Lab Data: she had xrays of mandible, head and neck. will go to dentist on 10/2/08

History: hx of asthma as a child

Prex Illness: none

Prex Vax Illns:

Vaers Id: **326580-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	29-Aug-2008	29-Aug-2008	0	30-Sep-2008	10-Oct-2008	NM		10-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Patient developed some urticaria after 1st injection on 6/27/08 but did not report this to anyone. Then within hours of her second vaccine on 8/29/08 developed urticaria that persists today.

Other Meds: Zovia ocp

Lab Data: na

History: Mild intermittent asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326596-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	21-Nov-2007	03-Dec-2007	12	30-Sep-2008	27-Oct-2008	FL		28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2136AA	0	Right leg	Intramuscular	
	HPV4	MERCK & CO. INC.	01884	0	Right leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Mom states child had hair loss after HPV shot. Refuses any more.

Other Meds:

Lab Data:

History: VSD, Status post trach, OSAS

Prex Illness: None

Prex Vax Illns:

Vaers Id: **326604-1** **Related reports:** 326604-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Sep-2008	25-Sep-2008	1	30-Sep-2008	28-Oct-2008	WI		03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Urticaria, Vomiting

Symptom Text: Urticaria began 1 day post vaccine, associated with nausea, vomiting. Duration of illness 1 week.

Other Meds:

Lab Data: Clinical diagnosis

History: NKDA, NKFO, No active medical illness

Prex Illness: None

Prex Vax Illns:

Vaers Id: **326604-2** **Related reports:** 326604-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Sep-2008	24-Sep-2008	0	02-Oct-2008	14-Oct-2008	WI		04-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Nausea, Pyrexia, Rash generalised, Rash pruritic, Vomiting

Symptom Text: BY EVENING OF DATE OF ADMINISTRATION OF HER FIRST DOSE OF GARDASIL, AMBER BROKE OUT IN A "RAISED, RED, ITCHY RASH ALLOVER". 2 DAYS LATER SHE BECAME NAUSEATED WITH VOMITING. BY THE 4TH DAY SHE'D DEVELOPED A LOW-GRADE FEVER IN ADDITION TO THE CONTINUATION OF THE OTHER SYMPTOMS. HER TEMP. WASN'T VERIFIED. HER STEP-MOM CALLED THE HEALTH DEPT. TO ASK IF HER SYMPTOMS COULD BE A RESULT OF THE INJECTION OF GARDISIL. RECOMMENDED THEY SEE A DOCTOR DUE TO THE PRESENCE OF FEVER/RASH ILLNESS, WHICH THEY DID. THE PROVIDER TOLD THEM THAT AMBER HAD AN ALLERGIC REACTION TO THE GARDASIL VACCINE AND TREATED THE SYMPTOMS.

Other Meds:

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **326634-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Jun-2008	24-Jun-2008	0	01-Oct-2008	14-Oct-2008	NJ		14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024EA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1740U	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	UC2632AA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Pallor, Syncope

Symptom Text: Immediately following the administrator had a syncopal episode. continued with symptoms of light-headedness, pale, coloring -> given PO fluids and sm snack, approx 1 hr after administration. another syncopal episode -> to ER

Other Meds: None

Lab Data: ER tests not available this time

History: NKDA

Prex Illness: None

Prex Vax Illns:

Vaers Id: **326658-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.1	U	Unknown	Unknown		01-Oct-2008	02-Oct-2008	MI	WAES0809USA04046	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Death neonatal, Drug exposure via breast milk, No adverse event

Symptom Text: Information has been received from a physician concerning a 6-week-old patient who's 25-year-old mother was vaccinated with the first 0.5 mL dose of GARDASIL two days post-partum (it was noted that she was not pregnant when she received the first dose). The patient was breast feeding. Subsequently, the patient died at six weeks of age. Autopsy results revealed that the patient died from suffocation. According to the physician, the death was not related to GARDASIL. Physician indicated that he had all dates and lot numbers of the vaccine (not reported at the time of this report). Additional information has been requested.

Other Meds: Unknown

Lab Data: autopsy, died from suffocation

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326660-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		01-Oct-2008	02-Oct-2008	--	WAES0809USA04359	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cardiac monitoring, Convulsion, Electroencephalogram, Loss of consciousness, Postural orthostatic tachycardia syndrome

Symptom Text: Information has been received from a registered nurse concerning her niece, a 17 year old female who about 2 years ago, in approximately 2006 was vaccinated with GARDASIL. It was reported that the patient had had seizure activity and had passed out since vaccination with GARDASIL. The niece had completed the GARDASIL series. The niece had been to the Emergency Room and may had been admitted to the hospital. She have been diagnosed with POTS syndrome (Postural Orthostatic Tachycardia Syndrome) . On unspecified dates, numerous tests including EEG and heart monitoring had been performed (no results reported). The patient had been seen by many doctors. At the time of the report, the patient had not recovered. Upon internal review, seizure activity was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326661-1 (S)** **Related reports:** 326661-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Feb-2008	04-Sep-2008	197	01-Oct-2008	02-Oct-2008	OH	WAES0809USA04227	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427F	2	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Depression, Drug dependence, Fall, Hallucination, Physical examination normal, Postictal state, Skin laceration, Suture insertion, Syncope, Tachycardia

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the third dose of GARDASIL 0.5 mL, IM. About one month after that vaccination, the patient developed syncope and had a seizure. The patient sought unspecified medical attention. Upon internal review, seizure was considered to be other important medical event. Additional information has been requested. 10/09/08-records received for DOS 9/2-9/4/08-DC DX: Seizure and or syncope. Laceration and suture repair to forehead. Tachycardia. Drug dependence. Presented to ED status post syncopal episode followed by seizure activity on 9/2/08. Noted to have bit tongue and was postictal after event. Orthostatics negative. 10/14/08-records received-date of 1st HPV4 vaccine 3/15/07-lot#1427F left arm, 2nd HPV4 6/1/07-Lot#0702F left arm. 2/20/08-C/O back problems and shoulder pain. HPV4 #3 lot#1427F right arm. Seen on 5/9/08-C/O depressed tried using parent's Prozac. Hallucinating in school. 9/10/08-new seizure meds making her sick, no appetite, nausea. 9/13/08-S/P seizure activity, injury to head. Stress. Neuro consult 9/22/08-uncertain as to whether the seizure caused the incident or the fall. PE: normal.

Other Meds: Unknown 9/9/08-records received-Oral contraception. Xanax for stress and anxiety.

Lab Data: Unknown 10/9/08-records received-Echo unremarkable. CT scan of head and neck negative. Toxicology screen positive for bezos. Prolactin level elevated. EEG showed presence of generalized potentially epileptogenic discharges some associated

History: Unknown 9/9/08-records received-PMH: some congenital heart valve anomaly.

Prex Illness:

Prex Vax Illns:

Vaers Id: **326662-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		01-Oct-2008	02-Oct-2008	FR	WAES0809AUS00077	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HEP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Deafness, Headache, Lethargy, Pyrexia, Visual disturbance

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning a 12 year old female who was vaccinated with GARDASIL. Other suspect therapy included hepatitis B vaccine, recomb (manufacturer unknown). Subsequently the patient experienced visual impairment, deafness, headache, lethargy and pyrexia. Subsequently, the patient recovered from visual impairment, deafness, headache, lethargy and pyrexia. The reporter felt that visual impairment, deafness, headache, lethargy and pyrexia were related to therapy with GARDASIL and hepatitis B vaccine, recomb (manufacturer unknown). The original reporting source was not provided. Upon internal medical review the adverse event of deafness was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326663-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		01-Oct-2008	02-Oct-2008	FR	WAES0809AUS00075	02-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Headache, Injection site pain, Palpitations, Syncope, Tremor, Visual disturbance, Vomiting

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning a 12 year old female who was vaccinated with GARDASIL. Subsequently 6 days after vaccination with GARDASIL, the patient experienced convulsion, headache, injection site pain, palpitations, syncope, tremor, visual impairment and vomiting. At the time of reporting to the agency on 16-APR-2008 it was not known if the patient had recovered from the convulsion, headache, injection site pain, palpitations, syncope, tremor, visual impairment and vomiting. The agency considered that convulsion, headache, injection site pain, palpitations, syncope, tremor, visual impairment and vomiting were related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review the adverse event of convulsion was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326681-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	29-Sep-2008	30-Sep-2008	1	01-Oct-2008	14-Oct-2008	GA		14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	MER0975L	2	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	PMCU2689AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	MSD0571X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Tenderness

Symptom Text: SCHOOL NURSE CALLED CLINIC THIS AM, 10-01-08. NURSE STATES PT C/O TENDERNESS IN RA. SCHOOL NURSE DESCRIBES REDNESS AND SWELLING NOTED. SCHOOL NURSE STATES SHE HAS ADMINISTERED ACETAMINOPHEN AND HAS APPLIED AN ICE PACK.

Other Meds: NONE

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **326690-1** **Related reports:** 326690-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Oct-2008	01-Oct-2008	0	01-Oct-2008	14-Oct-2008	NC		14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal behaviour, Dizziness, Restlessness

Symptom Text: Vaccine given at approximately 3:15 pm on 10-1-08. About 15-20 minutes after injection patient developed mild dizziness, restlessness, sensation that she had to move, and "giggling" (strong urge to laugh).

Other Meds: Zithromax 250 mg (5 day course beginning 9-26-08)

Lab Data: Treated with Benedryl 50mg IM at 4:20 pm on 10-1-08. Symptoms resolved in 15-20 minutes after Benedryl given.

History: None

Prex Illness: Acute Bronchitis (better with Zithromax)

Prex Vax Illns:

Vaers Id: **326690-2** **Related reports:** 326690-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Oct-2008	01-Oct-2008	0	17-Nov-2008	17-Dec-2008	--	WAES0810USA00247	02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Tremor

Symptom Text: Information has been received from a registered pharmacist concerning an 18 year old female with no pertinent medical history and no history of drug reactions or allergies who on 01-OCT-2008 was vaccinated with the first dose of GARDASIL 0.5ml IM. Concomitant therapy included YASMIN and Z-PAK. Within one hour of receiving the vaccine, the patient developed involuntary tremors of upper and lower extremities, as well as an involuntary nervous giggle. The patient's blood pressure elevated to 1160/96. The pharmacist stated that the patient just finished Z-PAK today for an unspecified medical condition. The patient was not recovered. The patient sought medical attention with a physician office visit. Additional information has been requested.

Other Meds: Z-Pak; Yasmin

Lab Data: Blood pressure, 10/01/2008, 160/96

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326692-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Oct-2008	01-Oct-2008	0	01-Oct-2008	14-Oct-2008	CA		14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB519AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1446U	1	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB247AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness, Immediate post-injection reaction, Vomiting

Symptom Text: WITHIN 2 MINS OF INJECTIONS ADMINISTERED PT FELT FAINT, AND VOMITTED B/P WAS CHECKED 80/40. 10 MINS LATER B/P WAS CHECKED 91/71 PATIENT WALKED OUT, NO PROBLEMS

Other Meds:

Lab Data:

History:

Prex Illness: URINARY TRACT INFECTION

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326694-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Sep-2008	30-Sep-2008	0	01-Oct-2008	14-Oct-2008	CA		14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	Q650X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Vomiting

Symptom Text: 2 hours after vaccine administered, patient turned "ghostly white" per her mother and started vomiting. She had multiple episodes of vomiting for the next 6 hours. No diarrhea or fevers to suggest a viral illness.

Other Meds: none

Lab Data: none

History: Seasonal allergies to cats, dust. No other medical history

Prex Illness: none

Prex Vax Illns: none~ ()~NULL~~In Patient|none~ ()~NULL~~In Sibling2|none~ ()~NULL~~In Sibling1

Vaers Id: **326706-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	29-Aug-2008	Unknown		01-Oct-2008	14-Oct-2008	AZ		14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0680U	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Diarrhoea, Dizziness, Nausea, Tremor, Vomiting

Symptom Text: Nausea, vomiting, diarrhea, trembling, confusion, feeling as if going to pass out.

Other Meds: ASA; Lipitor

Lab Data:

History:

Prex Illness: N/A - In office to discuss Gardasil

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326709-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	24-Sep-2008	26-Sep-2008	2	01-Oct-2008	14-Oct-2008	CA		14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0443X		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Induration, Skin warm

Symptom Text: approx. 2.5 x 2.5 area of slight erythema warmness, slight induration on the (R) deltoid area, warm compress on the affected area ADVIL 200 mg cap 2 caps every 6 hours prn

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **326713-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Sep-2008	30-Sep-2008	0	01-Oct-2008	14-Oct-2008	IN		14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2604AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0575X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Immediate post-injection reaction, Tooth injury

Symptom Text: Pt. received MCV-4 and HPV. Stood up after receiving vaccines and fell forward. Pt. hit mouth and last part of tooth. Pt. taken to E.R. and released.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326717-1** **Related reports:** 326717-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
3.0	F	01-Oct-2008	Unknown		01-Oct-2008	29-Oct-2008	KY		29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Patient was given GARDASIL injection by error.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **326717-2** **Related reports:** 326717-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
3.0	F	01-Oct-2008	01-Oct-2008	0	17-Nov-2008	17-Dec-2008	KY	WAES0810USA00200	22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Left leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Information has been received from a nurse practitioner and the patient's aunt concerning a 41 month old female, who on 01-OCT-2008, at 11:00Am was inadvertently vaccinated with 1 dose of GARDASIL (lot#660553/0070X), IM, into the left thigh instead of Hepatitis B vaccine (manufacturer unknown) she was supposed to receive. The GARDASIL was intended for the patient's older sister. The nurse accidentally gave the patient GARDASIL rather than switching to Hepatitis B vaccine. This was a case of human error. No adverse event was reported. The patient was seen in the office. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 326720-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Jan-2007	26-Jan-2007	0	17-Sep-2008	24-Oct-2008	OR	WAES0701USA04893	24-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1208F	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal behaviour, Anger, Feeling abnormal, Gaze palsy, Inappropriate schedule of drug administration, Loss of consciousness, Pallor

Symptom Text: Information has been received from a registered nurse concerning a 14 year old white female with attention deficit/hyperactivity disorder and mental illness who on 03-JAN-2007, at 1230, was vaccinated intramuscularly into left deltoid with the first 0.5 ml dose of GARDASIL vaccine (yeast). (Lot number 654741/1208F). On 26-JAN-2007, the patient was vaccinated intramuscularly into left deltoid with the second dose of GARDASIL vaccine (yeast), (Lot number 654741/1208F). There was no illness at the time of vaccination. Concomitant therapy given on 03-JAN-2007 intramuscularly into right deltoid included the first dose of MENACTRA vaccine (dip toxoid) (Lot number U1808AA). Concomitant therapy also included CONCERTA. The patient's mother reported that on 26-JAN-2007 night, the patient "tripped out". The patient threw things, her eyes rolled into back of head and passes out for 3 minutes. The patient had never had anything like that before. The mother reported that the patient was "like a zombie this weekend". The patient was pale on 29-JAN-2007 and continued with anger outbursts over the weekend. There was no fever and no further episodes. The patient was not evaluated by anyone over the weekend. The mother called to seek medical attention on 29-JAN-2007. The doctor advised her to continue to monitor and to call if increased with concerns. No further call came back regarding symptoms. 3 to 4 days post the onset of the events (approximately 30-JAN-2007) the patient recovered. No further information is available.

Other Meds: CONCERTA

Lab Data: Unknown

History:

Prex Illness: Attention deficit/hyperactivity disorder, Mental disorder

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326729-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	11-May-2007	11-May-2007	0	17-Sep-2008	28-Oct-2008	PA	WAES0706USA00288	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0087U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received through the Pregnancy Registry for GARDASIL from a physician concerning a 19 year old female who on 11-MAY-2007 was vaccinated in the left deltoid with the first dose of GARDASIL (Lot#655126/0087U). On 22-MAY-2007 the patient found out that she was pregnant. It is not known how many weeks pregnant she is. Patient plans to discontinue the series of injections. On 20-JUN-2007, the patient has an ultrasound for dating purposes which was within normal limits. On-08-AUG-2007, the patient had a normal serum alpha fetoprotein test which was negative. On 13-AUG-2007, the patient had an ultrasound for evaluation of growth which was within normal limits. On 02-JAN-2008, the patient gave birth to a 7 pond, five ounce normal male infant who was 20 1/2 inches long. The baby was born 39 weeks from LMP and stored a 9/9 on the apgar test. There were no congenital anomalies or abnormalities. There were no complications during pregnancy or labor/delivery. Follow-up information has been received in the form of medical records. On 10-JAN-2008 the baby's mother called the pediatrician's office reporting the baby had discharge from his eye. There was no redness and sclera was white. Mother advised to gently massage with warm compress. On 15-JAN-2008 the baby was seen for a routine visit with the pediatrician. Physician noted sacnt discharge from the right eye. Physician felt the baby had a right lacrimal duct stenosis and advised continuing with massage with warm washcloth. Physician examination otherwise normal. On 30-JAN-2008 the physician noted the baby's eye was improving and to continue duct massage. On 11-FEB-2008 mother to pediatrician after noticing a left inguinal lump. Physician noted a firm, non-tender lump approximately 2-3 cm in the left inguinal canal. Patient given referral to Urologist. On 13-FEB-2008, urologist saw the baby and his mom in consultation. The baby was 6 weeks of age. He was born at 7-lb 12 oz. On resent examination he was noted to have a mass in the l

Other Meds: None

Lab Data: Ultrasound 06/20/07 within normal limits; ultrasound 08/13/07 within normal limits; diagnostic laboratory 01/08/08 FA, AF or A Hemoglobinopathies/ hemoglobin isoelectric focusing: FA; diagnostic laboratory 01/08/08- value: 326.0uM >=40.0 G

History: Pregnancy NOS (LMP= Unknown)

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326730-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	18-Jul-2007	18-Jul-2007	0	17-Sep-2008	24-Oct-2008	NY	WAES0708USA01966	24-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information and follow up information has been received for Pregnancy Registry for GARDASIL vaccine (yeast) from a 23 year old Caucasian female consumer with asthma and penicillin allergy who on 18-JUL-2007 was vaccinated IM with a first dose of GARDASIL vaccine (yeast) (Lot # 658100/0525U). Concomitant therapy included albuterol. The consumer reported that "I found out today (10-AUG-2007) that I am pregnant". No adverse reaction was reported. She had a "pregnancy test" done. The patient sought unspecified medical attention. The outcome was unknown. On 15-OCT-2007 the patient had a normal ultrasound. Additional information has been requested. Information was received on 07-APR-2008. A normal female infant was born on 21-MAR-2008 (weeks from LMP = 38 5/7). The baby weighed 6lbs. 11 oz. and had an Apgar score of 9/9. There were no congenital anomalies. The baby did develop some jaundice in the first few days of life. This resolved on it's own and was felt to be physiological. No other information was reported concerning this pregnancy. Follow-up information has been received in the form of medical records. On 23-MAR-2008, all state Department of Health tests screen-negative and no follow-up action was requested. On 24-MAR-2008, the newborn's total serum bilirubin test was 15.3 mg/mL (normal range 2.0 to 12.0). On 25-MAR-2008, the newborn's total serum bilirubin test was 18.4 mg/mL (normal range 2.0 to 12.0). On 26-MAR-2008, the newborn's total serum bilirubin test was 18.1 mg/mL (normal range 2.0 to 12.0). On 27-MAR-2008, the newborn's total serum bilirubin test was 16.3 mg/mL (normal range 2.0 to 12.0). On 10-APR-2008, the patient had a 2 week well child visit and all appeared normal. On 21-MAY-2008, the patient presented for a scheduled 2 months well child visit and baby's mother was concerned about the baby spitting up a lot. The baby "seems to be spitty". The physician found that the baby appeared healthy and gaining weight appropriately, so in that point he did not feel that the "spitting" was of any clinical

Other Meds: albuterol

Lab Data: beta-human chorionic - Patient is pregnant, total serum bilirubin - 03/27/08 - 16.3 mg/mL - 2.0-12.0 - newborn, total serum bilirubin - 03/26/08 - 18.1 mg/mL - 2.0-12.0 - newborn, total serum bilirubin - 03/25/08 - 18.4 mg/mL - 2.0-12.0 - n

History: LMP = 6/23/2007, Penicillin allergy

Prex Illness: Pregnancy NOS, Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326731-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Jul-2007	18-Aug-2007	31	17-Sep-2008	24-Oct-2008	--	WAES0708USA03399	24-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Gestational diabetes

Symptom Text: Initial and follow up information has been received from a nurse practitioner concerning an 18 year old white female patient who on 18-JUL-2007, was vaccinated with a first 0.5ml dose of GARDASIL vaccine (yeast) (Lot# 657737/0522U). On 18-AUG-2007 a month later (4 weeks after her last menstrual period), the patient found out she was pregnant. The date of her last menstrual period was reported to be 17-JUN-2007. Her estimated delivery date was reported as 25-MAR-2008. Her pregnancy was confirmed by lab work and an ultrasound. It was reported that the patient had a total of 4 ultrasounds and al were within normal limits (WNL). Prenatal vitamins were reported to be taken during the pregnancy. The patient has not had any previous pregnancies or previous live births. On approximately 30-DEC-2007, 28 weeks from her last menstrual period, the patient developed gestational diabetes. On 14-MAR-2008, the patient gave birth to a liveborn infant male weighing 7 pounds 15 ounces. The infant was reported to be normal. It was unknown if the infant had any congenital anomalies or if there were any complications. At the time of this report, the patient's outcome was unknown. No product quality complaint was involved. Additional information is not expected.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound - x4 - All within normal limits (WNL)

History: LMP = 6/17/2007

Prex Illness: Pregnancy NOS

Prex Vax Illns:

Vaers Id: **326732-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Oct-2007	18-Oct-2007	0	17-Sep-2008	28-Oct-2008	--	WAES0712USA02621	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNK	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Dyspepsia, Pregnancy induced hypertension

Symptom Text: Initial follow up information has been received from a certified nurse midwife for the Pregnancy Registry for GARDASIL concerning an 18 year old obese, female who on 18-OCT-2007 was vaccinated intramuscularly with her first dose of GARDASIL (Lot# and site not reported). Subsequently, the patient found out she was pregnant (LMP approximately 07-OCT-2007). On and unspecified date in December 2007, the patient was prescribed ranitidine (unspecified) for heartburn. On 31-DEC-2007, 06-FEB-2008, and 03-MAR-2008, the patient had ultrasounds for "routine dating and follow up" which were reported to be within normal limits. On an unspecified date, the patient developed mild pregnancy induced hypertension (not further specified). The patient was induced at 37 weeks gestation. On 21-JUN-2008, the patient gave birth to a normal male infant (7 lb, 4 oz; 48.3 cm). There were no congenital anomalies. The infant had Apgar scores of 7 and 9. No additional information was provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Ultrasound 12/31/07 routine dating - within normal limits; ultrasound 02/06/08 - within normal limits; ultrasound 03/03/08 - within normal limits.

History: Pregnancy NOS (LMP = 10/7/2007) Obesity

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326733-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	08-Aug-2007	16-Sep-2007	39	17-Sep-2008	28-Oct-2008	--	WAES0801USA00891	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNK	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Insomnia, Pain

Symptom Text: Information has been received from a physician's assistant through a pregnancy registry concerning a 21 year old female who on 08-AUG-2007 was vaccinated with the first dose of GARDASIL. The physician's assistant reported that the patient became pregnant after receiving the first dose of GARDASIL. At the time of the report, the patient had a gestational age of 16 weeks, and no adverse reactions were reported. The patient's last menstrual period was approximately 16-SEP-2007 with an estimated due date of 24-JUN-2008. Follow up information received from the physician's assistant stated that on an unspecified dates during the patient's pregnancy she developed pain (NOS) which was treated with TYLENOL 325 mg, PO, PRN and insomnia which was treated with BENADRYL 25 mg, PO, PRN. The patient's unspecified pain and insomnia were considered to be nonserious events. On 22-JUN-2008 at 40 wk 2 days gestation the patient gave birth to a normal female infant. The baby weighed 7 lbs. 6 oz and had a 9/10 Apgar score. It was also reported that there were no complications with the delivery. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Pregnancy NOS (LMP = 9/16/2007)

Prex Illness:

Prex Vax Illns:

Vaers Id: 326734-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		17-Sep-2008	28-Oct-2008	TX	WAES0801USA02556	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received for the Pregnancy Registry for GARDASIL from a health professional concerning a 17 year old female with papilloma viral infection diagnosed in December 2007 history of 2 pregnancies, 1 live birth and a history of an elective termination who on an unspecified date was vaccinated with a first dose of GARDASIL. On 14-MAR-2007 the patient was vaccinated with a second dose of GARDASIL (lot#657006/0188U). Concomitant therapy included prenatal vitamins (CB Complete), iron (unspecified), PHENERGAN and ZOFRAN ODT. The patient's (last menstrual period) LMP date was 17-NOV-2007 and the (estimated date of delivery) EDD date is 23AUG-2008. The estimated date of conception was 30-NOV-2007. On 23-JAN-2008 a confirmation ultrasound was performed and was within normal limits. On 19-MAR-2008 a maternal serum alpha-fetoprotein test was performed for sequential screening and was within normal limits. There was no adverse experience was related to this event. Medical attention was sought in the office. The product quality complaint unit was not involved. Follow up information was received which indicated that the patient had one previous pregnancy and on elective termination (6-8 weeks from LMP). The patient had allergy to sulfa and iron deficiency anemia and a history of Papilloma viral infection (biopsies revealed mild to moderate (cervical) dysplasia) and ankle fracture in motor vehicle accident (in MAY of 2007). It was also reported that the patient was group B Strep carrier during pregnancy. On 20-Feb-2008, the patient underwent sequential screen and the result indicated normal. On 19-AUG-2008 (39 3/7 weeks from LMP) the patient delivered a normal male baby who was 8 LB 1oz with an Apgar score 9/9. Additional information is not expected.

Other Meds: Iron (unspecified); ZOFRAN ODT 8 mg; PHENERGAN TABLETS/SUPPOSITORIES 20 mg; vitamins (Unspecified)

Lab Data: Ultrasound 01/23/08 - within normal limits confirmational; ultrasound 01/14/08 - 9 wks; ultrasound 02/20/08 - 13 6/7 wk: NI NTL; diagnostic laboratory 02/20/08 - normal. Serum human - positive; serum alpha-fetoprotein 03/19/08 - within nor

History: Papilloma viral infection; termination of pregnancy - elective; cervical dysplasia; ankle fracture.

Prex Illness: Pregnancy NOS (LMP - 11/17/2007; sulfonamide allergy; bacterial infection due to streptococcus, group B; Iron deficiency.

Prex Vax Illns:

Vaers Id: 326735-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	04-Oct-2007	04-Oct-2007	0	17-Sep-2008	28-Oct-2008	WA	WAES0801USA04361	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Ear infection, Prophylaxis against Rh isoimmunisation

Symptom Text: Initial and follow up information has been received for the pregnancy registry for GARDASIL from a physician and a nurse concerning a 24 year old female with a past history of two previous pregnancies (1 full term delivery and 1 spontaneous abortion in the first trimester) and an allergy to AMOXYXILLIN who on 04-OCT-2007 was intramuscularly vaccinated with her first dose of GARDASIL (lot#658563/1063U). The patient received her second dose of GARDASIL (lot#658563/106U) on 29-NOV-2007. The patient was pregnant with an LMP of 30-Sep-2007, at the time of vaccination. Concomitant therapy included daily prenatal vitamins. No adverse events were reported. The patient sought unspecified medical attention by contacting the physician's office. On 14-Dec-2007 an ultrasound was performed to establish the expected delivery date. The patient is due 05-Aug-2008. On 21-Feb-2008 a MSAFP (alpha fetal) was performed, results were negative. the patient tested rH negative on an unspecified date. On 06-May-2008, the patient was given a single dose of globulin, immune. On an unspecified date, the patient was treated for an ear infection with an unknown dose of azithromycin for an unspecified period of time. The patient delivered a normal female baby on 03Aug2008 (39 weeks 5 days from LMP). The baby had APGAR scores of 6 and 9, weighed 9 lbs 8 oz, 48.3 cm long, and a head circumference of 37.0 cm. the patient had no complications during pregnancy or labor. Additional information is not expected

Other Meds: RHOGAM; vitamin (unspecified)

Lab Data: Ultrasound 12/14/07 -establish edc=8/5/08. Erythrocyte Rh antigen 05/06?/08 - rhogam prescribed 5/6/08; serum alpha-fetoprotein 02/21/08 - negative.

History: Penicillin allergy.

Prex Illness: Pregnancy NOS (LMP-09/30/2007); Rhesus antibodies negative; abortion spontaneous.

Prex Vax Illns:

Vaers Id: 326736-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	30-Jan-2008	30-Jan-2008	0	17-Sep-2008	27-Oct-2008	--	WAES0802USA00502	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0211U		Unknown	Intramuscular	
	PPV	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Wrong drug administered

Symptom Text: Initial and follow up information has been received from a registered nurse and through a Merck Pregnancy Registry concerning a 22 year old Hispanic female, with an obstetrical history of 0 pregnancies and 0 live births, who on 30-JAN-2008 was vaccinated intramuscularly with a dose of GARDASIL vaccine (yeast), (Lot # 0211U) and a dose of pneumococcal vaccine, polyval (MSD). Concomitant therapy include unspecified iron and vitamins. It was reported that the patient inadvertently received one dose of GARDASIL vaccine (yeast). The patient was suppose to get a hepatitis B virus vaccine rHBsAg (yeast), (manufacturer unknown) vaccine. The nurse said that this was not product confusion. The patient had not been notified at the time of the report. No other details were reported. It was reported that the patient was pregnant and last menstrual period (LMP) was 12-OCT-2007, (estimated date of delivery 19-JUL-2008). The patient had a urine pregnancy test, on 05-MAR-2008 an ultrasound was performed to determine the baby's growth, dates and anatomy. On 17-JUL-2008, 39.5 weeks from LMP, the patient delivered a normal, healthy male baby weighing 6 pounds 2 ounces, apgar 9/9. Additional information has been requested.

Other Meds: iron (unspecified) - 325 mg, vitamins (unspecified)

Lab Data: ultrasound - 03/05/08 - determine growth dates and anatomy, urine beta-humun

History: LMP = 10/12/2007

Prex Illness: Pregnancy NOS, Iron deficiency anemia

Prex Vax Illns:

Vaers Id: **326737-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
35.0	F	Unknown	Unknown		17-Sep-2008	27-Oct-2008	TN	WAES0804USA03643	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Wrong drug administered

Symptom Text: Information has been received for the Pregnancy Registry for GARDASIL vaccine (yeast) from a 35 year old female with no pertinent medical history or drug reactions/allergies who on 16-APR-2008 was vaccinated with the "first dose of three doses" of GARDASIL vaccine (yeast) (lot# 0152X) injection. Concomitant therapy included RHOGAM. On 16-APR-2008 the patient was administered GARDASIL vaccine (yeast) instead of another injection the patient was supposed to be receiving. On an unspecified date an ultrasound was performed. No adverse side effects were reported as a result of this. The patient's gestation was 28 weeks. The date of the last menstrual period (LMP) and the estimated date of delivery (EDD) was unknown. Follow-up information was received from a registered nurse RN. The RN reported that the patient should have received RHOGAM injection for Rh negative on 16-APR-2008 but instead received the GARDASIL vaccine (yeast). The RN stated that the nurse who administered the GARDASIL vaccine (yeast) mistakenly did so. There was no product confusion involved. The patient received the RHOGAM injection after the patient received the GARDASIL vaccine (yeast) on 16-APR-2008. On 16-APR=2008, the patient had an ultrasound which was reported as normal. Follow-up information was received. The patient had a history of 2 previous pregnancies with full-term deliveries. The patient had a history of macrosomia in both previous pregnancies. The birth weights were 9 pounds and 12 ounces and 10 pounds and 5 ounces. The patient's date of her last menstrual period was 06-OCT-2007, the estimated conception date was 20-OCT-2007 and the estimated date of delivery was 13-JUL-2008. On 05-MAR-2008 the patient had an ultrasound for AMA and it was within normal limits. On 14-MAY-2008 an ultrasound was within normal limits. On 09-JUL-2008 the patient delivered a normal, healthy male baby weighing 9 pounds and 15 ounces. The baby's length was 21.5 inches with apgar score 9. His head circumference was 38.7cm. There were no congenial anomalies a

Other Meds: RHOGAM

Lab Data: ultrasound - 04/16/08 - within normal limits, ultrasound, 05/14/08, within normal limits, ultrasound - 03/05/08 - within normal limits

History: Macrosomia, LMP = 10/6/2007, Rhesus antibodies negative

Prex Illness: Pregnancy NOS

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326738-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	17-May-2007	01-Apr-2008	320	17-Sep-2008	27-Oct-2008	--	WAES0804USA06334	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse concerning a 25 year old female with atypical squamous cells of undetermined significance and no known drug allergies who on 15-MAR-2007 was vaccinated with her first dose of GARDASIL vaccine (yeast) (Lot# not reported). On 17-May-2007, the patient was vaccinated with her second dose of GARDASIL vaccine (yeast) (Lot# not reported) and delivered a baby in April 2008. Unknown medical attention was sought in a clinic. It was reported that a PAP test, ultrasound, amniocentesis and Maternal Serum Alpha-Petoprotein Screening (MSAFP) were performed (no results provided). Follow-up information was received from the registered nurse. The patient only received vaccination with GARDASIL vaccine (yeast) there, not obstetrician care. Telephone call follow-up information was received from a healthcare professional at the obstetrician's office, who reported that the patient was last seen on 30-MAY-2008 for her 6 week postpartum check up. The patient had a full term elective induction, and delivered a healthy and normal baby, weighing 3135 grams, whose Apgar assessments were 8.9 and 9. No additional information is expected.

Other Meds: Unknown

Lab Data: Pap test , Apgar score - 8.9, Apgar score - 9

History: LMP = Unknown

Prex Illness: Pregnancy NOS, Atypical cells of undetermined significance

Prex Vax Illns:

Vaers Id: **326739-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Jun-2008	07-Jun-2008	0	17-Sep-2008	27-Oct-2008	GA	WAES0806USA01532	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	3	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Accidental overdose, Gastroenteritis viral, Inappropriate schedule of drug administration, Injection site pain

Symptom Text: Information has been received from a physician and a medical assistant concerning an 18 year old patient who on 29-AUG-2007 was vaccinated intramuscularly with the first dose of GARDASIL vaccine (yeast) (Lot # and site not reported). On 02-NOV-2007, the patient was vaccinated intramuscularly with a second dose of GARDASIL vaccine (yeast) (Lot # and site not reported). On 10-MAR-2008, the patient was vaccinated intramuscularly with a third dose of GARDASIL vaccine (yeast) (Lot # and site not reported). On 07-JUN-2008, the patient was "received an inadvertent fourth dose" of GARDASIL vaccine (yeast) intramuscularly (Lot # 660553/0070X site not reported). No adverse effect was reported. The patient outcome was not reported. No additional information was available. Follow-up information was received which reported that on 09-JUN-2008 at 10:30 am, the patient experienced soreness of the injection site arm which lasted for 2 days post-vaccination and was seen a 4 days later for presumed viral gastroenteritis that received on an unspecified date. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326740-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	01-Apr-2008	22-Apr-2008	21	17-Sep-2008	27-Oct-2008	CT	WAES0808USA00219	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Urticaria

Symptom Text: Information has been received from a physician concerning a 26 year old female who on approximately 01-APR-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) 0.5 ml, IM. On approximately 22-APR-2008, the patient experienced urticaria and nasal allergic reaction 3 weeks after her 1st dose of GARDASIL vaccine (yeast). BENADRYL helped the symptoms. An allergy testing was performed by a specialist which showed she was allergic to dust and mold. The patient was getting ready to get her second dose, but was hesitating based on her allergic reaction. At the time of this report, the patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: allergy test - ?/?/08 - allergic to dust and mold

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326741-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	20-Apr-2008	01-May-2008	11	17-Sep-2008	27-Oct-2008	AL	WAES0808USA00221	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts, Condition aggravated

Symptom Text: Information has been received from a 25 year old female patient with papilloma viral infection, without developed of genital warts before her first vaccination with GARDASIL vaccine (yeast), and no known drug reactions/allergies, who on 20-FEB-2008, was vaccinated with the first dose of GARDASIL vaccine (yeast). On 20-APR-2008, the patient was vaccinated with the second dose of GARDASIL vaccine (yeast), 5 ml. Lot# was not provided. There was no concomitant therapy. The patient reported that in May-2008, after the vaccination she experienced a few lesions. The patient sought unspecified medical attention. At the time of the report the patient was expecting to receive her third dose of GARDASIL vaccine (yeast) on 20-AUG-2008. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Papilloma viral infection

Prex Vax Illns:

Vaers Id: **326742-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Jun-2008	01-Jun-2008	0	17-Sep-2008	27-Oct-2008	--	WAES0808USA00242	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Fatigue, Headache

Symptom Text: Information has been received from a registered nurse (RN) concerning a 12 year old female with no pertinent medical history or allergies who "2 months ago", in approximately June 2008, was vaccinated intramuscularly with 0.5 ml first dose of GARDASIL vaccine (yeast). There was no concomitant medication. In approximately June 2008, after the vaccination, the patient experienced a "stomach ache, fatigue, and a headache". Unspecified Medical attention was sought. No laboratory diagnostics studies were performed. Subsequently, the patient recovered. On 01-AUG-2008 the patient was vaccinated intramuscularly with 0.5 ml second dose of GARDASIL vaccine (yeast) at the office. The patient was instructed to sit and wait 15 minutes post-vaccination and the patient did not have symptoms again. No additional adverse event information was reported. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326743-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	05-Jun-2008	05-Jun-2008	0	17-Sep-2008	27-Oct-2008	OR	WAES0808USA00972	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site pain

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter with a drug allergy to an unspecified antibiotic who "2 months ago", on approximately 05-JUN-2008 was vaccinated in the deltoid with a first dose of GARDASIL vaccine (yeast). There was no concomitant medication. On approximately 05-JUN-2008, "immediately after injection", the patient experienced severe pain at the injection site. "48-60 hours after injection", on approximately 08-JUN-2008 the patient recovered from severe pain at the injection site. At the time of the report, the patient was planning on receiving the second dose of GARDASIL vaccine (yeast) "in a few days". The patient sought physician's medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326744-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-Mar-2008	18-Apr-2008	28	17-Sep-2008	27-Oct-2008	--	WAES0808USA00973	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Gastric disorder, Vaccine positive rechallenge

Symptom Text: Information has been received from an office manager concerning a 16 year old female with irregular menstrual cycles and premenstrual syndrome and no drug reactions or allergies who on 21-MAR-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast). Concomitant therapy included LOESTRIN. "4 weeks post vaccination", on approximately 18-APR-2008 the patient developed severe upper gastric stomach cramps, which lasted for approximately 5 days. The patient had no fever, no vomiting. After that the patient would get some occasional stomach problem. It was reported that the pain was not associated with the patient's menstrual cycle and in fact the patient's menstrual cycle was "better and lighter". On 19-JUN-2008 the patient was vaccinated with her second dose of GARDASIL vaccine (yeast). "Weeks later", the patient developed the same symptoms but worse. The patient played volleyball and the pain was "so bad she could not run". PEPTO_BISMOL seemed to help relieve the symptoms somewhat. At the time of the report, the patient had not recovered from the events yet. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: LOESTRIN

Lab Data: None

History:

Prex Illness: Premenstrual syndrome, Menstruation irregular

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326745-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	27-Oct-2008	CA	WAES0808USA00986	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Weight decreased

Symptom Text: Information has been received from a physician concerning a female adolescent who on an unspecified date was vaccinated with a dose of GARDASIL vaccine (yeast). It was reported that during her GARDASIL vaccine (yeast) therapy, the patient experienced "significant weight loss (over 20 pounds)". The outcome of the patient was not reported. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 326746-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	05-Aug-2008	05-Aug-2008	0	17-Sep-2008	27-Oct-2008	TN	WAES0808USA00987	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Skin laceration, Syncope

Symptom Text: Information has been received from a physician concerning an 18 year old female with a history of syncope and no drug reactions or allergies who on 05-AUG-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast). Concomitant therapy included MENACTRA vaccine (dip toxoid). On 05-AUG-2008 the patient fainted. When the patient fell off the table, she cut her head open. It was reported that after the first dose of GARDASIL vaccine (yeast), the adverse events improved. The outcome of the patient was not reported. Additional information has been requested.

Other Meds:

Lab Data: None

History: Syncope

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326747-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	05-Aug-2008	05-Aug-2008	0	17-Sep-2008	27-Oct-2008	CA	WAES0808USA00990	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Feeling abnormal

Symptom Text: Information has been received from a physician concerning a female who on 05-AUG-2008 was vaccinated with her third dose of GARDASIL vaccine (yeast). After receiving GARDASIL vaccine (yeast), the patient left the office and a few minutes later, she returned. The patient's blood pressure dropped 18 points and she looked dazed. She was given juice. The outcome of the patient was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326748-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Jul-2008	30-Jul-2008	0	17-Sep-2008	27-Oct-2008	CT	WAES0808USA00998	27-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Head injury, Syncope, Vision blurred

Symptom Text: Information has been received from a nurse practitioner concerning a 12 year old female who at 11:30 am on 30-JUL-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) 0.5 ml. Other suspect therapy included hepatitis A vaccine (inactive) (manufacturer unknown) (duration and dose not reported) and varicella virus vaccine live (Oka/Merck) (MSD) (duration and dose not reported). Other concomitant therapy included MENACTRA vaccine (dip toxoid). Within several minutes, at 11:35 am, the patient felt dizzy and bumped her head on the side of the wall (also reported as at the receptionist's desk as she was walking down the hallway and she experienced syncope. The patient stated that she did not see that she was walking into the side of the wall as she started to feel dizzy and her vision went blurry. The patient did not lose consciousness. She was observed and then was able to leave the office. The patient recovered from the fall and syncope. The patient sought medical attention in the office. Additional information is not expected.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326749-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Jun-2008	01-Jun-2008	0	17-Sep-2008	27-Oct-2008	VA	WAES0808USA01000	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall

Symptom Text: Information has been received from a physician and a healthcare worker concerning a 13 year old female who in June 2008, was vaccinated with a dose of GARDASIL vaccine (yeast) (route and administration site not reported). Two weeks past the vaccination, the patient fell down the stairs. The fall was serious enough that the patient required follow-up with the patient's pediatrician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326750-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Jul-2008	01-Jul-2008	0	17-Sep-2008	28-Oct-2008	MA	WAES0808USA01010	08-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Anxiety, Body mass index increased, Cholelithiasis, Condition aggravated, Depression, Nausea, Pancreatitis acute, Vaccination complication

Symptom Text: Information has been received from a physician assistant concerning a 19 year old female who in approximately July 2008, was vaccinated with a second dose of GARDASIL vaccine (yeast) (route and administration site not reported). Two days past the vaccination, the patient had symptoms of pancreatitis. the patient went to the emergency room where the ER physician diagnosed her with gallstones and indicated that it was affiliated with the GARDASIL vaccine (yeast). Subsequently, the patient recovered from gallstones. Additional information has been requested. 1/2/09 Reviewed hospital medical records of 7/5-7/11/2008. FINAL DX: acute pancreatitis; possibly gallstone pancreatitis; Gardasil may have contributed; anxiety & depression; high BMI. Records reveal patient experienced nausea, acute abdominal pain. GI & surgery consults done. Progressed well w/conservative treatment & d/c to home on continued oral antibiotics. To f/u w/surgery for elective cholecystectomy.

Other Meds: Unknown

Lab Data: Unknown LABS:WBC 9,000. Amylase 172, lipase 593. MRCP c/w cholelithiasis, no cholecystitis or biliary duct obstruction, liver & pancrease normal. US of RUQ (+)gallstones; US of abdomen/pelvis c/w pancreatitits.Chemistry, LFTs WNL. Ur

History: Unknown PMH: obesity; major depression(celexa x 2 mo); gallstones x 10 yr; gallstone pancreatitis.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326751-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Oct-2007	01-Oct-2007	0	17-Sep-2008	28-Oct-2008	--	WAES0808USA01055	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a 25 year old female, for the Pregnancy Registry for GARDASIL vaccine (yeast), concerning herself who in October 2007, was vaccinated with the first dose of GARDASIL vaccine (yeast) and in June 2008, was vaccinated with the second dose of GARDASIL vaccine (yeast). After taking the first shot of GARDASIL vaccine (yeast), the patient found out that she was pregnant. In approximately 2008 the patient delivered a male baby. Her son was born with pulmonary problems along with other health issues. The patient did not seek medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: LMP = unknown

Prex Illness: Pregnancy NOS

Prex Vax Illns:

Vaers Id: 326752-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	29-Jul-2008	29-Jul-2008	0	17-Sep-2008	28-Oct-2008	PA	WAES0808USA01086	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Heart rate increased, Hypertension, Nausea, No reaction on previous exposure to drug, Pyrexia

Symptom Text: Information has been received from a physician concerning an 18 year old female who on 27-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). On 29-JUL-2008 the patient was vaccinated with the second dose of GARDASIL vaccine (yeast). After receiving the second dose, the patient experienced fever, stomach pain, nausea, a fast heart rate and high blood pressure. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326753-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	28-Oct-2008	CO	WAES0808USA01089	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysmenorrhoea, Menorrhagia

Symptom Text: Information has been received from a medical assistant which reported that there were at least two patients who had heavy and difficult periods and had more severe cramps after received GARDASIL vaccine (yeast). The medical assistant did not have any information regarding those patients. Follow up information was received which reported that the medical assistant did not know the names of the other 2 patients. She is wondering if the heavy and difficult periods are related to the girls starting to ovulate. Additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326754-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Mar-2008	01-Mar-2008	0	17-Sep-2008	28-Oct-2008	--	WAES0808USA01126	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Weight increased

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female with no known allergies or pertinent medical history who in March 2008, was vaccinated with the first dose of GARDASIL vaccine (yeast). There was no concomitant medication. The nurse practitioner reported that a patient gained weight after she received GARDASIL vaccine (yeast) in March 2008. The patient claimed a weight of 126 lb at the time of administration. (GARDASIL vaccine (yeast) was administered by another provider). The patient was evaluated by the physician in April 2008 and weighed 141 lb. The patient refused the second GARDASIL vaccine (yeast) injection at the 28-JUL-2008 follow up appointment because the weight had increased to 150 lb. No other symptoms. The physician evaluated the patient's blood work including a pregnancy test. The blood work results were unspecified but reported to be within normal range. At the time of the report the patient had not recovered, There was no product quality complaint. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory - Blood work: within normal range.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 326755-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		17-Sep-2008	28-Oct-2008	--	WAES0808USA01134	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Headache

Symptom Text: Information has been received from a physician assistant (also reported as nurse practitioner) concerning a 17 year old female with "allergies" who on an unknown date was vaccinated IM with the second dose of GARDASIL vaccine (yeast) 0.5 ml. The physician assistant reported that a patient was experienced headache and fatigue after received GARDASIL vaccine (yeast) vaccine. The patient did not seek medical attention. There was no product quality complaint. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

Vaers Id: **326756-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		17-Sep-2008	28-Oct-2008	CA	WAES0808USA01156	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Depression, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 16 year old female with history of depression who on unspecified dates was vaccinated the first and second doses of GARDASIL vaccine (yeast), "orally". The patient experienced increased depression associated with doses one and two of GARDASIL vaccine (yeast). The patient move out of state and is currently seeing another physician. She has not received her third dose. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Depression

Prex Illness:

Prex Vax Illns:

Vaers Id: **326757-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	31-Jul-2008	01-Aug-2008	1	17-Sep-2008	28-Oct-2008	--	WAES0808USA00243	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Muscular weakness, Pallor, Somnolence, Tremor

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter who on 31-JUL-2008 was vaccinated with a dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). On 01-AUG-2008, the patient "woke up feeling fine, but after riding her bike to work, she was dizzy and pale, her hands were shaking, and she felt her knees not going to hold her up". The consumer took her daughter home from work and the patient "fell right asleep". The reporter was concerned she would have to take the patient to the hospital to seek medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326758-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Jun-2008	02-Jun-2008	0	17-Sep-2008	28-Oct-2008	PA	WAES0808USA00256	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Pyrexia

Symptom Text: Information has been received from a nurse concerning an 18 year old female who on 02-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) at the doctor's office. The patient developed fever post vaccination. On approximately 23-JUN-2008, "3 weeks later", the patient went to the nurse's primary care provider's office and inadvertently vaccinated with a second dose of GARDASIL vaccine (yeast). The patient had diarrhea for 1 week post vaccination. At the time of this report, the patient recovered from fever and diarrhea. The patient called the office to seek unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 326759-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jan-2008	01-Jan-2008	0	17-Sep-2008	28-Oct-2008	--	WAES0808USA00263	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Joint range of motion decreased, Vaccine positive rechallenge

Symptom Text: Information has been received from a female consumer who in January 2008, was vaccinated with the first dose of GARDASIL vaccine (yeast). On 25-MAR-2008 the patient was vaccinated with the second dose of GARDASIL vaccine (yeast). The consumer mentioned that she developed flexion and extension difficulties with both her wrists for 48 hours after receiving her first and second dose. At the time of this report, the patient was fully recovered. The patient sought unspecified medical attention via office visit. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326760-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Jun-2008	02-Jun-2008	0	17-Sep-2008	28-Oct-2008	PA	WAES0808USA00266	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Diarrhoea, Pyrexia

Symptom Text: Information has been received from a licensed practical nurse concerning an 18 year old female with no pertinent medical history and no history of drug reaction or allergies who on 02-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot#: 660391/0063X) and on 25-JUN-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast). There was no concomitant medication. After the first vaccination the patient developed a fever. After the second vaccination the patient developed stomach cramps and diarrhea which lasted for a week. Subsequently, the patient recovered. The patient sought medical attention with a phone call. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326761-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-Mar-2008	05-Mar-2008	0	17-Sep-2008	28-Oct-2008	--	WAES0808USA00270	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site atrophy, Injection site pain

Symptom Text: Information has been received from a nurse practitioner concerning a 13 year old female with no pertinent medical history or history of drug reactions or drug allergies who on 30-OCT-2007 was vaccinated with the first dose of GARDASIL vaccine (yeast). On approximately 03-MAR-2008, "two days prior to" the second vaccination, the patient had received a steroid injection in the gluteal area, for the treatment of allergies. On 05-MAR-2008 the patient was vaccinated intramuscularly in the left arm with the first 0.5 ml dose of GARDASIL vaccine (yeast) (lot no. 655604/0052X). Concomitant therapy included YAZ, CLARITIN and ADDERALL TABLETS. On the same day, "after her second immunization", the patient developed pain and muscle tissue atrophy at the injection site. On 01-AUG-2008 the patient was vaccinated with the third dose of GARDASIL vaccine (yeast). At the time of this report, the patient was recovering from the symptoms. The patient sought unspecified medical attention via office visit. Additional information has been requested.

Other Meds: ADDERALL TABLETS, YAZ, CLARITIN

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326762-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	31-Jul-2008	01-Aug-2008	1	17-Sep-2008	28-Oct-2008	--	WAES0808USA00308	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Local swelling, Oedema

Symptom Text: Information has been received from a physician concerning a 26 year old female who on 31-JUL-2008 was vaccinated with a dose of GARDASIL vaccine (yeast) via intramuscular route. Within 2 days after the vaccine, the patient developed swelling of the neck and oedema. Her outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326763-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	28-Oct-2008	--	WAES0808USA00487	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscular weakness, Myalgia

Symptom Text: Information has been received from a female who was vaccinated intramuscularly with 0.5 ml third dose of GARDASIL vaccine (yeast). Subsequently the patient experienced "muscle pain and weakness". At the time of report, the outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326764-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	04-Aug-2008	04-Aug-2008	0	17-Sep-2008	28-Oct-2008	NY	WAES0808USA00489	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Aggression, Dizziness, Gaze palsy, Muscle rigidity, Tongue biting, Tremor

Symptom Text: Information has been received from a nurse concerning a 19 year old female who on 04-AUG-2008 was vaccinated intramuscularly with the 0.5 ml first dose of GARDASIL vaccine (yeast) (LOT# 0250X). After the vaccination, the patient stated that she felt faint. The nurse laid the patient down and the patient's eyes rolled back into her head and she began shaking and became rigid. The nurse used ammonia to bring the patient around. Oxygen was provided in the office since the patient looked grey. The nurse also mentioned that the patient tried biting her. There was no loss of consciousness or loss of bowel or bladder control. The patient was observed in the office and then discharged home with her sister. On the same day, the patient recovered from the symptoms. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326765-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	02-Jun-2008	02-Jun-2008	0	17-Sep-2008	28-Oct-2008	MI	WAES0808USA00500	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea, Nausea, No reaction on previous exposure to drug, Vomiting

Symptom Text: Information has been received from a registered nurse concerning a 21 year old female with an allergy to IMITREX and no pertinent medical history who on 02-MAY-2007 was vaccinated with the first dose of GARDASIL vaccine (yeast) and on 02-JUN-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast) (LOT#: 660389/1968U) 0.5ml IM. There was no concomitant medication. After the second dose of the vaccine, on 03-JUN-2008 the patient experienced nausea, vomiting and diarrhea. Subsequently, the patient recovered. The patient was seen in the office. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **326766-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Apr-2008	Unknown		17-Sep-2008	28-Oct-2008	--	WAES0808USA00506	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin discolouration

Symptom Text: Information has been received from a pharmacist concerning a female who "about 4 months ago," was vaccinated subcutaneously instead of intramuscularly with the first dose of GARDASIL vaccine (yeast) (lot number not reported). The physician's office who gave the dose has it documented as given in the left arm however the patient and her mother state it was given in the right arm. The patient has a big discoloration of the right arm. The patient was referred to a dermatologist. The patient's discoloration of the right arm persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326767-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	28-Oct-2008	--	WAES0808USA00543	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Information has been received from a physician who heard from another physician concerning a female (from a gymnastics class) who on an unspecified date was vaccinated with a dose of GARDASIL vaccine (yeast). Subsequently the patient experienced tingling in her lower extremities. The outcome of the patient was not reported. This is one of the several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326768-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	28-Oct-2008	MO	WAES0808USA00553	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a first dose of GARDASIL vaccine (yeast). Subsequently, post vaccination, the patient was nauseous all day. The outcome of the patient was not reported. Unspecified medical attention was sought. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326769-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-May-2007	04-Aug-2008	461	17-Sep-2008	28-Oct-2008	--	WAES0808USA00568	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Information has been received from a consumer concerning her daughter who in May or June 2007, was vaccinated with the first 0.5 ml dose of GARDASIL vaccine (yeast) and on 04-AUG-2008 was vaccinated with the second 0.5 ml dose of GARDASIL vaccine (yeast). The patient delayed the shot because of contacting mononucleosis from her classmate. The patient had had no ill effects from the delay. No product quality complaint was involved. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326770-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	28-Oct-2008	--	WAES0808USA00575	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported) and a dose of MENACTRA vaccine (dip toxoid). Subsequently the patient experienced hives. Unspecified medical attention was sought. At the time of this report, the outcome of the patient was unknown. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326771-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	05-Aug-2008	06-Aug-2008	1	17-Sep-2008	28-Oct-2008	NC	WAES0808USA01178	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Injection site pain, Nasal congestion, Paraesthesia

Symptom Text: Information has been received from a registered nurse concerning a 26 year old female with no known medical history and drug reactions/allergies, who on 05-AUG-2008, was vaccinated with GARDASIL vaccine (yeast) (Lot # 660553/0070X), 0.5 ml, via intramuscularly route. There was no concomitant medication. The physician reported that on 08-AUG-2008, the patient had site pain injection after she was vaccinated with GARDASIL vaccine (yeast). The physician also reported that a few hours later, on 08-AUG-2008, the patient developed nasal congestion, dizziness and tingling in the same arm as the injection site. The patient was treated with OTC BENADRYL. on 06-AUG-2008, the patient had recovered. The patient sought medical attention at physician's office. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326772-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Aug-2008	05-Aug-2008	0	17-Sep-2008	28-Oct-2008	TX	WAES0808USA01205	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Palpitations

Symptom Text: Information has been received from a medical assistant concerning a 17 year old female with no known drug allergies and who had childhood asthma, and positive family history of hypertension, stoke and cardiac disorder, who on 05-AUG-2008 was vaccinated with the first and only dose of GARDASIL vaccine (yeast), 0.5 ml. There was no concomitant medication. The medical assistant reported that on 05-AUG-2008, shortly after received GARDASIL vaccine (yeast), the patient experienced for 20 minutes racing heartbeat and chest pain. The medical assistant reporter that prior the vaccination, the patient had occasional chest pain for the six past months. On unspecified date an "EKG" was performed (results not provided). The patient saw the physician. At the time of the report the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Asthma, Chest pain

Prex Vax Illns:

Vaers Id: **326773-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	16-May-2008	16-May-2008	0	17-Sep-2008	28-Oct-2008	--	WAES0808USA01206	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discolouration, Vaccine positive rechallenge

Symptom Text: Information has been received from a 20 year old female with no pertinent medical history or drug allergies or drug reactions, who on 16-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot no. 660391/0063X). On 16-MAY-2008 the patient experienced white circle at the injection site that eventually went away. There was no concomitant therapy. On 17-JUL-2008 the patient was vaccinated with the second dose of GARDASIL vaccine (yeast) and the white circle at the injection site reappeared and it was still there. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326774-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		17-Sep-2008	28-Oct-2008	--	WAES0808USA01207	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site pruritus

Symptom Text: Information has been received from a 25 year old female medical assistant who on an unknown date, was vaccinated with the first dose of GARDASIL vaccine (yeast). On unreported date, the patient was vaccinated with the second dose of GARDASIL vaccine (yeast). The medical assistant reported that after the first dose she felt a little bit of pain at the injection site, and after 3 days it was itchy. She also, reported that she didn't have a reaction to the second dose. At the time of the report the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326775-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		17-Sep-2008	29-Oct-2008	--	WAES0808USA01275	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT General physical health deterioration, Lethargy, Rash

Symptom Text: Information has been received from the news media concerning a 17 year old female who was vaccinated with a dose of GARDASIL vaccine (yeast) (Batch #, Lot #, route and site of administration not reported). Subsequently the patient developed rash and then experienced progressive decline (what sounds like lethargy) months after vaccination with GARDASIL vaccine (yeast). The patient and her parents believe GARDASIL vaccine (yeast) is the cause. No additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326776-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	03-Jun-2008	Unknown		17-Sep-2008	29-Oct-2008	MD	WAES0808USA01302	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site urticaria

Symptom Text: Information has been received from a consumer concerning a 23 year old female who on 03-JUN-2008 was vaccinated with GARDASIL vaccine (yeast), she reports that she developed hives at the injection site after her second dose of GARDASIL vaccine (yeast) on 04-AUG-2008. The patient did not seek medical attention. The patient's hives at injection site persisted. Concomitant therapy included ACCUTANE. No further information available.

Other Meds: ACCUTANE

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326777-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Jan-2008	08-Jan-2008	0	17-Sep-2008	29-Oct-2008	IL	WAES0808USA01307	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information have been received from a nurse for the Pregnancy Registry for GARDASIL vaccine (yeast) concerning a 17 year old white female with allergic reaction to CECLOR and a history of one previous pregnancy, one elective termination and no full-term deliveries who on 08-JAN-2008 was vaccinated with GARDASIL vaccine (yeast) (Lot # 659439/1267U) and is pregnant. The patient had a pap test on 04-MAR-2008 that revealed atypical squamous cell of undetermined significance (ASCUS). An ultrasound test was performed on 12-MAR-2008 to established pregnancy due date of 15-SEP-2008. A colposcopy was performed on 18-APR-2008 and a biopsy from 30-APR-2008 provided a diagnosis of cervical intraepithelial neoplasia 1 (CIN 1). An ultrasound test was performed on 07-JUL-2008 and revealed an estimated fetal weight of 3 pounds and a fetal measurement of 28-30 weeks. A repeat pap test was performed on 21-JUL-2008 that revealed ASCUS. Pregnancy was reported as normal to date. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound - 03/12/08 - 13 weeks - Establish due date WNL, biopsy - 04/30/08 - CINI on Bx, ultrasound - 07/07/08 - EFW 3# measures 28-30 wks, Pap test - 03/04/08 - Abnormal and was positive for HPV type 16

History: Abortion, LMP = 12/15/2007

Prex Illness: Pregnancy NOS, Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326778-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Aug-2008	02-Aug-2008	1	17-Sep-2008	29-Oct-2008	--	WAES0808USA01331	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myalgia, Pyrexia, Vomiting

Symptom Text: Information has been received from a physician assistant concerning a 17 year old female who on 01-AUG-2008 was vaccinated with GARDASIL vaccine (yeast) intramuscularly (site unspecified) (Lot #: 660612/0229X). On 02-AUG-2008, after receiving a dose of GARDASIL vaccine (yeast), the patient experienced fever, vomiting and muscle aches. Fever, vomiting and muscle aches lasted 24 to 48 hours. Subsequently, on 07-AUG-2008, the patient recovered from fever, vomiting and muscle aches. It was not specified whether the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326779-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Apr-2008	Unknown		17-Sep-2008	29-Oct-2008	IL	WAES0808USA01361	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site fibrosis, Injection site scar

Symptom Text: Information has been received from a healthcare worker concerning a 19 year old female with no pertinent medical history, who in April 2008, was vaccinated with her first dose of GARDASIL vaccine (yeast) (dose and site not reported). In 2008 the patient developed a small raised fibrotic scar tissue near the injection site after receiving her first and only dose of GARDASIL vaccine (yeast). The patient sought medical attention by seeing the physician in the office. As of 07-AUG-2008, the fibrotic scar tissue persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326780-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	29-Oct-2008	IL	WAES0808USA01366	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site pain, Syncope

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL vaccine (yeast) and experienced pain during an injection and then fainted in the office. Subsequently, the patient recovered. The patient sought medical attention at the physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326781-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Jun-2007	19-Jun-2007	0	17-Sep-2008	29-Oct-2008	FL	WAES0808USA01379	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a female who on 16-FEB-2007 was vaccinated with the first dose of GARDASIL vaccine (yeast) (Lot No. 655619/1427F and on 19-JUN-2007 was vaccinated with the second dose of GARDASIL vaccine (yeast). On 27-AUG-2007 were received results back from a PAP that was abnormal. It was unclear whether or not the patient had the third dose of GARDASIL vaccine (yeast). The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test - 08/27/07 - abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326782-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	29-Oct-2008	--	WAES0808USA01382	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Postural orthostatic tachycardia syndrome

Symptom Text: Information has been received from a health professional concerning a female who on an unspecified date was vaccinated with the first dose of GARDASIL vaccine (yeast) (Lot # 656051/0244U), 0.5 mL, IM. On an unspecified date the patient was vaccinated with the second dose of GARDASIL vaccine (yeast) (Lot # 657736/0389U), 0.5 mL, IM. Recently, in 2008, the patient was diagnosed with postural orthostatic tachycardia syndrome, EKG and table tilt test were both positive for Postural Orthostatic Tachycardia Syndrome. The patient had not recovered from postural orthostatic tachycardia syndrome. The patient sought medical attention, in physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: electrocardiogram - ?/?/08 - positive for postural orthostatic tachycardia syndrome, tilt test - ?/?/08 - positive for postural orthostatic tachycardia syndrome

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326783-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	M	01-May-2008	01-May-2008	0	17-Sep-2008	29-Oct-2008	--	WAES0808USA01390	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Information has been received from a male who in May 2008, was inadvertently vaccinated with a dose of GARDASIL vaccine (yeast) instead of hepatitis B for the third dose. No adverse experiences reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326784-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	04-Aug-2008	04-Aug-2008	0	17-Sep-2008	29-Oct-2008	--	WAES0808USA01391	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse who reported to a representative that the physician's daughter, an 18 year old female was vaccinated with the third dose of GARDASIL vaccine (yeast). On 04-AUG-2008, after receiving the dose of GARDASIL vaccine (yeast) the patient experienced syncope. She also received a TB test during the same visit (results not provided). Subsequently, the patient recovered from syncope minutes later. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326785-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Nov-2007	01-Feb-2008	81	17-Sep-2008	30-Oct-2008	MD	WAES0808USA00615	21-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0960F	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Arthritis, Asthenia, Back pain, Fatigue, Hypokinesia, Joint range of motion decreased, Menstruation irregular, Musculoskeletal pain, Myalgia, Vitamin D deficiency

Symptom Text: Information has been received from a consumer concerning his 14 year old daughter who was vaccinated with GARDASIL vaccine (yeast). The consumer did not remember when his daughter's first and second dose of GARDASIL vaccine (yeast) were administered. On 20-APR-2008 or 25-APR-2008 the patient was vaccinated with the third dose of GARDASIL vaccine (yeast). The patient experienced muscle aches and pain on GARDASIL vaccine (yeast) and the consumer noticed she had slow movements while walking and getting dressed after her 1st and 2nd dose of GARDASIL vaccine (yeast). The doctor referred her to a rheumatologist, who told her to take high amounts of vitamin D. Lab tests showed her "antibodies went up". The doctor thinks patient has "rheumatism". Patient was getting worse everyday and needs help getting out of bed. Additional information has been requested. 11/06/2008 PCP records received. Pt reports developed irregular periods, knee pain, lower back pain and R wrist pain after 2nd HPV vax . Normal exam 5/5/08. Sent for labs and referred to Rheumatology. OV 5/22/08 with DX: Acute Arthritis. OV 8/5/08 with c/o decreased energy and parent noticed movements are slower. DX: Vit D deficiency. Fatigue. Rheum consult 7/8/08 for joint pain/(+) ANA. PE (+) for Wrist limitation. 11/12/2008 Rheumatology consults received dated 7/8 and 10/17/2008 with DX: Polyarthritis, chronic. Vit D deficiency. Anemia NOS. Pt presented with gradual onset of bilateral hand, knee, foot and back pain & morning stiffness. PE (+) for fatigue, generalized weakness, non-productive cough, and wrist limitation. Tx with anti-inflammatory

Other Meds: Unknown

Lab Data: diagnostic laboratory - the test showed antibodies went up. Labs and Diagnostics: LH high at 21.1. FSH 4.5. ANA 174. RF (-). EBV and Lyme (-). Wrist x-ray (-).

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326786-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Aug-2007	Unknown		17-Sep-2008	30-Oct-2008	--	WAES0808USA00616	30-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Information has been received from a medical assistant concerning a 15 year old female who on 01-AUG-2007 was vaccinated with the first dose of GARDASIL vaccine (yeast) and on 04-AUG-2008 she received the second dose of GARDASIL vaccine (yeast) (lot no. 0250X). In 2007 the patient experienced pain after her first vaccination. Subsequently, the patient recovered. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326787-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	16-Nov-2007	01-Jul-2008	228	17-Sep-2008	30-Oct-2008	OH	WAES0808USA00625	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Hypoaesthesia, Palpitations

Symptom Text: Information has been received from a physician concerning a 20 year old female with medical history of asthma when she was a child, and no known drug reaction, who on 16-NOV-2007 was vaccinated with the first dose of GARDASIL vaccine (yeast). On 17-JAN-2008 the patient was vaccinated with the second dose of GARDASIL vaccine (yeast). On 03-JUL-2008 the patient was vaccinated with the third dose of GARDASIL vaccine (yeast). The physician reported that after the patient completed the GARDASIL vaccine (yeast) series, in July 2008 she started to complained of shortness of breath, palpitations and numbness all over her body. The patient went to the emergency room 4 times in the last month for the symptoms she had experienced daily. The physician also reported that the ER was not able to find the problem. At the time of the report the patient had not recovered. Additional information has been requested. 121/19/2008 ER record received for 8/4/2008 with c/o 1 month hx of SOB and trouble breathing which began after HPV vaccine. Pt left w/o being seen by MD.

Other Meds: None

Lab Data: Unknown. Labs and Diagnostics: EKG abnorml with non-specific T wave abnormality.

History: Asthma PMH: asthma

Prex Illness:

Prex Vax Illns:

Vaers Id: **326788-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Nov-2007	Unknown		17-Sep-2008	30-Oct-2008	CO	WAES0808USA00626	30-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysmenorrhoea, Menorrhagia, Menstrual disorder

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female with no known pertinent medical history and drug reaction, who on 13-NOV-2007 was vaccinated with the first dose of GARDASIL vaccine (yeast). On 28-JAN-2008, the patient was vaccinated with the second dose of GARDASIL vaccine (yeast). On 04-AUG-2008, the patient was vaccinated with the third dose of GARDASIL vaccine (yeast) (Lot # 650391/0063X), 0.5 ml, via intramuscularly route. There was no concomitant medication. The medical assistant was reported that the patient experienced heavy and difficult periods after received GARDASIL vaccines (yeast). The patient also reported to had more severe cramps with menstruation than before. The patient was seen by a nurse. At the time of the report the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326789-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	30-Oct-2008	--	WAES0808USA00634	30-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a health care worker concerning a female who was vaccinated with GARDASIL vaccine (yeast). The health care worker reported that she heard from her professor that a girl had an "abnormal PAP smear" after getting GARDASIL vaccine (yeast). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326790-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	30-Oct-2008	PA	WAES0808USA00640	30-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site anaesthesia, Injection site pain, Injection site swelling, Nausea, Rash

Symptom Text: Information has been received from a nurse concerning a female who on unspecified was vaccinated IM with the first and second doses of GARDASIL vaccine (yeast). The lot numbers were not provided. The patient experienced swelling, pain and intermittent numbness of her arm where the second dose was administered. The patient also experienced nausea and rash on her stomach. The patient sought at the office medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326791-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	19-Jun-2008	19-Jun-2008	0	17-Sep-2008	30-Oct-2008	AR	WAES0808USA00644	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Constipation, Dizziness, Gastric disorder, Nausea, Vaccine positive rechallenge, Weight decreased

Symptom Text: Information has been received from a registered nurse concerning her 11 year old daughter with no pertinent medical history and no drug reactions/allergies, who on 19-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). On 25-JUL-2008, she received the second dose of GARDASIL vaccine (yeast). Since the first dose of GARDASIL vaccine (yeast) was given, the patient had been experiencing nausea, weight loss and dizziness. Additional x-ray results were within normal limits. The nurse's daughter sought medical attention and visited her doctor's office. At time of reporting, the patient had not recovered. Additional information has been requested. 12/10/08 MR received from PCP. Seen 6/4/2008 with c/o 3 day hx of nausea. Last BM 3 days ago. Assessment: constipation. Seen 7/31/08 with c/o nausea. Assessment: Stomach function d/o. Rx: Prilosec.

Other Meds: Unknown

Lab Data: abdominal x-ray - Within normal limits. Labs and Diagnostics: Abd X-ray (+) retained fecal matter

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326792-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Jul-2008	01-Jul-2008	0	17-Sep-2008	30-Oct-2008	NC	WAES0808USA00646	30-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Vomiting

Symptom Text: Information has been received from a physician concerning a 11 year old female who early in July 2008, was vaccinated with the first dose of GARDASIL vaccine (yeast), and soon after she became pale and proceed to vomit for about 30-45 minutes on and off. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326793-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-Jul-2008	29-Jul-2008	1	17-Sep-2008	31-Oct-2008	--	WAES0808USA00654	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acne, Swelling face

Symptom Text: Information has been received from a nurse concerning her daughter, a 14 year old female who on 28-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast), lot number was not provided. On 29-JUL-2008, the patient woke up with swelling on her entire face and a "raccoon and mask of pimples around her eyes". Then, on 31-JUL-2008, the patient got her period for the first time in her life. The nurse reported that the patient had been told since she is very athletic and a gymnast, so, she would not get her period for a really long time. The patient sought unspecified medical attention. The swelling and mask disappeared within 24 hours. No further information is available as the reporter did not provide physician's name.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326794-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		17-Sep-2008	31-Oct-2008	NC	WAES0808USA00779	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Injection site pain, Migraine

Symptom Text: Information has been received from a physician concerning her daughter, a 20 year old female with a family history of leave in migraine and multiple sclerosis who on an unknown dates was vaccinated with the first and second doses of GARDASIL vaccine (yeast). Shortly, after receiving the second dose, the patient developed a severe headache and a significant pain at the injection site. Prompting a trip to the emergency room and a computerized axial tomography scan of the brain were taken. She was given a diagnosis of migraine. The headache resolved in approximately 24 hours on pain medication. There were no other complaints than significant pain at injection site. Additional information is not expected.

Other Meds: Unknown

Lab Data: head computed axial - migraine

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 326795-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	29-Jul-2008	29-Jul-2008	0	17-Sep-2008	31-Oct-2008	ND	WAES0808USA00942	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contusion, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a health professional concerning a 25 year old white female teacher with no allergies or medical conditions, who on 29-JUL-2008 at 11:30 am was at the doctors office for an annual exam and was vaccinated intramuscularly into left arm with a second dose of GARDASIL vaccine (yeast) (lot # 0250X). On 29-JUL-2008, approximately 5 minutes after immunization (approximately 11:35 am) the patient experienced fainting and had a head contusion. She was transported to the Emergency department. The patient had no illness at the time of vaccination. Additional information is not expected.

Other Meds: Unknown

Lab Data: physical examination - 07/29/08 - results not reported

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326796-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Sep-2008	31-Oct-2008	TX	WAES0808USA00943	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a nurse concerning unknown number patients who were vaccinated with GARDASIL vaccine (yeast). The nurse reported that about 80% of her patients who received GARDASIL vaccine (yeast) experienced injection site pain. The outcome was unknown. It was unknown if the patients sought medical attention or not. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326797-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	31-Oct-2008	--	WAES0808USA00944	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Information has been received from a physician who heard from another physician concerning a female (from a gymnastics class) who on an unspecified date was vaccinated with a dose of GARDASIL vaccine (yeast). Subsequently the patient experienced tingling in her extremities. The outcome of the patient was not reported. This is one of the several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326798-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Feb-2008	01-Feb-2008	0	17-Sep-2008	31-Oct-2008	--	WAES0808USA00951	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Brachial plexus injury, Drug administered at inappropriate site, Hypoaesthesia, Hypoaesthesia facial, Immediate post-injection reaction, Neuralgic amyotrophy, Pain in extremity

Symptom Text: Information has been received from a physician concerning his daughter, a 25 year old female who in February 2008, was vaccinated in the left arm with the second dose of GARDASIL vaccine (yeast). Immediately after the vaccination, the patient experienced pain and numbness in the left hand and numbness on the left side of the face that never went away. The physician reported that the vaccination was not administered in the deltoid but was administered in the biceps and triceps area in the patient's left arm. The patient was referred to neurologists and was diagnosed with brachial plexus and Parsonage E28093 Turner syndrome. Numerous magnetic resonance imaging (MRI) studies and other unspecified tests were performed but no results were provided. The patient's symptoms persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326799-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	26-Jun-2008	26-Jun-2008	0	17-Sep-2008	31-Oct-2008	WI	WAES0808USA00969	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea

Symptom Text: Information has been received from a registered nurse (RN) concerning a 24 year old female with no drug reactions or allergies who on 26-JUN-2008 was vaccinated intramuscularly in the right deltoid with her first 0.5 ml dose of GARDASIL vaccine (yeast) (Lot #654272/0073X). On 26-JUN-2008, after vaccination with GARDASIL vaccine (yeast), the patient was nauseous for the entire day. Subsequently, the patient recovered from the event. The patient sought medical attention by speaking to the nurse. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326800-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		17-Sep-2008	31-Oct-2008	PA	WAES0808USA01658	01-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope

Symptom Text: Information has been received from a physician concerning a 17 year old female who was vaccinated with GARDASIL vaccine (yeast). Subsequently the patient developed pre-syncopal episodes were unspecified. The patient was referred to a neurologist. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326801-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		02-Oct-2008	03-Oct-2008	--	WAES0809USA04681	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse practitioner concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL. Concomitant therapy included VARIVAX (Oka/Merck). It was reported that the patient experienced an adverse reaction following vaccination with GARDASIL. The reporter stated that the patient had an adverse reaction (possible seizure) when VARIVAX (Oka/Merck) was administered concomitantly with GARDASIL. The details of the adverse reaction were not provided, thought it may have been a seizure. On an unspecified date, the patient recovered. It was unknown if the patient sought medical attention or not. Upon internal review, seizure was considered to be other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326802-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Jan-2008	25-Jan-2008	0	02-Oct-2008	03-Oct-2008	FR	WAES0809USA04541	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Intra-uterine death

Symptom Text: Information has been received from a specialist in a foreign country through the Sanofi Pasteur MSD Gardasil Pregnancy Registry. Case linked to serious-case number E2008-08869 (baby's case). A 16-year-old female came to see the reporting gynecologist on 25-Jan-2008 or on 28-Jan-2008 for a 1st prescription of oral contraceptive. The same day she received the first dose of GARDASIL (lot # not provided). The physician had asked her before the injection if there was a possibility that she was pregnant and she had answered with a categorical no. The patient only mentioned afterward (after receiving the injection) her delayed menstrual period which were due on 13-Jan-2008 or on 15-Jan-2008. Consequently the physician prescribed a serum beta HCG test which returned positive 3 days later. An echography at 12 amenorrhea weeks revealed nuchal translucency at 3.3 mm. After this the pregnant woman was followed at hospital and the gynecologist had no news until mid-September 2008: she was contacted by phone by the mother of the pregnant patient and learned that on the 5th month echography performed by the end of May-2008 the baby was found dead (no heart beat). The mother of the patient claimed this had a link with the vaccination with GARDASIL. No more information was provided to the gynecologist. Upon internal review, fetal death in-utero was considered to be an other important medical event. Other business partner number included: E2008-08846 and E2008-08869.

Other Meds: Unknown

Lab Data: Ultrasound, 05?Apr08, foetus presented with nuchal translucency at 3.3 mm; Ultrasound, ??May08, baby was found dead (no heart beat); Serum beta-human chorionic gonadotropin, 25?Jan08, returned positive 3 days later

History:

Prex Illness: Pregnancy NOS (LMP = 13Jan08)

Prex Vax Illns:

Vaers Id: **326803-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Mar-2008	Unknown		02-Oct-2008	03-Oct-2008	FL	WAES0809USA04538	03-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0536	2	Unknown	Unknown	HPV4

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Complex partial seizures, Confusional state, Eye movement disorder, Loss of consciousness, Neurological examination abnormal, Partial seizures with secondary generalisation, Tonic clonic movements

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who on an unknown date, was vaccinated with GARDASIL. After receiving the vaccine, the patient experienced seizure. The patient was in the physician's office when the adverse event occurred. An electroencephalography (EEG) was performed (results were not provided). Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested. 10/10/08 Reviewed vax records & office note of 8/4/08 when patient seen for recheck of axillary cyst & states EEG abnormal. No other records available. 10/14/08 Reviewed neuro medical records of 9/9/08. FINAL DX: complex partial seizure disorder w/secondary generalization Records reveal patient experienced seizure symptoms since 7/2007 each lasting appro 5-10 min. Starts w/eye deviation, progressed to LOC & tonic-clonic activity followed by confusion. Tx w/antiseizure meds.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown PMH: birth twin. c-section due to difficult delivery. Family hx: epilepsy.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326804-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		02-Oct-2008	03-Oct-2008	AL	WAES0809USA04394	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Central nervous system lesion, Cerebrovascular accident

Symptom Text: Information has been received from a physician concerning a female friend of the physician's patient who was vaccinated with a dose of GARDASIL. Subsequently the patient was diagnosed as having had a stroke. A computed axial tomography scan of the brain revealed an unspecified lesion or mass. The patient's outcome was unknown. It was unspecified if the patient sought medical attention or not. Upon internal review, stroke was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Computed axial, an unspecified lesion or mass

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 326805-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	23-Sep-2008	23-Sep-2008	0	02-Oct-2008	03-Oct-2008	--	WAES0809USA04344	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Fatigue, Gaze palsy, Loss of consciousness, Malaise, Nausea, Pulse pressure decreased, Tremor, Urinary incontinence, Vomiting

Symptom Text: Information has been received from a registered nurse concerning a 23 year old female who faints easily and with a history of seizures after car accident in 2004, and issues with a shot given in the past, but unknown what drug or vaccine, or unknown what type of reaction who on 23-SEP-2008 was vaccinated with the first dose of GARDASIL (Lot # 661044/0548X), 0.5 ml, intramuscularly, into the left deltoid. There was no concomitant medication. The registered nurse reported that 5 minutes post vaccination the patient experienced an adverse event. The nurse reported that the patient said that she did not feel good. The patient had seizure activity, some shaking, her eyes rolled back into her head, she passed out, and had loss of urine. When the client came to she experienced nausea and vomiting. Her pulse was weak, but her airway was open. The nurse reported that the patient was given oral fluids, crackers and was monitored. One hour later the patient's blood pressure was 110/72. Prior to administering the GARDASIL vaccine a unsuccessful blood draw was attempted on client, but after vaccination another blood drawn was taken. A cat scan was performed with negative results. At the time of the report a EEG was scheduled. The patient sought medical attention at internist office. At the time of the report the registered nurse called the patient and she said that she was "tired but was feeling much better today". Upon internal review, seizure was considered to be an other important medical event. Additional information is expected.

Other Meds: None

Lab Data: diagnostic laboratory, 09/23/08; blood pressure, 09/24/08, 110/7; computed axial, 09/24/08, negative results

History: Convulsion; Nonspecific reaction; Automobile accident

Prex Illness: Syncope

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326806-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	02-Apr-2008	07-Mar-2008	-26	02-Oct-2008	03-Oct-2008	--	WAES0809USA04331	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Intra-uterine death

Symptom Text: Information has been received from a 24 year old female who in February 2008 received her first dose of GARDASIL (lot # not provided) and on 02-Apr-2008 received the second dose of GARDASIL (lot # not provided) without knowing she was pregnant. The patient had no medical history or concurrent condition. Concomitant therapy included vitamins (unspecified). The patient's LMP was reported as 07-MAR-2008. The patient was scheduled to be due in December however when she went in for a Ultra Sound on 17-Sep-2008 the baby had no heart beat and was dead. The patient delivered the baby on 18-Sep-2008 and was hospitalized for 12 hours after giving birth. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 09/17/08, the baby had no heart beat and was dead; diagnostic laboratory

History:

Prex Illness: Pregnancy NOS (LMP = 3/7/2008)

Prex Vax Illns:

Vaers Id: **326807-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		02-Oct-2008	03-Oct-2008	FR	WAES0809AUS00076	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness, Muscle twitching, Tonic convulsion, Visual acuity reduced transiently

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning an 18 year old female who was vaccinated with GARDASIL. Subsequently after vaccination with GARDASIL, the patient experienced convulsion, loss of consciousness, muscle twitching, tonic convulsion and visual acuity reduced transiently. At the time of reporting to the agency on 07-APR-2008, the patient had recovered from the convulsion, loss of consciousness, muscle twitching, tonic convulsion and visual acuity reduced transiently. The agency considered that convulsion, loss of consciousness, muscle twitching, tonic convulsion and visual acuity reduced transiently were related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review the adverse event of convulsion and tonic convulsion were considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326812-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		02-Oct-2008	03-Oct-2008	FR	WAES0809AUS00073	03-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Convulsion, Syncope

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning a 15 year old female who was vaccinated with GARDASIL. Subsequently after vaccination with GARDASIL, the patient experienced anxiety, convulsion and syncope. At the time of reporting to the agency on 09-APR-2008, the patient had recovered from the anxiety, convulsion and syncope. The agency considered that anxiety, convulsion and syncope were related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review the adverse event of convulsion was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326821-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Jul-2008	21-Jul-2008	3	02-Oct-2008	04-Nov-2008	NY		04-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt reported having syncope episode 3 days after receiving vaccine

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326830-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	04-Sep-2008	04-Sep-2008	0	02-Oct-2008	30-Oct-2008	NH		30-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	19674	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Palpitations, Tachycardia, Vaccine positive rechallenge

Symptom Text: dizziness/palpatations/nausea x 48 hours. Tachycardia - pt had symptoms after 1st injection but did not report until same thing after 2nd injection.

Other Meds: synthroid

Lab Data:

History: e-mycin allergy, Ben peroxide, hypothyroidism

Prex Illness: none

Prex Vax Illns:

Vaers Id: 326876-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	22-Aug-2007	11-Sep-2008	386	02-Oct-2008	30-Oct-2008	SD		23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB163AB	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	03844	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Blood glucose decreased, Concussion, Depressed level of consciousness, Dizziness, Dyskinesia, Excoriation, Fall, Gaze palsy, Headache, Iron deficiency anaemia, Loss of consciousness, Pallor, Syncope, Syncope vasovagal

Symptom Text: 2/28/06 - Unconscious episode - Dx s/p concussion. 3/30/06 - Evaluated lightheadedness. 5/24/07 - Evaluated with syncope episode. 8/22/07, 10/22/07, 2/21/08 received GARDASIL. 8/22/07 - 2/21/08 received HEP A. 7/3/08 Evaluate syncope. 9/11/08 Mom states seizure disorder - requests form. 10/06/2008 PCP records received. Pt with several year hx of intermittant dizziness, lightheadedness, headaches and tunnel vision s/p concussion. W/u have been (-) thus far except iron deficiency anemia-treated. Most recent recorded incident 5/07 with low blood sugar. Seen 7/3/08 in F/U of ER visit for syncopal episode. Pt reported feeling weak prior to incident then pt's eyes rolled back and had jerking movements. Pt remained semi-conscious. Likely dx: Vasovagal Syncope. Referred for Echo and EEG. 1/16/2009 MR received for DOS 6/26/2008 with DX: Syncope. Pt presented after episode of dizziness and syncope with loss of consciousness while having an abrasion from a fall cleaned. Pt has appeared pale x several days. PE WNL exept for superficial abrasions. Assessment: Spell, 2' to vasovagal from pain.

Other Meds: None

Lab Data: EEG, CBC with Diff, Echocardiogram, MRI Labs and Diagnostics: CBC with WBC 12.2. Echocardiogram WNL. EEG WNL.

History: None. PMH: none

Prex Illness: None

Prex Vax Illns:

Vaers Id: **326881-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Jul-2008	Unknown		02-Oct-2008	04-Nov-2008	NH		04-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Nausea

Symptom Text: Vaccine administered 7/31/08, pt presented to local ER 8/1/08 with dizziness, nausea, weakness after physical activity; mother phone MERCK to be advised of side effects; physicians office notified on 9/29/08 if immunization services should be continued

Other Meds: None

Lab Data: Orthostatic vital signs performed at ER.

History: None

Prex Illness: None, routine PE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326889-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Aug-2008	06-Aug-2008	0	17-Sep-2008	31-Oct-2008	AK	WAES0808USA01662	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy, Pyrexia

Symptom Text: Information has been received from a physician assistant concerning a 15 year old female with exercise induced reactive airways disease and no allergies who on 06-AUG-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) IM in the deltoid 0.5 ml (lot # 657621/0387U). There was no concomitant medication. On 06-AUG-2008, six hours after receiving the first dose, the patient experienced high fever (reported by the patient's mother as 104 F). On 07-AUG-2008 the patient was examined by the provider and fever resolved, however, the patient had "exquisite" anterior cervical lymphadenopathy. The patient's anterior cervical lymphadenopathy was recovering. No other symptoms or treatment reported. The white blood cell count, urine analysis and liver function test were performed. The patient sought medical attention in an office visit. Additional information has been requested.

Other Meds: None

Lab Data: WBC count - 08/07?/08, urinalysis - 08/07?/08, hepatic function tests - 08/07?/08, body temp - 08/06?/08 - 104 F

History: Reactive airways disease

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326890-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	28-Jul-2008	29-Jul-2008	1	17-Sep-2008	31-Oct-2008	--	WAES0808USA01665	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Rash macular

Symptom Text: Information has been received from a nurse concerning a 24 year old female with sulfonamide allergy and a history or rosacea who on 28-JUL-2008 was vaccinated intramuscularly with the first dose of GARDASIL vaccine (yeast) into the left deltoid. There was no concomitant medication. On approximately 29-JUL-2008, "one to two days after the first vaccination"' the patient developed rashes and blotches on her face and neck. The rashes and blotches were still present at the time of this report, but were improving. The patient sought unspecified medical attention. No further information is available.

Other Meds: None

Lab Data: None

History: Rosacea

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: 326891-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Mar-2008	01-Mar-2008	0	17-Sep-2008	31-Oct-2008	--	WAES0808USA01666	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bladder disorder, Gastric disorder, Injection site erythema, Injection site pruritus, Morphoea, Rash macular, Skin discolouration, Vaccine positive rechallenge, Weight decreased

Symptom Text: Information has been received from a consumer concerning her 21 year old daughter with penicillin allergy and allergy to codeine who in March 2008, was vaccinated with the first dose of GARDASIL vaccine (yeast). Concomitant therapy included YAZ. After receiving the first dose, she had itching and redness at the injection site and developed patches on her back and hips that were the size of a baseball and were purple on the outside and white on the inside, and her skin is very hard. The consumer reported that her daughter saw the physician at school for about two months and they could not figure out what it was so they had then sent her to a dermatologist, in which they did a biopsy and could not figure out what the patches were. In June 2008 the patient was vaccinated with the second dose of GARDASIL vaccine (yeast). About two weeks later she had developed about eleven new patches on her breast, back, hips and other spots as well. The consumer reported that her daughter then came home from school and saw her own primary care physician who sent her to a dermatologist. The dermatologist as soon as she saw her daughter diagnosed her on site with localized morphea acleroderma, which is a build up of collagen that attacks the skin. The dermatologist also did a blood test, and first prescribed a topical steroid, name and manufacturer unspecified, which made some difference, but then was put up on prednisone for a month which had helped, and her daughter stated that "you can hardly see the patches but they are still there." The consumer also reported that "While taking prednisone, she lost about 5 pounds, even though she was eating normally, and she was having problems with her stomach and bladder. The patient has seen a physician about this and was tested for diabetes and bladder issues, but she did not have any and the physician feels it is from the prednisone. No further information is available.

Other Meds: YAZ

Lab Data: biopsy - 03?/??/08, diagnostic laboratory - 06?/??/08 - blood test, diagnostic laboratory - 06?/??/08 - bladder issues test - negative, blood glucose - 06?/??/08 - negative

History:

Prex Illness: Penicillin allergy, Hypersensitivity

Prex Vax Illns:

Vaers Id: **326892-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	31-Oct-2008	--	WAES0808USA01681	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a nurse practitioner concerning a female who was vaccinated with the first dose of GARDASIL vaccine (yeast) IM in her arm. The patient experienced a rash after receiving the vaccination, but did not notify the nurse. The rash went away without treatment after 1 week and it was not known where on the patient's body occurred. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326893-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	31-Oct-2008	--	WAES0808USA01692	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pelvic pain

Symptom Text: Information has been received from a physician, concerning a female patient who was vaccinated with the second dose of GARDASIL vaccine (yeast) and afterwards complained of pelvic pain. The physician thinks she may have been experiencing it prior to getting the second dose but he will have to check the charts. The patient sought medical attention. There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326894-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jun-2008	01-Jun-2008	0	17-Sep-2008	31-Oct-2008	NJ	WAES0808USA01701	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning a 16 year old female who in June 2008, about two months ago, was vaccinated with the first dose of GARDASIL vaccine (yeast). The patient experienced dizziness after vaccination. The patient sat down for a while and was given an "epi pen" just in case of an allergic reaction, but then recovered and was able to leave. The physician also reported that the patient has received the second dose of GARDASIL vaccine (yeast) and no adverse experienced occurred. The patient sought medical attention and saw physician. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326895-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	31-Oct-2008	--	WAES0808USA01707	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a physician assistant concerning some patient which were vaccinated with GARDASIL vaccine (yeast). The physician assistant reported that some patients experienced injection-site pain after receiving GARDASIL vaccine (yeast). Follow up information was received from the physician assistant which reported that the patients felt "minimal to mild discomfort" while receiving GARDASIL vaccine (yeast). The physician assistant also reported that the "pain was significantly less than with the tetanus shot". He added that he does not have any patient information to provide since none of the patients returned with a problem. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326896-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Aug-2008	08-Aug-2008	1	17-Sep-2008	31-Oct-2008	--	WAES0808USA01716	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning an 18 year old female with no allergies and no drug reactions, and a history of low blood sugar who on 07-AUG-2008 was vaccinated with the third dose of GARDASIL vaccine (yeast). There was no concomitant medication. The patient had been experiencing nausea and fainting on 08-AUG-2008. The patient sought medical attention at the office. At time of reporting, the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Blood sugar decreased

Prex Vax Illns:

Vaers Id: **326897-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	12-Feb-2008	12-Feb-2008	0	17-Sep-2008	04-Nov-2008	IN	WAES0808USA01717	04-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0929U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Urticaria, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 14 year old female with no allergies/drug reactions and no pertinent medical history, who on 12-FEB-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 658282/0929U) 0.5 mL, IM. On 15-APR-2008, the patient was vaccinated with the second dose of GARDSIL vaccine (yeast) (lot # 659964/1978U) 0.5 mL, IM. Concomitant therapy included MENACTRA. The patient experienced hives and itching after receiving the first and second dose of GARDASIL vaccine (yeast). The patient sought medical attention: phone call. At time of reporting. the patient was recovered. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326898-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	04-Aug-2008	04-Aug-2008	0	17-Sep-2008	12-Nov-2008	--	WAES0808USA01719	12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNK	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Diarrhoea, Headache, Nausea, Pain, Palpitations

Symptom Text: Information has been received from a consumer concerning her daughter, a 26 year old female with anxiety disorder and penicillin allergy who on 04-AUG-2008 was vaccinated with the first dose of GARDASIL. Concomitant therapy included escitalopram oxalate (LEXAPRO). On 04-AUG-2008, several hours after received the first dose, the patient experienced heart palpitations. On 05-AUG-2008, the patient improved but experienced the onset of chills, diarrhea and nausea. The nausea improved, but on 07-AUG-2008, the patient began to have widespread body aches and a headache in addition to the continuing diarrhea. The patient contacted her physician's office by phone and was advised to call again if the symptoms persist. No therapy was prescribed. The patient improved from nausea. At the time of reporting, chills, diarrhea and widespread had not recovered. The reporter states the physician does not feel that patient's symptoms are related to GARDASIL vaccine. Additional information is not expected as the consumer did not provide the physician's name

Other Meds: LEXAPRO

Lab Data: None

History:

Prex Illness: Anxiety disorder; Penicillin Allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326899-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		17-Sep-2008	12-Nov-2008	MA	WAES0808USA01724	12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Nausea, Pyrexia, Syncope, Vomiting

Symptom Text: Information has been received from a consumer concerning her daughter, a 23 year old female with no known drug allergies and no pertinent medical history reported, who on unspecified dates was vaccinated with the first and second doses of GARDASIL. In the summer of 2007, the patient was vaccinated with the third dose of GARDASIL. Concomitant therapy included PROZAC. On an unspecified date, the patient experienced fainted after receive the first dose of GARDASIL, for the second and third doses she was lying down while receiving it and she was fine. After receiving the third dose, the patient started experiencing nausea, vomiting, low grade fever and chills that come an go ever since. The patient sought unspecified medical attention. Blood work came back normal. At the time of reporting, the patient had not recovered. Additional information has been requested.

Other Meds: PROZAC

Lab Data: blood work - normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326900-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	12-Nov-2008	--	WAES0808USA01736	12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Infectious mononucleosis

Symptom Text: Information has been received from a consumer concerning her daughter who was vaccinated with the third dose of GARDASIL. Subsequently the patient experienced mononucleosis. the patient sought unspecified medical attention. No further information is available

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326901-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Sep-2008	12-Nov-2008	--	WAES0808USA01737	12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Medication error

Symptom Text: Information has been received form a registered nurse concerning an unknown number of patients who were vaccinated with GARDASIL (lot number not reported). The nurse reported that the patients received GARDASIL (lot number not reported) that had been stored at 33 degrees F for 12 hours. No adverse effects reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326902-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	29-Jul-2008	29-Jul-2008	0	17-Sep-2008	12-Nov-2008	--	WAES0808USA01799	12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	660389/1968U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia oral, Throat irritation

Symptom Text: Information has been received from a certified nurse midwife concerning a 22 year old white female with an allergy to CECLOR (causes rash) who on 29-JUL-2008 was vaccinated with the first dose of GARDASIL. The patient was sitting in the office for observation as recommended. Approximately ten minutes after the injection, she noticed numbness in her tongue and an "itchy" feeling in her throat, that became more noticeable over the next five minutes. She never had progression or symptoms behind these and never experienced shortness of breath or inability to speak. She was given 60 mg of Allegra suspension (sample) and monitored for approximately one hour. Her symptoms totally resolved within 40 minutes after receiving Allegra. She was given x420/2.5 mg x 7 to take at home nightly. Concomitant therapy included hormonal contraceptives (unspecified). No further information is available.

Other Meds: hormonal contraceptives

Lab Data:

History: Allergic reaction to antibiotics

Prex Illness:

Prex Vax Illns:

Vaers Id: **326903-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	07-Aug-2008	07-Aug-2008	0	17-Sep-2008	12-Nov-2008	MI	WAES0808USA01816	12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Drug exposure during pregnancy

Symptom Text: Information has been received from the Merck pregnancy registry, a physician reported on a 19 year old female with no pertinent medical history and no known drug reactions/allergies who on 07-AUG-2008 was vaccinated with the first GARDASIL (lot # 660393/0067X), 0.5mL. IM. Concomitant therapy included MENACTRA and ORTHO EVRA contraceptive patch. The patient experienced abdominal pain and was evaluated in an emergency room but she was not admitted to the hospital. On an unspecified date, an urine test was positive for pregnancy (LMP 26-JUN-2008) (estimated delivery date 02-APR-2009). Additional information has been requested.

Other Meds: ORTHO EVRA; MENACTRA

Lab Data: urine beta-human - positive

History:

Prex Illness: Pregnancy NOS (LMP = 6/26/2008)

Prex Vax Illns:

Vaers Id: **326904-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		17-Sep-2008	12-Nov-2008	--	WAES0808USA01886	12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dysmenorrhoea, Menorrhagia

Symptom Text: Information has been received from a physician concerning an 11 year old female who was vaccinated with GARDASIL (dose, therapy route, lot number not reported). The patient received GARDASIL and experienced dizziness and a profuse/painful menstruation. The patient reported feeling dizzy the day following vaccination with GARDASIL. It was unknown which dose of GARDASIL was administered. The patient also reported a profuse and painful menstruation following the dose of GARDASIL. The patient normally did not have profuse and painful menstruation and felt it was related to the dose of GARDASIL. On 11-AUG-2008 the patient sought medical attention by an office visit. Subsequently the patient recovered from the dizziness and a profuse/painful menstruation. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326905-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	14-Jul-2008	14-Jul-2008	0	17-Sep-2008	14-Nov-2008	--	WAES0808USA01898	17-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vaginitis gardnerella

Symptom Text: Information has been received form the pregnancy registry for GARDASIL from a 20 year old female patient, with no known pertinent medical history and no drug reactions/allergies, who on 14-JUL-2008 was vaccinated with the first dose of GARDASIL (Lot # 655604/0052X). There was no concomitant therapy. The health care worker reported that on 04-AUG-2008, the patient had a positive pregnancy test. The patient sought medical attention at physician's office. The last menstrual period was on 06-JUL-2008. Estimated date of delivery approximately 12-APR-2009. At the time of the report the pregnancy was normal. Follow up information was received from a health care worker which reported that the patient had a medical history of genital condyloma, who on 14-JUL-2008, was vaccinated with the first dose of GARDASIL (Lot # 9725103). The health care worker reported that the last menstrual period was on 05-JUL-2008. Estimated date of delivery approximately 10-APR-2009. On 16-JUL-2008, the patient was treated with metrogel and vaginal gel at bedtime for gardnerella vaginalis. Additional information has been requested.

Other Meds: Unknown

Lab Data: beta-human chorionic - 08/04/08 - positive pregnancy

History: Genital wart

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326906-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	14-Nov-2008	NJ	WAES0808USA01901	17-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a registered nurse concerning a female who in April 2008, was vaccinated with her second dose of GARDASIL (Lot number not reported). The patient developed the "wart like rashes" on her body 4 months after the second dose (in Aug 2008). the patient sought unspecified medical attention ant the "wart like rashes" persisted. This one of the several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326907-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Aug-2008	09-Aug-2008	3	17-Sep-2008	14-Nov-2008	NJ	WAES0808USA01903	17-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Local swelling

Symptom Text: Information has been received from a certified medical assistant concerning a 17 year old female with no pertinent medical history and no known drug reactions/allergies who on 06-AUG-2008 was vaccinated with a dose of GARDASIL and a dose of VARIVAX (Merck). there was no concomitant medication. On 09-AUG-2008 the patient experienced a swollen feeling in her neck and difficulty breathing. Subsequently the patient recovered from swollen feeling in her neck and difficulty breathing. At the time of the nurse report. The patient's medical chart was not available. The patient sought medical attention at the emergency room. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326908-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
37.0	F	25-Apr-2007	01-Jun-2007	37	17-Sep-2008	18-Nov-2008	--	WAES0808USA01935	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	1	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea, Headache, Inappropriate schedule of drug administration, Micturition urgency, Nausea, Pain, Pollakiuria, Rash, Urinary tract disorder, Urinary tract infection

Symptom Text: Information has been received regarding a case in litigation. A 39 year old female with no known allergies reported that on an unspecified date she was vaccinated with the second dose of GARDASIL. After receiving the second dose she broke out in a rash. In June 2007, the patient was vaccinated with the third dose of GARDASIL. After receiving the third dose, she broke out in a rash again and it was much worse. Also after the third dose, she started having recurring urinary track infection, nausea and headache. And she also reported she was having diarrhea and pains. At the time of this report, the patient's symptoms persisted. She sought unspecified medical attention. This is one of several reports received from the same source. Additional information has been requested. 1/23/09 Reviewed ER medical records of 5/24/2007. FINAL DX: Urinary anomaly Records reveal pt experienced frequency, pressure & rgency x 2 days.

Other Meds: Unknown

Lab Data: Urinalysis LABS: UA WNL.

History: Unknown PMH: HIV (+). Diabetes w/nephropathy. Prior UTIs.

Prex Illness:

Prex Vax Illns:

Vaers Id: **326909-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-Aug-2008	11-Aug-2008	0	17-Sep-2008	18-Nov-2008	--	WAES0808USA01949	18-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Device leakage, Pain in extremity, Underdose

Symptom Text: Information has been received from registered nurse (R.N.) concerning a 17 year old female who on 11-AUG-2008 was vaccinated with a dose of GARDASIL. On 11-AUG-2008, when administering GARDASIL, a small account of GARDASIL leaked out from the hub. The nurse reported that the patient had no problems other than reporting a "sore arm". The outcome of the patient was not reported. additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326910-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	11-Jun-2008	11-Jun-2008	0	17-Sep-2008	18-Nov-2008	OH	WAES0808USA02021	18-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	660393/0067X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling cold, Headache, Influenza like illness, Presyncope

Symptom Text: Information has been receiving from a physician's office manager and her co-worker concerning a 26 year old white female positive for high risk papilloma viral infection and no known allergies who on 11-JUN-2008 at approximately 12:00PM was vaccinated in her left deltoid with the first dose of GARDASIL (LOT# 660393/0067X). Concomitant therapy included DEPO-PROVERA. After the vaccination, the patient sat for about 10-15 minutes in the waiting room to make sure that she did not have an reaction to the injection. the patient "was absolutely fine" when she left the physician's office. About 1/2 hour after leaving the office, she went to pick up her kids and she started to experience flu-like symptoms. she felt to then cold. She got a headache and felt dizzy. She almost fainted and almost had a wreck in her car on her way home. She got home and slept for 4 hours. when she woke up, she took some aspirin and drank tea to help her feel better. She did not feel better until the next day. The patient did not seek medical treatment at a hospital or from any other doctor for these symptoms, nor did she call the physician's office. The other vaccines within a month before or after getting GARDASIL. No tests were ordered by any doctor or medical facility to try to determine her ailment at this time. On 08-AUG-2008, the patient called the physician's office. She wanted to cancel her scheduled appointment for her second vaccination. additional information is not expected.

Other Meds: DEPO-PROVERA mg/mL

Lab Data: None

History:

Prex Illness: Papilloma viral infection

Prex Vax Illns:

Vaers Id: **326911-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		17-Sep-2008	19-Nov-2008	NJ	WAES0808USA02084	19-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physicians concerning a 16 year old female who in approximately May 2008, about two and a half months ago, was vaccinated with the first dose of GARDASIL. The patient experienced dizziness after vaccination. The patient sat down for a while and was given an "epi pen" just in case of an allergic reaction, but then recovered and was able to leave. The physician also reported that the patient has received the second dose of GARDASIL and no adverse experienced occurred. The patient sought medical attention and saw physician. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326912-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	29-Oct-2007	Unknown		17-Sep-2008	19-Nov-2008	--	WAES0808USA02086	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Diarrhoea, Oropharyngeal pain, Pain, Rhinorrhoea, Urinary tract infection, Viral infection

Symptom Text: Information has been received regarding a case in litigation. A female consumer reported that her 14 year old daughter who on an unspecified dates were vaccinated with three doses of GARDASIL. The patient's mother reported that the patient started having stomach pains since then. It was also reported that the patient was having continually urinary track infection, diarrhea and pains. At the time of this report, the patient's symptoms persisted. She sought unspecified medical attention. this is one of several reports received from the same source. Additional information has been requested. 11/24/08-records received-10/31/07-presented with C/O social issues. Now in adoptive home. 4/14/08-C/O sore throat, mild nasal discharge. Upper viral infection. 8/6/08-seen for school exam.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown 11/24/08-records received-PMH: personal history of emotional abuse. Myopia. Obesity.

Prex Illness:

Prex Vax Illns:

Vaers Id: **326914-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Aug-2008	06-Aug-2008	0	17-Sep-2008	19-Nov-2008	CT	WAES0808USA02102	19-Nov-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hypoaesthesia, Immediate post-injection reaction, Presyncope

Symptom Text: Information has been received from a registered nurse concerning a 13 year old female who on 06-AUG-2008 was vaccinated with the first dose of GARDASIL {0.5 ml, left arm, lot number not reported} via IM route, and VARIVAX (MSD) (dose, route not reported) and hepatitis A virus vaccine (unspecified0 (manufacturer not known) (dose, route not reported) received in the right arm. Immediately following the injections the patient's left arm became numb and she felt dizzy and "almost passed out." The patient was observed for 10 minutes in the office and recovered fully and was discharged home. The nurse mentioned that the physician believed this to be a syncopal episode. No lab diagnostics studies was performed. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326915-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	04-Jun-2008	04-Jun-2008	0	17-Sep-2008	19-Nov-2008	LA	WAES0808USA02105	08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea

Symptom Text: Information has been received from a consumer concerning her 24 year old daughter with no pertinent medical history or drug allergy who on 04-JUN-2008 was vaccinated with the first dose of GARDASIL {0.5 ml, lot number not reported} via IM route. There was no concomitant medication. The patient had had diarrhea since her first GARDASIL shot on 04-JUN-2008. She did receive her second GARDASIL shot on 04-AUG-2008. The consumer could not provide the lot numbers. No lab diagnostic test was performed. The patient sought unspecified medial attention. The patient's diarrhea was not improved or recovered as of 12-AUG-2008. Additional information has been requested. 12/3/08 Per parent pt has not sought medical tx for diarrhea, only informed provider.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326916-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	19-Nov-2008	PA	WAES0808USA02118	19-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with GARDASIL. Subsequently the patient experienced fatigue. The patient's fatigue persisted. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326917-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	Unknown	Unknown		17-Sep-2008	19-Nov-2008	--	WAES0808USA02125	19-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dermatitis, Scar, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse practitioner concerning a 10 year old female with environmental allergy and penicillin allergy who in June 2008, was vaccinated with the first dose of GARDASIL 0.5 ml IM. ON approximately 29-JUL-2008, about 2 weeks ago, the patient was vaccinated with the second dose of GARDASIL 0.5 ml IM. Concomitant therapy included ZYRTEC as needed. The patient experienced dermatitis on her extremities after each of the 2 doses. The patient was treated with oral steroids. The patient has some scarring on her wrists from the dermatitis. the patient sought medical attention in an office visit. Additional information has been requested.

Other Meds: ZYRTEC

Lab Data: Unknown

History:

Prex Illness: Environmental allergy; Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326918-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	24-Nov-2008	FL	WAES0808USA02143	24-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Psoriasis

Symptom Text: Information has been received from a physician concerning a female with no known allergies or pertinent medical history who was vaccinated IM with the third dose of GARDASIL vaccine. The physician reported that a patient developed psoriasis after she received her third dose of GARDASIL. No lab diagnostics were performed. Unspecified medical attention was sought. there was no product quality complaint. No further information is available.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326919-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Sep-2008	24-Nov-2008	--	WAES0808USA02144	02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a nurse practitioner concerning an unknown number of patients, who on an unknown date were vaccinated with GARDASIL. The nurse practitioner reported that 99% of her patients who were administered GARDASIL complained of pain at the time of injection. No patient specific information was available. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326920-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	24-Nov-2008	--	WAES0808USA02147	24-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Presyncope

Symptom Text: Information has been received from a nurse concerning a female who was vaccinated with GARDASIL. Concomitant therapy included hepatitis A virus vaccine (manufactured unspecified) and MENACTRA. The registered nurse reported that the patient did not pass out, because the patient was squeezing her hand, but the mother thought that the patient passed out. This is one of the reports from the same source additional information has been requested.

Other Meds: MENACTRA

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326921-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		17-Sep-2008	24-Nov-2008	MA	WAES0808USA02148	24-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysmenorrhoea

Symptom Text: Information has been received from a physician concerning a 15 year old female who was vaccinated with GARDASIL, 0.5 ml, intramuscular route. The physician reported that the patient developed painful menses after a vaccination with GARDASIL. The patient sought medical attention at physician's office. At the time of the report the patient had not recovered

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326922-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	24-Nov-2008	GA	WAES0808USA02155	24-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Aggression, Ovarian cyst

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with the first dose of GARDASIL, lot number was not provided. A week later the patient developed atypical aggressive behavior. The patient did have some tests (unspecified) done and was diagnosed with having an ovarian cyst but that since has resolved. The patient sought unspecified medical attention. the patient will not receive the second and third dose of GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory ovarian cyst

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326923-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-May-2008	30-Jun-2008	39	17-Sep-2008	24-Nov-2008	--	WAES0808USA02157	24-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pain in extremity

Symptom Text: Information has been received from a 18 year old female with allergy to dust and mold who on 22-MAY-2008 was vaccinated with the first dose of GARDASIL and with the second dose of GARDASIL on 11-JUL-2008. There was no concomitant medication. On 07-AUG-2008 (last Thursday) the patient found out she was pregnant. On 12-JUL-2008 the patient experienced arm soreness which subsided on 13-JUL-2008 and went away on 14-JUL-2008. Therapy with human papilloma virus vaccine was discontinued. Her last menstrual period was approximately on 30-JUN-2008. On 07-AUG-2008, was performed a pregnancy test resulting positive. Estimated date of delivery approximately on 06-APR-2009. The patient sought medical attention by seeing a doctor. Additional information is not available.

Other Meds: None

Lab Data: beta-human 08/07/08 positive

History: Pregnancy NOS (LMP = 6/30/2008) House dust allergy; Mycotic allergy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326924-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Jul-2008	16-Jul-2008	0	17-Sep-2008	24-Nov-2008	WA	WAES0808USA02159	24-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	660557/0072X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: Information has been received from a physician, concerning a 17 year old female patient with a history of seizures up until 8 years old, who on 16-JUL-2008 was vaccinate with the first dose of GARDASIL (lot # 660557/0072X). Concomitant therapy included DEPO-PROVERA two days before GARDASIL. On 16-JUL-2008, the patient experienced fainting 15 minutes later after vaccination. The patient hit her head when she fainted. The patient recovered on an unspecified date. Th patient sought medical attention. There was no product quality complaint. Additional information is expected.

Other Meds: DEPO-PROVERA

Lab Data: Unknown

History: Convulsion

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326925-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	12-Aug-2008		17-Sep-2008	24-Nov-2008	CT	WAES0808USA02167	24-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Accidental exposure, Eye burns, Medical device complication, Paranasal sinus discomfort

Symptom Text: Information has been received from a medical assistant concerning a female medical assistant. On 12-AUG-2008 the medical assistant was preparing to attach a needle to prefilled GARDASIL syringe (Lot # 0250X) when the vaccine splashed into her left eye. She was going administer the injection, so before she attached the needle, she was trying to take off the gray colored syringe tip cap, when the plunger popped out through the back end and the vaccine splashed into her eyes. The safety device did not activate. The needle was not attached. The syringe was empty and there in no vaccine left. the syringe was the first one on the right side of the tray, when they took it out for use. There was no damage to the package or the tray. The medical assistant has been administered GARASIL vaccine for a long time. When the vaccine splashed into her left eye, she immediately flushed her eye. The eye was irrigated but still "Burns a little." There was no redness or pain. There was slight burning sensation and irritation in her sinuses. No visual problems are noted. At the time or the report the patient had not recovered. Information has been received from a medical assistant regarding GARDASIL in a prefilled syringe (lot number: 0250X). It was reported that the plunger of the vaccine prefilled syringe "came out the wrong way" as the tip cap was being removed. SR Number: 1-3088949518. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326926-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Jul-2008	Unknown		17-Sep-2008	26-Nov-2008	FL	WAES0808USA02168	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Skin hyperpigmentation

Symptom Text: Information has been received from a physician concerning an approximately 23 year old female with history of hyper pigmentation, who on 01-JUL-2008 was vaccinated with the second dose of GARDASIL. The physician reported that the patient developed hyper pigmentation on her skin where the vaccine was given. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Pigmentation

Prex Illness:

Prex Vax Illns:

Vaers Id: **326927-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	29-Apr-2008	29-Apr-2008	0	17-Sep-2008	26-Nov-2008	WA	WAES0808USA02169	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	657622/0388U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site rash, Rash generalised

Symptom Text: Information has been received from a physician concerning a 23 year old female who on 29-APR-2008 was vaccinated with the first dose of GARDASIL (lot # 557622/0388U). On 29-APR-2008 the patient developed a localized rash at the injection site. As of 06-MAY-2008, the rash spread over the body and still persisted. The patient sought unspecified medical attention. Additional information has been requested

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326928-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	05-Apr-2007		17-Sep-2008	01-Dec-2008	--	WAES0808USA02176	12-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	3	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Inappropriate schedule of drug administration, Nausea, Syncope, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female with no pertinent medical history and no drug reactions or allergies, who on 11-OCT-2006 was vaccinated with the first dose of GARDASIL 0.5 mL IM. On 05-APR-2007, the patient was vaccinated with second dose of GARDASIL 0.5 mL IM. On 08-JUN-2007, the patient received the third dose of GARDASIL 0.5 mL IM. On 23-JUL-2008, the patient received a fourth dose of GARDASIL (lot # 658558/1061U) 0.5 mL IM. Concomitant therapy included DEPO-PROVERA on 23-JUL-2008. Two weeks ago (approximately 29-JUL-2008), the patient developed the following symptoms: fainting, dizziness, nausea and vomiting. The patient sought medical attention and was seen by the nurse practitioner. No labs diagnostics studies were performed. At time of reporting, the patient had not recovered. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326929-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		17-Sep-2008	01-Dec-2008	--	WAES0808USA02180	01-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Biopsy skin abnormal, Drug hypersensitivity, Pruritus, Urticaria

Symptom Text: Information has been received from a nurse practitioner concerning an 18 year old female with penicillin allergy who on unspecified dates was vaccinated with the first and second doses of GARDASIL. In October 2007, was vaccinated with a third dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). In October 2007, the day after administration of her third dose, the patient developed pruritic urticaria in different areas of her body every day. An skin biopsy was performed on 21-JUL-2008 and the results showed urticarial lesion due to systemic antigen including drug. She has been treated with steroid dose packs, antihistamine and KENALOG INJECTIONS. She has been also examined by an allergist but the information is not available. At time reporting, the patient had not recovered. Additional information has been requested.

Other Meds: penicillin contraceptives

Lab Data: skin biopsy, 07/21/08 - urticarial lesion due to systemic antigen including drug

History: Penicillin allergy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326930-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		17-Sep-2008	02-Dec-2008	--	WAES0808USA02182	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Hypoaesthesia, Musculoskeletal pain

Symptom Text: Information has been received form an healthcare worker (also reported as an office administrator) concerning a 25 year old female patient who in May 2008, was vaccinated with the third dose of GARDASIL. Concomitant therapy included DEPO-PROVERA. On a date reported, the patient was seen by an orthopedic surgeon for pain at the shoulders and knees and numbness in ankles and feet. The orthopedic surgeon was unable to find the cause and referred the patient to another orthopedic surgeon. As of 12-AUG-2008 the patient's symptoms persisted. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326931-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-May-2008	01-May-2008	0	17-Sep-2008	02-Dec-2008	CA	WAES0808USA02357	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a licensed vocational nurse concerning a 25 year old white female who on 01-MAY-2008, at 11:30 AM, was vaccinated with a first dose of GARDASIL (Lot # 654272/0073X), intramuscularly into the first deltoid. It was reported that on 01-MAY-2008 (reported as 11:30 AM), patient had not eaten and within minutes, she a fainting episode. Patient was given juice and cookies and responded favorably. The patient recovered. Subsequent injection, on 01-JUL-2008 went without problems. It was not specified if there was illness at the time of vaccination. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326932-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	02-Dec-2008	--	WAES0808USA02378	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Pain in extremity

Symptom Text: Information has been received from the mother concerning her daughter who a couple of weeks ago was vaccinated with the first dose of GARDASIL. On an unknown date, the patient experienced leg pain associated with joint pain for about two weeks. This was just reported to the doctor. The pain has resolved and the parent doesn't want the daughter to receive the second or third dose. Patient was not given other medications and not involved in heavy exercise. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326933-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	02-Dec-2008	NJ	WAES0808USA02389	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Skin papilloma

Symptom Text: Information has been received from a registered nurse concerning the daughter of a physician who was vaccinated an unknown dose of GARDASIL (Lot number not reported). After the vaccination the patient developed the "wart like rashes" on her body. It was unknown if the patient sought medical attention. The patient's "wart like rashes" persisted. This is one of the several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326934-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	11-Aug-2008	12-Aug-2008	1	17-Sep-2008	02-Dec-2008	--	WAES0808USA02394	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pyrexia

Symptom Text: Information has been received from a pharmacist concerning her 22 year old daughter with CECLOR allergy who on 11-AUG-2008 was vaccinated with the first dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). On 12-AUG-2008 the patient developed fever of 100 degrees F and headache. The patient's fever persisted and was still present at the time of the report. The headache was not a complaint at the time of the report. The patient was treated with acetaminophen. The patient did not seek medical attention. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: body temp, 08/12/08 - 100 degre

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326935-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	Unknown	Unknown		17-Sep-2008	02-Dec-2008	--	WAES0808USA02405	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crying, Injection site pain

Symptom Text: Information has been received concerning a 10 year old female who within the last month (in July 2008), was vaccinated with the first dose of GARDASIL (Lot No. not reported). The patient complained that the injection was very painful and she cried. She was given 4 other injections after that. They gave her ice and elma after. The outcome of the adverse events was not reported. Additional information is not expected.

Other Meds: (therapy unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326937-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		17-Sep-2008	02-Dec-2008	UT	WAES0808USA02409	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness, Malaise

Symptom Text: Information has been received from a certified medical assistant (CMA) concerning a 21 year old female with no pertinent medical history or drug reactions or allergies who in February 2008, was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot no. 658563/1063U). There was no concomitant medication. In approximately March 2008, "about 1 month after the first dose", the patient was not feeling well. The CMA thought she was referring to flu-like symptoms. Subsequently, on an unspecified date the patient recovered from not feeling well and flu-like symptoms. The patient did not seek medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326939-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Jul-2008	30-Jul-2008	0	17-Sep-2008	02-Dec-2008	--	WAES0808USA02428	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Syncope

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female who on approximately 30-JUL-2008 was vaccinated with the first dose of GARDASIL. Concomitant therapy included "other vaccines" (therapy unspecified). On approximately 30-JUL-2008, the patient fainted and her blood pressure drop after vaccination with GARDASIL and other vaccines gave at the same time. The patient sought medical attention. On an unspecified date the patient recovered. This is one of two reports from the same source. Additional information has been requested. The doctor was going to call an ambulance for one of the girls (unspecified).

Other Meds: (therapy unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326941-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Jul-2008	18-Jul-2008	0	17-Sep-2008	02-Dec-2008	CT	WAES0808USA02432	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain lower, Fatigue, Lymphadenopathy, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 15 year old female with no pertinent medical history or drug reactions or allergies who on 09-MAY-2008 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL. On 18-JUL- 2008 the patient was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL (lot no. 0250X). There was no concomitant medication. The patient experienced almost identical symptoms after receiving the first and second dose. The patient developed enlarged lymph nodes with fatigue and lower abdominal pain within 24 hours of the vaccinations. The symptoms disappeared within 36 to 72 hours after the vaccination in both cases. The patient called the physician to seek unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326942-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	13-Aug-2008	13-Aug-2008	0	17-Sep-2008	02-Dec-2008	--	WAES0808USA02435	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician concerning a female with a history of "passing out" while having her blood drawn in the past who on 13-AUG-2008 was vaccinated with the first dose of GARDASIL. After receiving the first dose, the patient "passed out". No injuries noted. The outcome was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Passed out

Prex Illness:

Prex Vax Illns:

Vaers Id: **326943-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		17-Sep-2008	02-Dec-2008	--	WAES0808USA02444	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Drug exposure during pregnancy, Inappropriate schedule of drug administration, Musculoskeletal stiffness, Pain in extremity

Symptom Text: Information has been received from a consumer concerning her friend, an 18 year old female with no pertinent medical history and no history of drug reactions or allergies who in April 2008, was vaccinated with the second dose of GARDASIL 0.5ml and VAQTA . Soon after the vaccination the patient experienced a stiff neck, pain in her legs, arms and stomach. The patient may or may not be pregnant but if she was, she would only be approximately 5 days. The patient also received her second dose of GARDASIL later than the recommend 2 months after the first dose (specific time was not provided). The patient's adverse events persisted. The patient didn't seek medical attention. No further information is available.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **326945-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	31-Mar-2008	15-May-2008	45	17-Sep-2008	02-Dec-2008	--	WAES0808USA02449	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cardiac flutter, Dizziness

Symptom Text: Information has been received from a physician office manager concerning an 18 year old female with mitral valve prolapse and polycystic ovarian syndrome, a history of kidney stone and no history of drug reactions or allergies who on 30-JAN-2008 was vaccinated with the first dose GARDASIL (lot#: 654535/0950F) 0.5ml IM and on 31-MAR-2008 was vaccinated with the second dose of GARDASIL (lot#: 659962/1740U). Concomitant therapy included hydrochlorothiazide, Mg oxide, pyridoxine, ZOLOFT, YAZ and polycitric K crystals. In mid May 2008 the patient experienced dizziness and heart flutter. Subsequently, the patient recovered from dizziness and heart flutter. The patient sought medical attention with a telephone call. Additional information has been requested.

Other Meds: (therapy unspecified); YAZ; hydrochlorothiazide; magnesium oxide; pyridoxine; ZOLOFT

Lab Data: None

History: Kidney stone

Prex Illness: Mitral valve prolapse; polycystic ovarian syndrome

Prex Vax Illns:

Vaers Id: **326946-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	16-May-2008	16-May-2008	0	17-Sep-2008	02-Dec-2008	IL	WAES0808USA02455	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0802U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Feeling hot, Hyperhidrosis, Loss of consciousness, Syncope

Symptom Text: Information has been received from a licensed practical nurse (L.P.N.) concerning a 23 year old female with no pertinent medical history and no known drug allergies who on 02-NOV-2007, 17-JAN-2008 and 16-MAY-2007, was vaccinated intramuscularly with her first, second and third 0.5 ml doses, respectively, of GARDASIL (Lot # of the first dose 659435/1265U, Lot # of the second dose of 558282/1263U, Lot # of the third dose 658490/0802U). There was no concomitant medication. On 16-MAY-2008, after receiving the third dose GARDASIL, the patient became warm and sweaty. She fainted and was unconscious for 45 seconds. The patient had only eaten fruit prior to administration of GARDASIL. Subsequently, on 16-MAY-2008 the patient recovered from the events. The adverse events happened during office visit. This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326947-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	12-Aug-2008	12-Aug-2008	0	17-Sep-2008	02-Dec-2008	IL	WAES0808USA02467	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0802U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Feeling hot, Hyperhidrosis, Loss of consciousness, Syncope

Symptom Text: Information has been received from a licensed practical nurse (L.P.N.) concerning a 20 year old female with no medical history or no known drug allergies who on 12-AUG-2008 was vaccinated intramuscularly with her first 0.5 ml dose of GARDASIL (lot # 658490/0802U). There was no concomitant medication. On 12-AUG-2008 the patient experienced syncope after administration of GARDASIL. The patient became warm and sweaty. She fainted and was unconscious for 45 seconds. The patient had only eaten fruit prior to administration of GARDASIL. Subsequently, on 16-MAY-2008 the patient recovered from the events. The adverse events happened during office visit. This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **326948-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		17-Sep-2008	02-Dec-2008	NY	WAES0808USA02472	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a nurse concerning a12 year old female with no allergies who in 2007 was vaccinated with GARDASIL (lot # not reported). In September 2007, 11 months ago, the patient experienced headaches. The patient's headaches persisted. The patient sought medical attention seen by the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 326949-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Jun-2008	24-Jun-2008	0	17-Sep-2008	02-Dec-2008	--	WAES0808USA02447	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lethargy

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female who on 24-JUn-2008 was vaccinated with the first dose of GARDASIL 0.5 ml IM. Concomitant therapy included HAVRIX and ADACEL. On 24-JUn-2008 the patient experienced lethargic for about 24 hours after vaccination. Subsequently, the patient recovered from lethargic for about hours. The patient sought medical attention and called office. Additional information has been requested.

Other Meds: ADACEL; HAVRIX

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **326950-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	08-Jul-2007	10-Aug-2008	399	17-Sep-2008	02-Dec-2008	OH	WAES0808USA02479	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash macular

Symptom Text: Information has been received from a registered nurse concerning a 20 year old female with no pertinent medical history and no allergies who on 08-JUL-2007 was vaccinated with the first dose of GARDASIL 0.5 ml IM (lot # 660387/1967U). Concomitant therapy included NUVARING (birth control) and Ibuprofen as needed. The patient developed rash over her back 3-5 days after vaccination. The patient's mother called the office since the rash has persisted and she was referred to dermatologist. According to the patient's mother the rash looks like "blotches over the back like a sun burn. There is no itch and it is not raised." The patient was noted to be recovering. Additional information has been requested.

Other Meds: NUVARING; Ibuprofen

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326952-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
44.0	M	12-Mar-2008	15-Apr-2008	34	03-Oct-2008	08-Oct-2008	--		05-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0755U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mobility decreased, Myalgia, Off label use, Pain in extremity

Symptom Text: Subject reported the following to this study RN today. He had been experiencing muscle pain equally in both arms and had been seeing his PCP for this problem. The pain is worse in the mornings upon rising to where it is painful to raise his arms up. He is able to continue with his ADLs and does not take pain meds. He stated that the pain began over a month after his first GARDASIL injection (Day 1=3/12/2008) and after his doctor had changed his ARV regimen, and before his second GARDASIL injection. He started new HIV medication regimen on 3/25/08. His doctor (PCP) told him that his arm pain was a side effect of one of his new HIV medications such as TRUVADA and did not think it was caused by the GARDASIL vaccine. The pain did not subside so his physician switched the TRUVADA out for INTELENCE one month ago to see if his arm pain will subside. The arm pain continues, so one of the other HIV medications will be switched out to see if the symptoms improve. The subject states that he is otherwise well and that it is "not a big deal," yet agrees that it will be good to be rid of the arm pain. (The subject never reported this arm muscle pain on his report cards and stated that he tolerated the injections well without problem.)

Other Meds: ISENTRESS; NORVIR; PREZISTA; TRUVADA

Lab Data:

History: HIV infection

Prex Illness:

Prex Vax Illns:

Vaers Id: **326953-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-Jul-2008	07-Jul-2008	0	03-Oct-2008	08-Oct-2008	--		20-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Unknown	Unknown	

Seriousness: LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal distension, Abdominal pain lower, Abdominal pain upper, Activities of daily living impaired, Anorexia, Anxiety, Arthralgia, Arthropathy, Chest pain, Chills, Depression, Dyspepsia, Ear pain, Erythema, Eye pain, Fatigue, Gastrooesophageal reflux disease, Headache, Immunisation reaction, Influenza like illness, Joint stiffness, Joint swelling, Leukoplakia oesophageal, Malaise, Menstruation irregular, Myalgia, Nasal congestion, Nausea, Oral intake reduced, Oropharyngeal pain, Ovarian cyst, Pain in extremity, Pelvic pain, Pyrexia, Rhinorrhoea, Sinusitis, Sleep disorder, Vomiting, Weight decreased

Symptom Text: My daughter had the first GARDASIL shot on 7/7/08. 7 to 10 days later she began having severe pains and cramping in her pelvic area along with redness, fever, vomiting, and joint pains. Her doctor said it was just a reaction to the shot and after examining her told her to go home and take TYLENOL for headaches, pains, etc because she was the first case he had seen this severe and didn't know what to do other than to examine her once a month. Every week she has experienced severe joint pains, cramps, not feeling well enough to eat, etc. She lost 10 lbs. Since she is 17 years old and only weighed 105 lbs that didn't set well with me. She is naturally skinny. The gynecologist still doesn't know what to do with my daughter's pains. He did an EKG, ultrasound, urine test and they all came back ok. The ultrasound showed an enlarged cyst on one of her ovaries. This is getting ridiculous in the fact that she can no longer lead a normal life due to weekly pains and not feeling well. Isn't there anything she can take to reverse the medicine's side effects as I see this as being a lifetime adventure for her. PLEASE ADVISE on what I as a parent can do next. I feel this is all the medicine's fault because my daughter Never had anything wrong with her until after having this shot. I don't like reading all the articles about this shot and seeing that the company tries to blame every day life events or happenings for causing the bad things to happen to these girls. It is definitely the GARDASIL Shot that has caused the adverse health of these young girls having problems. 12/29/2008 PCP records received for several OVs between 9/29/08 and 11/10/2008. Pt initially presented with c/o painful joints, cramping chest pain. ROS (+) for fever, chills, fatigue, 10 lb weight loss, abdominal pain, nausea, vomiting, H/A, eye pain, ear pain, sore throat, congestion, runny nose and Flu-like sx since Gardasil vax in July. Pt also reports sleep disturbance, joint pain and swelling, morning stiffness, myalgias, anxiety and depres

Other Meds:

Lab Data: EKG, 9/15/08; Urine test, 7/7/08, 8/11/08, 9/15/08; Doctor exam, 7/7/08, 8/11/08, & 9/15/08; Ultrasound, 9/15/08

History: My daughter never had any health problems before the GARDASIL shot. I took her to the OB/GYN to get her on birth control pills hoping it would shorten her period. The doctor put her on YAZ and that seem to work just fine until we decided a few months later to get this shot. PMH: none. on Yaz

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326954-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	02-Dec-2008	NJ	WAES0808USA02493	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician's nurse concerning a female who "about one year ago", in approximately August 2007, was vaccinated intramuscularly with 0.5 ml dose of GARDASIL. In approximately August 2007, after receiving GARDASIL, the patient fainted. Subsequently, the patient recovered an later completed the GARDASIL series with no other symptoms noted. The patient was seen in office. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326964-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Sep-2008	19-Sep-2008	0	03-Oct-2008	11-Nov-2008	IN		12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Rash, Swelling, Swelling face

Symptom Text: Pt was dizzy and nauseous on 9-19 after receiving shot on 9-19. On 9-20 Pt woke with a swollen face and body with a rash on her arms and legs. Pt was given an IV with steroids, BENADRYL and PEPCID to counteract the reaction. PREDNISONE was prescribed for home use.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **326970-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	23-Sep-2008	24-Sep-2008	1	03-Oct-2008	11-Nov-2008	KY		12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	C548X	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2997AA	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Skin warm

Symptom Text: Arm warm to touch - left arm - quarter size are redness

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **326975-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.3	F	Unknown	17-Sep-2008		03-Oct-2008	11-Nov-2008	--		12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	FLU	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Nausea, Pyrexia, Retching, Tremor, Vaccine positive rechallenge

Symptom Text: Patient was administered GARDASIL (her second dose) as well as FLUZONE flu shot. Patient experienced fever, shakiness, weak, nausea and dry heaving. patient said she had a similar reaction with her first shot of GARDASIL, but much less severe.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **326987-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-Aug-2008	29-Aug-2008	1	03-Oct-2008	14-Oct-2008	WI		14-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0843X	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2638AA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0444X	1	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Cough, Headache, Irritability, Nausea, Pain in extremity

Symptom Text: Nausea post vaccine 10:30 AM. School, home ill 4 PM. Gradual increasing. took ibuprofen 200 mg 2-3 per 4-5 hours with some relief. Then stomach ache. Slight cough. Used ice. Office visit for severe headache. Appeared highly irritable and in pain. Moderately cooperative, appropriate for teenager in severe pain. 0-10 pain choice self rated "58". C/o headache, L arm pain.Demerol 20 mg IV given with some significant relief. Pain level 3-4-5/10. Home. Full recovery 4-5 days.

Other Meds:

Lab Data: CBC, blood culture negative

History: Icthyosis and mild eczema. Exercise induced cough. acne.

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **326989-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Oct-2008	02-Oct-2008	1	03-Oct-2008	14-Oct-2008	NC		14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF452CA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Pruritus, Skin warm

Symptom Text: Right arm swollen, hot to touch, erythema and itching starting 22 hours after injection.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **327002-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	26-Aug-2008	27-Aug-2008	1	03-Oct-2008	14-Oct-2008	TX		15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Flank pain, Injection site reaction, Pain in extremity

Symptom Text: VACCINE ADM IN THE LEFT ARM AND THE NEXT DAY SHE STARTED TO HAVE PAIN IN HER RIGHT ARM AND ELBOW. SHE ALSO HAD RIGHT FLANK PAIN. SHE HAS CONTINUED TO HAVE JOINT PAIN OFF AND ON. DR. SUGG THAT SHE NOT RECEIVE ANY FURTHER HPV VACCINE. 10/10/08 Reviewed PCP medical records & vaccine records. FINAL DX: none provided Records reveal patient experienced good health on 8/26/08. RTC 10/3/08 & reported back & joint pain since 8/08. Exam revealed reaction pain at injection site, right flank pain. Tx w/nsaids & heat. Provided flumist at that time. No further records available.

Other Meds:

Lab Data: NONE

History:

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327006-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Oct-2008	03-Oct-2008	0	03-Oct-2008	14-Oct-2008	IL		14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	7	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypotonia, Pain in extremity, Tremor, Unresponsive to stimuli

Symptom Text: With patient sitting in chair, Gardasil was administered IM to left arm. Pt. closed eyes and slumped in chair. Trembling noted to both arms. Pt. did not respond to verbal questions for 15 seconds. Pt. then opened her eyes. Pt. complained that her legs hurt. Pt. followed verbal commands and was assisted to exam table and laid down. 4:40pm - B/P - 92/54. Apical pulse - 80, regular. Pt. rested on exam table and was verbally reponsive. 5:10pm - 90/52. Apical pulse - 66, regular. Pt. then drank 8 ounces of juice and 4 ounces of water. 5:15pm - B/P - 96/54. Apical pulse - 70, regular. Pt. was assited from table and was able to walk without assistance. No further complaints voiced. Pt. left office, accompanied by mother.

Other Meds: None.

Lab Data:

History: None.

Prex Illness: None.

Prex Vax Illns: Immediately after last immunizations were administered, pt. had following reaction - eyes rolled back, color became ashen, arms

Vaers Id: **327008-1 (S)** **Related reports:** 327008-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Jun-2008	15-Jul-2008	21	03-Oct-2008	08-Oct-2008	OH		13-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Abdominal tenderness, Adrenal disorder, Anorexia, Arthralgia, Asthenia, Back pain, Dehydration, Diarrhoea, Diet refusal, Dizziness, Fall, Fatigue, Gait disturbance, Headache, Hypoaesthesia, Influenza like illness, Mouth ulceration, Muscular weakness, Nausea, Pain, Paraesthesia, Sensation of heaviness, Urinary tract infection, Vomiting, Weight decreased

Symptom Text: About 2 weeks post vaccine my daughter had flu like symptoms- severe nausea, stomach pain, back pain, headache. All persisted for about 3 weeks. At that point stomach and back pain lessened but nausea has continued 24/7 until the present date. 2 pediatric gastroentrologists could find nothing wrong despite numerous diagnostic tests and blood work. Hospitalized overnight once and to ER 3x for dehydration, refusal to eat, etc. She has lost 14 pounds. At about 8 weeks post injection she began complaining of severe joint pain all over, then tingling and numbness from her knees down-began walking strangely and fell twice per she couldn't feel lower legs. Doctor advised to go the ER. She was admitted overnight and had spinal MRI and full nuerological check that showed nothing wrong. Released - still cannot walk correctly, still has severe nausea and headache. On Zofran for 10 weeks. Has now been referred to infectious disease doctor...My daughter was the picture of health before this injection and no one has been able to find any reason for her illness. 10/13/2008 MR received for 3 ER visits 7/17, 7/19, and 7/27/2008 and Admission 9/29-30/2008. Final D/C DX: Subjective LE paresthsias and weakness. L Adrenal fullness on MRI. Initially presented to ER with 4 day hx of nausea, Had vomiting and diarrhea which have resolved. Lightheaded upon standing, mild H/A. PE (+) for epigastric tenderness and an ulceration of the lip. UA c/w UTI. Final DX: Urinary Tract Infection. Mild dehydration. Nausea. Tx with IVF, abx and Zofran. Returned to ER 2 days later with persistant nausea. Now with LLQ gnawing pain. DX: Nausea, NOS. Abdominal Pain, undifferentiated. 3rd ER visit to 2nd hospital 7/27/08 with DX: Undifferentiat abdominal pain. Pt still with persistant nausea. Refusing to eat/drink 2' to lost appetite and post-prandial nausea and abdominal pain. D/c with outpt UGI planned. UGI WNL. Returned again 9/29/08 with c/o bilateral leg weakness x 4-5 days. Began with aches, joint soreness, numbness and tingling of the t

Other Meds: none

Lab Data: CT Scan upper and lower GI, upper endoscopy, HIDA scan, MRI of spine, MRI of brain - all normal. Extensive bloodwork - all normal. Ultrasound of adrenal glands - pending. Labs and Diagnostics: CBC and CMP WNL. UA cloudy withl arge leuk es

History: reflux issue 4 years prior. PMH: GERD.

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327008-2 (S)** **Related reports:** 327008-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Jun-2008	Unknown		17-Oct-2008	11-Feb-2009	OH	WAES0809USA04837	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Fatigue, Nausea, Vomiting

Symptom Text: Information has been received from an RN concerning a 14 year old female who on 24-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) into her left arm. The patient had since experienced extreme tiredness and nausea and vomiting. Mother of the patient told nurse she saw these were side effects of GARDASIL vaccine (yeast). The patient was being seen by gastrointestinal specialist at the office and also followed up with another gastrointestinal specialist. The patient had not recovered yet. The RN considered the events to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327037-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Oct-2008	03-Oct-2008	0	03-Oct-2008	11-Nov-2008	MA		27-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN	MEDIMMUNE VACCINES, INC.	500541P	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0548X	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2734AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C3030AA	1	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	0954X	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injection site pain

Symptom Text: Dose of Tdap given after patient had received a previous dose of Tdap 8-11-06 (provider thought that a Td was given on that date). Patient complained of site tenderness.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327041-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Sep-2008	26-Sep-2008	2	03-Oct-2008	11-Nov-2008	CA		26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Unknown	Unknown	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia oral, Syncope, Vaccination complication

Symptom Text: patient has syncope episode s/p administration. Patient has numbness of nose and mouth beginning 2 days s/p vaccine 10/14/2008 Reviewed PCP office records of 9/29- FINAL DX: numbness of skin, vaccine adverse reaction Records reveal patient came into office w/numbness of nose & lips x 4 days starting 2 days s/p #2 HPV vaccine. Stated that had immediate syncope s/p #1 HPV vaccine received 6/30/08. Referred to neuro but no records available.

Other Meds:

Lab Data: LABS: 6/30 WBC 12.0(H), Hct 36.5(L), urine c/s neg.

History: None Known PMH: acne

Prex Illness: None

Prex Vax Illns: Syncope~HPV (Gardasil)~1~14~In Patient

Vaers Id: **327064-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-Apr-2008	07-Apr-2008	0	17-Sep-2008	02-Dec-2008	CA	WAES0808USA02854	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Dizziness, Nausea, Palpitations, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 17 year old female, who on 06-FEB-2008 was vaccinated with the first dose of GARDASIL (lot# 654488/1264U). On 07-APR-2008, the patient was vaccinated with the second dose of GARDASIL (lot# 659655/1486U). After receiving the first and second dose of GARDASIL, the patient experienced dizziness, nausea and heart palpitations. The patient also experienced fever after the second dose. The patient's symptoms started the same vaccination days. The AE symptoms began in the physician's office and unspecified medical attention was sought. Follow-up information was received which reported that the patient recovered from dizziness, nausea, heart palpitations, chills and fever the same date that the adverse events started. The patient also experienced a Fever on 06-FEB-2008. Also, chills and fever were reported in one occasion all day long. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327065-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	02-Dec-2008	--	WAES0808USA03090	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Papilloma viral infection

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a female with human papilloma virus who on an unspecified date, was vaccinated with a dose of GARDASIL and her human papilloma virus had gotten worse. At the time of reporting, the outcome was unknown. No product quality complaint was involved. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Papilloma viral infection

Prex Vax Illns:

Vaers Id: **327066-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		17-Sep-2008	02-Dec-2008	--	WAES0808USA03094	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a friend of the family concerning an 18 year old female with orthostatic hypertension who was vaccinated intramuscularly with the 0.5ml dose of GARDASIL. Subsequently the patient experienced black outs. The patient's outcome was unknown. Unspecified medical attention was sought. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Orthostatic hypertension

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327067-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	02-Dec-2008	--	WAES0808USA03139	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Malaise, No reaction on previous exposure to drug, Pallor, Pyrexia

Symptom Text: Information has been received from a pharmacist concerning a female who on an unspecified date was vaccinated with the first dose of GARDASIL and was well tolerated. On an unspecified date was vaccinated with the second dose of GARDASIL. After receiving the second dose, the patient felt ill, pale, fever, felt faint and possibly vomited. Her symptoms began immediately after the second dose. Subsequently, within 48 hours the patient recovered from pale, fever, felt faint, possibly vomited and felt ill. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327068-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	15-Aug-2008	16-Aug-2008	1	17-Sep-2008	02-Dec-2008	IL	WAES0808USA03147	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lip swelling

Symptom Text: Information has been received from a registered nurse. On 16-AUG-2008, the mother called the office and reported that her daughter a 19 year old female patient who on 15-AUG-2008, was vaccinated with the first dose of GARDASIL (Lot # 660612/0229X) 0.5ml, IM into the upper arm. On 16-AUG-2008, within 24 hours of receiving the first dose the patient experienced swollen lip. The mother has not called the office back at the time of the report, and the patient is assumed to be recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 327069-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Jun-2008	08-Jun-2008	5	17-Sep-2008	02-Dec-2008	LA	WAES0808USA03185	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a physician concerning a 11.5 year old female who on 03-JUN-2008 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. On 08-JUN-2008, "within a few days after getting her first dose", the patient experienced her first cycle. The patient has had a 4 menstrual periods since receiving GARDASIL. The menses were irregular but were not excessively heavy. The outcome was unknown. The patient was seen and sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory - normal blood count

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **327070-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	06-Aug-2008	06-Aug-2008	0	17-Sep-2008	02-Dec-2008	--	WAES0808USA03206	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	UNK	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Syncope

Symptom Text: Information has been received from a registered nurse concerning a 10 year old female who on approximately 06-AUG-2008 was by vaccinated with the first dose of GARDASIL. Concomitant therapy included "other vaccines" (therapy unspecified). On approximately 06-AUG-2008, the patient fainted and her blood pressure drop after vaccination with GARDASIL and other vaccines gave at the same time. The patient sought medical attention. On an unspecified date the patient recovered. This is one of two reports from the same source. Additional information has been requested. The doctor going to call and ambulance for one the girls (unspecified).

Other Meds: (therapy unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 327071-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Jun-2008	11-Jun-2008	0	17-Sep-2008	17-Dec-2008	TX	WAES0808USA03219	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Furuncle, Radiation exposure during pregnancy

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter who on 11-JUN-2008 was vaccinated with the first dose of GARDISIL and VARIVAX. At the time of vaccination, the patient was probably 6 weeks pregnant (LMP approx. 30-APR-2008, EDD 4 FEB-2009). In approximately July 2008, the patient had x-ray done at the dentist's office. Also, about a week ago, the patient had "two boils". The patient did not seek medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Pregnancy NOS (LMP = 4/30/2008)

Prex Illness:

Prex Vax Illns:

Vaers Id: **327072-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	03-Dec-2008	--	WAES0808USA03222	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Injection site pain

Symptom Text: Information has been received form a receptionist concerning a female who was vaccinated with GARDASIL. The patient expressed that the vaccine really hurt. It burned all the way down her arm. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327073-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	13-Aug-2008	13-Aug-2008	0	17-Sep-2008	03-Dec-2008	--	WAES0808USA03571	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Rash generalised, Urticaria

Symptom Text: Information has been received form a pharmacist concerning his 21 year old daughter with no known allergies/ reactions who in early June 2008, was vaccinated with the first dose of GARDASIL. On 13-AUG-2008, the patient was vaccinated with the second dose of GARDASIL. Concomitant therapy included YASMIN. On 13-AUG-2008, after the second dose was given, the patient experienced rashes and hives throughout the body (from the trunk to elbow and shoulder of both arms). There were occasional hives and rashes on the front of the hips also. The pharmacist has been treating his daughter with BENADRYL and an unspecified topical steroid. The patient did not have a reaction after receiving the first dose of GARDASIL. The patient sought medical attention with the pharmacist. Additional information has been requested.

Other Meds: YASMIN

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327074-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	03-Dec-2008	--	WAES0808USA03576	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Malaise

Symptom Text: Information has been received from a nurse concerning a female who was vaccinated with a fourth dose of GARDASIL vaccine because of an unknown vaccination history for the patient, when the fourth dose was given. the day after the fourth dose was given; the patient stated that she felt sick. The patient sought medical attention. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327075-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Sep-2008	03-Dec-2008	OH	WAES0808USA03581	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety

Symptom Text: Information has been received form a physician concerning a patient who was vaccinated with a dose of GARDASIL vaccine. Subsequently the patient experienced increase in anxiety after vaccine administration. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327076-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	03-Dec-2008	MI	WAES0808USA03591	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Infectious mononucleosis

Symptom Text: Information has been received from a medical assistant concerning a female who in October 2007, was vaccinated with the first dose of GARDASIL, after receiving the first dose the patient developed a severe case of mononucleosis. The provided did not have treatment information because the patient received the vaccine and treatment for mononucleosis at a college health center. The patient fully recovered by an unspecified date and on 19-AUG-2008 received the second dose of GARDASIL. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **327077-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Sep-2007	20-Sep-2007	0	17-Sep-2008	03-Dec-2008	IN	WAES0808USA03594	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	657868/0523U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, Syncope, Vertigo

Symptom Text: Information has been received form a licensed practical nurse (L.P.N.) concerning a 17 year old female with no pertinent medical history or no known drug allergies who on 20-SEP-2007 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot # 657868/0523U), on 04-JAN-2008 was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL (lot # 659439/1267U) and on 20-JUN-2008 was vaccinated intramuscularly with the third 0.5 ml dose of GARDASIL (lot # 660393/0067X). Concomitant therapy included BENZACLIN, SUMYCIN, MENACTRA (20-JUN-2008). On 20-SEP-2007 the patient experienced syncope. The patient had also experienced intermittent vertigo and nausea since May 2008. The patient's syncope and intermittent vertigo and nausea persisted. Medical attention was sought via office visit. No product quality complaint was involved. Additional information has been requested.

Other Meds: BENZACLIN; SUMYCIN

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **327078-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	19-Feb-2008	Unknown		17-Sep-2008	03-Dec-2008	MD	WAES0808USA03598	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	659553/1448U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Tooth discolouration, Weight decreased

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a 21 year old female with significant mitral regurgitation and an allergy to VERSED and a history of miscarriage (at age 18), gallbladder surgery and appendicectomy (in 2000) who on 02-AUG-2007, 30-OCT-2007 and 19-FEB-2008 was vaccinated intramuscularly with 0.5 ml first, second and third dose of GARDASIL (lot #658556/1060U, 659437/1266U and 659653/1448U), respectively. Concomitant therapy included NUVARING and VALTREX. On 30-OCT-2007 and the patient weighed 144 lbs. "After her third dose", the patient stated that she lost 25 pounds after receiving GARDASIL. Colonoscopy was performed and the result indicated negative. The nurse did not have the current weight of the patient. The nurse also mentioned that recently she observed that the patient's teeth were brown and white which resembled someone who had anorexia or bulimia. The patient initially called her primary care physician and was told to contact the nurse's office. At the time of this report, the events persisted. Additional information has been requested.

Other Meds: NUVARING; VALTREX

Lab Data: colonoscopy negative

History: Miscarriage; Gallbladder operation; Appendicectomy

Prex Illness: Mitral regurgitation; Hypersensitivity

Prex Vax Illns:

Vaers Id: **327079-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	03-Dec-2008	NC	WAES0808USA02774	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Muscle spasms

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a series of three doses of GARDASIL. The patient developed cramps after her first two doses of GARDASIL. Subsequently, the patient recovered from cramps. She did not have cramps (type unknown) after the third dose of GARDASIL. Medical attention was sought in the physician's office.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327080-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		17-Sep-2008	03-Dec-2008	--	WAES0808USA02780	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received from a registered nurse (R.N.) concerning an 18 year old female who on an unspecified date, was vaccinated with the second dose of GARDASIL and for a couple days after that the patient was experiencing a fever of 103 degrees. At the time of reporting, the outcome was unknown. No product quality complaint was involved. This is one of several reports received form the same source. Additional information has been requested. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: body temp 103 degree

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327081-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Jun-2008	Unknown		17-Sep-2008	04-Dec-2008	OH	WAES0808USA02785	05-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Myalgia, Pyrexia

Symptom Text: Information has been received from a physician concerning a 17 year old female with PENICILLIN allergy and no other pertinent medical history who on 06-JUN-2008 was vaccinated with the first dose of GARDASIL 0.5 ml IM (lot# 660389/1968U). There was no concomitant medication. Subsequently the patient experienced myalgas and fever that lasted for three days after receiving the first dose. STD panel routine PAP were performed. On an unspecified date, the patient recovered from myalgas and fever. The patient sought medical attention seen by the practice. Additional information has been requested.

Other Meds: None

Lab Data: Diagnostic laboratory, STD panel; serum prostatic acid

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **327082-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	14-Aug-2008	14-Aug-2008	0	17-Sep-2008	04-Dec-2008	--	WAES0808USA02789	05-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Nausea

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female with asthma and no known drug allergies/reactions who on an unspecified date was vaccinated with the first dose GARADSIL and on 14-AUG-2008 was vaccinated with the second dose of GARDASIL (Lot No. 659184/0843X). Concomitant therapy included SEASONIQUE. On 14-AUG-2008 the patient developed dizziness and nausea immediately after administration and throughout the evening. Patient has not responded back to the office's attempt to follow-up. Patient sought medical attention, at the office. Additional information has been requested.

Other Meds: SEASONIQUE

Lab Data:

History:

Prex Illness: Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327083-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	15-Aug-2008	15-Aug-2008	0	17-Sep-2008	07-Dec-2008	OH	WAES0808USA02790	08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Nausea

Symptom Text: Information has been received from a physician concerning a 22 year old female with history of fainting when receiving needles and no drug reaction/allergies who on an unspecified date was vaccinated with the first dose of GARDASIL and on 15-AUG-2008 was vaccinated with the second dose of GARDASIL (Lot no. 0250X). Concomitant therapy included drospirenone (+) ethinyl estradiol (YAZ). On 15-AUG-2008m the patient passed out the needle was injected. When the patient became alert she complained of nausea and lightheadedness. The patient did receive GARDASIL. At the time of the reporting the patient was recovering. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: YAZ

Lab Data: None

History: Syncope

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327084-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	07-Dec-2008	--	WAES0808USA02796	08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Stomatitis, Vaccine positive rechallenge

Symptom Text: Information has been received from a female who on unspecified dates, was vaccinated with the three doses of GARDASIL intramuscularly. The patient reported that she developed mouth sores after receiving each of the three doses of GARDASIL vaccine. The patient had also injection site pain. The patient recovered on an unspecified date. Unspecified medical attention was sought. There was no product quality complaint. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 327085-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Aug-2008	14-Aug-2008	0	17-Sep-2008	07-Dec-2008	--	WAES0808USA02797	08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	660612/0229X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a nurse practitioner concerning a 13 year old female with rheumatoid arthritis and no known drug reactions/allergies and a history of passing out who on 14-AUG-2008 was vaccinated intramuscularly in left arm with the 0.5ml first dose of GARDASIL. The patient also was vaccinated in her right arm with a dose of MENACTRA. Concomitant therapy included nabumetone (RELAFEN) and ranitidine HCL (ZANTAC). The patient passed out after administration of the vaccine while in the office. On the same day, the patient recovered. Medical attention was sought in the physician's office. Additional information has been requested.

Other Meds: RELAFEN; ZANTAC

Lab Data: Unknown

History: Passed out

Prex Illness: Rheumatoid arthritis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327086-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	10-Jan-2008	01-Apr-2008	82	17-Sep-2008	07-Dec-2008	GA	WAES0808USA02802	16-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	1	Unknown	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Hypoaesthesia, Joint instability, Musculoskeletal pain

Symptom Text: Information has been received from a licensed practical nurse concerning a 25 year old female with no medical history and no known allergies, who on 25-OCT-2007 was vaccinated with a first dose of GARDASIL (lot and site unspecified). On 10-JAN-2008 was vaccinated intramuscularly into the right deltoid with a second dose of GARDASIL (lot # 658560/1062U) and on 09-MAY-2008 was vaccinated intramuscularly into the left deltoid with a third dose of GARDASIL (lot # 659962/1740U). Concomitant therapy included DEPO-PROVERA. The patient reported that she developed shoulder and knee pain with numbness in her feet with an onset in April 2008. The pain and numbness were described as "off and on". The pain was described as worsening with increased intensity and frequency. On 11-AUG-2008 the pain was described as becoming more constant. The patient saw an orthopedic physician and her primary care physician. The orthopedic physician diagnosed the pain as "joint instability" and no treatment was given. The nurse noted that the patient started exercising in April 2008. At the time of reporting the patient had not recovered. The patient sought for medical attention: office call. There was no product quality complaint. Additional information has been requested. 12/19/2008 Patient does not recall having ortho consult & no f/u done w/PCP. Has recovered completely w/o residual.

Other Meds: DEPO-PROVERA

Lab Data: None

History: None HPV#3 given 5/29/08, Lot # 1740U

Prex Illness:

Prex Vax Illns:

Vaers Id: **327087-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Apr-2008	01-Apr-2008	0	17-Sep-2008	23-Dec-2008	KY	WAES0808USA02805	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Smear cervix abnormal

Symptom Text: Information has been received from two medical assistants concerning a 17 year old female who in July 2007, was vaccinated with the first dose of GARDASIL. In November 2007, the patient was vaccinated with the second dose of GARDASIL. In April 2008, the patient was vaccinated with the third dose of GARDASIL. The medical assistants reported that the patient came back to the office in July 2008 for her annual checkup and had "abnormal pap atypical squamous cells of undetermined significance". The patient also had a colposcopy. The outcome was unknown. The patient saw the physician to seek unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: colposcopy, 07/??/08; Pap test, 07/??/08, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327088-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Aug-2008	12-Aug-2008	0	17-Sep-2008	07-Dec-2008	PA	WAES0808USA02906	08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Syncope

Symptom Text: Information has been received from a mother concerning her 16 year old daughter with sulfonamide allergy who on 12-AUG-2008 was vaccinated with the first dose of GARDASIL. Concomitant therapy included varicella virus vaccine live (manufacturer unknown) and Hepatitis A vaccine (inactive) (manufacturer unknown). The mother reported that her daughter fainted after receiving the first dose of GARDASIL. Blood pressure test was performed for half an hour after the experience, (results not provided). The mother also reported that her daughter currently had redness and hardness at the injection site about 4 inches big. At the time of report, the daughter had not recovered. The patient sought unspecified medical attention. There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327089-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	07-May-2008	21-May-2008	14	17-Sep-2008	16-Dec-2008	MD	WAES0808USA02809	18-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information has been received from a physician concerning a 19 year old female with a history of urinary tract infection who on 07-MAY-2008, was vaccinated with the third dose of GARDASIL. The dates of administration for the first and second dose was not known. There was no concomitant medication. The physician reported that on 21-MAY-2008, after the administration of all three doses of GARDASIL, the patient developed about 25 facial common flat warts and 15 warts on the back of her hands. The patient was initially examined by a dermatologist who prescribed acne cream the first visit. The dermatologist began treatment for warts after the second examination. At the time of the report, the patient was recovering. The patient sought medical attention at the physician's office. There was no product quality complaint. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Urinary tract infection

Prex Illness: Urinary tract infection

Prex Vax Illns:

Vaers Id: **327090-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Aug-2008	15-Aug-2008	0	17-Sep-2008	16-Dec-2008	CT	WAES0808USA02821	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood glucose, Loss of consciousness

Symptom Text: Information has been received from a health professional, concerning a 17 year old female patient who on 15-AUG-2008 was vaccinated with 0.5 mL dose of GARDISIL IM. On 15-AUG-2008, the patient "passed out as she was walking out of the room". On the same date, the patient recovered. Glucose test was performed and the result was not provided. The patient did seek medical attention. There was no product quality complaint. Additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327091-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	07-Dec-2008	FL	WAES0808USA02826	08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a female patient who in February 2008, was vaccinated with the first dose of GARDASIL. In May 2008, was vaccinated with the second dose of GARDASIL. In February 2008, since the first dose was given the patient experienced rash. In May, 2008, after the second dose was given the patient's rash got worse. The patient's rash persisted. The patient spoke to the physician for medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327092-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	17-Dec-2008	CA	WAES0808USA02843	01-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female who on an unknown date was vaccinated with the first dose of GARDASIL and fainted. Subsequently the patient recovered. The patient since, has received her second and third dose and did not have any more fainting episodes. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327093-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	05-Aug-2008	Unknown		17-Sep-2008	07-Dec-2008	--	WAES0808USA02848	09-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Rash pustular, Rash vesicular

Symptom Text: Information has been received from a physician assistant concerning a female who on 05-Aug-2008 was vaccinated with the first dose of GARDASIL in the right deltoid. In 2008, the patient developed a rash on both her upper and lower extremities. The rash was pus filled blisters that were greater on the left arm. The rash resolved on its own. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327095-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		06-Oct-2008	07-Oct-2008	--	WAES0809USA04628	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amyotrophic lateral sclerosis

Symptom Text: Information has been received from a pharmacist via her brother who was told by a neurologist that a female patient who received a dose of GARDASIL developed amyotrophic lateral sclerosis (ALS). The patient was seen by a neurologist. The outcome of the event was unknown. Upon international review, amyotrophic lateral sclerosis was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 327096-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Apr-2008	17-Sep-2008	169	06-Oct-2008	07-Oct-2008	TN	WAES0809USA04288	13-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Drug exposure during pregnancy, Evacuation of retained products of conception, Intra-uterine death, Premature rupture of membranes, Premature separation of placenta, Retained products of conception, Umbilical cord abnormality, Vaginal haemorrhage

Symptom Text: Information has been received from a 20 year old female consumer, for the Pregnancy Registry for GARDASIL, concerning herself, who in October 2007, was vaccinated with a dose of GARDASIL, injection. In April 2008 the patient received a third dose of GARDASIL. Concomitant therapy included vitamins (unspecified). Subsequently, she became pregnant, and the last menstrual period is 11-MAY-2008. The patient had blood work performed several times during her pregnancy, results not reported. On 17-SEP-2008, the patient's placenta ruptured. The patient experienced a blood clot between her uterus and placenta, a tear in her placenta and her umbilical cord was partially attached on the side. The baby was delivered, was too small and died. The patient was hospitalized for a day after giving birth. Additional information has been requested. 3/10/09 MR received for DOS 9/17-18/2008 with D/C DX: Premature ROM. Previable fetus. Marginal abruption. SVD. Pt presented at 19 wks of pregnancy with cramping, vaginal bleeding and rupture of membranes. Non-viable fetus delivered. Pt had retained products of conception tx with D&C. Unremarkable post-op course.

Other Meds: vitamins (unspecified)

Lab Data: hematology. Labs and Diagnostics: surgical pathology report for markedly disrupted placenta. Fibrinogen (H) 653. CBC with WBC 27.0. Hgb 11.9. Hct 33.9 down slightly after delivery. UC (-). GC and Chlamydia (-).

History: PMH: PCOD. NKDA.

Prex Illness: Pregnancy NOS (LMP = 5/11/2008)

Prex Vax Illns:

Vaers Id: 327098-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Nov-2007	22-Nov-2007	12	06-Oct-2008	07-Oct-2008	FR	WAES0809USA04882	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Autonomic nervous system imbalance, Feeling cold, Feeling hot, Hyperaesthesia, Hypoaesthesia, Inflammation, Neck pain, Pain in extremity

Symptom Text: Information has been received from a Health Authority (reference number TS20080315) concerning a 16 year old female with no previous medical history reported who on 10-NOV-2007 was vaccinated with the first dose of GARDASIL in right deltoid, via intramuscular route. On 07-JAN-2008 was vaccinated with the second dose of the same vaccine. Ten to twelve days after the first dose, on approximately 22-NOV-2007, and during an abduction (due to an important effort of the arm), the patient experienced pain in the base of the right thumb. One to two weeks after the second dose, on approximately 14-JAN-2008, occurred pains in right arm and forearm. Three weeks after i.e at a consultation dated on 08-FEB-2008, it was observed in right arm, inflammatory pains irradiating, hyperesthesia poorly systematized, vasomotor disorders i.e. cold and white or erythrosic bands associated with low and right cervical pains with hypoesthesia of C6 and trapezalgy. There was no adenopathy or axillary inflammation. Two neurological consultations with cervical radiographies, scan, cerebral MRI, neck Doppler arterial vessels, right axillary ultrasound performed in February - March 2008 and electromyography performed in June 2008, did not found any anomaly. Treatment with analgesics and corticosteroids were given and disorders partially regressed. In June 2008, persisted a pain in the base of the thumb, hypoesthesia of first and second fingers and vasomotor disorders. The whole picture evoked an algodystrophy. Kinesitherapy sessions were started. Two months later, the patient still experienced vasomotors disorders. Bone scan was planned on an unspecified date. The events were reported as medically significant. Other business partner numbers included: E2008-08929. Additional information has been requested.

Other Meds: Unknown

Lab Data: neurological examination, ??Feb?08, with cervical radiographies: did not find any anomaly; Neurological examination, ??Feb?08, scan: did not find any anomaly; Magnetic resonance imaging, ??Feb?08, cerebral: did not find any anomaly; Neurolo

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **327099-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	05-Mar-2008	05-Mar-2008	0	06-Oct-2008	07-Oct-2008	--	WAES0809USA04825	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Presyncope, Vision blurred, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a 24 year old female with a history of cerebrovascular accident perinatal and mental disorder who on 05-MAR-2008 was vaccinated intramuscularly with the first dose of GARDASIL. On 05-MAR-2008 evening, the patient experienced vomiting, blurred vision and near syncope. The nurse practitioner reported that they thought the patient might had a TIA (mini stroke). However, this has not been proven. The patient was referred to a neurologist for further evaluation. The patient was hospitalized, but the length of hospitalization was unspecified. The patient's last seizure happened in June 2008. The patient's outcome were unknown. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Cerebrovascular accident; Mental disorder

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327100-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Jun-2007	Unknown		06-Oct-2008	07-Oct-2008	FL	WAES0809USA04703	10-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Deafness

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date, was vaccinated with a dose of GARDASIL 0.5ml, intramuscularly. The physician reported that the patient became deaf after receiving the HPV vaccine. Outcome was not reported. The patient sought unspecified medical attention. "Became deaf after receiving the GARDASIL vaccine" was considered to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327101-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Aug-2008	25-Aug-2008	0	06-Oct-2008	07-Oct-2008	CA	WAES0809USA04534	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Drug exposure during pregnancy, Headache, Syncope

Symptom Text: Information has been received through the Merck pregnancy registry for GARDASIL from staff member at a physician's office (not the office that vaccinated) concerning her close friend a 17 year old female patient who on approximately 25-AUG-2008, one month ago, was vaccinated with the first dose of GARDASIL. On approximately 25-AUG-2008, after receiving the vaccine, the patient fainted, had a seizure and had headaches. The patient is pregnant. Date of last menstrual period was not reported. On an unknown date, the patient recovered from fainted and seizure. The patient sought medical attention at physician's office. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327102-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	01-May-2008	01-Aug-2008	92	06-Oct-2008	07-Oct-2008	AR	WAES0809USA04511	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a patient who in May 2008, completed the series of GARDASIL (lot # was not available). In August 2008, the patient experienced seizures episodes. At the time of recovering, the patient was recovering from seizures episodes. Physician noted that the patient is blaming GARDASIL for her seizures. The patient sought medical attention with the physician. Telephone follow-up information was received from the nurse for the physician reporting that the physician not feel that the seizure was caused by GARDASIL. The patient was seen in the ER, but not hospitalized. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327108-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		06-Oct-2008	07-Oct-2008	FR	WAES0810USA00109	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Pancreatitis necrotising, Parenteral nutrition

Symptom Text: Information has been received from a specialist concerning a female patient who on an unspecified date was vaccinated with the third dose of GARDASIL (batch number not reported). Within the week following the vaccination the patient experienced severe abdominal pain. She was hospitalized. She presented with lipase increased at 20000 and amylase increased at 15000. Gamma glutamyl transferases and transaminases were normal. There was no other associated symptom (neither fever, nor nausea). Auto antibodies were negative and biological tests were normal. There was no associated risk factor. CT scan revealed a diagnosis of pancreatitis necrotizing with Balthazar CT score at D. There was no treatment prescribed besides parenteral feeding. on 27 or 28-SEP-2008 analysis revealed increased transaminases twice normal ranges and increased phosphatases leading to suspect biliar microlithiases. At time of reporting the patient had not recovered and remained in intensive care services at hospital. As to her medical history the patient experienced abdominal epigastric pain 5 to 6 days after first and second doses of GARDASIL (unspecified dates). Other business partner numbers included E200809018. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 27?Sep08, transaminases twice normal ranges and increased phosphatases leading to suspect biliar microlithiases; diagnostic laboratory test, Auto antibodies negative and biological tests normal; computed axial to

History: Epigastric pain

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327111-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Aug-2008	01-Aug-2008	0	06-Oct-2008	07-Oct-2008	NY	WAES0810USA00044	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness

Symptom Text: Information has been received from a physician concerning a 13 year old female who back in August-2008, was vaccinated with GARDASIL. Lot number was not available. The physician reported that 5 to 10 minutes after the patient received GARDASIL she passed out and then had seizure. The patient sought medical attention. On an unknown date the patient recovered. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 327112-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jul-2007	01-Jul-2007	0	06-Oct-2008	07-Oct-2008	TN	WAES0809USA04885	05-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anaphylactic reaction, Angioedema, Auricular swelling, Chills, Dehydration, Diarrhoea, Dizziness, Dyspnoea, Erythema, Feeling hot, Flushing, Generalised erythema, Hypersensitivity, Lip swelling, Menstruation irregular, Nausea, Oropharyngeal pain, Pruritus generalised, Rhinorrhoea, Social avoidant behaviour, Tremor, Vomiting projectile

Symptom Text: Information has been received from a pharmacy technician concerning her 14 year old female daughter with no previous medical history reported who in May 2007, was vaccinated with the first dose of GARDASIL and in July 2007 was vaccinated with the second dose of GARDASIL. There was no concomitant medication. The patient received the second dose of GARDASIL and about one week later she woke in the middle of the night. The patient's lips and ears were swollen and her whole body was red. The patient then developed diarrhea and projectile vomiting followed by chills that caused her whole body to shake. The whole episode lasted for about one hour to one and one half hour. The patient has had 6 similar "bad" reactions, the worst was in January 2008. The patient has had numerous "moderate" reactions (at least 6 in 2008) which involved diarrhea, vomiting or nausea. The patient has also sought treatment for continual menstrual bleeding since September 2007 that was treated with hormones (birth control). The patient was hospitalized in September 2007 for dehydration. The patient experienced nausea and felt like she was going to pass out on 22-Sep-2008. She has also experienced breathing difficulty (EPI PEN) and was starting to be emotionally effected (wanted to be by herself). The patient never received the third dose of GARDASIL. Numerous blood tests and unspecified tests were performed (resulted were not provided). There was no product quality complaint. As of 29-SEP-2008; the patient was not recovered. Lips and ear swelling; whole body red, diarrhea, vomiting, chills, nausea, going to pass out, continual menstrual bleeding, breathing difficulty and emotionally affected were considered to be disabling by the pharmacy technician. Breathing difficulty requiring EPI-PEN was considered to be an other important medical event by the pharmacy technician. Additional information has been requested. 10/10/08 Reviewed ER records of 8/9-8/10/2007. FINAL DX: acute allergic reaction, vomiting & diarrhea Records reveal patient exp

Other Meds: None

Lab Data: Unknown LABS: WBC 18.3(H), neutros 74.9%(H), chemistry WNL. prolactin 17.2(H). EKG WNL.

History: None PMH: contraception, acne, pneumonia. Allergy: ragweed. Family hx: DM, heart disease, CVA, cancer.

Prex Illness:

Prex Vax Illns:

Vaers Id: **327113-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		06-Oct-2008	07-Oct-2008	IL	WAES0809USA04629	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Cellulitis

Symptom Text: Information has been received from an office manager, concerning a female patient who "recently" (in approximately 2008) was vaccinated with the first dose of 0.5 mL GARDASIL (Lot # not available) and later developed cellulitis. The patient was brought to emergency room and was admitted to the hospital. It was unknown whether the patient was still in the hospital or how long was the hospitalization. There was no product quality complaint. Additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 327114-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Oct-2007	20-May-2008	216	06-Oct-2008	07-Oct-2008	NJ	WAES0809USA00718	17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0962F	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Premature labour

Symptom Text: Information has been received from a physician for the pregnancy registry for GARDASIL, concerning a female patient who on an unspecified date, was vaccinated with first dose of GARDASIL. The physician reported that the patient became pregnant after receiving her first dose of GARDASIL. At the time of the report the patient had already given birth. On follow-up information it was reported that the patient was a 18 year old female patient with a history of low platelet count and no previous pregnancies, who on 17-OCT-2007, was vaccinated with the first dose of GARDASIL (lot# 654510/0962F). Concomitant medication included prenatal vitamins. On 08-NOV-2007, the patient had an ultrasound which results were an intrauterine pregnancy of 6 weeks and 2 days. On an unspecified date, during pregnancy, the patient had repeat CBC to follow PLT count which dropped to 109,000. On 20-MAY-2008, the patient went to preterm labor and had a normal male liveborn infant. There were no congenital anomalies. The baby's weight was 4 pounds 2 ounces, length 18.5 inches, head circumference 13 inches and apgar score 8/9. It was 33 weeks from LMP. Because of prematurity the baby was treated in the new born nursery for 3 days with ampicillin and gentamycin. Baby's weight at discharge was 4 pounds 8 ounces. On 05-JUN-2008, the patient was vaccinated with the second dose of GARDASIL (lot# 660387/1967U) and on 23-JUL-2008, the patient was vaccinated with the third dose of GARDASIL (lot#660393/0067X). No further information is available.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 11/08/07, IUP 6 weeks 2 days-dating; complete blood cell, PLT count dropped to 109,000

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Platelet count low

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327116-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Sep-2008	01-Sep-2008	0	06-Oct-2008	07-Oct-2008	FR	WAES0810USA00107	07-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pulmonary embolism

Symptom Text: Initial case was reported on 26-SEP-2008 by a Health Care Professional to SPMSD. It was reported that on an unspecified date in September 2008, a 16 year old woman was vaccinated with GARDASIL (batch number, route and site of administration not reported). Two weeks post vaccination the patient was diagnosed with lung emboli. The outcome is unknown. The reported considered this case as not related to vaccination, but reported it since patient's mother required it. The lung emboli was considered an other important medical event. Other business partner numbers included E200808960. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 327118-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Jan-2007	21-Jul-2008	537	06-Oct-2008	13-Oct-2008	KS		15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2155CA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0961F	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Benign intracranial hypertension, Headache, Mass, Papilloedema, Visual disturbance

Symptom Text: Papilledema, pseudotumor with benign intracerebral hypertension, optic nerve edema 10/08/08-records received for DOS 7/21/08-Assessment:Papilledema with enlarged physiologic blind spots and episodes of visual dimming. Classic for pseudotumor cerebri. Occasional occipital nuchal headaches for past two months. C/O vision very dim and dark for about 10 seconds for past month.

Other Meds:

Lab Data: MRI- MRA Brain, 6-19-08; Lumbar puncture, 7-21-08; MRI Orbits, 7-22-08; ESR, 8-13-08 10/8/08-records received-MRA head normal.MRI paranasal sinusitis. CSF neutrophils 10, monocytes 10, gram stain negative.

History: 10/8/08-records received-PMH:Obesity. History of sinus infections.

Prex Illness: None

Prex Vax Illns:

Vaers Id: 327134-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Jul-2007	Unknown		17-Sep-2008	16-Dec-2008	NJ	WAES0808USA03611	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Headache, Vomiting

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female with no pertinent medical history and no history of drug reactions or allergies who on 30-JUL-2007 was vaccinated with the first dose of GARDISIL (lot#: 657621/0387U) 0.5ml IM into the right arm. There was no concomitant medication. Subsequently the patient experienced severe vomiting, headache and abdominal pain. Subsequently, the patient recovered from severe vomiting, headache and abdominal pain. The patient sought medical attention with a physician office visit. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **327135-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		17-Sep-2008	16-Dec-2008	PA	WAES0808USA03641	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pyrexia, Syncope

Symptom Text: Information has been received from a physician concerning a 15 female who on an unspecified date was vaccinated with the first dose of GARDISIL. On an unspecified date was vaccinated with the second dose of GARDISIL. The patient experienced fever and syncope after the first and second dose. The first incident was not as severe as the second. Subsequently, on an unspecified date, the patient recovered from fever and syncope. The patient sought medical attention at physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327137-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Jul-2008	01-Jul-2008	0	17-Sep-2008	17-Dec-2008	--	WAES0808USA03668	06-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Dizziness, Headache, Heart rate increased, Injection site pain, Pain in extremity, Pyrexia, Rhinorrhoea

Symptom Text: Information has been received from a consumer concerning her 12 year old daughter with no medical history, who in July 2008, was vaccinated with a first dose of GARDASIL 0.5 ml, hepatitis A vaccine (manufacturer unknown), Tdap (unspecified) (manufacturer unknown) and meningococcal vaccine (manufacturer unknown). The consumer reported that her daughter developed symptoms after receiving her first and only dose of GARDASIL. She had fever for 3 days and it went up as high as 102.5 F degrees. She had also experienced severe headache, cough, runny nose, fast heart rate, sore arm and dizziness several hours after the vaccination. The patient recovered from all of the symptoms after 3 days, except the sore arm at the injection site which had lasted a week. The patient sough medical attention: The patient's mother called the office. There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **327138-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		17-Sep-2008	16-Dec-2008	FL	WAES0808USA03672	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 15 year old female with no known allergies who on an unspecified date was vaccinated with a third dose of GARDASIL (Lot number not provided). On an unspecified date the patient received the third dose of GARDASIL and experienced syncope. The patient recovered on an unspecified date. Unspecified medical attention was sought. There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 327139-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Feb-2008	01-Mar-2008	19	17-Sep-2008	17-Dec-2008	PA	WAES0808USA03679	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Nasal congestion, Nasal turbinate abnormality, Vaccine positive rechallenge, Vision blurred

Symptom Text: Information has been received from a 16 year old female with no medical history and no known allergies, who in January 2008, was vaccinated with a dose of GARDASIL. Concomitant therapy included PAMELOR 25 mg. She reported she was experiencing headaches after receiving her first and second dose of GARDASIL. The headache occurred above both eyes. Laboratory/diagnostic tests performed: CAT scan: Results not provided. At the time of reporting the patient had not recovered. Unspecified medical attention was sought. There was no product quality complaint. Additional information has been requested. 10/10/08 Reviewed PCP medical records of 12/29/06-8/14/08. FINAL DX: Records reveal patient experienced usual state of good health on day of HPV vaccines, HPV #1 on 2/11/08 & HPV #2 on 4/19/08. RTC 5/6/08 w/intermittent HA, dizziness & blurred vision since 3/08 & worsening after HPV #2. Exam revealed nasal congestion & boggy turbinates, tx w/allergy meds w/ no improvement in s/s. Tx w/antibiotics unsuccesful & referred to neuro. Neuro consult included. Tx w/meds. No further records available.

Other Meds: Pamelor mg

Lab Data: Unknown LABS: CT head & sinus.

History: None HPV #2 given 4/19/2008, Lot #1978U, LA. Family hx heart disease & glaucoma.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327140-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	12-Aug-2008	13-Aug-2008	1	17-Sep-2008	16-Dec-2008	--	WAES0808USA03680	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site haematoma, Injection site mass

Symptom Text: Information has been received from a 25 year old female with no medical history and no known allergies who on 12-AUG-2008 was vaccinated with a dose of GARDASIL. There was no concomitant medication. On 13-AUG-2008 the patient experienced a bruise on the same are where she received GARDASIL. Also, a white bump developed at the injection site. No lab/diagnostic tests were performed. At the time of reporting the patient had not recovered. Unspecified medical attention was sought. There was no product quality complaint. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **327141-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	17-Dec-2008	--	WAES0808USA03683	19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Oral herpes, Vaccine positive rechallenge

Symptom Text: Information has been received from an office receptionist concerning a female cousin with a history of cold sores who on an unspecified dates was vaccinated with the first and second dose of GARDASIL. After each doses the patient experienced cold sores that were larger and clustered, more intense outbreaks than ever before. At the time of the reporting the outcome of the patient was unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: Cold sores

Prex Illness:

Prex Vax Illns:

Vaers Id: 327142-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		17-Sep-2008	17-Dec-2008	CA	WAES0808USA03698	19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 13 year old female who on unspecified dates was vaccinated with the first and second dose of GARDASIL. After receiving the first dose her arm was numb for a couple of hours, and after receiving her second dose her arm was even more numb. The patient sought unspecified medical attention. At the time of the reporting, the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327143-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	18-Aug-2008	18-Aug-2008	0	17-Sep-2008	16-Dec-2008	CA	WAES0808USA03711	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Vomiting

Symptom Text: Information has been received from a physician concerning a 13 year old female who on 18-AUG-2008 was vaccinated with the first dose of GARDISIL (Lot No. 659184/0843X). After receiving the first dose, the patient experienced dizziness and vomiting at the physician's office. At the time of the reporting, the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327144-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Aug-2008	01-Aug-2008	0	17-Sep-2008	16-Dec-2008	AZ	WAES0808USA03717	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a physician concerning a 25 year old female who on an unspecified date was vaccinated with the first dose of GARDASIL and on 01-AUG-2008 was vaccinated with the second dose of GARDASIL. After receiving her second dose the patient's arm was very sore, when her shirt touches it, it was very painful. The patient sought unspecified medical attention. At the time of the reporting, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 327145-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	U	16-Aug-2008	16-Aug-2008	0	17-Sep-2008	23-Dec-2008	--	WAES0808USA03720	02-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	
MNQ	SANOFI PASTEUR	NULL	1	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
DTAP	GLAXOSMITHKLINE BIOLOGICALS	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Skin warm

Symptom Text: Information has been received from a licensed visiting nurse concerning a 11 year old patient, with no pertinent medical history and no drug reactions/allergies, who on 16-AUG-2008 was vaccinated IM with the first 0.5mL dose of GARDASIL. Secondary therapy included the second dose of VARIVAX (Merck) (MSD). Other concomitant vaccinations included MENACTRA and Tdap. No concomitant medication was included. On 16-AUG-2008 the patient experienced warmth on the same arm as that of GARDASIL and this warmth traveled to her chest. The patient sought unspecified medical attention (was seen). At the time of the reporting, the patient had recovered. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327146-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	17-Dec-2008	CA	WAES0808USA03725	19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal stiffness, Syncope

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with the first dose of GARDASIL. Concomitant therapy included 2 other injections (therapy unspecified), prior to having GARDASIL. After receiving the first dose, the patient went stiff and then fainted for about 20 seconds. Lot number was not provided. The patient sought unspecified medical attention. At the time of the reporting the outcome of the patient was unknown. Additional information has been requested.

Other Meds: (therapy unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327147-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Oct-2007	01-Oct-2007	0	17-Sep-2008	17-Dec-2008	--	WAES0808USA03975	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a consumer, concerning her 25 year old female daughter with a history of malaria, who in October 2007 was vaccinated with the first dose of GARDASIL. Concomitant medication included ORTHO TRI - CYCLEN. The patient fainted after getting the first dose of GARDASIL. The patient recovered on an unknown date. The patient has not received the second and third dose yet. The patient sought unspecified medical attention. There was no product quality complaint. No further information is expected.

Other Meds: ORTHO TRI-CYCLEN

Lab Data: None

History: Malaria

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327148-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	07-Dec-2008	TN	WAES0808USA03982	08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Loss of consciousness, Pallor, Syncope

Symptom Text: Information has been received from a physician, concerning a female patient, who in July 2008 was vaccinated with 0.5ml GARDASIL IM. A few minutes post vaccination. the patient got very pale and fainted. While the patient was still unconsciousness her body jerked several times, and then she regained consciousness. The patient was fully recovered on an unknown date. The patient was fully recovered on an unknown date. the patient sought medical attention in the office. There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327149-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		17-Sep-2008	17-Oct-2008	--	WAES0808USA04012	17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Malaise

Symptom Text: Information has been received from a unspecified nurse concerning her 21 year old niece who on an unspecified date was vaccinated with a dose of GARDASIL and was seriously ill in the intensive care unit. An unspecified physician at the hospital said the patient was seriously ill due to GARDASIL. The niece was under the care of the infectious disease service in intensive care unit. The nurse did not provide any further information on herself or her niece's case. At the time of the reporting, the patient hads not recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327150-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Jun-2008	30-Jun-2008	0	17-Sep-2008	16-Dec-2008	MA	WAES0808USA03994	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Immediate post-injection reaction, Mouth injury, Syncope

Symptom Text: Information has been received from a Licensed Practical Nurse, concerning a 14 year old female patient with no previous medical history reported, who on 30-JUN-2008 was vaccinated with 0.5 mL first dose of GARDASIL (Lot #660553/0070x) IM. There was no concomitant medication. On 30-JUN-2008, the patient fainted immediately following the vaccination. The patient did sustain a cut to her lip from the fall when her face hit the stool. The patient was observed in the office and was discharged home with her parent and was considered recovered on 30-JUN-2008. There was no product quality complaint. Additional information is expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **327151-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Apr-2008	16-Apr-2008	0	17-Sep-2008	18-Dec-2008	MI	WAES0808USA03998	19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2542AA	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Aphthous stomatitis, Contusion, Hyperhidrosis, Liver function test abnormal, Malaise, Pain, Syncope, Tremor, Vomiting

Symptom Text: Information has been received from a office manager, concerning an 17 year old female patient with mononucleosis diagnosed in the beginning of April 2008. On 14-APR-2008, the patient had a recheck for the mononucleosis. On 16-APR-2008, the patient was vaccinated with the first dose of GARDASIL (Lot #14870) and MENACTRA. The patient experienced feeling sick and fainted immediately after the vaccinations. The patient also experienced a lot of bruising on an unspecified arm within 24 hours of the vaccinations and her hair was falling out (unspecified date). The patient recovered on an unknown date. The patient sought medical attention in the office and called the office. There was no product quality complaint. Follow up information was received from the physician's office and laboratory records concerning a 17 year old white female with infectious mononucleosis (recovering; last day re-checked on 14-APR-2008 and "she was ok") and an allergy to sulfa who on 16-APR-2008 was vaccinated with a first dose of GARDASIL into the right arm and with a first dose of MENACTRA (Lot # U2542AA) into the left arm. In between 16-APR-2008 and 31-JUL-2008, the patient complained about sweating, shaking, vomiting and being extremely sore all over. On 14-APR-2008 the patient underwent a hepatic panel and complete blood count which revealed an elevated liver enzymes which were noted to be "improving." (refer to lab data field). On 31-JUL-2008 the patient had a thyroid stimulating hormone and free thyroxine level and CBC. The TSH was low at 0.30 uIU/mL (nl 0.50 - 5.20) and the FT4 was normal 1.1 ng/dL (nl 0.8 - 1.8). The MCH and MCHC were low. (refer to lab fields). On 08-MAY-2008 patient developed canker sores treated with FAMVIR. On 31-JUL-2008 the patient developed hair loss (checked with Blood work) and was bruising easily. The patient had recovered on an unknown date. Additional information is expected.

Other Meds: Unknown

Lab Data: free serum thyroxine, 07/31/08, 1.1 ng/dL; serum TSH, 07/31/08, 0.30 uIU/m, abnormal: low; WBC count, 07/31/08, 4.8 bil/L; red blood cell count, 07/31/08, 5.30 tril/, abnormal: high; hemoglobin, 07/31/08, 13.5 g/dL; hematocrit, 07/31/08, 42

History:

Prex Illness: Infectious mononucleosis; Sulfonamide allergy

Prex Vax Illns:

Vaers Id: 327152-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-Aug-2008	15-Aug-2008	4	17-Sep-2008	16-Dec-2008	MD	WAES0808USA04000	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lip swelling, Lymphadenopathy, Swelling face

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female with no pertinent medical history and no allergies who on 11-AUG-2008 was vaccinated with the first dose of GARDASIL IM 0.5 ml (lot # not reported). There was no concomitant medication. On 15-AUG-2008 the patient experienced swelling of her lips, unilateral facial swelling and swollen glands after administration of her first dose. On 19-AUG-2008 the throat culture result indicated negative. The patient's swelling of her lips and unilateral facial swelling and swollen glands persisted. The patient sought medical attention in the office visit. Additional information has been requested.

Other Meds: None

Lab Data: throat culture, 08/19/08, negative

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **327153-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Aug-2008	11-Aug-2008	0	17-Sep-2008	17-Dec-2008	--	WAES0808USA04008	06-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Gaze palsy, Presyncope

Symptom Text: Information has been received from a nurse practitioner concerning a 11 year old female who on approximately 11-AUG-2008 was vaccinated with a dose of GARDASIL. Concomitant therapy included MENACTRA and Tdap. While getting the shot the patient's mother had her arms around her for support. After the patient had received the dose of GARDASIL, the patient's eyes rolled back and she started to slide down. The nurse practitioner stated that this seemed like a fainting motion but the patient was conscious the whole time. Subsequently, the patient recovered. The patient was seen by physician to seek medical attention. No product quality complaint was involved. Additional information has been requested.

Other Meds:

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327154-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-Aug-2008	19-Aug-2008	0	17-Sep-2008	16-Dec-2008	NC	WAES0808USA04013	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a 12 year old female with a history of syncope (similar response) with other injections who on 19-AUG-2008 was vaccinated intramuscularly with the with the first 0.5 ml dose of GARDASIL. On 19-AUG-2008 the patient experienced syncope. Subsequently, the patient recovered on the same day. The patient did not seek medical attention. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Syncope; Injection

Prex Illness: Syncope; Injection

Prex Vax Illns:

Vaers Id: **327155-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Jun-2008	01-Jun-2008	0	17-Sep-2008	17-Dec-2008	--	WAES0808USA04024	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Pruritus generalised, Rash, Urticaria, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning her daughter, a 23 year old female with no known pertinent medical history or drug reactions/allergies, who in approximately June 2008, was vaccinated with a first dose of GARDASIL 0.5 ml. Concomitant therapy included hormonal contraceptives (unspecified). Soon after receiving her first dose of GARDASIL the patient experienced some minor itchiness. In approximately August 2008, the patient was vaccinated with a second dose of GARDASIL 0.5 ml. The patient experienced severe itchiness over most of her body, rash and hives. The patient was prescribed ZYRTEC, which was a big help. The patient would be seeing an allergist in the near future. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327157-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	17-Dec-2008	--	WAES0808USA04060	19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a healthcare worker concerning a female who was vaccinated with a first dose of GARDASIL. Subsequently the patient developed severe headaches. At the time of this report, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327158-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	17-Dec-2008	--	WAES0808USA04073	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Information has been received from a certified nurse midwife concerning a female who was vaccinated intramuscularly with a 0.5 ml second dose of GARDASIL. Subsequently the patient developed Bell's palsy. Unspecified medical attention was sought. At the time of this report, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327159-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	17-Dec-2008	--	WAES0808USA04077	19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a nurse practitioner concerning a female who on an unspecified date was vaccinated with a first dose of GARDASIL. Shortly after receiving the first dose of GARDASIL the patient experienced lightheadedness. Subsequently, the patient recovered from lightheadedness. The adverse event occurred at office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327160-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		17-Sep-2008	17-Dec-2008	IL	WAES0808USA04079	19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Dizziness, Dyspnoea

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female with asthma who on an unspecified date was vaccinated with a first dose of GARDASIL. "5 days after vaccination", the patient experienced faintness, shortness of breath and chest tightening in the morning. She went to the Emergency room and was given an unspecified inhaler but it did not relieve her symptoms. She had some labs done, which came back negative. The emergency physician believed that this could be a late response from GARDASIL. The patient was sent home and recovered next day. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, negative

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: 327161-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-Dec-2007	18-Aug-2008	255	17-Sep-2008	18-Dec-2008	NY	WAES0808USA04085	19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Muscular weakness, Paraesthesia

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female who in June 2008 (date discrepant), was vaccinated with the first dose of GARDASIL. On 07-DEC-2007 the patient vaccinated intramuscularly with the third 0.5 ml dose of GARDASIL. On 10-AUG-2008 the patient returned to the physician's office with numbness, tingling and weakness in her arms and fingers after receiving her third dose of GARDASIL. At the time of this report, the patient's symptoms persisted. The physician felt that the patient's condition was not a result of GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, several other tests; complete blood cell;

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327162-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Aug-2008	15-Aug-2008	1	17-Sep-2008	18-Dec-2008	MN	WAES0808USA04087	29-Dec-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0329X	1	Unknown	Unknown	
HPV4	MERCK & CO. INC.	1978U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 14-AUG-2008 was vaccinated with the third dose of GARDASIL (lot no. 659964/1978U) and the second dose of VARIVAX (lot no. 659953/0329X). On 15-AUG-2008 the patient had a "quarter size rash" on her arm. Subsequently, on an unspecified date, the patient was recovered. The patient contacted the physician's office to seek unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327163-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	18-Aug-2008	18-Aug-2008	0	17-Sep-2008	16-Dec-2008	CA	WAES0808USA04118	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 21 year old female who on 18-AUG-2008 was vaccinated with the first dose of GARDASIL. (Dose and site of administration not reported). (Lot # 60616/0570X). Concomitant therapy included birth control medication. The patient fainted after first dose within 2 minutes of receiving injection. No injury sustained. No hospitalization was required. It was unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327189-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	16-Sep-2008	02-Oct-2008	16	06-Oct-2008	15-Oct-2008	--		15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0423X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0843X	2	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Rash pruritic, Scab

Symptom Text: 10/2/2008 Rash appeared in clusters on R side of back in dermatome distribution and also in L groin in cluster and L flank. Patient was seen 10/6/2008 in my office. Rash was puritic and some areas were scabbed from scratching. There were no vessicles or oozing.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327193-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Sep-2008	15-Sep-2008	0	06-Oct-2008	15-Oct-2008	MA		15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Local reaction, Pain, Swelling

Symptom Text: Local swelling and pain lasting 3 weeks. Fatigue lasting more than 3 weeks

Other Meds: Concerta, Clindamycin gel, Clonidine

Lab Data:

History: ADHD Mild MR

Prex Illness: none

Prex Vax Illns:

Vaers Id: **327197-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Sep-2008	30-Sep-2008	1	06-Oct-2008	15-Oct-2008	CA		15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Chest pain, Chills

Symptom Text: CHEST AND BACK PAIN, CHILLS

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns: ~ ()~2~~In Patient

Vaers Id: **327212-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	04-Oct-2008	04-Oct-2008	0	06-Oct-2008	15-Oct-2008	AZ		16-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Right arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	A52B030AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drooling, Gaze palsy, Immediate post-injection reaction, Muscle twitching

Symptom Text: Pt received Tdap then HPV #2 as soon as MD finished with HPV 2, pt eyes rolled back and pt started to twitch and drool x 5 seconds. Recovered vital signs taken, water given, observed pt x 30 min. Pt states "I feel fine" and Dad feels comfortable taking pt home.

Other Meds:

Lab Data: BP 110/84; Pulse 64; RR 12

History: None per family

Prex Illness: None per family

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327219-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-Sep-2008	04-Oct-2008	12	06-Oct-2008	15-Oct-2008	NY		16-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0789X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0572X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site cellulitis

Symptom Text: Cellulitis at injection site. Rx for Keflex.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327231-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Aug-2008	Unknown		17-Sep-2008	19-Dec-2008	NY	WAES0808USA04140	19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 13 year old female patient who on 12-AUG-2008, was vaccinated with the first dose of GARDASIL (Lot # 659184/0843X) for prevention of HPV. The physician reported that the patient fainted after receiving GARDASIL. The physician noted that the patient was already sweating and anxious prior to receiving the vaccine. At the time of the report, the patient had recovered. The patient sought medical attention by the physician. This is one of two reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327232-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	12-Dec-2007	01-May-2008	141	17-Sep-2008	19-Dec-2008	NY	WAES0808USA04146	22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Myalgia

Symptom Text: Information has been received from a consumer concerning her 20 year old daughter with no medical history, no known allergies who in December 2007, was vaccinated with a third dose of GARDASIL (Lot # not reported). There was no concomitant medication. In May 2008, the patient experienced severe headaches, dizziness and muscle pain after receiving three doses of GARDASIL (dates of first and second dose were not reported). The patient's mother reported that the patient is in so much pain she is unable to lift her head off her pillow. An MRI and CAT scan were reported as normal. At the time of reporting the patient had not recovered. The patient sought medical attention at the office. There was no product quality complaint. Additional information has been requested.

Other Meds: None

Lab Data: magnetic resonance, normal; computed axial, normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **327233-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Aug-2008	20-Aug-2008	0	17-Sep-2008	19-Dec-2008	IN	WAES0808USA04147	19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Syncope

Symptom Text: Information has been received from a nurse concerning a 17 year old female with a fear of needles who on 20-AUG-2008 was vaccinated with the third dose of GARDASIL 0.5mg, IM. Subsequently on 20-AUG-2008 the patient fainted and fell on her head Subsequently, the patient recovered. The patient didn't seek medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Fear of needles

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327234-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Dec-2007	01-Dec-2007	0	17-Sep-2008	19-Dec-2008	CA	WAES0808USA04154	19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician, concerning a 17 year old female patient who toward the end of 2007 was vaccinated with the first dose of GARDASIL (Lot#not reported). There were no concomitant medication. The patient fainted within few minutes after her first dose. No injuries were sustained. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327235-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Aug-2008	15-Aug-2008	0	17-Sep-2008	19-Dec-2008	OK	WAES0808USA04157	19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 16 year old female with no pertinent medical history, who on 15-AUG-2008 was vaccinated with the first dose of GARDASIL vaccine, IM into her deltoid. There was no concomitant medication. The patient fainted immediately after receiving the first dose of GARDASIL. She did get her color back within a few seconds after fainting and recovered soon after. The patient sought medical attention at the office. There were no lab or diagnostic studies performed. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327237-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		07-Oct-2008	08-Oct-2008	FL	WAES0809USA03441	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Renal failure

Symptom Text: Information has been received from physician, via the patient's mother, who reported that her daughter was vaccinated with a dose of GARDASIL. Subsequently the patient experienced renal failure and was hospitalized. The physician thought renal failure was possibly related to GARDASIL. No outcome was reported. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327238-1** **Related reports:** 327238-2; 327238-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Jul-2008	14-Jul-2008	3	17-Sep-2008	19-Dec-2008	--	WAES0808USA04162	27-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Arthropathy, Joint range of motion decreased, Joint stiffness, Nodule on extremity, Oedema peripheral, Pain, Pain in extremity, Synovitis, Tenosynovitis

Symptom Text: Information has been received from caller started her daughter concerning an 18 year old female with history of asthma who on 11-JUL-2008 was vaccinated with GARDASIL vaccine. Concomitant therapy included ALBUTEROL. On approximately 14-JUL-2008 the patient experienced arthritic symptoms and pain throughout her body shortly after receiving her initial dose of GARDASIL. The patient's arthritic symptoms and pain throughout her body persisted. Caller stated her daughter will not receive any future dose of GARDASIL. No further information is available. 2/23/09 MR received from Rheumatologist which include PCP recs as well. Initially seen by PCP 7/18/08 & 8/1/08 with c/o joint pain x 2 months. PE (+) for finger edema with decreased ROM and pain in toes. DX: Synovitis and tenosynovitis. Referred to ortho. Pt reports knots around elbows, wrists, ankles, fingers and toes with morning stiffness. Referred to rheum. OV 8/6/08. PE (+) fro swelling of digits and trace in hands. DX: Polyarthargias. Tenosynovitis. Tx with NSAIDs and steroids Labs: ANA (-). RF (-). anti-CCP (-). X-rays hands and feet WNL. Gliadin Ab (H) at 14.

Other Meds: ALBUTEROL

Lab Data: X- ray; hematology,negative

History: Asthma. PMH: ear popping.

Prex Illness:

Prex Vax Illns:

Vaers Id: **327238-2** **Related reports:** 327238-1; 327238-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	M	Unknown	11-Jul-2008		09-Feb-2009	11-Feb-2009	--		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gastric disorder, Grip strength decreased, Joint swelling, Rheumatoid arthritis

Symptom Text: GARDASIL shot induced RA symptoms within the week. We have seen three RA doctors. Completely healthy 18 year old until the first GARDASIL shot. Did not continue other shots per doctors. Massive swelling and knot in joints- arms, hands, feet-. Hands would not close. Currently on several medications. No way to reverse effects. Unknown if it will go away over time. Now have complications with stomach and appointment with Gastro specialist scheduled. Pictures are available.

Other Meds:

Lab Data:

History: No pre conditions. Healthy 18 year old

Prex Illness:

Prex Vax Illns:

Vaers Id: **327238-3** **Related reports:** 327238-1; 327238-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Jul-2008	18-Jul-2008	7	12-Feb-2009	17-Feb-2009	NC		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Joint swelling, Oedema peripheral, Pain in extremity, Synovitis, Tenosynovitis

Symptom Text: Ref # 339290- Gradual/increasing symptoms of pain in joints/swelling initially in hand. Seen 7/18/08 DX Synovitis/Tenosynovitis. Labs ordered - normal - seen 8/1/08 increasing pain/edema (R) hand + (R) toes - referred to Orthopedist and he referred to Rheumatology

Other Meds:

Lab Data: 7/18/08 - Labs ordered, Normal; CBC; IgR; C-Reactive Protein; ANA; Metabolic panel; Thyroid and Rheumatoid factor

History: NKA

Prex Illness: Otitis Externa

Prex Vax Illns:

Vaers Id: **327239-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jul-2008	01-Jul-2008	0	17-Sep-2008	19-Dec-2008	CA	WAES0808USA04167	19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Flushing, Headache

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter who on 01-JUL-2008 was vaccinated with the first dose of GARDASIL. The patient has been getting dizzy "almost every single day" when she stands up, she sits down then this happens, and when the dizziness goes away her face feels flushed and she gets a headache. Prior to getting the vaccination, she would feel dizzy sometimes when she got out of bed in the morning shortly before her menstrual cycle. She will not be getting the rest of the series. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **327240-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	19-Jun-2008	19-Jun-2008	0	17-Sep-2008	19-Dec-2008	IL	WAES0808USA04179	22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0151X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypomenorrhoea

Symptom Text: Information has been received from a pharmacist concerning that her 22 year old female pharmacy technician who on 19-JUN-2008, was vaccinated with her first dose of GARDASIL (Lot# 0151X) 0.5ml, IM. The patient experienced extremely light periods ever since she was vaccinated. The patient's extremely light periods persisted. The pharmacist does not think her technician had contacted her physician regarding this. A pregnancy test was negative, PAP was normal. Additional information has been requested.

Other Meds: Unknown

Lab Data: Beta-human chorionic, negative; serum prostatic acid, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327241-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		17-Sep-2008	23-Dec-2008	NJ	WAES0808USA04186	23-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Headache, Vomiting

Symptom Text: Information has been received from a physician concerning a 16 or more years old female patient who over one year ago was vaccinated with her first dose of GARDASIL. The same day post vaccination, the patient experienced headache, vomiting and abdominal pain. Subsequently, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 327242-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-Aug-2008	19-Aug-2008	0	17-Sep-2008	23-Dec-2008	IL	WAES0808USA04189	02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hypoaesthesia, Nausea, Paraesthesia, Rash, Tremor

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female patient who on 19-AUG-2008 was vaccinated with the first dose of GARDASIL(lot# 660620/0571X) IM in the left deltoid. Concomitant therapy included MENINGOCOCCAL vaccine (unspecified) 4 weeks prior to GARDASIL, DROSPIRENONE(+) ethinyl estradiol (YASMIN), fexofenadine hydrochloride (+) pseudoephedrine hydrochloride (ALLEGRA D) and ALBUTEROL(inhaler). The same day, the patient experienced rash on both forearms. The next morning the patient experienced numbness and tingling in her extremities, shaking and lightheadedness that lasted 3 to 4 hours. The patient also experienced nausea for 48 hours on 21-AUG-2008, the temperature was normal. Additional information has been requested.

Other Meds: ALBUTEROL; YASMIN; ALLEGRA- D

Lab Data: Body temp, 08/21/08,normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327243-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Aug-2008	15-Aug-2008	0	17-Sep-2008	23-Dec-2008	TX	WAES0808USA04202	23-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Muscle twitching, Syncope

Symptom Text: Information has been received fro physician concerning a female patient between 14 and 16 year old who on 15-AUG-2008 was vaccinated with the first dose of GARDASIL. After receiving the vaccine, the patient fainted and experienced twitching. The patient recovered. Medical attention was sought. This is one of two reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327244-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Aug-2008	20-Aug-2008	1	17-Sep-2008	23-Dec-2008	AL	WAES0808USA04203	23-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	
	FLUN	MEDIMMUNE VACCINES, INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Angioedema

Symptom Text: Information has been received from a healthcare worker from a physician's office concerning a 17 year old female with no medical history and allergic to SULFAMETHOXAZOLE (+) TRIMETHOPRIM (BACTRIM) who on 28-MAR-1996 was vaccinated with a first dose of VARICELLA (Lot# 660495/0431X) and experienced no adverse side effects. On 19-AUG-2008 the patient was vaccinated with a second dose of GARDASIL on the left arm and with a dose of FLUMIST. On 20-AUG-2008, an angioedema developed on her upper right arm where the VARICELLA was administered. At the time of reporting, the patient had not recovered. Unspecified medical attention was sought. There was no product quality complaint. Additional information has been requested.

Other Meds:

Lab Data: None

History: Sulfonamide allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **327245-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-May-2008	01-May-2008	0	17-Sep-2008	23-Dec-2008	ID	WAES0808USA04226	23-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fatigue

Symptom Text: Information has been received from a nurse concerning her 11 year old daughter who in approximately May 2008, was vaccinated with the first dose of GARDASIL. In approximately May 2008, the patient also received DTap-IPV. MENACTRA and medroxyprogesterone acetate (DEPO-PROVERA). About 7 to 10 days post vaccination, the patient experienced dizziness and fatigue. The patient was taken to the ER were unspecified test and studies were performed. The patient recovered. The nurse thought her daughter may have had the flu and did not attribute the event to the vaccine. No further information is available.

Other Meds:

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 327246-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-May-2008	13-May-2008	0	17-Sep-2008	20-Dec-2008	ID	WAES0808USA04230	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2665AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1968U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Muscle twitching, Neurological examination normal

Symptom Text: Information has been received from a physician concerning a 12 year old female with no pertinent medical history and no drug reaction/allergies who on 13-MAY-2008 was vaccinated IM with the first dose of GARDASIL. There was no concomitant medication. On 13-MAY-2008, the patient experienced jerky movements in the upper torso. On an unspecified date. an electromyography was performed (no results provided). The patient sought unspecified medical attention. At the time of the reporting, the patient had not recovered. Additional information has been requested. 10/16/08-records received-neurology consult:Assessment-Suspect akathisia. presented for evaluation of abnormal movements described as muscular twitching occurring diffusely throughout her extremities. Twitching became more prominent after Gardasil injection several weeks ago. Normal neurological exam. 9/8/08-office visit for congenital pes planus. Twitching has not progressed, changed, worsened or gone away.

Other Meds: None

Lab Data: Unknown 10/16/08-records received-EEG normal.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **327252-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Sep-2008	23-Dec-2008	TN	WAES0808USA04160	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with a dose of GARDASIL. The patient fainted after receiving GARDASIL. No additional information. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327254-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		07-Oct-2008	08-Oct-2008	FL	WAES0809USA04131	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Renal failure

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with a dose of GARDASIL. Subsequently the patient experienced renal failure and was hospitalized. The physician thought the patient's hospitalization due to renal failure was related to GARDASIL. No outcome was reported. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327255-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		07-Oct-2008	08-Oct-2008	NY	WAES0809USA03454	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Lupus-like syndrome

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with GARDASIL, date therapy started was unspecified by reporter. Subsequently the patient experienced lupus like reactions and was identified as requiring hospitalization. The patient was hospitalized locally and then transferred to another hospital for treatment and was reported to have been in the intensive care unit (ICU). The patient present status was recovering. Lupus-like reactions was considered to be life-threatening. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327256-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		17-Sep-2008	23-Dec-2008	--	WAES0808USA02499	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lip swelling, Local swelling, Swelling face

Symptom Text: Information has been received from a physician's assistant concerning a 26 year old female with no pertinent medical history who was vaccinated with a 0.5 ml second dose of GARDASIL. There was no concomitant medication. Subsequently, the patient developed a swollen face, neck and lips. Eight days after the vaccination, the patient went to an emergency room, she was given an unspecified antibiotic and was released from the emergency room. At the time of this report, the outcomes were unknown. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327258-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Mar-2008	11-Mar-2008	0	17-Sep-2008	23-Dec-2008	--	WAES0808USA02502	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling abnormal

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female with no pertinent medical history or allergies who on 11-MAR-2008 was vaccinated with her third dose of GARDASIL (lot# 660389/1968U). There was no concomitant medication. On 11-MAR-2008 after the patient received the vaccine, she felt very funny. No laboratory diagnostics studies were performed. She sat for 10 minutes, was ok and went home. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **327259-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		17-Sep-2008	23-Dec-2008	--	WAES0808USA02508	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a nurse practitioner concerning a 14 year old female who on an unspecified date was vaccinated with a dose of GARDASIL. Concomitant medication was not reported. Subsequently on an unspecified date, the patient experienced a sore arm for three to four days. The outcome of the event was not reported. Additional information has been requested.

Other Meds:

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327260-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	23-Dec-2008	IN	WAES0808USA02609	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL. The patient was diagnosed with human papilloma virus shortly after receiving a dose of GARDASIL. It was not known as to type of HPV or what dose of GARDASIL was administered. The patient's HPV persisted. Unspecified medical attention was sought. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327261-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	23-Dec-2008	GA	WAES0808USA02617	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated intramuscularly with a 0.5 ml dose of GARDASIL. On the same office visit as vaccination, the patient had syncope after getting GARDASIL. In the office that day, the patient recovered from syncope. The patient saw the doctor and sought unspecified medical attention. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 327262-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Aug-2007	02-Oct-2007	61	17-Sep-2008	23-Dec-2008	--	WAES0808USA02619	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Nephrotic syndrome

Symptom Text: Information has been received from a physician concerning an 18 year old female with a history of nephrotic syndrome who on 11-JAN-2007, 16-MAR-2007 and 02-AUG-2007, was vaccinated intramuscularly with the first, second and third 0.5 ml doses, respectively, of GARDASIL (Lot # of the first dose 654702/0011U, Lot # of the second dose 656049/0187U). Concomitant therapy included LOESTRIN 24 PE and KENALOG. "2 months after the third dose", on approximately 02-OCT-2007, the patient experienced an exacerbation of nephrotic syndrome. The outcome of the patient was not reported. The patient did not seek medical attention. Additional information has been requested.

Other Meds: Loestrin 24 PE, Kenalog

Lab Data: Unknown

History: Nephrotic syndrome

Prex Illness:

Prex Vax Illns:

Vaers Id: 327263-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	24-Jul-2008	24-Jul-2008	0	17-Sep-2008	23-Dec-2008	--	WAES0808USA02620	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Headache

Symptom Text: Information has been received from a consumer concerning her 19 year old daughter with allergic reaction to Tdap (the patient was starting into space and constantly crying) and a history of shingles (onset when she was five years old) who "about three weeks ago", on approximately 24-JUL-2008, was vaccinated with a first dose of GARDASIL. "About 6 weeks ago", on approximately 03-JUL-2008, the patient had a neurological episode where she losing her vision, muscle spasms and had severe headaches. It was reported that the patient was seen by a neurologist who did blood work, spinal tap and at first they thought she was having a brain amorism, and then they ruled that out with everything else and diagnosed her with having a full blown migraine episode. The reporter stated that the patient was hospitalized for a short time for blood patches because her spinal fluid was leaking for three days, and she was having severe spinal headaches. It was reported that at hospital the patient was given VICODIN and other medications, which were unspecified. The reporter stated that it took her sometime for the headaches to go away. But "about three weeks later", on approximately 24-JUL-2008, the patient went to her pediatrician and was given a dose of GARDASIL. After the vaccination, the patient was "still having mild headaches", but the patient had been given medication, which the name and manufacturer was unspecified, to treat her migraines. It was reported that the patient needed hospitalization or prolonged hospitalized. At the time of the report, the patient was recovering from the event. No further information is available.

Other Meds: Unknown

Lab Data: None

History: Migraine; Shingles; Hospitalisation; Staring; Epidural blood patch; Cerebrospinal fluid leakage; crying

Prex Illness: Allergy to vaccine

Prex Vax Illns:

Vaers Id: **327264-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		17-Sep-2008	23-Dec-2008	MT	WAES0808USA02631	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope

Symptom Text: Information has been received from a licensed practical nurse concerning a 14 year old female who was vaccinated with the first dose of GARDASIL. There was no concomitant medication. Subsequently the patient experienced a near fainting episode. The patient recovered from near fainting episode after 5 - 10 minutes. It was unspecified if the patient sought medical attention. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327265-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	12-Feb-2008	16-Jul-2008	155	17-Sep-2008	20-Dec-2008	OH	WAES0808USA02644	31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNK		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Blood product transfusion, Decreased appetite, Demyelinating polyneuropathy, Fall, Fatigue, Guillain-Barre syndrome, Head injury, Headache, Muscular weakness, Nasal congestion, Oropharyngeal pain, Pain in extremity, Pharyngitis streptococcal, Polyneuropathy, Pyrexia, Rhinorrhoea

Symptom Text: Information has been received from a nurse concerning a friend of a friend's 13 year old daughter who was vaccinated with a dose of HPV rL1 11 16 18 VLP vaccine (yeast). On an unspecified date the patient developed "Guillain Barre". The outcome of the patient was not reported. The patient was seen by the physician. Upon internal review, "Guillain Barre" was determined to be an other important medical event. Additional information has been requested. 11/17/08-records received from Clinic-2/12/08-seen for C/O sore throat and fever. Rhinorhea and nasal congestion, belly pain, headache, fatigue and not eating as much. DX: Strep pharyngitis. Received HPV vaccine. Office visit 7/16/08-C/O muscle weakness times 1 month in arms and legs getting worse over last month. 7/30/08- DX infect polyneuritis. 8/1/08-suture removal from back of head. Headaches times 1 week.7/16/08-C/O knee and thigh pain and weakness times 6 weeks becoming worse some weakness in arms times 1 month. 7/16/08-Seen for Guillain Barre syndrome diagnosed 3 weeks ago and hospitalized. 11/26/08-records received for DOS 7/23-7/25/08-DC DX: Subacute demyelinating polyneuropathy. Presented with 2 month history of progressive bilateral extremity weakness worse in lower than upper extremities. First noted bilateral knee pain 2 months ago progressed in ascending manner. Difficulty climbing stairs, falling a lot. Few days before onset of knee pain had a URI with rhinorrhea and productive cough lasted 3 days. Received Gardasil in February. Treated with IVIG.

Other Meds: Unknown

Lab Data: Unknown 11/17/08-records received-Lymph % increased 43.0, mono% increased 6.4. ANA by EIA increased 1.9. UA trace protein with moderate leukocyte esterase. ANA mildy elevated to 1.9.CSF protein 75. EMG showed evidence of diffuse sensori mo

History: Unknown records received- PMH: allergic rhinitis.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327266-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	04-Aug-2008	11-Aug-2008	7	17-Sep-2008	23-Dec-2008	--	WAES0808USA02654	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site haematoma, No reaction on previous exposure to drug

Symptom Text: Information has been received from a registered nurse concerning a 21 year old female with no pertinent medical history and no allergies who on 12-MAY-2008 was vaccinated with the first dose of GARDASIL 0.5 ml IM. On 04-AUG-2008 the patient was vaccinated with the second dose of GARDASIL 0.5 ml IM (lot # 660391/0063X). Concomitant therapy included YASMIN. Approximately on 11-AUG-2008, one week after receiving her second dose, the patient experienced bruise on the injection site. The bruise seemed to spread down to her bicep. She has no fever and no redness. She has full range of motion. She had no problem with her first dose. The patient was noted to be recovering. The patient sought medical attention and saw the nurse practitioner. Additional information has been requested.

Other Meds: YASMIN

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327267-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Aug-2008	11-Aug-2008	4	17-Sep-2008	23-Dec-2008	AZ	WAES0808USA02660	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, No reaction on previous exposure to drug

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 03-JUN-2008 was vaccinated with the first dose of GARDASIL (lot # 659184/0843X) and no AE was reported. On 07-AUG-2008 the patient was vaccinated with the second dose of GARDASIL (lot # 659184/0843X). On 11-AUG-2008 the patient experienced an on going dizziness and faint feeling after getting the second does. The patient sought medical attention. The patient was noted to be recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327268-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Aug-2008	12-Aug-2008	11	17-Sep-2008	23-Dec-2008	OR	WAES0808USA02679	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received from a physician concerning a 12 year old female with no pertinent medical history and no allergies who in approximately August 2008, was vaccinated with the third dose of GARDASIL 0.5 ml IM. There was no concomitant medication. On 12-AUG-2008 the patient experienced fever after receiving the third dose. On 13-AUG-2008 the patient recovered from fever. The patient sought medical attention seen by the physician. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327269-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Jul-2008	01-Jul-2008	0	17-Sep-2008	23-Dec-2008	--	WAES0808USA02681	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a nurse concerning a 12 year old female who in July 2008, was vaccinated with the third dose of GARDASIL. In July 2008, the patient passed out 1-5 minutes after her 3rd dose. Subsequently, the patient recovered immediately after gaining consciousness. The patient sought medical attention and saw nurse. No further information is available.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327270-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	12-Aug-2008	12-Aug-2008	0	14-Sep-2008	14-Oct-2008	KS	WAES0808USA02682	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Pruritus

Symptom Text: Information has been received from a healthcare worker concerning a 21 year old female with no allergies who on 12-AUG-2008 was vaccinated with a first 0.5 ml dose of GARDASIL intramuscularly in the deltoid (lot number not reported). On 12-AUG-2008 the patient developed itching to her left foot then redness and swelling to both hands. Unspecified medical attention was sought. The patient's events persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327271-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	23-Dec-2008	--	WAES0808USA02712	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a female who was vaccinated with GARDASIL. The registered nurse reported that the patient had a syncopal episode. This is one of two reports from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327272-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		17-Sep-2008	23-Dec-2008	--	WAES0808USA04449	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Asthma, Condition aggravated

Symptom Text: Information has been received from a physician concerning a 13 year old female with asthma who was vaccinated with GARDASIL. The patient experienced an asthma attack 24 hours after receiving the vaccine. Subsequently, the patient recovered. The asthma attack was considered to be immediately life-threatening. There were not lab diagnostic studies performed No further information is available.

Other Meds: Unknown

Lab Data:

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **327273-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		17-Sep-2008	23-Dec-2008	--	WAES0808USA04240	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Staphylococcal infection

Symptom Text: Information has been received from a Nurse Practitioner concerning a 14 year old female who was vaccinated with her third dose of GARDASIL. On an unspecified date, the patient developed a staph infection on her face. She sought unspecified medical attention. The patient's staph infection persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 327276-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jun-2008	01-Jun-2008	0	07-Oct-2008	08-Oct-2008	FR	WAES0809USA04866	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Aphthous stomatitis, Dysuria, Fungal infection, Incorrect route of drug administration, Oral contraception, Polydipsia, Polyuria, Type 1 diabetes mellitus, Vision blurred, Weight decreased

Symptom Text: Information has been received from a health authority (HA ref # ST20080864) concerning a 17 year old female who in approximately June 2008 (three months ago), was vaccinated with GARDASIL (lot no. not reported) via intradermal route instead of intramuscular. On an unspecified date, the patient presented with small aphtha and white stains which were diagnosed as mycosis by the attending physician. Since three weeks, she complained of burning urine associated with polyuria and polydipsia. Approximately in Aug 2008 (the last month), the patient experienced loss of weight of 7 Kg. The physician observed glycaemia at 5.9 g/dl and visual disorder described as blurred. She was diagnosed with type 1 diabetes. The patient had a concomitant therapy of oral contraceptives. At the time of the report, the outcome was considered as resolved with sequelae. The patient had a medical family history of autoimmune diathesis and her sister had Berger's disease. Follow-up information received from the health authorities (HA ref #ST20080864) which reported that patient's height was 56 Kg and height was 164 cm. Other business partner numbers included: E2008-08919. No further information is available.

Other Meds: hormonal contraceptives (unspecified), Unk - Unk

Lab Data: blood glucose, 5.9 g/dL

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327277-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	16-Jun-2008	20-Jun-2008	4	07-Oct-2008	08-Oct-2008	FR	WAES0809USA04872	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Musculoskeletal pain, Pain, Pyrexia

Symptom Text: Information has been received from a health authority (HA ref # DJ20080746) concerning an adult female with major depressant syndrome treated with ZOLOFT for several years and hirsutism treated with PROMAVES and ANDROCUR for at least 10 years. On 01-DEC-2007 the patient was vaccinated with the first dose of GARDASIL IM. In February 2008, the patient received the second dose of GARDASIL IM and on 16-JUN-2008 received the third dose of GARDASIL IM. Approximately since 20-JUN-2008, the patient was subfebrile at 37.8 C and 38 C, had asthenia and generalised pains especially at shoulder girdle punctually treated with EFFERALGAN. Clinical examination did not find any particularity. There was no evidence for focus infection. On biological standpoint, red and white blood cell count was normal, erythrocyte sedimentation rate was at 13 at first hour, hepatic check-up and thyrotropin were normal, cytomegalovirus and Epstein-Barr virus serologies were negative. Sinus scan and pelvic abdominal ultrasound did not find any particularity. At office visit date on 30-JUL-2008, it was observed that the patient was still febrile at 38 C and still presented pains. Symptoms did not regressed or worsened. The reporter considered the events to be other important medical events. Other business partner numbers included: E2008-08953. Additional information has been requested.

Other Meds: ANDROCUR, unk, unk; Estradiol, unk, unk

Lab Data: Diagnostic laboratory test, hepatic check up - normal; Sinus probe, normal; Abdominal ultrasound, normal; Pelvic ultrasound, normal; Epstein-Barr virus antibodies, negative; WBC count, normal; Serum TSH, normal; Red blood cell count, normal

History:

Prex Illness: Major depression; Hirsutism

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327278-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Feb-2008	01-May-2008	90	07-Oct-2008	08-Oct-2008	FR	WAES0809USA04994	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inflammation, Retinal vasculitis, Visual disturbance

Symptom Text: Information has been received from a physician concerning a 23 year old female who on unspecified dates was vaccinated with the first and the second dose of GARDASIL which were well tolerated. In the end of February 2008, was vaccinated with the third dose of GARDASIL IM into the upper arm. In May 2008, the patient experienced retinal vasculitis at both eyes. The patient was treated at an outpatient department of a hospital. At the time of the reporting, the outcome of the patient was not reported. Follow-up information was reported by the physician who sent the report from the outpatient neurological department of a hospital: since beginning of May-2008 the patient presented with visual disturbance ("dot shaped") of the right eye. CSF on 15-MAY-2008 showed inflammatory CSF syndrome with intrathecal igAa and IgM synthesis, but without detection of oligoclonal bands in the CSF. Borreliosis was ruled out by serology (serum and CSF). Serology for systemic vasculitis showed normal results. Cranial MRI with contrast medium showed no inflammatory foci with affinity to contrast medium. Neurological examination was normal. Immunosuppressive therapy was not indicated. The final outcome was not reported. A follow-up examination was planned. Retinal vasculitis and visual disturbance were considered to be other important medical events. Other business partner number included: E2008-08878. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, 15May08, diagnosis of CSF: inflammatory CSF syndrome with intrathecal IgA and IgM synthesis; Diagnostic laboratory test, 15May08, borrelia in CSF and in serum: no indication for neuriborreliosis; Diagnostic labor

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327279-1** **Related reports:** 327279-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	16-Jun-2008	20-Jun-2008	4	07-Oct-2008	08-Oct-2008	FR	WAES0809USA05046	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Musculoskeletal pain, Pain, Pyrexia

Symptom Text: Information has been received from Health Authorities under reference number DJ20080746, concerning an adult female patient with depressive syndrome treated with ZOLOFT for several years and hirsutism treated with PROVAMCE and ANDROCUR for at least 10 years, who in December 2007, was vaccinated with the first dose of GARDASIL, in February 2008 was vaccinated with the second dose of GARDASIL and on 16-JUN-2008 was vaccinated with the third dose of GARDASIL IM. Concomitant therapy included estradiol and ANDROCUR. Approximately since 20-JUN-2008, the patient was subfebrile at 37.8 C and 38 C, had asthenia and generalized pains especially at shoulder girdle punctually treated with Efferalgan. Clinical examination did not find any particularity. There was no evidence for focus of infections. On biological standpoint, blood cell count was normal, erythrocyte sedimentation rate was at 13 at first hour, hepatic check-up and thyroid stimulating hormones were normal, cytomegalovirus and Epstein-Barr virus serologies were negative. Sinus scan and pelvic abdominal ultrasound did not find any particularity. At consultation on 30-JUL-2008, the patient was still febrile at 38 C and still presented pains. Symptoms did not regressed or worsened. Fever, asthenia and pain were considered to be other important medical events. Other business partner number included: E2008-08953. Additional information has been requested.

Other Meds: ANDROCUR, unk, unk; Estradiol, unk, unk

Lab Data: Diagnostic laboratory test, hepatic check-up and thyroid stimulating hormone: normal; Diagnostic laboratory test, Epstein-Barr virus serologies: negative; Diagnostic procedure, sinus scan: did not find any particularity; Abdominal ultrasoun

History:

Prex Illness: Depression; Hirsutism

Prex Vax Illns:

Vaers Id: **327280-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	30-Jul-2008	30-Jul-2008	0	07-Oct-2008	08-Oct-2008	NY	WAES0810USA00015	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Haemorrhage, Muscle spasms

Symptom Text: Information has been received from a registered nurse, for the pregnancy registry for GARDASIL concerning a 26 year old female with drug hypersensitivity to AMOXIL who on 26-JUL-2007 was vaccinated with the first dose of GARDASIL (lot n. 657868/0523U), 0.5 mL, intramuscularly. On 30-JUL-2008, the patient was vaccinated with the second dose of GARDASIL (lot n. 0250X) 0.5 mL, intramuscularly. On 12-SEP-2008, the patient experienced cramping and bleeding. The nurse reported that the patient had a miscarriage after receiving GARDASIL. LMP occurred on 08-JUL-2008. On 17-SEP-2008, an ultrasound was done with no fetal heart beats. She "passed" the fetus on her own. The patient saw the physician. A pregnancy blood work was done but the results were not provided. Subsequently, the patient recovered on an unspecified date. Upon internal review miscarriage was considered to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Ultrasound, 07/17/08, no fetal heart beats

History:

Prex Illness: Pregnancy NOS (LMP = 7/8/2008); Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327281-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Sep-2008	02-Sep-2008	1	07-Oct-2008	08-Oct-2008	FR	WAES0810USA00106	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blood urine present, Epistaxis

Symptom Text: Information has been received from a paediatrician concerning a 14 year old female who in June 2008, was vaccinated with the first dose of GARDASIL, which was well tolerated and in September 2008 (39th calendar week), was vaccinated with the second dose of GARDASIL (lot no., route and injection site not reported). One day post vaccination, the patient developed epistaxis and blood in her urine. On 29-Sep-2008 she presented to the reporter's office. Urine analysis was macroscopical with blood. She was admitted to hospital the same day. Outcome for epistaxis was not reported. Other business partner number included: E2008-08971. Additional information has been requested.

Other Meds: Unknown

Lab Data: Urinalysis, 29Sep08, macroscopal with blood

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 327282-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	19-Feb-2008	23-May-2008	94	07-Oct-2008	08-Oct-2008	FR	WAES0810USA00276	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0513U	1	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Areflexia, Back pain, Demyelination, Gait disturbance, Hypoaesthesia, Neck pain, Pallanaesthesia, Paresis, Pleocytosis, Sensory disturbance, Spinal osteoarthritis, Visual acuity reduced, Visual disturbance

Symptom Text: Information has been received from a gynecologist and a hospital report concerning a 24 year old female who on 19-FEB-2008 was vaccinated with the first dose of GARDASIL (lot # 0467U; batch NG14290) IM into her left upper arm which was well tolerated. On 17-APR-2008, the patient received the second dose of GARDASIL (lot # 0513U; batch NG34780) IM into her left arm. Concomitant therapy included hormonal contraceptives for systemic use. The patient was hospitalized on 23-MAY-2008 due to pain of the nape and back as well as sensory disturbance in the jaw region, face and the whole trunk and extremities (exact date of events not reported). Suspicion of postvaccinal polyradiculitis was diagnosed in hospital. The patient was treated with methylprednisolone 500 mg IV for 5 days. The patient additionally complained of visual disturbance, impaired accomodation of the eyes with an initial visual acuity of 50% (bilateral) and 80 to 90% in the further course. Neurological examination revealed absent tendon reflexes of the lower limbs slight paresis of hip flexion and foot and toe extension on the left side, unsteady gait, subjective feeling of numbness in the area of the palate and the cheeks, "patchy" hypoasthesia in face, both arms trunk and legs and pallhypaesthesia (malleolus 5/8). In cranial Magnetic Resonance Imaging (MRI), two small demyelinating foci in the ventral corpus callosum were detected. Cervical MRI was normal except small spondylosis. CSF showed slight pleocytosis and increased protein. Extensive serology was negative (hepatitis A, B and C virus, HIV 1 and 2, measles virus, rubella virus, varicella virus and borrelia), CMV-IgG >250 IE/mL, CMV-IgM negative. ANA 1:5120. ENA, c-ANCA, p-ANCA, ANCA were negative. AMA, lupus antibodies and campylobacter antibodies were not yet available at the time of reporting. The symptoms improved but the final outcome was not reported. The patient was discharged on 02-JUN-2008. Other business partner numbers included: E2008-08924. Additional information has been requested.

Other Meds: hormonal contraceptives (unspecified), Unk - Unk

Lab Data: Visual evoked potential, 26May08, normal; Somatosensory evoked potential, 26May08, normal; Neurological examination, 26May08, see narrative; Electroneurography, 28May08, consistent with polyradiculitis; Magnetic resonance imaging, Cranial M

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327283-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Apr-2008	15-Apr-2008	14	07-Oct-2008	08-Oct-2008	FR	WAES0810USA00279	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Crohns disease, Diarrhoea, Fatigue, Large intestinal ulcer, Vaccine positive rechallenge

Symptom Text: Information has been received from a pharmacist concerning her 15 year old granddaughter with congenital cataract of the right eye and no allergies who on 01-APR-2008, was vaccinated with the first dose of GARDASIL (lot number not reported) IM into her deltoid. Fifteen days later, on 15-APR-2008, the patient experienced diarrhoea, tiredness and anemia. Treatment not reported. On 31-MAY-2008, the patient received the second dose of GARDASIL (lot number not reported) IM into her deltoid. On 15-JUN-2008 she experienced diarrhoea, tiredness and anaemia. On 23-JUN-2008, the patient was diagnosed a Crohn's disease. She received treatment: -MEDROL (start date: 23-JUN-2008, 32 mg/day). -IMURAN (start date: 19-AUG-2008), 50 mg/day). -PENTASA (start date: 19-AUG-2008, 1 g/day). - CACIT-vitD3 start date: 23-JUN-2008, 1 per day). Lab exams included: On 29-May-2008, serum hemoglobin test, 10.4 g/dL; whole blood hematocrit, 32.8%; white blood cell count, 12500/uL; blood neutrophil count, 47%; blood eosinophilic leukocyte count, 7%; blood monocyte count, 15%; serum ferritin assay, 8 ug/dL; erythrocyte sedimentation rate, 41 mm/H; serum C-reactive protein tet, 1.8 mg/dL; laboratory test to coproculture-negative; serum immunoglobulin G test to antigliadine IgG-negative; serum immunoglobulin A test to antigliadine IgA-negative; serum immunoglobulin A test to transgutaminase IgA-negative; serum immunoglobulin G test to transglutalinase IgG-negative. On 23-Jun-2008, colonscopy: extensive Crohn's disease. On 04-Jul-2008, colonoscopy: Crohn's Pan-cholitis and terminal ileitis; On 19-Aug-2008, colonoscopy: active crohn lesions with ulcerous lesions. The patient's grandfather has Crohn's disease. She was still pending. Other business partner numbers included: E2008-08990 and BGAR2008-117. Additional information has been requested.

Other Meds: Unknown

Lab Data: colonscopy, 23Jun08, extensive Crohn's disease; colonscopy, 04Jul08, Crohn's Pan-cholitis and terminal ileitis; colonscopy, 19Aug08, active crohn lesions with ulcerous lesions; WBC count, 29May08, 12500/uL; eosinophil count, 29May08, 7%; he

History:

Prex Illness: Cataract congenital

Prex Vax Illns:

Vaers Id: **327284-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-May-2008	Unknown		07-Oct-2008	08-Oct-2008	FR	WAES0806usa01096	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy, Menstruation delayed

Symptom Text: Information has been received from a general practitioner through the Sanofi Pasteur MSD GARDASIL Pregnancy Registry concerning a 17 year old female who on 23-MAY-2008 was vaccinated with the second dose of GARDASIL. The patient was well tolerated the first dose of GARDASIL given in January 2008. She had no oral contraceptive. At the end of the medical consultation the patient mentioned that she had delayed menstruation of one week. The physician prescribed a pregnancy test. The patient used condom as preservative. In case of pregnancy the patient will ask for requested legal abortion. No adverse effect was reported. Additional information received on 04-JUN-2008 by telephone: pregnancy test was positive. The reporter had not seen the patient again and did not manage to contact her. Follow-up information received from a phone call to the physician on 30-SEP-2008: Case upgraded to serious. The patient decided a voluntary termination of her pregnancy (unspecified date). The case was closed. No further information is available. Other business partner numbers included E2008-04790.

Other Meds: None

Lab Data: Beta-human chorionic gonadotropin (unsp), positive

History: Immunisation; Condom; The patient was well tolerated the first dose of GARDASIL given in January 2008.

Prex Illness:

Prex Vax Illns:

Vaers Id: **327286-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-May-2008	19-Sep-2008	119	07-Oct-2008	08-Oct-2008	FR	WAES0809USA04993	08-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Epilepsy, Loss of consciousness, Tongue biting

Symptom Text: Information has been received from a pediatrician concerning a 15 year old female who on 23-MAY-2008 was vaccinated with the first dose of GARDASIL IM, into the left arm, which was well tolerated. On 19-SEP-2008 the patient developed an epileptic fit with loss of consciousness and tongue biting. She recovered and was hospitalized for diagnostic for 2 days (exact dates not reported). Other business partner number included: E2008-08903. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327287-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	13-Aug-2008	13-Aug-2008	0	17-Sep-2008	23-Dec-2008	MO	WAES0808USA04247	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0205X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Syncope

Symptom Text: Information has been received from a physician concerning a 23 year old white female who on 13-AUG-2008 was vaccinated with the first dose of GARDASIL (lot no. 0250X). On 13-AUG-2008, after the vaccination, the patient felt lightheaded and left the treated room and fainted. The patient fell to the floor. The patient was not injured. Patient was un-injured. Subsequently the patient recovered fine and wanted to continue the series of GARDASIL. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327288-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		17-Sep-2008	23-Dec-2008	--	WAES0808USA04340	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a physician concerning a 16 year old female who was vaccinated with her first dose of GARDASIL. Subsequently, within two weeks the patient experienced a mid-cycle, very heavy menstrual period and then had another period two weeks later when she would normally have her period. No additional issues or concerns and periods went back to normal, but they had "discounted" further doses of GARDASIL until they were more comfortable with the vaccine. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327289-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		17-Sep-2008	23-Dec-2008	--	WAES0808USA04364	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician, concerning a 17 year old female patient who had unspecified "issues with injections" and no known allergies, who on an unknown date was vaccinated with 0.5 mL GARDASIL IM. The patient experienced fainted after receiving the dose of GARDASIL. The patient recovered on an unknown date. The patient sought unspecified medical attention. There was no product quality complaint. Additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327290-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	23-Dec-2008	--	WAES0808USA04373	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information has been received from a nurse practitioner concerning a female who was vaccinated with a dose of GARDASIL. Subsequently the patient broke out in warts all over her feet. At the time of reporting, the outcome was unknown. Unspecified medical attention was sought. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327291-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Aug-2008	01-Aug-2008	0	17-Sep-2008	23-Dec-2008	NC	WAES0808USA04390	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bone pain, Nausea

Symptom Text: Information has been received from a nurse concerning her 16 year old daughter who on 01-AUG-2008 was vaccinated with the second dose of GARDASIL. Concomitant therapy included an unspecified birth control medication. On approximately 01-AUG-2008 the patient experienced nausea and bone pain for about 2 weeks. The nurse noted that the only new factor between the first dose and the second dose was an initiation of an unspecified birth control medication. The patient recovered without any intervention. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327292-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jan-2008	Unknown		17-Sep-2008	29-Dec-2008	SC	WAES0808USA04398	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pain, Pyrexia, Vomiting

Symptom Text: Information has been received from a registered nurse concerning a female patient who on an unspecified date was vaccinated with her first dose of GARDASIL. In January 2008, she was vaccinated with her second dose of GARDASIL and reported pain, nausea, fever and vomiting. Subsequently, on an unspecified date, the patient recovered from pain, nausea, fever and vomiting. The reporter also indicated the patient's sister had the same symptoms after receiving GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: fever, nausea, pain, vomiting~HPV (Gardasil)~UN~0~In Sibling

Vaers Id: **327293-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	08-Jan-2008	01-Apr-2008	84	17-Sep-2008	23-Dec-2008	CT	WAES0808USA04408	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Uveitis

Symptom Text: Information has been received from a physician concerning a 19 year old female who was vaccinated with the three dose series of GARDASIL (lot # 657868/0523U), 658556/1060U, 659439/1267U, respectively), was completed on 08-JAN-2008. In April of 2008, the patient experienced uveitis and was treated with Prednisone. The symptoms continued to the time of the report, 22-AUG-2008. No other information was available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327294-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	03-Jul-2008	Unknown		17-Sep-2008	24-Dec-2008	PA	WAES0808USA04417	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a female who on 03-JUL-2008 was vaccinated with the first 0.5mL dose of GARDASIL (Lot # 0250X) IM into the right deltoid. After receiving the first dose of GARDASIL, the patient experienced rash behind one of the ears. The patient sought medical attention, spoke to the physician. At the time of the reporting, the outcome of the patient was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327295-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	24-Dec-2008	--	WAES0808USA04453	24-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Thrombosis

Symptom Text: Information has been received from a nurse concerning her daughter, who on an unspecified date was vaccinated with a dose of GARDASIL, 0.5 mL, I.M., and developed blood clots. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327296-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Aug-2008	15-Aug-2008	0	17-Sep-2008	24-Dec-2008	TX	WAES0808USA04587	24-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: Information has been received from a physician concerning a female patient between 14 and 16 year old who on 15-AUG-2008 was vaccinated with the first dose of GARDASIL. After receiving the vaccine, the patient experienced vomiting. The patient recovered. Medical attention was sought. This is one of two reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327297-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	24-Dec-2008	--	WAES0808USA04608	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a consumer concerning a female patient who on unspecified dates, was vaccinated with GARDASIL. The consumer reported that she was speaking with another mother who stated her daughter was experiencing terrible headaches since receiving GARDASIL. Outcome was not reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327298-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Jul-2008	02-Jul-2008	0	17-Sep-2008	24-Dec-2008	MD	WAES0808USA04612	24-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Headache, Nausea

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter who on 02-JUL-2008, was vaccinated with her third dose of GARDASIL. Soon after receiving her third dose, the patient experienced nausea, fatigue, headaches and dizziness. The patient sought medical attention at pediatrician's office and unspecified blood work was performed. Her symptoms persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327299-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	30-Jul-2007		17-Sep-2008	24-Dec-2008	--	WAES0808USA04617	24-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Vaccine positive rechallenge

Symptom Text: Information has been received from a Nurse Practitioner concerning a 12 year old female who on 30-JUL-2007, was vaccinated with her first dose of GARDASIL. On 27-SEP-2007, she was vaccinated with her second dose of GARDASIL. On 27-DEC-2007, she was vaccinated with her third dose of GARDASIL. At a recent wellness visit, the patient told the nurse practitioner, that she had had some hair loss on her scalp, following each dose. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327300-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	24-Dec-2008	OH	WAES0808USA04637	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Menstruation irregular

Symptom Text: Information has been received from a consumer concerning a female who was vaccinated intramuscularly with the third 0.5 ml dose of GARDASIL. A consumer reported that her step daughter has experienced headaches, that have been pretty intense, since her third dose of GARDASIL. He also stated there was an interruption in her menstrual cycle. Unspecified medical attention was sought. At the time of the report, the patient had not recovered. No additional AE information was reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327301-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Mar-2008	01-Mar-2008	0	17-Sep-2008	24-Dec-2008	PA	WAES0808USA04650	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysmenorrhoea, Vaccine positive rechallenge

Symptom Text: Information has been received from a 16 year old female with asthma and no drug allergies who in March 2008, was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL and in June 2008, was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL. There was no concomitant medication. The patient experienced menstrual cramping after the first and second dose of GARDASIL. Cramping was more severe after second dose. The reporter was undecided as to whether to receive final dose of GARDASIL. On an unspecified date, the patient recovered. The patient was not experiencing any menstrual cramping at the time of reporting. Unspecified medical attention was sought. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327302-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	24-Dec-2008	VA	WAES0808USA04658	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mononucleosis syndrome

Symptom Text: Information has been received from a nurse concerning a female patient who was vaccinated with GARDASIL. The patient came down with mono within one month of getting the vaccine. The patient sought medical attention. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327303-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jan-2007	01-Jan-2007	0	17-Sep-2008	24-Dec-2008	SC	WAES0808USA04663	24-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Initial and follow-up information has been received from a physician concerning a 17 year old female with no relevant medical history or allergies who in spring of 2007, was vaccinated with a first dose of GARDASIL (lot number ,injection site and route not reported). About two weeks after the vaccination, the patient developed intermittent fevers. The physician also reported that the patient completed the series of GARDASIL (the vaccine was given on a 0, 2, 6 month schedule) without any pattern of injection-related fever or associated symptoms. The patient has had three episodes of unexplained fever as high as 103-104 degrees F with no other localizing signs since her first dose. These episodes lasted up to several weeks and then resolved spontaneously. Medical work-up was negative except for a markedly elevated C-reactive protein. At the time of this report, the patient's event persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: serum c-reactive protein, elevated; body temp, 103 - degre;

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327304-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	Unknown	Unknown		17-Sep-2008	24-Dec-2008	--	WAES0808USA04668	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Vaccine positive rechallenge

Symptom Text: Information has been received from a pharmacist concerning an approximately 10 year old female with no pertinent medical history who was vaccinated with the first and second dose of GARDASIL, 0.5 ml (dates, therapy route and lot number not reported). There was no concomitant medication. The patient experienced joint pain after getting first and second dose of GARDASIL. No lab diagnostics studies was performed. The patient sought unspecified medical attention. The outcome of the adverse events were not reported. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327305-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Sep-2007	01-Oct-2007	7	17-Sep-2008	24-Dec-2008	MA	WAES0808USA04685	02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Fatigue

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female with a history of dysmenorrhoea and attention deficit/hyperactivity disorder and no drug reactions/allergies who on 24-SEP-2007 was vaccinated with the first 0.5mL dose of GARDASIL (Lot No. 658560/1062U) IM and on 03-DEC-2007 was vaccinated IM with the second dose 0.5 mL dose of GARDASIL (Lot No. 659437/1266U). She has not yet received the third dose. Concomitant therapy included Tdap (unspecified) , influenza virus vaccine (unspecified) and MENACTRA. In October 2007 de patient experienced abdominal pain and fatigue. She was examined with endoscopy and colonoscopy. In October 2007, she was diagnosed with, the possible inflammatory bowel disease. The patient sought medical attention was seen by a physician. At the time of the reporting, the patient had not recovered Additional information has been requested.

Other Meds:

Lab Data: colonoscopy, 10/??/07, possible inflammatory bowel disease; endoscopy, 10/??/07, possible inflammatory bowel disease

History: Dysmenorrhoea; Attention deficit/hyperactivity disorder

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327306-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Aug-2007	14-Aug-2007	0	17-Sep-2008	24-Dec-2008	CA	WAES0808USA04707	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning a 13 year old female with no pertinent medical history and no drug reactions/allergies who on 14-AUG-2007 was vaccinated with the first dose of GARDASIL. Immediately after receiving GARDASIL the patient vomited. Also, for six months thereafter, the patient periodically experienced dizziness, nausea and vomiting. The patient sought unspecified medical attention. At the time of the reporting, the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327307-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	25-Aug-2008	25-Aug-2008	0	17-Sep-2008	24-Dec-2008	--	WAES0808USA04712	24-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye disorder, Vision blurred

Symptom Text: Information has been received from a registered nurse concerning a female who on 25-AUG-2008 morning was vaccinated intramuscularly with her second dose of GARDASIL. (Dose, site of administration and lot number not reported). Couple hours later the patient called the office back and said she had pulsating in her right eye and was unable to focus. The patient went to the emergency room and was still there. The outcome of the patient was known. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327308-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	Unknown	Unknown		17-Sep-2008	24-Dec-2008	MO	WAES0808USA04714	24-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site rash, Rash generalised

Symptom Text: Information has been received from a nurse concerning a 24 years old female who was vaccinated with the first dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). The patient developed a rash around the site of injection the day after receiving GARDASIL. Also, the patient developed a generalized rash two weeks after vaccination. At the time of the report, the patient had not recovered. The patient sought medical attention via telephone. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327309-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jan-2008	Unknown		17-Sep-2008	24-Dec-2008	SC	WAES0808USA04717	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pain, Pyrexia, Vomiting

Symptom Text: Information has been received from a registered nurse concerning a female patient who on an unspecified date was vaccinated with her first dose of GARDASIL. In January 2008, she was vaccinated with her second dose of GARDASIL and pain, nausea, fever and vomiting. Subsequently, on an unspecified date, the patient recovered from pain, nausea, fever and vomiting. The reporter also indicated the patient's sister developed the same symptoms after receiving GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327310-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jun-2008	01-Jun-2008	0	17-Sep-2008	29-Dec-2008	--	WAES0808USA04754	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crying, Dysmenorrhoea, Menstrual disorder, Muscle spasms, Pain in extremity

Symptom Text: Information has been received from a consumer concerning her daughter, a 15 year old female who in April-2008 was vaccinated with GARDASIL (unknown if this was the 1st or 2nd dose) and 01-JUN-2006, was vaccinated with the third dose of GARDASIL. The patient was the entire GARDASIL series. The mother reported that her daughter received the last dose of GARDASIL and her menstrual cramps have changed. It was about 15 days apart and a change in color; also she experienced severe cramps and pain in her legs. Her daughter cried over the severe menstrual cramps. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327311-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	29-Dec-2008	--	WAES0808USA04816	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Headache, Lethargy, Malaise, Pain

Symptom Text: Information has been received from a receptionist and a physician's assistant, concerning a female who was vaccinated with the first dose of GARDASIL. After the first dose, the patient's body was achy and wasn't generally feeling well. Approximately 3 hours after the second dose of GARDASIL, she had difficulty with breathing. She also experienced, lethargy, aches and headaches. The patient sought unspecified medical attention. The patient outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327312-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	11-Jun-2007	01-Jul-2007	20	17-Sep-2008	29-Dec-2008	MA	WAES0808USA04819	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy, Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from a clinical director/ registered nurse, concerning a 25 year old female patient, who on 11-JUN-2007 was vaccinated with the first dose of GARDASIL 0.5mL IM, the second dose of GARDASIL (Lot #658094/0524U) on 13-AUG-2007 and the third dose of GARDASIL (Lot #659439/1267U) on 02-JAN-2008. The patient experienced facial paralysis and numbness and tingling of the hands and feet one and a half months (approximately in July 2007) after get the first dose of GARDASIL. The patient had been seen by the primary care physician and a neurologist for the symptoms. All laboratories and diagnostic studies came back negative (computed tomography scan, spinal tap and magnetic resonance imaging) for cause and GARDASIL is now the primary suspect. At the time of reporting the patient did not recovered. There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: computed axial, negative; spinal tap, negative; magnetic resonance, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327313-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-May-2008	01-May-2008	0	17-Sep-2008	29-Dec-2008	ID	WAES0808USA04835	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a female who in approximately May 2008, was vaccinated with a dose of GARDASIL (route and administration site not reported). Shortly after the vaccination, the patient fainted in the waiting room. Subsequently, the patient recovered from fainting. There was no injury associated with the fainting episode. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327314-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		17-Sep-2008	29-Dec-2008	OH	WAES0808USA04838	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Information has been received from a physician concerning a 20 year old female who on an unspecified date was vaccinated with a dose of GARDASIL 0.5 ml IM. Subsequently the patient experienced joint pain. The patient's joint pain persisted. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327315-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Sep-2008	29-Dec-2008	--	WAES0808USA04841	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse reaction

Symptom Text: Information has been received from a physician assistant, concerning a patient who received a dose of GARDASIL. The patient had a reaction after receiving GARDASIL. The physician assistant refused elaborate on the nature of the reaction. There was no product quality complaint. Additional information is not available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327316-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Jul-2008	16-Jul-2008	0	17-Sep-2008	29-Dec-2008	CA	WAES0808USA04846	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injection site anaesthesia, Injection site pain

Symptom Text: Information has been received from a physician concerning a 13 year old female with no relevant medical history or allergies who on 12-APR-2007 was vaccinated with a first dose of GARDASIL (lot number 1926F) (injection site and route not reported). On 12-JUN-2007 the patient was vaccinated with a second dose of GARDASIL (lot number 655324/0089U) (injection site and route not reported). On 12-OCT-2007 the patient was vaccinated with a third dose of GARDASIL (lot number 658222/0927U) (injection site and route not reported). On 16-JUL-2008, the patient was vaccinated with a fourth 0.5 ml dose of GARDASIL (lot number 0063A) intramuscularly (injection site not reported). Secondary suspect therapy included a dose of VARIVAX (Oka/Merck) (lot number, injection site and route not reported). On 17-JUL-2008 the patient experienced numbness, soreness and pain at the injection site. There is no redness or induration. The patient went to see the physician. The patient's events persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **327317-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-May-2008	08-Jul-2008	63	17-Sep-2008	29-Dec-2008	CO	WAES0808USA04857	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Nausea

Symptom Text: Information has been received through the pregnancy registry for GARDASIL from a physician concerning a 16 year old female with no pertinent medical history and no history of drug reactions or allergies who no 06-MAY-2008 was vaccinated with the first dose of GARDASIL. On 08-JUL-2008 the patient had her last menstrual period. On 18-AUG-2008 the patient was vaccinated with the second dose of GARDASIL (lot#:). On 26-AUG-2008 the patient was seen in the physician's office due to nausea. Urine pregnancy test result was positive. The patient was pregnant at 7 weeks gestation. The estimated delivery date is 15-APR-2009. Additional information has been requested.

Other Meds: Unknown

Lab Data: urine beta-human, 08/26/08, positive;

History:

Prex Illness: Pregnancy NOS (LMP - 7/8/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327318-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-May-2008	14-May-2008	0	17-Sep-2008	29-Dec-2008	OH	WAES0808USA04863	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Loss of consciousness

Symptom Text: Information has been received from a consumer concerning her 13 year old daughter with no relevant medical history or allergies who in February 2008, was vaccinated with a first dose of GARDASIL (lot number, injection site and route not reported). On 15-JUN-2008 the patient was vaccinated with a second dose of GARDASIL (lot number, injection site and route not reported). There was no concomitant medication. According to the reporter, the patient became sexually active on "April 2008". And the patient's mother was not sure if the clinical conducted a pregnancy test prior to giving the second dose of vaccine. On 15-JUN-2008 the patient passed out and was brought to emergency room and on that day, pregnancy was confirmed after blood and urine was taken for tests. The patient was not admitted to the hospital. The patient's mother noted that the patient was fine at time of this report and her due date was on 28-JAN-2009. At time of this report, the patient was 19 weeks pregnancy. Additional information has been requested.

Other Meds: None

Lab Data: computed axial; ultrasound, 07/15/08; diagnostic laboratory, 07/15/08, blood test; urinalysis, 06/15/08

History:

Prex Illness: Pregnancy NOS (LMP = 4/15/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327319-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	25-Aug-2008	25-Aug-2008	0	17-Sep-2008	29-Dec-2008	PA	WAES0808USA04864	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received from a physician concerning a 20 year old female with Crohn's disease, sulfonamide allergy to nuts and environmental allergies who on 02-JAN-2008, 13-MAR-2008 and 25-AUG-2008, was vaccinated intramuscularly with her first, second and third 0.5 ml doses, respectively, of GARDASIL (Lot # of the third dose 659184/0843X). Concomitant therapy included ASACOL, SINGULAIR, ALLEGRA and 6-MP. On 25-AUG-2008, after receiving the third dose of GARDASIL, the patient developed a fever with a temperature of 102 degrees F. The patient was treated with MOTRIN and acetaminophen TYLENOL. At the time of the report, the patient was recovering from fever. Medical attention was sought via phone call. Additional information has been requested.

Other Meds: ALLEGRA, mercaptopurine, ASACOL, SINGULAIR

Lab Data: body temp, 08/25/08, 102 F;

History:

Prex Illness: Crohn's disease; Sulfonamide allergy; Allergy to nuts; Environmental allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327320-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	29-Dec-2008	--	WAES0808USA04866	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a female who on an unspecified date was vaccinated with the second dose GARDASIL and fainted. The outcome was unknown. The patient sought unspecified medical attention in the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327321-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	11-Jul-2008	11-Aug-2008	31	17-Sep-2008	29-Dec-2008	DC	WAES0808USA04869	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Pelvic pain, Urinary tract infection

Symptom Text: Information has been received from a registered nurse, concerning a 25 year old female patient with a history of psychiatric disorder, who on 11-JUL-2008 was vaccinated with 0.5 mL GARDASIL intramuscularly in the left arm. Concomitant therapy included EFFEXOR, XANAX and SYNTHROID. Approximately in August, a month after receiving the first dose of GARDAIL, the patient experienced pelvic pain and joint pain. On 18-AUG-2008, the patient sought treatment for abdominal pain from an emergency room and was treated for a urinary tract infection. On 20-AUG-2008, the patient underwent a magnetic resonance imaging that indicated there was abnormal abdominal tissue. There was no product quality complaint. Additional information has been requested.

Other Meds: XANAX, SYNTHROID, EFFEXOR;

Lab Data: magnetic resonance, 08/20/08; abnormal abdominal tissue;

History:

Prex Illness: Psychiatric disorder NOS

Prex Vax Illns:

Vaers Id: **327322-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	29-Dec-2008	GA	WAES0808USA04884	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date, was vaccinated with her first dose of GARDASIL 0.5ml, IM. Concomitant therapy included INFANRIX received during the same visit. The patient experienced syncope after administration of her first dose. She was unconscious for 10 seconds. On unspecified date, the patient recovered from syncope. The patient sought medical attention via: office visit. She has since received her second dose of GARDASIL 0.5ml, IM and did not experienced any adverse event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327323-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	12-Aug-2008	12-Aug-2008	0	17-Sep-2008	29-Dec-2008	FL	WAES0808USA04888	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus

Symptom Text: Information has been received from a healthcare worker concerning a 22 year old female with no pertinent medical history and no allergies who no 12-AUG-2008 was vaccinated with the first dose of GARDASIL (lot # 0152X). There was no concomitant medication. On 12-AUG-2008 the patient experienced itching in 4 hours of receiving the first dose. The patient took BENADRYL, but it did not help the itching. On 14-AUG-2008 the patient called office. On an unspecified date the patient recovered from itching. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327324-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
50.0	F	22-Aug-2008	22-Aug-2008	0	17-Sep-2008	29-Dec-2008	IN	WAES0808USA04898	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Loss of consciousness

Symptom Text: Information has been received from a physician concerning a 50 year old female who on 22-AUG-2008 was vaccinated with the first dose of GARDASIL. On 22-AUG-2008 the patient passed out within minutes after receiving a first dose. The patient fully recovered. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327325-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-Aug-2008	Unknown		17-Sep-2008	29-Dec-2008	NY	WAES0808USA04922	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 12 year old female patient who on 13-AUG-2008, was vaccinated with the first dose of GARDASIL (Lot # 659962/1740U). The physician reported that the patient received GARDASIL and then fainted. On an unknown date, the patient recovered. It is unknown if the patient sought medical attention. This is one of two reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327327-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	29-Dec-2008	VA	WAES0808USA04965	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Infectious mononucleosis

Symptom Text: Information has been received from a nurse concerning a female patient who was vaccinated with GARDASIL. The patient came down with mono within one month of getting the vaccine. The patient sought medical attention. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327328-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	27-Jun-2008	04-Jul-2008	7	17-Sep-2008	29-Dec-2008	MO	WAES0808USA04977	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash generalised, Rash pruritic

Symptom Text: Information has been received from a physician concerning a 22 year old female with no pertinent medical history who in June 2008, was vaccinated intramuscularly with a first 0.5 ml dose of GARDASIL. Concomitant therapy included oral contraceptive. "One week after administration of her first dose of GARDASIL", the patient developed generalized pruritic rash on her body. The patient took BENADRYL and then symptoms resolved when the patient woke up "the next morning". "One week later", the rash reappeared for the second time and resolved the next day after taking BENADRYL. The rash reappeared for the third time "one week later" and again symptoms resolved after taking BENADRYL. The patient was seen in office. These events were also reported as a "head to toe rash" that developed one week post vaccination which resolved the next morning after OTC BENADRYL use. The rash returned a second time about one week after the first rash appeared which again resolved after using OTC BENADRYL. Follow-up information was received from the physician via phone call on 08-SEP-2008 indicating that the patient received the first dose of GARDASIL on 27-JUN-2008. The patient went to bed one night and woke up the next day with a total body rash one week after the injection. The patient took BENADRYL and the rash resolved. "One week later", the same total body rash reappeared. After taking hydrochloride BENADRYL, the rash resolved. "One week later", the same total body rash reappeared for the third time. After taking BENADRYL, the rash resolved. So the patient had 3 episodes of total body rash that resolved with BENADRYL. On 27-AUG-2008 the patient returned for her second dose of GARDASIL and reported her experiences to the physician. As far as the physician knows, no further episodes had occurred. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327334-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Jul-2008	16-Jul-2008	0	07-Oct-2008	17-Oct-2008	TX		17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2572AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea

Symptom Text: Nausea since rec. vaccines

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **327337-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	30-Sep-2008	30-Sep-2008	0	07-Oct-2008	17-Oct-2008	MN		13-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Flushing, Nausea

Symptom Text: Received vaccine (HPV) GARDASIL at 10:05. returned to clinic at 2:45. States she felt flushed and nauseated. States she had a granola bar to eat today. Unsure if related to vaccine.

Other Meds: LEXAPRO, NUVA RING

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327343-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Sep-2008	Unknown		07-Oct-2008	17-Oct-2008	AK		17-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2658AA	0	Right arm	Unknown	
HPV4	MERCK & CO. INC.	0072X	0	Left arm	Unknown	
VARCEL	MERCK & CO. INC.	0789X	0	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral

Symptom Text: Large, swollen, red area on left posterior upper arm. 8 x 6.5cm. First day after vaccine was swollen. Next day was larger after being seen and taking Benadryl area was not swollen anymore. Swelling resolved on 3rd day.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327356-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	04-Oct-2008	04-Oct-2008	0	07-Oct-2008	15-Oct-2008	AZ	AZ0814	16-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	A52B030AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drooling, Gaze palsy, Immediate post-injection reaction, Muscle twitching

Symptom Text: Pt received Tdap then HPV #2 as soon as MA finished w/HPV #2- pt's eyes rolled back and pt started to twitch and drool x 5 seconds. Recovered vital signs taken, water given, observed pt x 30 minutes. Pt staes "I feel fine"; Dad feels comfortable taking pt home. BP 110/84, P 64, R 12. Spoke with Dr. on 10/06/08 at 0945. Physician stated to have parents call to schedule an appointment for this week. 0950 called family and spoke with Mom. She stated that pt is fine. Told Mom that the physician would like to see the patient this week and that Mom should call to make an appointment.

Other Meds: no

Lab Data: none

History: none per family

Prex Illness: none per family

Prex Vax Illns: no~ ()~~0~In Patient|no~ ()~~0~In Sibling

Vaers Id: **327374-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
33.0	U	16-Sep-2008	10-Apr-2008	-159	07-Oct-2008	13-Oct-2008	--		15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	AHVA006BA	1	Left arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Menstruation delayed

Symptom Text: I GOT THE CERVARIX FIRST SHOT ON SEPT 16, 2008. MY MENSES IS DELAYED FOR ABOUT A WEEK NOW. NEVER I HAD A LONGEST DELAY OF MENSES SUCH AS THIS.

Other Meds:

Lab Data: FSH, LH, BLOOD LEVELS WERE NORMAL.

History:

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **327384-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	28-Jul-2008	28-Jul-2008	0	07-Oct-2008	17-Oct-2008	TX		17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C2996A15	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Feeling abnormal, Hot flush

Symptom Text: Was given vaccine 7-28-08. 30-40 minutes after administration, patient experienced dizziness, fatigue, hot flashes, seemed very "out of it". Was extremely fatigued x 1 1/2 days.

Other Meds:

Lab Data:

History: Allergies, eczema

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327400-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-May-2008	09-Jun-2008	10	07-Oct-2008	17-Oct-2008	NC	NC08100	17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	2	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0090X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia

Symptom Text: C/O paresthesias across upper chest - came & went for one month after onset - resolved.

Other Meds: CLARITIN, PREVACID, YAZ

Lab Data:

History: Polycystic ovarian syndrome, gastric reflux, migraines

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327435-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Sep-2008	22-Sep-2008	0	07-Oct-2008	29-Dec-2008	HI		30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	VFC0391X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus

Symptom Text: 3 days after immunization Left arm posterior distal aspect has red, itchy 5 x 9 cm area.

Other Meds:

Lab Data:

History: No known drug allergies

Prex Illness:

Prex Vax Illns:

Vaers Id: **327438-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Jul-2008	24-Jul-2008	0	17-Sep-2008	29-Dec-2008	PA	WAES0808USA04985	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Hyperhidrosis, Malaise, Pallor

Symptom Text: Information has been received from a physician concerning a 17 year old female with no pertinent medical history or drug allergies who on 24-JUL-2008 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot # 660553/0070X). Concomitant therapy included ALLEGRA. It was reported that the patient was not feeling well, looked pale, and complained of fatigue and diaphoresis when she came in to get her GARDASIL. Labs done that day after she got GARDASIL came back that she is anemic and the mom was blaming the GARDASIL. On an unspecified date, the patient recovered. The patient was seen by doctor. No product quality complaint was involved. Additional information has been requested.

Other Meds: ALLEGRA

Lab Data: she is anemic

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 327439-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	26-Aug-2008	26-Aug-2008	0	17-Sep-2008	29-Dec-2008	OH	WAES0808USA04994	05-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Gaze palsy, Loss of consciousness, Syncope, Tremor

Symptom Text: Information has been received from a physician concerning a 13 year old female with sulfonamide allergy who on 26-AUG-2008 was vaccinated with a first dose of GARDASIL (lot number 660557/0072X) intramuscularly (injection site not reported). After the vaccination, the patient "passed out, her arms were shaking, and her eyes rolled back". The patient was sent to the emergency room but was not admitted. The patient was diagnosed with syncope and released. The physician also reported that the patient came to the physician's office for a "sick visit" and had symptoms of "not feeling well for one month, right knee pain, sore throat, and out of breath when running or in the pool." During the visit it was decided to give her the GARDASIL. The physician reports that "the father requested to start GARDASIL series." Subsequently on 26-AUG-2008, also reported as "yesterday", the patient recovered from syncope. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Feeling unwell; Knee pain; Sore throat; Breath shortness; Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327440-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	13-Aug-2008	20-Aug-2008	7	17-Sep-2008	29-Dec-2008	OH	WAES0808USA05013	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain, Rash generalised, Rash pruritic

Symptom Text: Information has been received from a consumer concerning her 19 year old daughter who on approximately 13-AUG-2008, "two weeks ago", was vaccinated with the second 0.5 ml dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). On approximately 20-AUG-2008, "last week", the patient developed a rash over her body and it had become itchy and painful. At the time of this report, the patient's symptoms persisted. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **327441-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	29-Dec-2008	AZ	WAES0808USA05021	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a first 0.5 ml dose of GARDASIL by intramuscular injection (lot number and injection site not reported). Concomitant therapy included MENACTRA and an unspecified vaccine. Immediately after injection, the patient experienced dizziness. The patient went to see the doctor. Subsequently the patient recovered from the event. The physician also reported that on an unspecified date the patient was vaccinated with a second dose of GARDASIL (lot number, injection site and route not reported). The patient felt fine after the vaccination. Additional information has been requested.

Other Meds:

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327442-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	26-Aug-2008	26-Aug-2008	0	17-Sep-2008	29-Dec-2008	IN	WAES0808USA05022	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a registered nurse concerning a female with no medical history and with penicillin allergy who on 26-AUG-2008 was vaccinated intramuscularly with 0.5 ml of GARDASIL (Lot # 0152X). There was no concomitant medication. Later that night, on 26-AUG-2008 the patient developed hives all over her body including in her throat. She took OTC BENADRYL and the symptoms resolved on 27-AUG-2008. Unspecified medical attention was sought. There was no product quality complaint. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327443-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	01-Aug-2008		17-Sep-2008	29-Dec-2008	--	WAES0808USA05028	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cystitis, Papilloma viral infection

Symptom Text: Information has been received from a consumer, concerning her 22 year old daughter with no previous medical history reported, who was vaccinated with the complete series of GARDASIL (Lot # not reported). On beginning of summer 2008 (approximately 01-AUG-2008) the patient had her yearly pap smear and her physician advised her that she needs to come back to the office because she was positive for HPV. The reporter stated that the physician did not specify what type of HPV does the patient have. The patient also experienced bladder infection recently. As of 27-AUG-2008, the patient had not recovered. The patient sought medical attention with the physician. There was no product quality complaint. No additional information is expected.

Other Meds: Unknown

Lab Data: cervical smear, positive for hpv;

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327444-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jan-2007	Unknown		17-Sep-2008	29-Dec-2008	--	WAES0808USA05033	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Familial risk factor, Injection site discolouration

Symptom Text: Information has been received from a nurse practitioner concerning a female teenager who in 2007 was vaccinated with the first dose of GARDASIL and an unspecified dates was vaccinated with the second and the third dose of GARDASIL. Concomitant therapy included therapy unspecified. Following the second dose of GARDASIL the patient developed a small lighter skin discoloration at the injection site. The patient sought medical attention, office visit. At the time of the reporting, the patient was recovering. The reporter also indicated the patient's twin sister had the same symptoms after receiving the second dose of GARDASIL. Additional information is not expected.

Other Meds: [therapy unspecified]

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327445-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Dec-2007	22-Jan-2008	52	17-Sep-2008	29-Dec-2008	TX	WAES0808USA05034	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Neurological examination abnormal, Orthostatic hypotension, Visual impairment

Symptom Text: Information has been received from a physician concerning a 12 year old female who in May 2007, was vaccinated with the first dose of GARDASIL, in August of 2007 was vaccinated with the second dose of GARDASIL and in December of 2007 received the third dose of GARDASIL. The lot numbers were not known. On 22-JAN-2008, the patient experienced black out episodes 1&1/2 months after administration of her third dose of GARDASIL. The patient has been examined by a neurologist who diagnosed her with orthostatic hypotension. She has not had seizures or any episodes of syncope. She experienced visual disturbances but remains conscious at the time of reporting, the event persisted. The physician did not have any additional information because she is not her patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327446-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		17-Sep-2008	29-Dec-2008	MD	WAES0808USA05035	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eosinophilia, Thrombocythaemia

Symptom Text: Information has been received from a hematologist concerning a 14 year old female with no pertinent medical history, nor drug reaction/allergies, who was vaccinated with the first two doses of GARDASIL. No concomitant medication reported. Subsequently, the patient developed thrombocytosis (platelet count 1,500,000) and eosinophilia after receiving the first two doses of GARDASIL. The immunoglobin E level was elevated at 2,600 too. At the time of the report, the patient had not recovered. Medical attention was sought at the physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: hematology; platelet count, 1,500,000; serum immunoglobulin E, elevated at 2,600;

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327447-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Jan-2008	17-Jun-2008	168	17-Sep-2008	29-Dec-2008	--	WAES0808USA05037	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Infection

Symptom Text: Information has been received from a licensed practical nurse through the Merck Pregnancy registry concerning a 19 year old Hispanic female with no previous pregnancies and no significant past medical history, who on an unspecified date during her first trimester of pregnancy was vaccinated (given by her primary care physician) with GARDASIL (lot number not reported). On 17-JUN-2008 the patient was treated with 1 gram of ZITHROMAX for infection. The patient was put on prenatal vitamins (unspecified) QD. On 22-JUN-2008 the patient underwent an ultrasound indicated for dating, which showed that she was 9 weeks and 3 days. On 12-JUL-2008 the patient underwent MSAFP which was negative. The reporter noted the patient's estimated delivery date as 01-JAN-2009. The patient's LMP was approximately 17-APR-2008. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, 06/22/08, for dating= 9w 3 days; serum alpha-fetoprotein, 07/12/08, Neg;

History:

Prex Illness: Pregnancy NOS (LMP = 4/17/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327448-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	13-Jun-2008	13-Jun-2008	0	17-Sep-2008	29-Dec-2008	--	WAES0808USA05277	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope

Symptom Text: Information has been received from a nurse concerning a female who on 13-Jun-2008 was vaccinated with the third dose of GARDASIL. On the same day, after receiving her third dose, the patient passed out in the office and experienced syncope. Subsequently, the patient recovered fully from syncope on the same day. The patient saw the nurse practitioner. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327449-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	07-Aug-2008	07-Aug-2008	0	17-Sep-2008	29-Dec-2008	--	WAES0808USA05279	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope

Symptom Text: Information has been received from a nurse concerning a female who on 07-Aug-2008 was vaccinated with a dose of GARDASIL. On the same day, the patient passed out in the office and experienced syncope. Subsequently, the patient recovered fully from syncope on the same day. The patient saw the nurse practitioner. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327450-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	29-Dec-2008	--	WAES0808USA05280	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope, Vertigo

Symptom Text: Information has been received from a nurse concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL. On the same day the patient experienced syncope and vertigo. Subsequently, the patient recovered fully from syncope and vertigo on the same day. The patient saw the nurse practitioner. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327451-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	30-Jun-2008	30-Jun-2008	0	17-Sep-2008	29-Dec-2008	--	WAES0808USA05278	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope

Symptom Text: Information has been received from a nurse concerning a female who on 30-Jun-2008 was vaccinated with a dose of GARDASIL. On the same day, the patient passed out in the office and experienced syncope. Subsequently, the patient recovered fully from syncope on the same day. The patient saw the nurse practitioner. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327452-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	19-Feb-2008	19-Feb-2008	0	17-Sep-2008	29-Dec-2008	--	WAES0808USA05009	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope

Symptom Text: Information has been received from a nurse concerning a female who on 19-FEB-2008 was vaccinated with the third dose of GARDASIL. On the same day, after receiving her third dose, the patient passed out in the office and experienced syncope. Subsequently, the patient recovered fully from syncope on the same day. The patient saw the nurse practitioner. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327453-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Jul-2008	15-Aug-2008	32	17-Sep-2008	17-Oct-2008	--	WAES0808USA05313	17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Myalgia

Symptom Text: Information has been received from a pharmacist who reported that his 18 year old daughter with no pertinent medical history and no drug reaction/allergies on 14-JUL-2008 was vaccinated with her third dose of GARDASIL. On 15-AUG-2008, the patient experienced muscle pains and joint pain and was hospitalized for 2 days. The patient's muscle pains and joint pain persisted. No adverse event was reported with the first and second dose of GARDASIL. Laboratory test include blood work and numerous other tests (results not provided). Follow-up information has been received from the patient's father who reported that his daughter had a spinal tap that did not confirm a specific diagnosis, and was negative for Guillain-Barre syndrome. The patient's muscle and joint pains persisted. Additional information has been requested.

Other Meds: None

Lab Data: spinal tap, negative to Guillain-Barre syndrome

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 327454-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-May-2008	01-Aug-2008	73	17-Sep-2008	29-Dec-2008	FL	WAES0808USA05298	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Areflexia, Blood product transfusion, Constipation, Depression, Facial palsy, Fatigue, Guillain-Barre syndrome, Headache, Hypoaesthesia, Hypoaesthesia oral, Nausea, Oropharyngeal pain, Pain, Pyrexia, Tension headache, Vomiting

Symptom Text: Information has been received from a physician concerning a 15 year old female who in May 2008, was vaccinated with her first dose of GARDASIL. Subsequently the patient developed numbness of her feet about 2-3 months later. Then the numbness spread to the hands and tongue. She had fevers of up 103F, body aches, sore throat, stomach aches and headaches. The numbness of the tongue had gotten better and the numbness in the hands were less. She was seen by several physicians including her primary physician and OB/GYN. Physician thought that this could be from other causes. Numbness of feet, hands and tongue, fevers, body aches, sore throat, stomach aches and headaches were recovering. Laboratory diagnostic studies performed include: CBC, SMA-12, basic metabolic tests, positive epstein barr virus antibody, thyroid test, liver function tests, urinary tests and chest x-ray. No further information is available. 2/23/09-records received for DOS 8/31/08-9/5/08 DC DX: Guillain9-Barre syndrome. Left facial nerve palsy. Situational depression. Constipation. Muscle tension headaceh. Sore throat and fatigue and with continued fatigue developed numbness of right fifth toe.PE demonstrated positive left Bell phenomenon.Deep tendon reflexes suprressed throughout. Treated with IVIG/9/7-9/19/08-DC DX: Gait disturbance and disability to due recent Guillain-Barre syndrome event. Left facial nerve palsy. Situational depression. Constipation. Muscle tension headache. Presented with C/O headache, nausea and vomiting.

Other Meds: Unknown

Lab Data: Epstein-Barr virus, positive; 2/23/09-records received-EEG normal. MRI normal. CSF slightly elevated protein102 . Liver and spleen enlarged.

History: Unknown

Prex Illness: 2/23/09-records received-Developed signs and symptoms of monoucleosis about 3 weeks ago.

Prex Vax Illns:

Vaers Id: **327455-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	29-Dec-2008	--	WAES0808USA05312	07-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from a female patient who after receiving the first dose of GARDASIL in her left arm the left side of her body feels numb and tingling including her stomach. No further adverse event information provided. Consumer stated she was going into her physician and would call back with additional information. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327456-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	29-Dec-2008	NY	WAES0808USA05317	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with the second dose of GARDASIL. A few weeks after receiving the second dose, the patient had broken out in genital warts. The patient had come into the office about the experience and the physician referred her to an Obstetrician/Gynecologist. The physician did not know at the time when the patient received the first dose because she received it in Texas. At the time of this report, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 327457-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Aug-2008	28-Aug-2008	0	17-Sep-2008	29-Dec-2008	--	WAES0808USA05351	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a nurse concerning a 17 year old female with no pertinent medical history or drug reactions or allergies who on 28-AUG-2008 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot no. 659184/0843X). Concomitant therapy included LOESTRIN 24 FE. Subsequently the patient passed out when she was signing out at the front desk to leave. The patient was observed and recovered and went home. On the same day, urine pregnancy test was performed and the result was negative. Additional information has been requested.

Other Meds: LOESTRIN 24 FE

Lab Data: urine beta-human, 08/28/08, negative

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 327458-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	12-Aug-2008	12-Aug-2008	0	17-Sep-2008	29-Dec-2008	OH	WAES0808USA05378	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Unknown	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea, Grip strength decreased, Hypoaesthesia, Myalgia, Nausea

Symptom Text: Information has been received from a medical assistant concerning a 23 year old female with allergy to penicillin and amoxacillin and a history of cervical dysplasia who on 10-JUN-2008 was vaccinated with the first dose of GARDASIL (Lot # 658556/1060U). On 12-AUG-2008 was vaccinated with the second dose of GARDASIL, (Lot # 660612/0229X), 0.5 mL, IM. The medical assistant reported that the patient experienced diarrhea after receiving the second dose of GARDASIL. The diarrhea began shortly after she received the second dose and has persisted. The numbness persisted. The patient sought medical attention, called the physician. Additional information has been requested. 11/21/08 Reviewed GYN medical records of 6/10-9/10/2008. FINAL DX: right arm myalgia from 2nd Gardasil shot Records reveal patient received HPV#1 on 6/10/08, lot # 1060U. Experienced drowsiness & mild nausea which resolved. RTC 8/12/08 for HPV #2, lot# 0229X, RA. Had immediate numbness of right forearm & fingertips. RTC 8/28 w/continued numbness & decreased right hand grip strength. Referred to neuro. RTC 9/10 w/same complaints. Had not seen neuro yet. No other records available.

Other Meds: Unknown

Lab Data: Unknown

History: Cervical dysplasia PMH: 1 miscarriage, smoker, contraception. PAP smear abnormal, colposcopy revealed mild cervical dysplasia. Allergy: PCN, amoxcillin.

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327459-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jan-2007	Unknown		17-Sep-2008	29-Dec-2008	--	WAES0808USA05387	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Familial risk factor, Injection site discolouration

Symptom Text: Information has been received from a nurse practitioner concerning a female teenager who in 2007 was vaccinated with the first dose of GARDASIL and an unspecified dates was vaccinated with the second and the third dose of GARDASIL. Following the second dose of GARDASIL the patient developed a small lighter skin discoloration at the injection site. The patient sought medical attention, office visit. At the time of the reporting, the patient was recovering. The reporter also indicated the patient's twin sister had the same symptoms after receiving the second dose of GARDASIL. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: injection site~HPV (Gardasil)~UN~0~In Sibling

Vaers Id: **327460-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	29-Dec-2008	OH	WAES0808USA05401	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity

Symptom Text: Information has been received from a medical assistant concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (route and administration site not reported) at another office. Subsequently the patient experienced an allergic reaction after receiving GARDASIL. Subsequently, the patient recovered from the allergic reaction. The patient sought medical attention by seeing a physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327461-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Jun-2008	05-Jun-2008	0	17-Sep-2008	29-Dec-2008	CA	WAES0808USA05402	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bronchitis, Chest discomfort, Condition aggravated, Dyspnoea, Epstein-Barr virus infection, Fatigue

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 31-MAR-2008 was vaccinated with a first dose of GARDASIL (route and administration site not reported). The patient was healthy prior to her second dose of GARDASIL. On 05-JUN-2008 the patient was vaccinated with a second dose of GARDASIL (route and administration site not reported). On 05-JUN-2008 the patient experienced severe fatigue, shortness of breath and chest discomfort. She was seen in urgent care sometime between June 5th and 9th. She was treated with an inhaler. On 09-JUN-2008 she followed-up with her physician. Her chest X-ray showed bronchitis. She was prescribed MEDROL DOSEPAK and albuterol as needed. The patient was referred to a pulmonologist and an allergist. She saw the allergist on 11-JUN-2008, the allergist agreed that the patient had bronchitis. He treated her with Z-PAK and albuterol, then added CLARINEX, "Cymbicort" and prednisone (manufacturer unknown) 40 mg. The patient was followed-up on 17-JUN-2008 with her primary care physician and she diagnosed her with dyspnea. Another follow up visit was made on 05-AUG-2008, her shortness of breath was resolved, but she still complained of severe fatigue. Her blood work showed reactivation of Epstein-Barr Virus. A follow up visit was made on 25-AUG-2008 she still complained of chronic fatigue. Additional information has been requested.

Other Meds: Unknown

Lab Data: chest X-ray, 06/09/08, bronchitis; diagnostic laboratory, 08/05/08, epstein bar virus;

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327462-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		17-Sep-2008	29-Dec-2008	--	WAES0808USA05409	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female who on an unspecified date was vaccinated with a dose of GARDASIL 0.5 ml IM. 30 to 40 minutes after the vaccination, the patient passed out and vomited in her car. Subsequently, the patient recovered from passing out and vomiting. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327463-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	25-Jul-2008	25-Jul-2008	0	17-Sep-2008	29-Dec-2008	SC	WAES0808USA05491	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inflammation, Injected limb mobility decreased, Pain in extremity

Symptom Text: Information has been received from a registered nurse concerning a 22 year old female who on 25-JUL-2008 was vaccinated with a first dose of GARDASIL 0.5 ml IM in her left arm. Other suspect therapy included a dose of RECOMBIVAX HB (MSD) which was received 2 weeks before 25-JUL-2008. On 25-JUL-2008 the patient developed soreness in the arm which was progressively worse. The patient developed difficulty raising the arm above the head. The patient was treated with the primary care physician. The physician ordered a MRI of the arm that indicated inflammation and the patient was prescribed prednisone. The patient's arm inflammation persisted. There were no other symptoms or treatment reported. The patient sought medical attention in the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance, arm inflammation;

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **327464-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Jun-2008	01-Jun-2008	0	17-Sep-2008	30-Dec-2008	VA	WAES0809USA00010	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Gallbladder disorder

Symptom Text: Information has been received for the Pregnancy Registry for HPV vaccine from a nurse concerning a 19 year old female patient who in June 2008, was vaccinated with the first dose of GARDASIL. Concomitant therapy included ADDERALL and PROZAC. The patient was pregnant when she was given the first dose of HPV vaccine in June 2008. Currently in approximately August 2008, the patient was having gall bladder problems, but no other symptoms reported. The patient's LMP was 02-FEB-2008 and EDD 08-NOV-2008. The patient sought medical attention. No further information is available.

Other Meds: PROZAC

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 2/2/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327465-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Aug-2008	Unknown		17-Sep-2008	29-Dec-2008	PA	WAES0809USA00024	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a registered nurse concerning a 12 year old female who in approximately August 2008, also reported as last couple of weeks, was vaccinated with a first dose of GARDASIL (lot number, injection site and route not reported). Subsequently the patient had a delayed menstrual. The menstrual period was delayed by seven days. Unspecified medical attention was sought. Subsequently, the patient recovered from the event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327466-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Aug-2008	14-Aug-2008	2	17-Sep-2008	29-Dec-2008	--	WAES0809USA00040	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Stomach discomfort

Symptom Text: Information has been received from patient's mother who reported that her 17 year old daughter on 12-AUG-2008 was vaccinated with GARDASIL. There was no concomitant medication. On 14-AUG-2008, two days after her daughter was vaccinated she began to have an upset stomach which has been ongoing up until now. The patient's mother said that the stomach discomfort has been occurring approximately 15 minutes after she eats or drinks something. At the time of the report, the patient had not recovered from her upset stomach. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 327467-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Jun-2008	17-Jun-2008	0	17-Sep-2008	29-Dec-2008	MA	WAES0809USA00049	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site haematoma, Pain in extremity

Symptom Text: Information has been received from the patient's mother who reported that her 13 year old daughter with a history of idiopathic thrombocytopenic purpura when she was very young and has not had any problems since; on 17-JUN-2008 or 18-JUN-2008 was vaccinated with her first dose of GARDASIL. There was no concomitant medication. The daughter's arm was painful and developed a bruise following vaccination. The daughter's arm started to hurt 20 minutes after vaccination with GARDASIL and then developed a bruise at the injection site. The daughter had trouble raising her arm for about one week after the vaccination. Subsequently, on 25-JUN-2008 the patient recovered from arm was painful, bruise at injection site and trouble raising her arm. No other information reported. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Idiopathic thrombocytopenic purpura

Prex Illness:

Prex Vax Illns:

Vaers Id: **327472-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	08-Jan-2008	08-Jan-2008	0	08-Oct-2008	09-Oct-2008	AZ	WAES0802USA00493	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Premature labour

Symptom Text: Information has been received from a licensed practical nurse concerning a 20 year old female, with asthma and an allergy to shellfish and iodine, who on approximately 08-JAN-2008 was vaccinated with her first dose of GARDASIL. There was no concomitant medication. The patient was 4 weeks and 3 days pregnant when vaccinated. The patient sought medical attention. As of 01-FEB-2008, the patient was 7 weeks 6 days gestation. In follow-up, the nurse reported that the patient delivered a preterm, where the baby had some sort of "loss of amniotic fluid" and that had needed surgery. Subsequently, the patient whose estimated delivery date was 15-SEP-2008, delivered a vaginally on 06-AUG-2008 at 34 week estimated gestational age. The nurse reported that the patient was last seen in the office at her 32 week prenatal visit on 23-JUL-2008. The nurse was able to access the patient's chart information. On 05-AUG-2008, the patient had called the practice to report a significant decrease in fetal movement. She was sent to the hospital for a non-stress test (NST) and a biophysical profile (BPP) by ultrasound. The result of the BPP were that the patient scored only a 4 out of 8 and had amniotic fluid index (AFI) of 3.6, which is the diagnostic for oligohydramnios, and subsequently needed to be induced. She did not specify the results of the NST. It was also noted on the ultrasound at that time that the baby had a distended bladder with bilateral hydronephrosis and had an obstructed bladder outlet. And would require surgery after delivery. The patient was then sent to a major medical center where she delivered on 06-AUG-2008 and the baby had subsequent surgery (exact date of surgery not specified). According to the nurse, the mother was seen last week (week of 23-SEP-2008) and she was doing quite well at her postpartum visit and the baby was doing well and was at home with her. The nurse reported that she would offer the patient the informed consent sheet at her next visit. Upon internal review, premature baby, distended bladder, o

Other Meds: None

Lab Data: fetal nonstress test, 08/??/08; ultrasound, 08/??/08, biophysical profile (BPP) - scored only a 4 out of 8; amniotic fluid analysis, 08/??/08, index of 3.6, diagnosis for oligohydramnios

History:

Prex Illness: Pregnancy NOS (LMP = 12/8/2007); Asthma; Shellfish allergy; Iodine allergy

Prex Vax Illns:

Vaers Id: **327474-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		08-Oct-2008	09-Oct-2008	AZ	WAES0809USA04969	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Amniorrhoea, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician from the Pregnancy Registry for GARDASIL concerning a female who was vaccinated with GARDASIL. The patient became pregnant and went into labor. On an unknown date, the patient experienced loss of amniotic fluid and had to undergo surgery. No information is available on the outcome of both, mother and child. Loss of amniotic fluid was considered to be immediately life-threatening. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **327476-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	06-Oct-2007	26-Nov-2007	51	08-Oct-2008	20-Oct-2008	OH		23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1036U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal pain, Pain in extremity, Vaccine positive rechallenge

Symptom Text: 10/06/2007 2nd HPV; 11/26/2007-Left leg pain- no injury; 01/09/2008-shoulder pain; 01/30/2008 Ortho referral; 02/09/2008-3rd HPV vaccination; 04/11/2008 and 04/12/2008 -shoulder pain. She has had MRI of shoulder pain. Normal injection and physical therapy.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **327478-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Sep-2008	25-Sep-2008	0	08-Oct-2008	09-Oct-2008	CA	WAES0810USA00270	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0575X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction, Injection site pain, Loss of consciousness, Syncope vasovagal

Symptom Text: Information has been received from a physician concerning a 15 year old female with a history of fainting twice in the past who on 25-SEP-2008 was vaccinated with the first dose of GARDASIL (LOT# 661530/0575X). The patient also received MENACTRA at the same visit. The patient said that the injection was painful. She went into a seizure immediately after the injection and passed out for about 30 seconds. The physician pulled her hair back and she came to. The physician thought that this was a vasovagal reaction. Subsequently, the patient recovered from the events in the same day. An electrocardiogram was scheduled for the patient as follow-up. The patient sought medical attention. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Syncope

Prex Illness:

Prex Vax Illns:

Vaers Id: **327480-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		08-Oct-2008	09-Oct-2008	--	WAES0810USA00463	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dyspnoea, Immediate post-injection reaction, Syncope vasovagal

Symptom Text: Information has been received from a nurse practitioner concerning a female with extremely anxiety about receiving vaccine who was administered her first dose of GARDASIL, 0.5 ml, IM. The patient experienced severe vasovagal reaction, seizure like activity and difficulty in breathing within seconds of administration. The patient was given oxygen and transported to the hospital via ambulance. It was unknown if the patient was hospitalized. On an unspecified date, the patient recovered from all symptoms. Severe vasovagal reaction, seizure-like activity and difficulty breathing were considered to be other important medical events because oxygen was given. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Anxiety

Prex Vax Illns:

Vaers Id: **327482-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	21-Feb-2008	01-Aug-2008	162	08-Oct-2008	09-Oct-2008	NC	WAES0810USA00483	12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a 13 year old female who in February 2008, was vaccinated with the third dose of GARDASIL, 0.5 milliliter intramuscular. In "August 2008", the patient developed a seizure. The patient sought medical attention, she contacted the doctor. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested. 11/11/08-records received-seen in office 8/20/08-after ER visit for seizure.Assessment questionalbe seizures.Gardasil #3 given on 2/21/08. UA showed blood at time of sports physical, also trying to loose weight.

Other Meds: Unknown

Lab Data: Unknown 11/11/08-records received-UA showed blood at time of sports physical, CT scan of head negative. EEG shows slowing over right cerebral hemisphere.

History: Unknown 11/11/08-records received- PMH: febrile seizure at 3 years of age.

Prex Illness:

Prex Vax Illns:

Vaers Id: **327484-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	02-Oct-2008	02-Oct-2008	0	08-Oct-2008	09-Oct-2008	AZ	WAES0810USA00494	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Gaze palsy, Immediate post-injection reaction, Tremor, Unresponsive to stimuli

Symptom Text: Information has been received from a registered nurse concerning a 12 year old female with no pertinent medical history and no drug reactions/allergies who on 02-OCT-2008 was vaccinated with the first dose of GARDASIL (Lot# reported as 660557/0072X), 0.5 milliliter intramuscular in left deltoid. Concomitant therapy included DTaP, varicella virus vaccine (MSD), hepatitis A vaccine (inactive) and MENACTRA, all these vaccines were received at the same office visit as GARDASIL. The patient developed a seizure within 3 minutes of receiving the first dose of GARDASIL on 02-OCT-2008. The seizure was described as follows: "The patient's limbs shook, the eyes rolled back, and the patient was unresponsive for about one minute". Subsequently the patient recovered from the seizure. The patient sought medical attention at physician's office. No other symptoms or treatment was reported. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **327490-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-May-2008	01-Jun-2008	31	08-Oct-2008	09-Oct-2008	FR	WAES0810USA00329	09-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Balance disorder, Encephalitis viral, Epstein-Barr virus infection, Pyrexia

Symptom Text: Information has been received from a health authority (reference no. PA20080269 and PA0800294) concerning a 20-year-old female patient with no known infections medical history who received an injection of GARDASIL in May-2008. 2 weeks later on 01-Jun-2008 the patient experienced viral encephalitis. On 06-Jun-2008 she was hospitalized for physical and equilibrium troubles in a febrile context. Diagnosis was Epstein Barr virus viral encephalitis. There was a progressive amelioration until regression of troubles in 2 months. The patient had recovered without any sequelae. Other business partner numbers included: E2008-09118. No additional information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327492-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	05-Aug-2008	06-Aug-2008	1	08-Oct-2008	02-Jan-2009	GA	GA08070	11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2564AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52D021AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB289BA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Pain, Pain in extremity, Pyrexia

Symptom Text: 8/11/08 patient states she has had a fever 20 minutes after she received vaccines and still has fever today. 8/11/08 states she has headache and pain in arm and feels achy. State Tylenol and Motrin do not control fever reported to MD. Saw doctor 8/11/08. 8/27/08 mom said child recovered.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327497-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Sep-2008	15-Sep-2008	0	08-Oct-2008	07-Dec-2008	GA	GA08076	09-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3027AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2686AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	051OY	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1061U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Pallor

Symptom Text: Feel dizzy after vaccines administered stood up started walking and fell to floor

Other Meds:

Lab Data: BP Resp. Pale due to hitting head

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327501-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	08-Oct-2008	08-Oct-2008	0	08-Oct-2008	20-Oct-2008	OH		20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1263U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Nausea

Symptom Text: After vaccinated Pt immediately got dizzy and felt like vomiting. Pt stayed 20-30 min and then was able to leave.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **327509-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	29-Dec-2008	--	WAES0809USA00052	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning 4 female patients who on an unspecified date were vaccinated with GARDASIL. It was reported that all 4 patients fainted within the 15 minute period following vaccination. No specifics known about the patients. At the time of reporting, the patients had recovered. The patients sought medical attention in the office. Attempts are being made to obtain additional identifying information to distinguish the individual patients. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327510-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	29-Dec-2008	ND	WAES0809USA00058	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia oral, Limb discomfort, Posture abnormal, Skin discolouration, Syncope

Symptom Text: Information has been received from a registered nurse concerning a female patient who on an unspecified date, was vaccinated with a dose of GARDASIL. The nurse reported that the patient had a fainting episode after receiving GARDASIL. Soon after the vaccination, the patient complained that her arm felt "funny" and lips became numb. Her skin color turned "dusky" and her hand became "postured". The patient was then lowered to the floor. She was sent to an emergency room and determined that she did have a fainting episode. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327511-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Jun-2008	15-Jul-2008	22	17-Sep-2008	29-Dec-2008	NJ	WAES0809USA00059	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with obesity who on 23-JUN-2008, was vaccinated with the first dose of GARDASIL (lot # 660389/1968U), 0.5 ml intramuscularly. There was no concomitant medication. The physician reported that on 15-JUL-2008, the patient developed widespread urticaria. The patient was treated with a course of prednisone and completely recovered. On 21-AUG-2008, the patient was administered the second dose of GARDASIL (lot # 660612/0229X), 0.5 ml intramuscularly, and on 26-AUG-2008, she developed urticaria of the upper chest and upper extremities. On 29-AUG-2008, the patient was prescribed a MEDROL dose pack. At the time of the report, the patient had not recovered. The patient sought medical attention at the physician's office. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Obesity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327512-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Sep-2008	29-Dec-2008	AZ	WAES0809USA00061	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	660612/0229X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a first dose of HPV rL1 6 11 16 18 VPL vaccine (yeast) (lot number 660612/0229X) (injection site and route not reported). Shortly after being vaccinated, the patient passed out in the waiting room. Unspecified medical attention was sought. The physician reported that the patient recovered in a short while and went home. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327513-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		17-Sep-2008	29-Dec-2008	WI	WAES0809USA00064	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a medical assistant concerning her 17 year old daughter who on an unspecified date was vaccinated with the first dose of HPV rL1 6 11 18 VLP vaccine (yeast). In November 2007 the patient was vaccinated with the second dose of HPV rL1 6 11 16 18 VLP vaccine (yeast). The patient experienced fever and flu like symptoms after both of the doses were given. The third dose has not yet given to the patient. Subsequently, the patient recovered from fever and flu like symptoms.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 327514-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		17-Sep-2008	29-Dec-2008	--	WAES0809USA00396	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy, Vaccination complication

Symptom Text: It was reported in a published article, titled as above. A 26 year old woman came to a family practice clinic to receive the first of three doses of GARDASIL. She returned 5 days later with swollen lymph nodes in the left side of her neck. The patient noticed enlarging lymph nodes 3 days after receiving the GARDASIL, which had been injected intramuscularly into her left deltoid muscle. At this visit and all sequent clinic visits, the patient denied any recent upper respiratory infection, pharyngitis, cough, fever, or left upper extremity skin infections or rashes. She also denied any significant medical or surgical history. Her drug therapy only consisted of a daily oral contraceptive, and she denied recent antibiotic and nonsteroidal antiinfammatory treatment. She had received no other immunizations recently and reported no previous vaccine-related lymphadenopathy. The patient also denied any drug or seasonal allergies, asthma, or eczema. Physical examination revealed normal vital signs and several palpable anterior cervical and supraclavicular subcentimeter lymph nodes on the left side of the patient's neck. These were soft and fully mobile, without matting. The remainder of her physical examination was normal with no other regional lymphadenopathy. Due to the patient's lack of systemic symptoms, laboratory evaluation, pharmacologic therapy, and lymph node biopsy were not indicated. The patient remained afebrile and exhibited no signs or symptoms of systemic infection over the next several days. She was reevaluated at the family practice office 17 days after her initial vaccination. The lymphadenopathy had completely resolved. The patient received her second dose of GARDASIL 2 months after the initial immunization and experienced no associated lymphadenopathy. This patient's lymphadenopathy was spatially and temporally related to administration of GARDASIL, given that it developed in the left side of her neck, ipsilateral to the vaccination site, within 3 days of immunization. Her history and

Other Meds: Hormonal contraceptives

Lab Data: Unknown

History:

Prex Illness: Contraception

Prex Vax Illns:

Vaers Id: **327515-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Sep-2008	29-Dec-2008	GA	WAES0809USA00629	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Medical device complication

Symptom Text: Information has been received from an office manager who reported that the GARDASIL vaccine (Lot #655604/0052X) leaked out of the syringe onto the nurse's pants before it can be given to a patient. No adverse effect reported. SR number 1-3094846504. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327516-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	11-Jun-2008	Unknown		17-Sep-2008	29-Dec-2008	--	WAES0809USA00694	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Presyncope

Symptom Text: Information has been received from a nurse concerning a female patient who on 11-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine, Lot #659657/1487U. It was reported that the patient was lightheaded, but she did not actually faint. The patient received the second dose of GARDASIL and was fine. The patient sought medical attention in office. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327528-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Sep-2008	18-Sep-2008	0	08-Oct-2008	15-Oct-2008	PR		16-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	19786		Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2562AA		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyskinesia, Pallor

Symptom Text: Involuntary movements, dizziness and pale. Symptoms lasted for 5 minutes.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **327529-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Oct-2008	01-Oct-2008	0	08-Oct-2008	15-Oct-2008	PR	PR 08 10	16-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyskinesia, Immediate post-injection reaction, Loss of consciousness, Pallor

Symptom Text: When the vaccine was administered the patient became pale, dizzy with loss of consciousness and involuntary movements.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **327540-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	07-Oct-2008	07-Oct-2008	0	08-Oct-2008	17-Oct-2008	MD		17-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEP	MERCK & CO. INC.	AHBVB647BA	2	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1447F	0	Left arm	Intramuscular	
IPV	SANOFI PASTEUR	A-0491-4	3	Right arm	Subcutaneously	
VARCEL	MERCK & CO. INC.	1002X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis

Symptom Text: Pt became diaphoretic within 5 minutes of receiving vaccinations.

Other Meds: None

Lab Data: BP-72/54 immediateley after becoming symptomatic.BP 80/58 after 5 minutes,diaphoresis subsided. Pt. never lost consciousness

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **327550-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	Unknown	Unknown		08-Oct-2008	17-Oct-2008	IL		17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2889AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0573X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: SYNCOPE APPROXIMATELY 1-2 MINUTES AFTER INJECTION. NO TREATMENT NECESSARY

Other Meds: YASMIN

Lab Data: BLOOD SUGAR 112

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **327553-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Oct-2008	05-Oct-2008	0	08-Oct-2008	17-Oct-2008	CA		17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	88636	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0572X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: SYNCOPE WITH BRIEF 5 SEC. SEIZURE

Other Meds:

Lab Data: PULSE OX 99% EKG NORMAL

History: NO

Prex Illness: NO

Prex Vax Illns:

Vaers Id: **327557-1 (S)** **Related reports:** 327557-2; 327557-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Mar-2008	27-Mar-2008	2	08-Oct-2008	14-Oct-2008	NM		27-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Back pain, Conversion disorder, Convulsion, Cyanosis, Emotional disorder, Eye disorder, Fatigue, Grand mal convulsion, Headache, Injury, Kidney infection, Pain, Respiratory arrest, Urinary tract infection

Symptom Text: Within a day or two after the first shot on 03/25/08 she developed severe back pain. On 04/27/08 she had a seizure and went to the ER. She had the second shot on 05/06/08 and had another seizure. She had two more seizures between then and 06/20/08 when she had three seizures at work and was admitted to the hospital. She had daily seizures throughout the summer, was diagnosed with epilepsy and put on anti-seizure meds. After a cluster of 4 seizures when she turned blue and stopped breathing she was admitted to the hospital and a Video EEG done. Epilepsy was ruled out and psuedoseizures diagnosed and meds stopped. She continued to have seizures and saw a psychiatrist as suggested. The psychiatrist said the seizures were not psychological and were medical. Put back on anti-seizure meds until she became toxic from the meds and was admitted to the hospital through the ER where she was given charcoal. After discharge she began to start feeling better and has been seizure free now for 30 days. Also from March until now she suffered from severe stomach aches, eye problems, headaches, one kidney infection and one urinary infection (never had any in her life before this), severe fatigue (this is a very hyper kid)and body aches. She is not currently on seizure meds and is slowly gaining her strength and getting back to her independent life as before the shot. She lost the ability to drive, to be left alone, was injured repeatedly from the drop seizures, lost her job and her confidence with the way the medical community threw her back and forth between treatments and diagnosis and labeled her as emotionally disturbed. This was a very happy, Dean's list, independent college kid before this shot. Thankfully, she appears to be coming back to us but still has fatigue and stomach issues which we are treating with diet and vitamins. 10/27/08-records received for DOS 6/20-6/21/08-DC DX: Generalized tonic clonic seizures. First seizure 4/26/08 a partial seizure and two additional ones. Did not begin her anti-seizure medication unt

Other Meds: None

Lab Data: EEG, MRI, blood work, Cat Scan 10/28/08-records received-MRI normal.

History: Allergies: penicillin, sulfa, percocet, milk; Asthma 10/27/08-records received-PMH: two concussions. Motor vehicle accident with head injury and broken nose. Mononucleosis, asthma, cervical dysplasia. Four knee surgeries, 3 ACL and one meniscus surgery.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **327557-2 (S)** **Related reports:** 327557-1; 327557-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Mar-2008	27-Mar-2008	2	26-Jan-2009	02-Feb-2009	NM		02-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Back pain, Blood test normal, Convulsion, Electroencephalogram normal, Fatigue, Headache, Pain, Smear cervix abnormal, Urinary tract infection, Visual impairment

Symptom Text: My daughter received her first GARDASIL vaccine in March 2008. Within 24 hours she began experiencing a horrible backache that did not go away for a couple of weeks. she had her first seizure at the end of April. She received her second shot at the beginning of May. She had three more seizures and in June began having daily seizures. She also experienced severe stomach aches, headaches, vision problems, UTI's, body aches and extreme fatigue. She also had an abnormal pap after this vaccine. She was hospitalized multiple times and had to have paramedics come multiple times as well. Fortunately, we figured this out before the third shot or I'm not sure she would have survived. She was perfectly healthy, none of these symptoms prior to the GARDASIL. She is getting better now and the seizures are less frequent though she just had one on January 8, 2009. She is still experiencing stomach aches and body aches and fights the fatigue. I know GARDASIL Caused this. She was a very athletic, active, healthy girl before that vaccine and now she is not. I can't believe anyone is still endorsing giving this vaccine. It makes me furious, especially when I've discovered there have been nearly 15,000 adverse reactions to this vaccine. All EEGS, bloodwork, etc. have been normal and the Neurologist cannot explain the seizures and other health problems. In addition, the doctor that gave her this vaccine gave her no information and just told her she needed to have the vaccine.

Other Meds:

Lab Data: Multiple hospitalizations, June 20-21, July, August, 2008. Multiple ambulance calls, June 2008-August 2008.

History: Allergies: penicillin, sulfa, PERCOCET, milk products

Prex Illness:

Prex Vax Illns:

Vaers Id: **327557-3 (S)** **Related reports:** 327557-1; 327557-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Mar-2008	25-Mar-2008	0	06-Mar-2009	09-Mar-2009	--	WAES0902USA04390	09-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Alopecia, Back pain, Contusion, Convulsion, Dysplasia, Headache, Hypovitaminosis, Immediate post-injection reaction, Kidney infection, Urinary tract infection

Symptom Text: Information has been received from a consumer concerning her 19 year old daughter with penicillin and sulfa allergy who on 25-MAR-2008 was vaccinated with the first dose of GARDASIL. Immediately after getting the vaccine her daughter had a severe backache, severe headaches, a urinary tract infection, a kidney infection, seizures, hair loss and bruising. On 6-MAY-2008 the patient received the second dose of GARDASIL and then had seizures everyday. It was also reported that the patient tested positive for dysplasia after being vaccinated with the GARDASIL vaccine. The reporter stated her daughter almost died from the seizure. On an unspecified date the patient was hospitalized. A complete blood work was performed and everything was normal other than a vitamin deficiency. The patient did not receive the third dose of GARDASIL vaccine and she continues to get seizures about every six weeks. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory, vitamin deficiency

History:

Prex Illness: Penicillin allergy; Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **327570-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Oct-2008	06-Oct-2008	0	08-Oct-2008	20-Oct-2008	AR		20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	.5 ML	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	.5 ML	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Tingling in lower part of arm that shots were administered (upper arm, muscle). Often when arm was suddenly moved or the elbow was placed on a desk.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327672-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Sep-2008	03-Sep-2008	1	09-Oct-2008	23-Dec-2008	ID	ID08036	18-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Injection site anaesthesia, Injection site induration, Paraesthesia

Symptom Text: Numbness of left arm and leg; then felt left side radiating from injection site within 12 hours after injection. Numbness subsided except for a 1 inch area around injection site. 10/15/2008 office note received for DOS 9/3/2008. Pt presented with c/o numbness/tingling on L side of body including leg, arm and torso. Innjection site has the worst numness at visit, approx 1 in in diameter. PE (+) for mild induration. Assessment: Numbness..

Other Meds:

Lab Data:

History:

Prex Illness: 3-4 days of sore throat; cold symptoms

Prex Vax Illns:

Vaers Id: **327724-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Jul-2007	Unknown		09-Oct-2008	10-Oct-2008	TN	WAES0709USA01935	10-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Gestational diabetes

Symptom Text: Information has been received from a health professional concerning a 24 year old female with no medical history who in July 2007, was vaccinated with a second dose of GARDASIL. After the vaccination the patient found to be pregnant. Medical attention was sought. No product quality complaint was involved. On 06-MAR-2008, the patient delivered a normal, healthy male baby weighing 8 lb and 4.75 onz, length not reported, apgar score 8/9, head circumference not reported. No congenital anomalies. Complications during pregnancy included gestational diabetes. Complications during labor/delivery included labor stalled at 9cm and the patient subsequently underwent a Caesarian section. Upon internal review stalled at 9 cm was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Ultrasound; Diagnostic laboratory, prenatal; Urine beta-human

History:

Prex Illness: Pregnancy NOS (LMP = 6/3/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327725-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Jul-2008	23-Jul-2008	1	09-Oct-2008	10-Oct-2008	FR	WAES0808USA02080	10-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1208U	2	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Chest pain, Impaired work ability, Pyrexia

Symptom Text: Information has been received from a general practitioner concerning a 14 year old female who in January 2008, was vaccinated with the first dose of GARDASIL, on 13-MAR-2008 was vaccinated with the second dose of GARDASIL and on 22-JUN-2008 was vaccinated with the third dose of GARDASIL (batch number not reported). On an unspecified date the patient experienced dorsal pain and thoracic pain. At time of reporting the outcome was not specified. Follow-up information was received. Case initially reported as non serious was upgraded. It was specified that the patient received the third dose of GARDASIL (Lot No. 1208U; Batch No: NH13360) in the left arm via subcutaneous route on 22-JUL-2008 instead of 22-JUN-2008 as initially reported. On approximately 23-JUL-2008, twenty hours after vaccination, the patient experienced moderate fever for two days. Twenty four hours after vaccination and during 4 days, the patient also experienced severe and serious lumbar pain with disabling of both lower limbs leading to 4 days temporary interruption of work. Thoracic pain was no more reported. Corrective treatment with paracetamol and ibuprofen were given. Lumbar pain, thoracic pain and fever were considered to be an other important medical events. Other business partner numbers included: E2008-07180. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 327726-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	07-Jul-2008	07-Jul-2008	0	09-Oct-2008	10-Oct-2008	FR	WAES0809MEX00009	10-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Uterine dilation and curettage

Symptom Text: Information has been received from a physician concerning a female who in 2008 was vaccinated with GARDASIL. At the time of the report the patient has received two doses to GARDASIL. On 25-AUG-2008 the patient informed to the physician to be pregnant. HPV vaccine dose 3 was not administered. Pregnancy outcome is unknown. After several attempts no further details could be obtained. On 29-SEP-2008 additional and clarification information was received from the physician who confirmed that the patient is a 23 year old female with a history of 0 pregnancies and 0 live births who on 07-JUL-2008 was vaccinated with GARDASIL (only first dose of vaccine received). No concomitant therapy. Last menstrual period occurred on 04-JUL-2008. On 28-AUG-2008 pregnancy was confirmed through agency that reported pregnancy with 6 weeks live embryo. On 18-SEP-2008 the patient experienced abortion spontaneous and was hospitalized to perform curettage. The patient was discharged on 19-SEP-2008 recovered and without complications. The physician stated that he could not define if abortion spontaneous was related or no with GARDASIL. Additional information is not expected.

Other Meds: None

Lab Data: ultrasound, 28Aug08, 6 weeks pregnancy, live embryo

History:

Prex Illness: Pregnancy NOS (LMP = 04Jul08)

Prex Vax Illns:

Vaers Id: **327727-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	19-Sep-2008	28-Sep-2008	9	09-Oct-2008	10-Oct-2008	FR	WAES0810USA00332	10-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diplegia

Symptom Text: Information was received from a general practitioner on 01-Oct-2008. A 19-year-old female patient received the third dose of GARDASIL (lot # not reported) on 19-Sep-2008. It was reported the patient had no reaction after her previous vaccinations. On 28-Sep-2008 the patient experienced a facial diplegia. She consulted her general practitioner on 29-Sep-2008 who prescribed a medical consultation with a neurologist. No diagnosis was established. A brain MRI was scheduled on 06-Oct-2008. At time of reporting the patient had not recovered. At the time of adverse event onset, the patient had an aphtha treated with ROVAMYCINE and BOROSTYROL. The general practitioner considered the diplegia to be an other important medical event. Other business partner numbers included E200809105. Additional information has been requested.

Other Meds: BOROSTYROL, Unk - Unk; ROVAMYCIN, Unk - Unk

Lab Data: magnetic resonance imaging, 06Oct08

History:

Prex Illness: Aphthous ulcer

Prex Vax Illns:

Vaers Id: **327728-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		09-Oct-2008	10-Oct-2008	--	WAES0810USA00475	10-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Myoclonic epilepsy

Symptom Text: Information has been received from a healthcare worker concerning a female relative of hers who has been experiencing seizures since she received a dose of GARDASIL (therapy started date, dose, route, site unknown) and has been diagnosed with Juvenile myoclonic epilepsy (JME). The patient's medical history and drug reactions/allergies were unspecified by the reporter. The patient has been evaluated by an unspecified obstetrician/gynecologist and a neurologist. The patient has not recovered. No other information is available at this time. Upon internal review, juvenile myoclonic epilepsy was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **327870-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.8	F	08-Oct-2008	09-Oct-2000	-2921	09-Oct-2008	20-Oct-2008	GA		20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise, Pharyngolaryngeal pain, Pyrexia

Symptom Text: Patient called this am and stated that since she had her injection yesterday, has a sore throat, fever and doesn't feel well.

Other Meds: allegra

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **327897-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		09-Oct-2008	10-Oct-2008	FR	A0750346A	10-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Dizziness, Fatigue, Hypoaesthesia, Influenza like illness, Lymphadenopathy, Malaise, Migraine, Nausea, Paraesthesia, Paralysis, Rash, Syncope, Tinnitus, Vomiting

Symptom Text: This case was reported by a manufacturer via regulatory authority and described the occurrence of paralysis in a 14-year-old female subject who was vaccinated with TWINRIX (GlaxoSmithKline) and GARDASIL (Merck). On an unspecified date the subject received unspecified dose of TWINRIX (unknown), GARDASIL (unknown). At an unspecified time after vaccination with TWINRIX and GARDASIL, the subject experienced paralysis, syncope, dizziness, rigors, paresthesia, hypoesthesia, fatigue, tinnitus and migraine. Three days after vaccination with TWINRIX and GARDASIL, the subject experienced rash. Four days after vaccination with TWINRIX and GARDASIL, the subject experienced lymphadenopathy. Five days after vaccination with TWINRIX and GARDASIL, the subject experienced influenza like symptoms. Nine days after vaccination with TWINRIX and GARDASIL, the subject experienced malaise, nausea and vomiting. This case was assessed as medically serious by GSK. At the time of reporting the outcome of the events were unspecified.

Other Meds:

Lab Data: UNK

History:

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **327925-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-Sep-2008	19-Sep-2008	0	09-Oct-2008	30-Dec-2008	MA		20-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0535X	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2666AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Chest pain, Dizziness, Dysphagia, Oropharyngeal pain, Pallor, Tinnitus

Symptom Text: Immediately after receiving vaccines, c/o generalized weakness, color pale, ringing in ear. Child did not lose consciousness, vital signs remained stable; monitored, left office without further concerns. Child returned to office 9/23/08 with c/o chest pain, sore throat, slight dizziness, difficulty swallowing - Evaluated by physician again on 9/29/08, all symptoms resolved.

Other Meds: None

Lab Data: None noted

History: Allergies to cats, do, nasonex nasal spray

Prex Illness: None noted

Prex Vax Illns:

Vaers Id: **327986-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	12-Sep-2008	13-Sep-2008	1	10-Oct-2008	30-Dec-2008	MI		31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	127U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Retching, Vomiting

Symptom Text: Following day, patient reported vomiting w/o fever, nausea or any other symptom. Vomiting was accompanied by a constant "gagging" feeling. Only lasted one day.

Other Meds: YAZ birth control

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: Vomiting~HPV (Gardasil)~2~21~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **327998-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Oct-2008	03-Oct-2008	0	10-Oct-2008	31-Dec-2008	MA		31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2768AA	5	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0319X	0	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Syncope

Symptom Text: Within 1 minute of receiving GARDASIL (last of 4 vaccines given) pts eyes fluttered & she had syncopal episode for a few seconds with several jerks of lower legs concurrent with syncope. Recovered from that in several seconds. No change with pulse, BP or O2 sat throughout

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328018-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Apr-2008	08-Jul-2008	85	10-Oct-2008	13-Oct-2008	FR	WAES0810USA00689	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthritis reactive, Inflammation, Proteinuria, Pyrexia, Rash, Serum sickness

Symptom Text: Information has been received from health authorities, as a part of a business agreement with Sanofi Pasteur MSD (manufacturer report # E200809087, lot # not report), concerning a 16 year old, height 168 centimeter, weight 62 kilogram female who on 14-APR-2008 was vaccinated with the first dose of GARDASIL. On 15-JUN-2008 the patient was vaccinated with the second dose of GARDASIL. On 08-JUL-2008 the patient was hospitalized to be taken in charge for a serum sickness appeared with reactional arthritis, proteinuria, syndrome febrile, inflammatory syndrome and cutaneous rash which needed a systemic corticotherapy. Evolution was favourable in 1 month. At the time of reporting the patient had not fully recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328019-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-Aug-2008	21-Aug-2008	1	10-Oct-2008	13-Oct-2008	FR	WAES0810USA00688	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Bedridden, Computerised tomogram normal, Headache, Laboratory test normal, Nausea, Neurological examination normal, Ocular discomfort, Ophthalmological examination normal, X-ray normal

Symptom Text: Information has been received from a Health Authority (reference numbers NT20080417 and NT0800400) concerning a 15 year old female with no relevant medical history reported who on 20-AUG-2008 was vaccinated IM with her third dose of GARDASIL. On 21-AUG-2008 the patient presented with severe cephalgia, nausea, asthenia and visual discomfort (to read or watch TV). She was confined to bed. She had no fever, no vomiting and no notion of trauma. She was transferred to hospital to perform a work-up on 28-AUG-2008. There was no meningeal syndrome therefore no lumbar puncture. Ophthalmology, stomatological and neurological tests were normal. Pain was not qualified as migraine. Biological tests were without any particularity, radiography of sinus was normal, CT scan with and without injection were normal. The patient was treated with level 2 analgesics and IV NSAID'S and then per os. Evolution was favorable after symptomatic treatment and the patient was discharged on 31-AUG-2008. The patient had recovered without any sequelae. The case is closed. Other business partner numbers included E2008-09155.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328020-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	17-Jun-2008	01-Aug-2008	45	10-Oct-2008	13-Oct-2008	FR	WAES0810USA00330	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1208U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Autoimmune thrombocytopenia, Contusion, Ecchymosis, Menorrhagia

Symptom Text: Information has been received from a health authority (reference numbers NT20080403 and NT0800407), concerning a 19 year old female patient with no relevant medical history reported who on 15-JAN-2008 was vaccinated with the first dose of GARDASIL (Batch #NS37380) IM, on 14-MAR-2008 with the second dose of GARDASIL (Lot #1201U and Batch #NH0090) IM and on 17-JUN-2008 with the third dose of GARDASIL IM (Lot # 1208U and Batch #NH13370). On 05-SEP-2008, the patient had post traumatic ecchymoses on her lower limbs. The patient also mentioned the notion of spontaneous bruises since one month and the notion of menstrual flow very important (beginning of August 2008). A numeration was performed on 05-SEP-2008 revealed a severe thrombocytopenia (19G/L) isolated. After analysis of marrow the conclusion was thrombocytopenia of peripheral origin. On 06-SEP-2008, a treatment with corticosteroids was begun. A complete aetiologic work up was performed: hepatic, renal and ionic results were normal, viral serologies (hepatitis, cytomegalovirus, EBV) were negative or revealed past infections. Rheumatismal serologies were negative. Antiplatelets antibodies were highly positive (anti GPIIb/IIIa and GPIbIX). Diagnosis was auto immune thrombocytopenia of unknown origin. Evolution was favourable with 99 giga of corticotherapy from 10-SEP-2008. The patient had recovered without any sequelae. The patient had been hospitalized (unspecified dates). Other business partner numbers included: E2008-09133. No further information is available.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, complete aetiologic work up: hepatic, renal and ionic results were normal; Platelet count, 05Sep08, 19 g/l; Platelet count, 10Sep08, 99 g/l; Serum rheumatoid factor, negative; Clinical serology test, viral serolo

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 328021-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Sep-2007	12-Aug-2008	332	10-Oct-2008	13-Oct-2008	FR	WAES0810USA00281	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Autonomic nervous system imbalance, Blood pressure decreased, Dyspnoea, Eye rolling, Fatigue, Headache, Loss of consciousness, Malaise, Pyrexia, Similar reaction on previous exposure to drug, Sinusitis, Syncope vasovagal, Vaccination complication

Symptom Text: Information has been received from a consumer concerning her daughter a 14 year old patient who on 15-SEP-2007 was vaccinated with the first dose of GARDASIL (batch number not reported). One hour and a half later, the patient experienced headache, abdominal pain, feeling unwell, breathing difficult and loss of consciousness. Diagnosis of vagal malaise at the emergency unit (no hospitalisation). To note, it was during patient's menstrual period, and the patient was suffering from sinusitis on the morning of 15-SEP-2007. The same day, treatment with SOLUPRED was prescribed. On 12-AUG-2008, the patient was vaccinated with a second dose of GARDASIL (batch number not reported). 1 hour later the patient experienced headache, abdominal pain, blood pressure decreased at 10, fatigue, short losses of consciousness, eyes rolling and fever. She was hospitalized one night to be under medical surveillance. Evoked diagnosed was neurovegetative troubles related to injection of the vaccine. At time of reporting the outcome was not specified. It was not during her menstrual period and she had no concomitant treatment. Other business partner numbers included: E2008-09002. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 328022-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Feb-2008	Unknown		10-Oct-2008	13-Oct-2008	FR	WAES0810USA00114	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Erythema nodosum, Leukocytosis, Lymphadenopathy, Pyrexia

Symptom Text: Information has been received from an specialist concerning an 18 year old female who on 15-FEB-2008 was vaccinated with the first dose of GARDASIL (batch number not reported). A few days post vaccination, the patient was hospitalized for bilateral cervical adenopathies with fever, hyperleukocytosis and erythema nodosum. She recovered after a treatment with corticosteroids. By the end of September 2008, there was a new episode with similar symptoms. Infectious analysis were negative. No etiology was found. At time of reporting the patient had not recovered. Other business partner numbers included: E2008-09061. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, Infectious analysis were negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328023-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	18-Oct-2007	21-Jan-2008	95	10-Oct-2008	13-Oct-2008	NJ	WAES0712USA07879	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received through the Merck Pregnancy Registry through a physician concerning a female who was intramuscularly vaccinated with her first dose of GARDASIL and found out she was pregnant. No adverse events were reported. Follow up information was received from the physician who reported that the 24 year old female with a history of two previous pregnancies (1 spontaneous abortion and 1 elective termination) who on 18-OCT-2008 was vaccinated with a first dose of GARDASIL. On 21-JAN-2008 the patient underwent elective termination. Upon internal review, elective termination was determined to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 328024-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Jul-2007	27-Jul-2007	0	10-Oct-2008	13-Oct-2008	KS	WAES0708USA00940	13-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Pre-eclampsia, Premature baby

Symptom Text: Information has been received through the Merck pregnancy registry from a consumer concerning her 14 year old daughter with a sulfonamide allergy who on 27-JUL-2007 was vaccinated with the second dose of GARDASIL and then found out she was pregnant on 31-JUL-2007. There was no concomitant medication. As of 03-AUG-2007, the patient was approximately 13 weeks pregnant with an estimated delivery date of 07-FEB-2008. No medical attention was sought. Telephone follow-up information was received from a nurse who reported that the 14 year old patient did deliver her baby and that mom and baby were both doing well now. The mother experienced severe pre-eclampsia resulting in the baby being born early at 28 weeks "probably by c-section" weighing 836 grams in November 2007. The nurse indicated that the baby was on oxygen for some time while in the Neonatal Intensive Care Unit (NICU) post delivery and that the baby was normal with no congenital anomalies. This was the mother's first pregnancy. Upon internal review pre-eclampsia requiring baby to be born early at 28 weeks "probably by C-section" were determined to be an other important medical events. No further information is available.

Other Meds: None

Lab Data: Beta-human chorionic, 07/31/07, 13 weeks pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 5/3/2007); Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **328036-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-Jun-2008	Unknown		10-Oct-2008	13-Oct-2008	FR	WAES0810USA00327	03-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Idiopathic thrombocytopenic purpura, Incorrect route of drug administration

Symptom Text: Information has been received from a Health Authorities concerning an 18 year old female with no pertinent medical history and no concomitant drugs, who on 12-JUN-2008 was vaccinated with the first dose of GARDASIL (Lot # was not reported) via subcutaneous route (instead of intramuscular route). In JAN-2008 first symptoms (unspecified) appeared. In JUN-2008 an idiopathic thrombocytopenic purpura was put in relief. It was regressive with corticosteroids. The patient was hospitalized (unspecified dates). At the time of reporting, the patient had not recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328081-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Oct-2008	03-Oct-2008	0	10-Oct-2008	20-Oct-2008	IN		20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Injection site pain, Injection site swelling, Loss of consciousness, Menstruation irregular, Muscle spasms, Nausea, Pyrexia

Symptom Text: injection site swelling and pain; passed out within 20 minutes of injection. 1st 2 days fatigue diziness and nausea. days 3-5 severe cramps, fever, diziness, nausea. day 6 began period more than 1 week early and continued cramps, fatigue, nausea. This report is made on day 7 and early period, cramps, fatigue and fever continue. Events were reported to physcian via phone on 10/10/08.

Other Meds: Claritin as needed for seasonal allergies

Lab Data:

History: seasonal allergy to pollen

Prex Illness: none known

Prex Vax Illns: seisure~DTP (no brand name)~UN~4~In Sibling1

Vaers Id: **328082-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	03-Oct-2008	03-Oct-2008	0	10-Oct-2008	20-Oct-2008	IN		20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Headache, Injection site pain, Injection site swelling, Muscle spasms, Nausea, Pyrexia

Symptom Text: injection site swelling and pain; 1st 4 days fatigue and diziness. days 5-6 severe headache and cramps, fever, diziness, nausea. This report is made on day 7 and fatigue continues. Events were reported to physcian via phone on 10/10/08.

Other Meds: provintel as needed

Lab Data:

History: activity induced asthma

Prex Illness: none known

Prex Vax Illns: seizuer~DTP (no brand name)~UN~0~In Patient|cramping, fever, headache, vomitting, early period~HPV (Gardasil)~2~16~In Sibling1

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328085-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	30-Sep-2008	02-Oct-2008	2	10-Oct-2008	20-Oct-2008	WI		20-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN	MEDIMMUNE VACCINES, INC.	500559P	0	Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	0103X	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	42623AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema

Symptom Text: Redness in area of injection site where Varicella was given.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **328087-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	11-May-2007	15-Jun-2007	35	10-Oct-2008	20-Oct-2008	CA		19-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Erythema, Insomnia, Joint swelling, Musculoskeletal stiffness, Rheumatoid arthritis, Skin nodule, Tenosynovitis

Symptom Text: Three injections in HPV4 (Human papillomavirus, quadrivalent) series provided on 01/07/2008, 08/08/2007, 05/11/2007. Began to experience gradually increasing joint pain in June 2007, with nodule formation (on right wrist) by August 2007. Joint pain, swelling, redness increased until diagnosed with rheumatoid arthritis in September 2008. 12/22/08 Reviewed PCP clinic records. FINAL DX:Rheumatoid arthritis; right wrist tenosynovitis. Records reveal patient experienced right wrist pain since 2/07. PRogressed to include multiple joints w/AM stiffness, difficulty sleeping due to pain. Seen by PCP, PT & ortho. Failed conservative treatment. Referred to Rheum & seen 8/08 & second opinion 9/08. Tx w/steroids & antiarthritis meds. Responded well to steroids & continued arthritis meds w/intermittent use of steroids.

Other Meds: Yasmin, Midrin

Lab Data: LABS: RF 19.7(H). ESR 31(H) ANA neg. (+)anti-CCP. CRP 2.4. X-ray & MRI right wrist abnormal.

History: none PMH: obesity, seasonal allergy, asthma, migraines. Family hx: RA, scleroderma & unknown autoimmune diseases.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **328089-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-Dec-2007	12-Dec-2007	-15	11-Oct-2008	21-Oct-2008	TX		08-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0637F	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Cystitis, Fatigue, Gastrooesophageal reflux disease, Lymphadenopathy, Pharyngitis, Seasonal allergy, Sensorimotor disorder, Sinusitis, Thyroid function test abnormal, Tonsillar hypertrophy, Urinary tract infection, Vaginal disorder, Viral infection, Vulvovaginal candidiasis

Symptom Text: My daughter became very sick after the second shot. Her glands swelled up and also her tonsils. She experienced exhaustion and a number of vaginal, female problems. We spent a lot of money on the Dr. and tests to find out what was wrong. I took her to a specialist who said he thought she had mono, but all tests were negative. After the third shot her hair began to fall out. Another doctor visit and specialist visit. Apparently her thyroid (of which we have no history) was not functioning properly. Eventually her thyroid began to function, but she still suffers from various female problems and swollen glands and tonsil issues. We NEVER had these problems before. I want to sue this company for making my daughter SICK! 1/9/09 Reviewed PCP medical records of 1/31/08-12/12/08. FINAL DX: none provided Records reveal that on following office visits patient experienced: 1/31/08 - UTI, vaginal yeast infection, seasonal allergies, GERD 2/14/08- acute pharyngitis 7/11/08 - acute cystitis 7/30/08 - alopecia x several months, fatigue, focal motor & sensory deficits & resolved viral syndrome. 12/12/08 - acute sinusitis

Other Meds:

Lab Data: Strep Test, urinalysis, vaginal tests, thyroid test with a full blood panel, mono test... LABS:CT head WNL. Urine c/s (+). EBV test neg.

History: None HPV#2 given 4/11/08, RA, lot #0637F. No record of HPV#3 receipt.

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328098-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	06-Oct-2008	10-Oct-2008	4	12-Oct-2008	21-Oct-2008	TX		21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives all over body (head to toe) 4 days after 1st dose. Doctor prescribed (1)Diphenhydramine -25 mg and (2)Methylphednisolone - 4 mg. Also using OTC Aveeno Anti-Itch Concentrated Lotion.

Other Meds: flonase

Lab Data: none

History: unknown allergies

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328109-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Sep-2008	Unknown		10-Oct-2008	31-Dec-2008	MI		02-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0952X	1	Left arm	Subcutaneously	
MNQ	SANOFI PASTEUR	2688AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0667X	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB245AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pregnancy test positive

Symptom Text: Client had positive pregnancy test within one month of immunization.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 328256-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	19-Mar-2008	19-May-2008	61	13-Oct-2008	14-Oct-2008	OK	WAES0810USA00858	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	1	Unknown	Unknown	HPV4

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Amnesia, Aphasia, Arnold-Chiari malformation, Complicated migraine, Condition aggravated, Convulsion, Disorientation, Drooling, Fall, Gaze palsy, Hemiplegia, Migraine, Neurological examination abnormal, Posturing, Pregnancy test, Syncope, Unresponsive to stimuli

Symptom Text: Information has been received from a consumer concerning her daughter a 14 year old female with migraine who on 07-SEP-2007, 14-NOV-2008 and 19-MAR-2008 was administered her first, second and third doses with GARDASIL. Concomitant therapy included propranolol HCL. On 19-MAY-2008 the patient experienced seizure. On 20-MAY 2008 the patient "had another seizure in her sleep. Her eyes rolled back into her head", subsequently she was hospitalized for 5 days. On 23-AUG-2008 the patient came into the house "disoriented" after falling outside. Her mother suspected she had a seizure. The hospital did an X-ray which came out fine. Patient's right arm could not move, she did not remember the falling incident, and she was not herself at all. One of her eyes would go off to the side and her other eye to the other side, her mouth was twisted, her right side paralyzed, and she could not walk or talk or feel her right side. Even though her vision was checked and was 20/20, the patient's eyes still "kind of go off to the side when being talked to." Lab diagnostics studies performed included: MRI, MRA, EKG, EEG, X-ray, tests for drugs, heart problems diabetes, STD's, and pregnancy (results not reported). The patient will see a neurologist 09-OCT-2008. The patient present status was unknown. No more information reported. Upon internal review, right side paralysis was considered to be an other important event. Additional information has been requested. 12/2/08 Reviewed hospital medical records of 5/20-5/24/2008. FINAL DX: right-sided weakness; possible seizures Records reveal patient experienced episodes of weakness & unresponsiveness. Had been picked up from school w/migraine HA. Had posturing movements, was unresponsive, & collapsed in restaurant. Taken to ER & released. Next AM had recurrent symptoms. Taken to peds clinic & admitted. Neuro consult done. 11/18/08 Reviewed neuro medical records of 06/12/2008. FINAL DX: Spell, seizure vs complex migraines vs non-epileptic/functional; HA migraines vs stress vs function

Other Meds: propranolol hydrochloride

Lab Data: X-ray, "fine"; Ophthalmological exam, 20/20 LABS: video EEG abnormal. MRI revealed Chiari I. MRA WNL. CT scan of neck WNL.

History: PMH: migraine HAs s/p MVA x 3, last on 6/9/08 w/o injury but severe HA. Family hx: migraine HAs, seizures, CVA.

Prex Illness: Migraine

Prex Vax Illns:

Vaers Id: **328257-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		13-Oct-2008	14-Oct-2008	FR	WAES0810USA00500	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Disturbance in attention, Fatigue, Loss of consciousness, Malaise, Myoclonus, Syncope

Symptom Text: Information has been received from a neurologist, via a health authority, concerning an 18 year old female who on an unspecified date was vaccinated with a dose of GARDASIL, (Lot number, route and injection site not reported). The patient developed malaise and fatigue at the end of vaccination. Admittedly an anaemia was diagnosed and lab findings revealed also a raised ESR without evidence of an inflammatory focus. These symptoms persisted for some weeks. Finally she experienced loss of consciousness with myoclonic jerks. Differential diagnosis was conclusive syncope but EEG showed rhythmic potentials which looked like deformed SW-complexes. In the further course an epilepsia was not confirmed but the patient experienced once again a myoclonus-like tremor syndrome of the upper right extremity. Other loss of consciousness did not occur but impaired concentration with feeling of short mental blackouts. A second and a third EEG showed again rhythmic potentials, whereas the symptoms improved within 2 to 3 months. Cranial MRI was normal. CSF was not examined. The final outcome was not reported. The patient's experiences were considered to be other important medical events. File closed. Other business partner numbers included: E2008-08982 and PEI2008014831. No further information is available.

Other Meds: Unknown

Lab Data: electroencephalography, rhythmic potentials which looked like deformed SW-complexes; magnetic resonance imaging, cranial MRI: normal; erythrocyte sedimentation rate, Without evidence of an inflammatory focus

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **328258-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	12-Dec-2007	14-May-2008	154	13-Oct-2008	14-Oct-2008	NE	WAES0807USA04422	14-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Intra-uterine death, Umbilical cord abnormality

Symptom Text: Initial and follow-up information has been received from a medical assistant, for the Pregnancy Registry for GARDASIL, concerning a 21 year old female with no known drug allergies and a history of chickenpox and depression in past who on 12-OCT-2007 was vaccinated with the first dose of GARDASIL (lot no. 658556/1060U). On 12-DEC-2007 the patient was vaccinated with the second dose of GARDASIL (lot no. 659435/1265U). On 12-JUN-2008 the patient was vaccinated with the third dose of GARDASIL (lot no. 659964/1978U). The patient is now pregnant. As of 22-JUL-2008, it was reported that the pregnancy was normal to date. The patient was seen in the office to seek unspecified medical attention. Follow-up information was received which reported in September 2004 the patient had one previous pregnancy and delivered a baby boy at 39 week gestation. The previous live born child was healthy and well. On 05-AUG-08, the initial physical examination was performed. The pregnancy was essentially unremarkable. On 02-SEP-2008, the follow-up physical examination was performed. No fetal heart tones were detected. On the same day, ultrasound confirmed the intrauterine fetal demise. On 08-SEP-2008 the baby was delivered in the evening at approximately 18:00. The mother denied use of tobacco and alcohol in excess during the pregnancy. Her only medications include prenatal vitamins, some Omega-3 fatty acids over-the-counter and acetaminophen over-the-counter. On 08-SEP-2008, the parents reported the baby was active until approximately a week ago. The physical examination of the baby was performed. The infant weighted 85 grams. Cranium was intact. Ears were normally formed and positioned for a 17 week gestation. Palpebral opening were horizontal with very slight fusion still present. Nose, cheeks and philtrum appeared to be normal. Palate is intact. Tongue appeared to be normal. Mandible is only slightly recessed. Cervical area was unremarkable. Thorax was normally developed. Abdomen was negative palpably. There was a very small narrowing a

Other Meds: Acetaminophen; Omega-3 marine triglycerides; Vitamins (unspecified)

Lab Data: Ultrasound, 09/02/08, intrauterine fetal demise; Blood pressure, 08/05/08, 102/5; Physical examination, 08/05/08, 12 weeks gestation; fetal heart count 160; Physical examination, 09/02/08, 16 weeks gestation; no fetal movement; no fetal hea

History: Depression; Chickenpox

Prex Illness:

Prex Vax Illns:

Vaers Id: **328265-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	M	22-Aug-2008	22-Aug-2008	0	13-Oct-2008	22-Oct-2008	OK		31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB233AA	0	Left arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBUB431BA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cyanosis, Dizziness, Pallor

Symptom Text: Color lose, Lips turned blue, felt faint, placed cool rag on forehead, laid down on exam table. Recovered in about 10 minutes.

Other Meds:

Lab Data:

History:

Prex Illness: Allergic Rhinitin / Sports physical

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328273-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Oct-2008	07-Oct-2008	1	13-Oct-2008	22-Oct-2008	GA		22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	MSD05104-VF	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	MS017406-VF	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Injection site erythema, Injection site pain, Injection site pruritus, Injection site swelling

Symptom Text: Pt. received vaccine in her left arm. She said it started itching today about 10:00 and she started scratching it. Pt. said it then became red and raise and hurt to touch. School nurse called pt's mom- mom brought pt to HD. area measure 2X1 1/2 red, raised. Just to give BENADRYL and TYLENOL and cool cloth.

Other Meds: None

Lab Data: None

History: Heart Murmur

Prex Illness: None

Prex Vax Illns:

Vaers Id: **328282-1** **Related reports:** 328282-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Oct-2008	06-Oct-2008	0	13-Oct-2008	22-Oct-2008	IL		22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	08437X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Convulsion, Hypoaesthesia, Pain in extremity, Pallor, Sensation of heaviness, Shock, Syncope, Tremor, Vaccine positive rechallenge

Symptom Text: 1st dose to arm feeling numb and Heavy . 2nd dose to Arm Felt immediately numb and heavy, Fainted 1HR 50minutes ago. Pale Clammy "shock like" 5 seconds of shaking (seziure) other arm and feet felt a little numb pain in fist.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: Numbness, Fainting~HPV (Gardasil)~2~16~In Patient

Vaers Id: **328282-2** **Related reports:** 328282-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Oct-2008	06-Oct-2008	0	04-Nov-2008	05-Nov-2008	IL	WAES0810USA01989	05-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Cold sweat, Convulsion, Heart rate decreased, Hypoaesthesia, Musculoskeletal chest pain, Pallor, Sensation of heaviness, Syncope, Tremor

Symptom Text: Information has been received from a registered nurse concerning a 16 year old female patient with no previous medical history and no illness at time of vaccination reported who on an unknown date was vaccinated with the first dose of GARDASIL IM, 0.5 mL. After the first dose, the patient reported that her arm was numb for about 24 hours and then it resolved. On 06-OCT-2008 at 16:30, the patient was vaccinated with the second dose of GARDASIL (Lot # 659184/0843X) IM in the left deltoid, 0.5 mL, and within 10 minutes after became white (pale) and experienced syncope. The patient felt clammy and her heart rate decreased. She appeared to had seizure, shook for 3 to 5 seconds and her blood pressure decreased for 88/50 to 90/52. When she came to, she said she felt numbness in her arms, a heavy feeling in her feet (dull/numb), a sharp pain in her ribs and was shakey. The patient's blood pressure remained low during an hour of monitoring and her heart rate resolved to within normal limits. The patient also complained that the other arm and feet felt "numb/dull". On 07-OCT-2008, the patient recovered. No treatment was noted. The patient not had any laboratory test done. The patient sought medical attention at the office. Upon internal review, seizure (shook 3-5 seconds) was determined to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **328319-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.1	F	02-Oct-2008	04-Oct-2008	2	13-Oct-2008	22-Oct-2008	MD		05-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	2	Left arm	Intramuscular	FLU

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acne, Acrochordon, Melanocytic naevus, Muscle twitching, Pain, Tremor

Symptom Text: tremors of her left hand starting about 2 days after vaccination. lasted for 2 days then resolved for 3 days then started again on left hand then involving right hand. 10/24/08 Reviewed PCP medical records of 8/18-10/09/2008. FINAL DX: tremor NOS Records reveal patient experienceced good overall health. On 10/6 visit noted to have left arm twitching & aching x 2 days & then resolved in 3 days. Hand shakes when in use. Had rec hpv vax 4 days prior & started new acne med 5 days prior. RTC 10/9 w/recurrence of right hand tremor & left fingers. Referred to neuro & counselor. Seen by dermatologist 9/08 due to very fair skin, acne, benign nevi & inflammed skin tag which was removed.

Other Meds: minocycline

Lab Data: electrolytes normal including calcium liver function tests normal. LABS: chemistry, LFTs, T4, ceruloplasmin all WNL

History: none PMH: Mom dx recently w/frontotemporal dementia. Sinusitis 9/9/08 w/rhinorrhea & cough, thick nasal discharge.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **328348-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	17-Oct-2007	29-Oct-2007	12	13-Oct-2008	20-Oct-2008	AZ		06-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abnormal behaviour, Bipolar I disorder, Confusional state, Crying, Delusion, Feeling abnormal, Headache, Impaired work ability, Mania, Mental status changes, Metal poisoning, Mood swings, Obsessive thoughts, Speech disorder, Stress

Symptom Text: My daughter was given the 3 Gardasil vaccinations. They were given over a 6 month time, beginning in October of 2007. Shortly after receiving the first injection, she complained of feeling "thick-headed" and had difficulty comprehending things. She had started a new job, that was similar to a previous one, but couldn't seem to grasp what was being told. Following the second injection, she began having frequent crying spells, continued feelings of confusion, and she broke up with a then boyfriend, and quit her job. This was the first time she hadn't worked since she was 15 years old. She began a new job in March, after taking a couple months off. Things were going OK, until she received the third injection in April. By July, she was exhibiting confusion and mania. She was taken to see her family physician, who advised seeing a psychiatrist. She was told that she was having a "manic episode and was possibly bipolar." By the end of Aug. it was necessary to hospitalize her for treatment. In the interim, she was diagnosed with having high mercury levels in her blood and adipose tissue. A decision was made to treat her for an acute immune response, due to the combination of the reaction to the Gardasil injections, mercury levels and stress. Every physician who had seen her asked the same questions about her past medical history, and every one of them, consisting of MD's, a DO, and 2 Naturopaths felt that her illness was due to an acute reaction, or a combination of "things" that overwhelmed her body. She is now on psychiatric drugs, and is receiving supportive care from the Naturopaths. The hope is to detoxify her body. She has not had any previous issues with mental instability. 11/21/2008 MR received for DOS 8/29-9/01/2008 with D/C DX: Bipolar Disorder with Manic and Delusion, resolved. Pt presented to ER after escalating bizzare behaviors, mania and delusions. Neurology consult reports changes in mental status and behavior began in Oct 2007 following receipt of HPV vaccine. Impression: Acute mani

Other Meds: yasmin

Lab Data: bloodwork, including tests for toxins. Labs and Diagnostics: Brain MRI WNL. CBC WNL. Albumin 2.9. T protein 5.9. ALT 9. Drug screen (-). Labs: Lead & Mercury levels high.

History: none. PMH: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **328351-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Oct-2008	13-Oct-2008	0	13-Oct-2008	22-Oct-2008	IA		22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Left arm	Intramuscular	FLUN
	MNQ	SANOFI PASTEUR	U2642AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury

Symptom Text: Patient received vaccinations. Left the immunization room and was speaking with her mother. Fell onto her mother's chest and onto the floor. Patient hit her head on mother's chest during the fall. Able to roll patient onto her back. Patient was able to sit up and was alert and oriented.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 328357-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	29-Sep-2008	29-Sep-2008	0	14-Oct-2008	22-Oct-2008	WY		22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Headache, Lip swelling, Oedema peripheral, Pain, Pyrexia, Rash pruritic

Symptom Text: About 6 hours after receiving vaccine, pt states she had a headache and fever to 102. Felt achy and fatigued the entire next day and also developed slight swelling of upper lip. On day of presentation to clinic (2 days after receiving vaccine) pt developed itchy rash/slight swelling of both hands.

Other Meds: piroxicam, singulair, patanol

Lab Data: None.

History: allergic rhinitis

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328389-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Sep-2008	29-Sep-2008	0	13-Oct-2008	22-Oct-2008	MA		22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0785X	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	4273244	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction

Symptom Text: Immediately after receiving three (3) vaccines, child c/o dizziness. Vital signs were monitored & stable. Child was observed for 15 minutes, reported no further complaints and left office with father.

Other Meds: None

Lab Data: None

History: Allergies: nuts, pecans.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328390-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Sep-2008	12-Sep-2008	1	13-Oct-2008	22-Oct-2008	NH		03-Nov-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2904AA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2621AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0067X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Immunizations administered Friday 9/11/08 and Pt reports a rash on her legs developed Saturday morning. Pt states rash only developed on legs, no other Sx, and rash disappeared within 48 hours (just reported to Us on 10/9)

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **328397-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-Aug-2008	04-Sep-2008	7	14-Oct-2008	15-Oct-2008	FR	WAES0810USA00694	15-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	HEP	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anorexia, Asthenia, Back pain, Blood product transfusion, Bone pain, Coagulation factor V level, Ecchymosis, Eosinophil count normal, Eosinophilia, Hepatic vein thrombosis, Hepatosplenomegaly, Lymphocyte count abnormal, Mesenteric vein thrombosis, Pain in extremity, Petechiae, Portal vein thrombosis, Pulmonary embolism, Pyrexia, Splenic vein thrombosis

Symptom Text: Information has been received from a health authority (reference #'s AN20080564 and LA200810580) concerning a 13 year old female who was vaccinated with the first dose of GARDASIL (lot #, route and site not reported) and the third dose of RECOMBIVAX HB (manufacturer unknown) on 28-AUG-2008. Concomitant therapy included Ibuprofen on 05-SEP-2008. The patient was hospitalized on 06-SEP-2008 for multiple ecchymoses. There was a notion of asthenia and of loss of appetite since 1 week. The patient had fever at 38.5 centigrade by the evening of 05-SEP-2008. At clinical examination the patient presented with multiple ecchymoses: back of left hand, 2 on her elbows, 2 on her knees and on her posterior side of left calf. The patient also presented with petechiae on lower limbs, on abdomen and on her palate. There was no hemorrhagic bubbles and no epistaxis. She had pain of vertebral column and lower limbs. Biological and complementary tests indicated schistocyte was negative. On 09-SEP-2008 B12 vit was 1064 ng/l. Analysis of lymphocyte with flow cytometry indicated that there was no argument in favour of an underlying clonal lymphoproliferation. Rheumatoid factor was normal (below 8 UI/ml). Frank medullar hypereosinophilia was 34%, no excess of blasts. On 10-SEP-2008 an abdominal echography showed hepatosplenomegaly, partial portal thrombosis extending to left and right portal branch. On 11-SEP-2008 antithrombin activity was of 63%. CT scan thorax abdomino-pelvian revealed a total thrombosis of veinous affluents of right subhepatic vein and of portal trunk; partial thrombosis of superior mesenteric vein and of splenic vein. Pulmonary embolism of left basal lateral and posterior segmental artery. There was no tumourous lesion. Concerning the evolution and symptomatic treatment: 2 fresh blood plasma were frozen on 07-SEP-2008 at 2h 30 and at 3h 20. There was a platelets blood transfusion on 07-SEP-2008 at 1h 15. The patient was treated with curative dose of heparin. On 12-SEP-2008 platelets reincreased at 95G/l. Eosinophilia

Other Meds: RECOMBIVAX HB, 13Oct07; RECOMBIVAX HB, 24Nov07; Ibuprofen, 05Sep08 - 05Sep08

Lab Data: Abdominal ultrasound, 10Sep08, hepatosplenomegaly, partial thrombosis extending to left and right portal branch; Diagnostic laboratory test, 14Sep08, soluble complexes was positive; Myelography, 34%, frank medullar hyper eosinophilia, no ex

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328405-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	23-Sep-2008	01-Oct-2008	8	14-Oct-2008	20-Oct-2008	--		21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Stomatitis, Vaccine positive rechallenge, Vaginal inflammation

Symptom Text: Patient with stomatitis and vaginal mucositis beginning one week after each of her first two Gardasil injections.

Other Meds: None

Lab Data: Office exam 7/8/08 and 10/8/08

History: No known allergies. Uses no regular medications. 1/2 ppd smoker.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328415-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	14-Oct-2008	14-Oct-2008	0	14-Oct-2008	22-Oct-2008	TX		22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	2	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2768AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pallor

Symptom Text: Pt became pale, light headed and nauseas after administration. Event reported to Provider - B/P and finger glucose obtained. After lying down for aprrox 5-10 mionutes, S/s disapeared and Pt stated that she felt fine. No treatment given

Other Meds: none

Lab Data: Orthostatic BP - Lying 90/64 pulse 74, Sitting- 88/67 pulse 63, Standing 94/73 pulse 74. 5-1- min later 96/69 pule 66 - BP WNL for Pt.

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328417-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Jul-2007	01-Oct-2007	82	14-Oct-2008	22-Oct-2008	MT		02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Dyspepsia, Headache, Hypoaesthesia, Menstruation irregular, Neuropathy peripheral, Paraesthesia, Urticaria

Symptom Text: Developed numbness in arms, hands, feet and legs. Headaches, irregular periods, heartburn, hives. Began 2-3 months after first HPV vaccine administered. Had brain MRI to look for MS with no lesions seen. 10/24/08 Office notes received from PCP. Parent reports continued numbness/tingling of feet/legs/hands, severe headaches and severe heartburn which began 2 months after 1st HPV shot. 12/1/2008 MR received from neurologist. Referred from PCP for intermittent peripheral neuropathy in variable distribution. Pt presented with a several week hx of intermittant episodes of numbness of the feet, hands, and extremities. Neuro exam normal as pt was asymptomatic at time of exam. Impression: Paresthesias. F/u reports 3/4/08 with continued numbness all over, interfering with pt's ability to run.

Other Meds: Lutera (oral contraceptive)

Lab Data: Labs and Diagnostics: Brain MRI (+) for a small fluid collection w/in the posterior inferior R frontal lobe. Lyme (-). CBC WNL. Albumin 5.1. Alk Phos 65.

History: no. PMH: none noted

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328418-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Aug-2008	07-Sep-2008	34	14-Oct-2008	22-Oct-2008	MN		22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Menorrhagia

Symptom Text: Menorrhagia (1 month duration of bleeding) with anemia

Other Meds:

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 328425-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	09-Oct-2008	13-Oct-2008	4	14-Oct-2008	22-Oct-2008	SC		22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Nausea

Symptom Text: diarrhea and severe nausea

Other Meds: bcp, simply sleep

Lab Data:

History: NKDA

Prex Illness: none at time of injection

Prex Vax Illns: abd.cramps,n/v/d to er~HPV (Gardasil)~1~23~In Patient

Vaers Id: **328470-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	14-Oct-2008	Unknown		14-Oct-2008	24-Oct-2008	MN		24-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB294BA	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2811AA	4	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Pt. received two 0.5cc FLUZONE lot#U2811AA

Other Meds:

Lab Data:

History: Asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328472-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-Aug-2008	13-Aug-2008	0	14-Oct-2008	24-Oct-2008	PA		24-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2685AA		Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C2998BA		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Nausea, Pain, Pain in extremity, Skin warm, Somnolence, Vomiting

Symptom Text: Patient c/o nausea and body aches, vomiting 1 1/2 hrs after shots given. Both arms sore with some redness and warm to touch. Patient slept rest of that day and the next day s/s subsided by the 3rd day without treatment .

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **328474-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Sep-2008	Unknown		14-Oct-2008	24-Oct-2008	VA		24-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	AFLUA155AA	5	Right arm	Intramuscular	
	FLU	GLAXOSMITHKLINE BIOLOGICALS	0548X	5	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Rash on abdomen right side, appears on (day4) after infection.

Other Meds: BCP'S , Lexa pro

Lab Data:

History: Allergic to morphine

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328475-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Oct-2008	11-Oct-2008	1	14-Oct-2008	24-Oct-2008	SC		24-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2828AA	4	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0387U	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0101X	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Burning sensation, Erythema, Pain, Pruritus, Skin warm

Symptom Text: 10CM X 5cm Red area, burning, itching, warm and painful to touch for eight to ten hours. Benadryl given by mother for relief.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **328477-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	10-Oct-2008	10-Oct-2008	0	14-Oct-2008	24-Oct-2008	IL		24-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2670AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0067X	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB247AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain

Symptom Text: 10-10-08 Complained of chest pain, sharp, Midsternal after receiving vaccines ~ Approximately 10-15 min post vaccination was given Ibuprofen, 2 tabs. Pain seemed to lessen when recumbent. Status checks 2hrs later - patient. Felt better, still had slight pain.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 328495-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-Sep-2008	11-Sep-2008	0	09-Oct-2008	13-Feb-2009	MA	200802949	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	0843X	0	Right arm	Intramuscular	TDAP
	HPV4	MERCK & CO. INC.	U2636A		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Feeling of body temperature change, Headache, Hypoaesthesia facial, Paraesthesia, Paraesthesia oral, Swelling face

Symptom Text: Initial report was received 18 September 2008 from a health care professional. A 12-year-old female patient had received a left deltoid intramuscular injection of MENACTRA, lot number U2636AA and a first dose right deltoid intramuscular injection of GARDASIL, lot number 0843X (manufacturer Merck) on 11 September 2008, and on the evening of vaccination, she developed numbness in her face. By the following morning, the numbness had worsened and she complained of a prickly feeling in her cheeks and around her lips, and her face felt hot and cold. The patient's face also appeared pink and puffy. By the afternoon, her lips became tingly. The patient's mother called their health care provided to report the symptoms and stated the patient complained that her head was hurting (onset time and date not reported). The patient had not experienced any fever and no other symptoms occurred. The patient received corrective treatment with BENADRYL. By the following morning (date not reported), all symptoms had resolved. The patient had also received an injection of ADACEL (lot number not reported) within four weeks prior to receipt of MENACTRA and GARDASIL. No further information was provided.

Other Meds: FLONASE

Lab Data: None

History: The patient had no illness at the time of vaccination. Her past medical history included chronic rhinitis and she had known allergies to AMOXIL, AUGMENTIN, CEFZIL, dustmites, and cats. Concomitant medications included FLONASE. The patient had also received ADACEL (date not reported) within four weeks prior to receiving MENACTRA and GARDASIL.

Prex Illness:

Prex Vax Illns:

Vaers Id: **328504-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Sep-2007	Unknown		15-Oct-2008	16-Oct-2008	--	WAES0810USA01669	16-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Bed rest, Blood test, Drug exposure during pregnancy, Premature labour, Ultrasound foetal

Symptom Text: Information has been received from a Registered Nurse for the Pregnancy registry for GARDASIL concerning a female with a history of obesity who in September 2007, was vaccinated with the first dose of GARDASIL (lot 658556/1060U). The patient became pregnant at the end of November 2007. The patient's estimated date of confinement was 03-SEP-2008, and the patient delivered on 20-AUG-2008. At some unspecified point in the pregnancy, the patient experienced premature contractions and was treated with bed rest. Unspecified blood tests and fetal ultrasounds were performed. No other information was available at this time. Upon internal review, premature contractions which required bedrest was considered disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Obesity

Prex Illness:

Prex Vax Illns:

Vaers Id: **328505-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Oct-2008	16-Oct-2008	--	WAES0810USA01674	16-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse concerning a female who was vaccinated with a dose of GARDASIL on an unspecified date at a University Student Health Center. No specific provider information was available. Subsequently the patient developed seizures after vaccination. No other symptoms or treatment reported. At the time of the report, the outcome of seizures was unknown. Upon internal review, seizures were determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328524-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		15-Oct-2008	24-Oct-2008	AZ		24-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2683A	0	Left arm	Unknown	
MMR	MERCK & CO. INC.	0891X	1	Unknown	Subcutaneously	
HPV4	MERCK & CO. INC.	0575X	0	Left arm	Unknown	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB555	1	Right arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030	0	Right arm	Unknown	
VARCEL	MERCK & CO. INC.	0970X	1	Unknown	Subcutaneously	
IPV	SANOFI PASTEUR	A1060	1	Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site pain, Syncope

Symptom Text: pt seen in office for health maintenance visit, not up to date on vaccines, given VARIVAX, ENGERIX B, MENACTRA, BOOSTRIX, IPOL, MMRII, GARDASIL. GARDASIL last injection, while withdrawing needle, pt stated ow that hurt + fainted for approx 30 sec- 45 sec

Other Meds:

Lab Data: BP done post syncope same as prior injections

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **328525-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Oct-2008	02-Oct-2008	1	15-Oct-2008	27-Oct-2008	IA		03-Dec-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0485X	1	Right arm	Subcutaneously	
TDAP	SANOFI PASTEUR	C2938AA	6	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2661AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0843X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site pain, Injection site pruritus, Injection site warmth

Symptom Text: Came into office 10-3-2008 at 4 pm with red induration on right arm. Measures Measures 48 mm long X 52 mm wide. Itches warm to touch, Tender, site where Varicella was given on 10-1-2008. Instructed to apply ice and to take Tylenol for pain and benedryl for itching and see MD in morning if not better.10 - 6 - 2008 TC to mother to flu. She reports area was much better 10- 4 - 2008 am and did not see MD-RM

Other Meds: None

Lab Data:

History: No med Allergies, Has environmental allergies, Bells palsey last year

Prex Illness: No

Prex Vax Illns:

Vaers Id: **328552-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Oct-2008	05-Oct-2008	1	15-Oct-2008	12-Nov-2008	NY		12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial palsy, Facial paresis

Symptom Text: Bell's Palsy - Received vaccine on 10/ 04/ 2008 developed facial weakney Treatment zorivax / Prednisone on 10/05/2008. Seen on 10/06/2008, follow up pending for 1 week.

Other Meds: No

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **328603-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	15-Oct-2008	15-Oct-2008	0	15-Oct-2008	24-Oct-2008	FL		24-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0573X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood glucose normal, Convulsion, Gaze palsy, Hyperhidrosis, Muscle rigidity, Pallor

Symptom Text: Patient had seizure following gardasil injection. BP 156/86, pale, eyes rolling, rigid, diaphoretic, EMT called, blood sugar 82, refused transport to ER, appointment made with primary doctor for evaluation same day.

Other Meds:

Lab Data:

History: Allergic PCN

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: **328607-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Jul-2008	31-Jul-2008	1	15-Oct-2008	24-Oct-2008	IL		24-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0847Y	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Vision blurred

Symptom Text: Dizziness, blurred vision and nausea for 5 hours the day following the immunization

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **328615-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	M	09-Oct-2008	09-Oct-2008	0	15-Oct-2008	24-Oct-2008	KS		24-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2770AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy, Hypoaesthesia, Injection site pain, Nausea, Pain

Symptom Text: She experienced pain in right arm where shot was administered. Also had nausea, soreness, and numbness on R side of body. She was diagnosed with Bell's Palsy and given Medrol and Valtrex.

Other Meds: Clindamycin HCL, Spironolactone, Prenatal Vitamins

Lab Data: none

History: 1. Allergies to sulfa and ceclor/ 2. High testosterone/ 3. Ear pain/ 4. Adenoidectomy and Tonsilectomy

Prex Illness: Elevated testosterone

Prex Vax Illns:

Vaers Id: **328617-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Sep-2008	03-Sep-2008	1	16-Oct-2008	21-Oct-2008	CA		29-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2658AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0843X	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB238AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Dehydration, Dysuria, Hypertension, Hypokalaemia, Nausea, Pollakiuria, Pyelonephritis, Vomiting

Symptom Text: Patient developed intractable vomiting within 72 hours of vaccine administration resulting in dehydration and hypokalemia. Patient also developed hypertension. Symptoms lasted approximately 3-1/2 weeks. 10/27/08-records received for DOS 9/6/08-presented to ED with C/O vomiting times 3 days with abdominal pain (LUQ) and persistent nausea. Slight dysuria and frequency. DX: left pyelonephritis with abdominal pain and vomiting.

Other Meds: none

Lab Data: Normal: CT abdomen/pelvis, abdominal ultrasound, esophagogastroduodenoscopy, serum amylase, CBC, H. pylori antibody, pregnancy test, comprehensive metabolic panel (except for low potassium due to the vomiting) 10/27/08-records received-Uri

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 328665-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	20-Feb-2008	Unknown		16-Oct-2008	29-Dec-2008	MA		16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Amenorrhoea, Anxiety, Constipation, Depression, Dizziness, Dysuria, Ear pain, Erythema, Fatigue, Gastrooesophageal reflux disease, Hypoaesthesia, Intestinal functional disorder, Malaise, Nausea, Pain, Paraesthesia, Throat tightness, Viral infection

Symptom Text: Red soreness at time of vaccine, extreme fatigue, numbness tingling in hands & feet, severe nausea still to this date, lightheadedness, lack of premenstruation. Bowel issues possible blockage in March/2008. Healthy child is now so very ill!! 12/02/2008 Reviewed PCP office records which consisted only of lab reports & vaccine records w/o lot #s. 12/23/08 Reviewed additional PCP office records which are difficult to read but reveal patient experienced feeling unwell & being fatigued since 1/08. Started w/possible GERD, abdominal pain & throat tightness in 6/08. GI viral illness, ear pain, anxiety, dysuria. GI clinic eval of 7/08 included Endoscopy 9/08 for GI issues. Seeing counselor for anxiety & depression. Per follow-up: October 8, 2008. To Whom It May Concern: I have enclosed the adverse reporting form with a copy of my daughters shot records. I am Very concerned about the HPV shots that she received this past year. She has always been a very healthy child until the first shot of HPV. I mean healthy!!! WE have been to several gastroenteritis's, counselors, specialists as well as frequently to our pediatrician looking for answers. I had asked my pediatrician months ago if it could be the HPV shots and always got "not possible" as an answer. I am very frustrated with all that my child is still going through and curious if there is anything else I should be doing or could be doing, or persons I should be in contact with. I am at a loss of what to do to help my daughter with these horrible side effects. Please contact me with any suggestions small or large. Thanking you in advance!!

Other Meds:

Lab Data: Bloodwork; upper GI; endoscopy; specialist visits LABS: UGI & upper endoscopy WNL. LABS: 6/2/08: H.pylori, stool & urine c/s, EBV, Lyme, ANA neg. Mono (+). CBC, ESR, chemistry WNL. KUB revealed constipation.

History: none PMH: plantar fasciitis, chickenpox.

Prex Illness: none/very healthy

Prex Vax Illns:

Vaers Id: **328690-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Dec-2007	25-Dec-2007	22	16-Oct-2008	17-Oct-2008	RI	WAES0802USA02056	17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0243U	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received through the Merck pregnancy registry from a physician concerning a 15 year old female with a history of dysmenorrhoea and bee sting who on 03-DEC-2007 was vaccinated intramuscularly with her first dose of GARDASIL (lot# 656372/0243U). Concomitant therapy included MENACTRA, NAPROSYN, PAMPRIN and TUMS. On 05-FEB-2007 the parents of the patient called the office to report the patient was pregnant. Her LMP was 25-DEC-2007 with an expected due date of 30-SEP-2008. The patient had 2 positive pregnancy tests via urine and blood through another office. On 15-FEB-2008, the patient experienced an elective termination of her pregnancy at 11 weeks from LMP. It is unknown if the products of conception were examined and if the fetus was normal. Physician reported that the patient was not actually exposed to GARDASIL during pregnancy since her first dose was given during LMP and the second dose after threatened abortion (TAB). The patient did not use any medication during her pregnancy. Upon internal review elective termination was considered to be an other important medical event. Additional information is not expected.

Other Meds: PAMPRIN; TUMS; NAPROSYN

Lab Data: Urine beta-human, positive; Serum beta-human, positive

History: Dysmenorrhoea; Bee sting

Prex Illness:

Prex Vax Illns:

Vaers Id: **328691-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		16-Oct-2008	17-Oct-2008	NC	WAES0810USA00612	17-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, SERIOUS

MedDRA PT Cardiomyopathy

Symptom Text: Information has been received from a physician concerning a 16 year old female who on an unknown date was vaccinated with an unspecified GARDASIL (lot number was not available). Physician reported that he heard from a nurse at the local hospital that on an unspecified date a patient experienced cardiomyopathy after receiving a dose of GARDASIL. The patient went to the emergency room and from there was transferred to a different hospital. It is not known if she was admitted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328704-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Oct-2007	03-Oct-2007	0	14-Oct-2008	13-Feb-2009	SD	200703371	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	SANOFI PASTEUR	U1813B		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	10606	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Pallor, Syncope vasovagal, Unresponsive to stimuli, Vision blurred

Symptom Text: This case was reported by a health professional on 04 October 2007. An 11-year-old female patient with no reported history received an intramuscular right deltoid injection of TRIPEDIA (lot number U1813BA) and an intramuscular left deltoid injection of GARDASIL (Merck, lot number 10606) on 03 October 2007. Within 15 minutes, the patient had blurred vision, and subsequently became pale and unresponsive. She slid to the floor, and was responsive within one minute. No respiratory distress was noted, and no EMS was required. The patient recovered. Additional information received 05 November 2007. An 11-year-old female patient received TRIPEDIA (Per product insert, indicated through six years of age). The reporter verified that the patient had not received any concomitant medications at the time of vaccination and had no prior history of fainting. Diagnostic and laboratory testing had not been performed. The reporter stated that this event was felt to be a vasovagal response. No further information was provided. Additional information received from a health car professional on 04 January 2008. The reporter confirmed that the patient was 11-years-old and that the product administered with TRIPEDIA (TDAP was the intended vaccine). 17/Sep/2008: A corrective version with the same latest received date as the previous version (04/Jan/2008) was created to add the event of vasovagal response.

Other Meds:

Lab Data: None

History: Reported a "none". The patient had not been taking any concomitant medications and had no history of fainting.

Prex Illness:

Prex Vax Illns:

Vaers Id: **328707-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	12-Mar-2007	12-Mar-2007	0	15-Oct-2008	14-Nov-2008	IN	WAES0705USA02924	17-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0187U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Mastitis

Symptom Text: Initial and follow up information has been received from two registered nurses for the Pregnancy Registry for GARDASIL concerning a 22 year old female, with no relevant medical history, no known drug allergies and no previous pregnancies, who on 12-MAR-2007 was vaccinated IM with 0.5 ml of the first dose of GARDASIL (Lot #656049/0187U). There was no concomitant medication. The patient was currently pregnant with a LMP of 15-FEB-2007. All prenatal labs were normal. It was reported that on an unspecified date, the patient began taking prenatal vitamins. Medical attention was sought. On 17-JUL-2007, the patient had a routine ultrasound which was normal (not further specified). On 21-NOV-2007, the patient gave birth to a healthy baby girl (3510 gm; 20 in), with Apgar scores of 9 and 9. There were no congenital anomalies, complications or abnormalities. There were no complications during the pregnancy or during labor and delivery. Follow-up information was received indicated that in approximately December 2007, the patient experienced mastitis and was treated recently (unspecified). The outcome was unknown. Pediatric medical records were received, refer WAES # 0810USA00111. No further information is available.

Other Meds: None

Lab Data: diagnostic laboratory, prenatal labs normal; ultrasound, 07/17/07

History: Pregnancy NOS (LMP = 2/15/2007)

Prex Illness:

Prex Vax Illns:

Vaers Id: **328708-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	05-Apr-2007	01-Jun-2007	57	15-Oct-2008	14-Nov-2008	AZ	WAES0707USA01947	17-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0960F	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Immotile cilia syndrome, Lung infection

Symptom Text: Initial and follow-up information has been received through the Merck Pregnancy Registry from a physician concerning a 20 year old female with bronchitis, Kartagener's syndrome, pregnancy and lung infection with a history of 1 pregnancy, 1 live birth and no birth defects in previous pregnancies who on 05-APR-2007 was vaccinated with GARDASIL (lot # 654535/0950F). Concomitant therapy included albuterol 6.7 gm. QID as needed, salmeterol 50 mcg BID, and fluticasone propionate 10mcg BID for chronic bronchitis. Prenatal vitamins, iron (unspecified) and calcium (unspecified) taken once to twice daily for pregnancy and amoxicillin TID for lung infection. On 12-JUL-2007 the patient was vaccinated with a second dose of GARDASIL (lot# unknown). On 12-JUL-2007 the patient was found to be pregnant, in the first trimester. The patient's last date of menstrual period was 01-JUN-2007 and the estimated date of delivery is 10-MAR-2008. Unspecified medical attention was sought. An ultrasound was performed for dates and surveillance on 10-SEP-2007 and 25-OCT-2007 and was within normal limits: growth as expected. It was reported pregnancy was normal to date. Follow-up information was received from the physician. The physician reported that the patient delivered an 11 pound male on 11-MAR-2008 via vaginal delivery. The mother was formula feeding. There was no additional information on the baby at the time of reporting. Follow-up information was received via medical records. On 16-MAR-2008 the baby had neonatal physiologic jaundice in face only. On 16-MAR-2008 the baby's body temperature measurement was 99.2, respiratory rate measurement was 36, pulse oximetry was 94 and total heartbeat count was 142. Follow-up visit was scheduled for 2 weeks. On 27-MAR-2008 the baby had his 2 week old well child visit. The baby lost weight, was down to 5% from 10%. The baby had thrush and constipation issues, and changed formula to try to improve constipation and treat thrush. Try to increase daily formula amount to about 30 oz. day. Plan was to rec

Other Meds: albuterol, 6.7 gm; amoxicillin; calcium (unspecified); fluticasone propionate, 100 microgm; iron (unspecified); salmeterol, 50 microgm; vitamins (unspecified)

Lab Data: ultrasound, 09/10/07, within normal limits: growth as expected; ultrasound, 10/25/07, within normal limits: growth as expected; pulse oximetry, 03/16/08, 94; complete blood cell, 03/27/08, normal; body temp, 03/16/08, 99.2; total heartbeat

History:

Prex Illness: Pregnancy NOS (LMP = 6/1/2007); Bronchitis; Kartagener's syndrome; Pregnancy; Lung infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328709-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	18-May-2007	14-Jun-2007	27	15-Oct-2008	14-Nov-2008	OR	WAES0708USA02670	17-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Initial and follow up information has been received for the Pregnancy Registry for GARDASIL from a health professional concerning a 25 year old female patient with allergic reaction to codeine, allergic reaction to antibiotics, genital herpes (onset 2006) and a history of d pelvic inflammatory disease (2005) who on 18-MAY-2007 was vaccinated IM with a first dose of GARDASIL (lot #657621/0387U). Concomitant therapy included VALTREX. The reporter mentioned that they found out that patient was pregnant one day before her second injection was due (LMP= 14-JUN-2007). The second dose of GARDASIL was not administered. Patient had cervical smear test and enzyme immunoassay HIV antibody screen laboratory tests were done. On 11-OCT-2007 the patient had a normal serum alpha fetal protein and on 26-NOV-2007 the patient had a normal ultrasound. On 09-APR-2008 (41 weeks from LMP) the patient delivered a normal male infant (weight 9 pounds, 0 ounces). Apgar score were 8 and 9. There were no congenital anomalies, complications or abnormalities. Follow-up information was received via medical records. The baby developed jaundice on 14-APR-2008. On 23-APR-2008 bilirubin test was performed the result was 14.7. On 02-MAY-2008 the baby's skin looked good. On 27-MAY-20087 the baby vomited twice. There was no fever, cough etc. The patient subsequently recovered from the jaundice and vomiting. No further information is expected.

Other Meds: VALTREX

Lab Data: cervical smear; ultrasound, 11/26/07, norma, Full fetal survey; HIV alpha-fetoprotein, 10/11/07, norma; total serum bilirubin, 04/23/08, 14.7

History: Pelvic inflammatory disease

Prex Illness: Pregnancy NOS (LMP = 6/14/07); Hypersensitivity; Allergic reaction to antibiotics; Herpes simplex; Genital herpes

Prex Vax Illns:

Vaers Id: **328710-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		15-Oct-2008	14-Nov-2008	--	WAES0711USA03927	14-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pregnancy induced hypertension, Ultrasound scan normal

Symptom Text: Information has been received for the Merck Pregnancy Registry for GARDASIL from a 25 year old white female with crohn's disease, hypothyroidism and no drug reactions/allergies and has received the complete series for GARDASIL series. ON 13-APR-2007 the patient was vaccinated with GARDASIL (lot # unknown) injection. Concomitant therapy included SYNTHROID and ASACOL). In May 2007 the patient received a second dose of GARDASIL. In August 2007, the patient received a third dose of GARDASIL. The patient's date of the last menstrual period was on 17-SEP-2007. Medical attention was sought. The patient reported that she conceived on 29-SEP-2007. On an unspecified date the patient also had a blood test performed. To date the patient has not experienced any adverse reactions. The estimated date of delivery is 23-JUN-2008. Follow-up information was received. ON unspecified date the patient developed gestational hypertension. Concomitant therapy also included prenatal vitamins. The patient developed a normal healthy baby boy weighing 6 pounds and 15 ounces. The apgar score was 9 and 9. the patient was 39 and 4/7 weeks for LMP. Additional information is not expected.

Other Meds: SYNTHROID; 25; microgm ASACOL; 1600; mg vitamins (unspecified); tab

Lab Data: Diagnostic laboratory ultrasound - 12/06/07 - viable pregnancy - anatomy u/s 05-FEB-2008 was normal limits.

History: Pregnancy NOS (LMP = 9/17/2007) Crohn's disease; Hypothyroidism; Pregnancy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328711-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	04-Dec-2007	04-Dec-2007	0	15-Oct-2008	14-Nov-2008	--	WAES0712USA01370	17-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Hypertension, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a registered nurse concerning a 27 year old female with no drug allergies, who on 04-DEC-2007 was vaccinated intramuscularly with a 0.5mL first dose of GARDASIL (Lot# 655619/1427F). There were no concomitant medications. Subsequently, the patient was 21 weeks pregnant at the time of this first dose. The patient was not experiencing any known symptoms. The patient was seen in our office. At the time of the report, the outcome of the patient was unknown. No product quality complaint was involved. This was the patient's first pregnancy. Follow up information was received from a nurse practitioner that the LMP of the patient was 08-JUL-2007; EDD was 15-APR-2008. Ultrasounds were done on 30-NOV-2007 and 30-JAN-2008 for size/date and review of systems which were born within normal limits. The patient took prenatal vitamins during pregnancy. She was diagnosed with hypertension later in pregnancy, she was prescribed no medications. On 09-APR-2008 (41 weeks 3 day from LMP) the patient delivered a normal, healthy female baby weighing 6lb. 4oz., length was 31.5 cm, head circumference was "49 cm". The infant was considered normal; no congenital anomalies or complications were noted. APGAR score was 8/9. The pregnancy and delivery were considered as having no complications. Additional information is not expected.

Other Meds: Unknown

Lab Data: ultrasound, 11/30/07, WNL. Age 20 wk 2d-10d; ultrasound, 01/30/08, WNL. Age 31 wk 4d-17d

History: Pregnancy NOS (LMP = 7/8/2007)

Prex Illness: Pregnancy NOS (LMP = 7/8/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328712-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Nov-2007	01-Nov-2007	0	15-Oct-2008	09-Dec-2008	IN	WAES0801USA00133	09-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Drug exposure during pregnancy, Papilloma viral infection, Pre-eclampsia, Premature labour, Smear cervix abnormal

Symptom Text: Information has been received through the pregnancy registry for GARDASIL from a health professional concerning a 16 year old adopted female who in November 2007 was vaccinated with the second dose of GARDASIL. Per the reporter, the patient may have been pregnant when she was given her second dose of GARDASIL (LMP=01-NOV-2007). No adverse events were reported and no further information was available. Follow up information was received which reported that the routine obstetric labs were normal and the first and second trimester metabolic panel screens were within normal limits. On 25-FEB-2008 the patient's PAP smear was abnormal: "epithelial cell, abnormality squamous: low grade squamous intraepithelial lesions. HPV changes, possible CIN1." Repeat Pap smear will be performed in 6 months. During pregnancy and labor, the patient had preeclampsia. The patient was treated with magnesium sulfate. On 16-JUl-2008 the patient delivered a baby boy at 36.4 weeks gestation. The infant's weight was 5lb 10oz. The infant was normal and no congenital abnormalities. Additional information is not expected.

Other Meds: None

Lab Data: cervical smear, 02/25/08, abnormal-epithelial cell; ultrasound, 01/28/08, normal; ultrasound, 04/08/08, normal; ultrasound, 07/02/08, normal

History:

Prex Illness: Pregnancy NOS (LMP = 11/1/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328713-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	12-Dec-2007	12-Dec-2007	0	15-Oct-2008	09-Dec-2008	PA	WAES0801USA04501	09-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed practical nurse (L.P.N.), for the pregnancy registry for GARDASIL concerning a 21 year old female with a history of anemia, Crohn's disease and abnormal papanicolaou smears who on 28-JUN-2007 was vaccinated intramuscularly with her first dose of GARDASIL. Concomitant therapy included ORTHO-NOVUM. On 22-AUG-2007 the patient was vaccinated intramuscularly with her second dose of GARDASIL. On 12-DEC-2007 the patient was vaccinated intramuscularly with her third dose of GARDASIL. On 17-DEC-2007 the patient found out she was pregnant with a positive home pregnancy test the patient's LMP was 10-NOV-2007 (also reported as 06-NOV-2007) (due date = 13-AUG-2007). The patient was seen on 03-JAN-2008 for her first prenatal visit and an ultrasound was preformed; results showed a viable pregnancy. The patient was placed on daily prenatal vitamins. The patient has not experienced any difficulties with the pregnancy at this time. Follow-up information was received on 02-SEP-2008 from a L.P.N. indicating that on 01-JUL-2008 the patient delivered a normal female baby weighing 5 pounds, 1.1 ounces. There was no congenital abnormalities. There was no infections or illness during pregnancy. There was no complication during delivery. Other medications used during pregnancy included Celestone and Procardia. Additional information is not expected.

Other Meds: Celestone, Ortho-Novum, Procardia, Vitamins

Lab Data: Ultrasound 10/03/08 Viable pregnancy , beta - human chronic 12-17-2007

History: Anaemia; Crohn's disease; Papanicolaou smear abnormal

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328714-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Oct-2007	19-Oct-2007	10	15-Oct-2008	09-Dec-2008	CA	WAES0803USA01458	09-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Drug exposure during pregnancy, Nasopharyngitis, Premature labour

Symptom Text: Information has been received through the Merck pregnancy registry from a health professional concerning a 16 year old female who on 09-OCT-2007 was vaccinated with the first dose of GARDASIL (lot #not provided). On an unknown date, "the patient received the second dose of GARDASIL (658554/0928U). * Concomitant suspect therapy included varicella virus vaccine live. Per the reporter, the patient came back into the office because she was having a cough and cold, which turned out to be prenatal symptoms. The physician did a pregnancy test on the patient which came back positive. Per the reporter, the patient received the first dose of varicella virus on 06-DEC-2006. The lot # for varicella virus vaccine live was 659692/1767U, unspecified which dose. Additional information received from pregnancy questionnaire (31-MAR-2008): The lot# for the first dose of GARDASIL was provided as 658094/0524U and the date of the second was listed as 06-FEB-2008. Follow up information was received which reported that on 16-JUN-2008 the patient delivered a female infant. The infant's weight was 12.3 (unit not reported), length was 23.25 inches. The infant was normal, there were no congenital anomalies and no other complications or abnormalities. Additional information is not expected.

Other Meds: Unknown

Lab Data: beta-human chorionic - positive

History:

Prex Illness: Pregnancy NOS (LMP= 9/16/2007)

Prex Vax Illns:

Vaers Id: 328715-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	27-Nov-2007	27-Nov-2007	0	15-Oct-2008	13-Feb-2009	--	WAES0805USA04755	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner for the Pregnancy Registry for GARDASIL concerning a 22 year old female who on 27-NOV-2007 was vaccinated with her first dose of GARDASIL (lot # 659437/1266U) and is pregnant. The patient's LMP was reported as 18-NOV-2007. The patient had routine prenatal labs. Subsequently the patient experienced no known symptoms. Follow-up information was received from a nurse practitioner which reported that the 22 year old female with a history of 2 pregnancies and 1 live birth and a history of cervical intraepithelial neoplasia II-III in 2006, atypical cells of undermined significance (ASCUS)/negative HPV and loop electrosurgical excision procedure (LEEP) and sepsis (February 2006) delivered a normal, healthy male baby weighting 8 pounds on 22-AUG-2008 (weeks from LXP: 39). On 08-APR-2008. 09-JUN-2008 and 07-AUG-2008 ultrasound indicated there were no anomalies. On 28-APR-2008, maternal serum alpha-fetoprotein (MSAFP) was negative. Prenatal vitamins were taken from 22-JAN-2008. There were no complication during pregnancy and labor/delivery. There were no infections or illnesses during pregnancy. Additional information is not expected.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound 04/08/08 - no anomalies; ultrasound 06/09/08 - no anomalies; ultrasound 08/07/08 - no anomalies; beta-human chorionic - routine prenatal labs; serum alpha-fetoprotein 04/28/08 - negative

History: Cervical intraepithelial neoplasia III; Cervical intraepithelial neoplasia II; Loop electrosurgical excision procedure; Atypical glandular cells of undetermined significance; Sepsis

Prex Illness:

Prex Vax Illns:

Vaers Id: 328716-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	08-Jan-2008	08-Jan-2008	0	15-Oct-2008	13-Feb-2009	TX	WAES0806USA02213	04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Hydronephrosis, Ureteric obstruction, Uterine contractions during pregnancy

Symptom Text: Information has been received from the Merck Pregnancy Registry for GARDASIL via a medical assistant concerning a 26 year old white female with "kidney problems" who on 08-JAN-2008 was vaccinated IM with a first 0.5ml dose of GARDASIL vaccine (Lot # 659437/1266U) and was " 4 weeks pregnant at the time of the vaccine." Last menstrual period was approximately 10-DEC-2007. Estimated date of delivery is 15-SEP-2008. There were no concomitant medications. No adverse event occurred. Laboratory studies performed were "blood work" and an "OB profile" (results not reported). The patient sought unspecified medical attention. At the time of the report the outcome was unknown. Follow-up information was received indicating that on 30-AUG-2008, the patient delivered a normal baby. During pregnancy, the patient had hydronephrosis and obstructed right ureter. She also received terbutaline sulfate 2.5 mg every 4 hours on 04-AUG-2008 for contractions. The patient took prenatal vitamins during pregnancy. No diagnostic tests during pregnancy. There were no complications during labor/delivery. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: diagnostic laboratory - blood work and OB profile (result not reported); ultrasound 02/07/08 - pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 12/17/2007) Renal disorder

Prex Vax Illns:

Vaers Id: 328717-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	26-Dec-2007	26-Dec-2007	0	15-Oct-2008	11-Feb-2009	PA	WAES0806USA02842	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received for the pregnancy registry for GARDASIL vaccine (yeast) from a nurse concerning an 18 year old female with pertinent medical history reported as none and no known drug reactions or allergies who on 17-APR-2007 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 657621/0387U) 0.5 ml, IM. The second dose of GARDASIL vaccine (yeast) (lot # 657736/0389U0), 0.5 ml, IM was given on 15-JUN-2007. Concomitant therapy included prenatal vitamins (unspecified) and ferrous sulfate (unspecified). The third dose of GARDASIL vaccine (yeast) (lot # 659055/1522U), 0.5 ml, IM was given on 26-DEC-2007. Subsequently the patient became pregnant. She sought medical attention via an office visit. Her last menstrual period was reported as 29-NOV-2007. Her estimated delivery date was 04-SEP-2008. No adverse event was reported. Follow-up information was received from a licensed practical nurse which reported that on 23-AUG-2008 the patient gave vaginal birth to a live born male weighing 5 lbs. 12.3 oz, APGAR = 9/10. She was 37 weeks from her last menstrual period. The infant was reported to be normal and there were no congenital anomalies or complications. Additional information is not expected.

Other Meds: ferrous sulfate; vitamins (unspecified)

Lab Data: ultrasound, 02/19/08; diagnostic laboratory, 03/21/08, MSAFP: negative

History: LMP = 11/29/2007

Prex Illness: Pregnancy NOS, Iron low

Prex Vax Illns:

Vaers Id: **328718-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Oct-2008	09-Dec-2008	--	WAES0806USA08881	09-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Medical device complication

Symptom Text: Information has been received from a health professional concerning a quality issue regarding a pre-filled syringe of GARDASIL. It was reported that the syringe's safety mechanism released before it can be given to the patient . No adverse events were reported.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328719-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	13-Jun-2008	13-Jun-2008	0	15-Oct-2008	12-Feb-2009	MA	WAES0807USA00126	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Medication error, No adverse event

Symptom Text: Information has been received from a nurse and an office manager concerning an 18 year old female patient, with no known medical history, who on 13-JUN-2008 at 11:30 am was vaccinated intramuscularly with a third dose of GARDASIL vaccine (yeast) (Lot # 659435/1265U), which had been improperly stored. The nurse reported that the vaccine was stored in a refrigerator that had gone below an acceptable range. No adverse events were reported. It is unknown if the patient sought medical attention. No product quality complaint was involved. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328720-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Oct-2008	12-Feb-2009	--	WAES0807USA00542	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1209U		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Medical device complication

Symptom Text: Information has been received from a medical assistant via the PQC- Product Quality Complaints reporting that a prefilled syringe (size of container: one prefilled syringe) of GARDASIL vaccine (yeast) (lot # 654540/1209U) prematurely activated. The event was considered to be a medical device complication. No adverse event was reported. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328721-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Jun-2008	06-Jun-2008	0	15-Oct-2008	12-Feb-2009	MA	WAES0807USA03123	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Medication error, No adverse event

Symptom Text: Initial and follow-up information has been received from an office manager concerning a 15 year old female, with no known medical history who on 06-JUN-2008 was vaccinated IM with her first dose of GARDASIL vaccine (yeast) (lot#660553/0070X) which had been improperly stored. The nurse reported that the vaccine was stored in a refrigerator that had gone below an acceptable range. No adverse events reported. It is unknown if the patient sought medical attention. This is one of many reports from the same source. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **328722-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
6.0	F	21-Jul-2008	Unknown		15-Oct-2008	12-Feb-2009	FL	WAES0807USA04099	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: Information has been received from a physician concerning a 6 year old female who on 21-JUL-2008 was vaccinated with GARDASIL vaccine (yeast) 0.5 mL IM. Subsequently the patient inadvertently received GARDASIL vaccine (yeast) instead of hepatitis A vaccine and no symptoms were reported. No other information was available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328723-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Jul-2008	18-Jul-2008	0	15-Oct-2008	13-Feb-2009	CA	WAES0807USA04396	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 12 year old female who on 18-JUL-2008 was vaccinated with a second dose of GARDASIL vaccine (yeast) (lot# 658560/1062U) injection. On 18-JUL-2008 the patient left the office, walked out to the parking lot and fainted. Medical attention was sought. There was no additional information provided. At the time of the report the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328724-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	30-Jul-2008	30-Jul-2008	0	15-Oct-2008	12-Feb-2009	MN	WAES0807USA05787	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner through the pregnancy registry for GARDASIL vaccine (yeast) concerning an 18 year old female with no medical history and allergic to penicillin, who on 30-JUL-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) (Lot # 660389/1968U). There was no concomitant medication. On 30-JUL-2008 the patient was found to be pregnant. No problems reported. Date of LMP was 29-JUN-2008. Estimated delivery date is 05-APR-2009. Urine pregnancy test, PAP and STD test (sexually transmitted diseases) were performed. There was no product quality complaint. Follow up information has been received from a nurse practitioner concerning an 18 year old Native American female with a history of 1 previous pregnancy and 1 full term delivery, with no significant past medical history who on 30-JUL-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) (Lot # 660389/1968U) (Lot # reported as "1968 U"). Concomitant medications included prenatal vitamin daily for pregnancy started on 30-JUL-2008. Birth defect(s) in previous pregnancies and infant complications in previous pregnancies were reported as unknown. Estimated conception date was on 13-JUL-2008. Date of last menstrual period was on 29-JUN-2008 and estimated delivery date is 05-APR-2009. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: urine beta-human, positive

History: LMP = 6/29/2008; Penicillin allergy

Prex Illness: Pregnancy NOS

Prex Vax Illns:

Vaers Id: **328725-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	03-Apr-2008	03-Apr-2008	0	15-Oct-2008	10-Feb-2009	--	WAES0808USA00767	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAPHE	GLAXOSMITHKLINE BIOLOGICALS	AC42B020AA		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2543AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1487U		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Dizziness, Inappropriate schedule of drug administration, Pyrexia

Symptom Text: This report was identified from a line listing obtained on request by the Company. A 10 year old female with no pertinent medical history or drug allergies or drug reactions, who on 04-APR-2008 was vaccinated with GARDASIL vaccine (yeast) intramuscular into the right arm (lot no. 659657/1487U), meningococcal ACYW conj vaccine (dip toxoid) intramuscular into the left arm (lot no. U2543AA), and diphtheria toxoid(+) hepatitis B virus vaccine rHBsAg (yeast) (+) pertussis acellular 3-component vaccine (+) poliovirus vaccine inactivated (Vero) (+) tetanus toxoid intramuscular into the left arm (lot no. AC42B020AA). On 03-APR-2008 the patient received three vaccines, she ran a fever 103 degrees temperature, she complained of dizziness and stayed in bed all day post vaccination. No further information is available. The original reporting source was not provided and considered the events to be non-serious.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **328726-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Oct-2008	09-Dec-2008	--	WAESO80USA010400	09-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Medical device complication

Symptom Text: information has been received from a woman's clinic regarding GARDISAL in a pre filled syringe. It was reported that the syringe was leaking. No adverse event was reported. In follow up it was reported that the patient received the dose of HPV Vaccine the same day using a different syringe. The problem was identified before patient was injected so patient never received any of the faulty dose, therefore this reports being deleted from our files, and a healthcare professional did not come into direct contact with the vaccine as a result of the complication . No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328727-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	28-Jul-2008	28-Jul-2008	0	15-Oct-2008	10-Feb-2009	AZ	WAES0808USA01709	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a Caucasian registered nurse for the pregnancy registry for HPV vaccine, concerning a 23 year old female with sulfonamide allergy who on 28-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 660553/0070X, exp: 22-OCT-2010) 0.5ml, intramuscularly. There was no concomitant medication. The nurse reported that the patient received her first dose of HPV vaccine and then discovered that she was pregnant. On 28-JUL-2008, the patient had a urine pregnancy test that was negative, and on 06-AUG-2008 she had another pregnancy test that was positive. The patient's LMP was on 25-JUN-2008 and the EDD is on 01-Apr-2009. No adverse event was reported. The patient sought medical attention at the physician's office. Follow up information was received on 27-AUG-2008 from a registered nurse which reported that the patient's LMP was on 27-JUN-2008. Additional information has been requested.

Other Meds: None

Lab Data: urine beta-human, 07/28/08, negative; urine beta-human, 08/06/08, positive

History: LMP = 06/27/2008; Sulfonamide allergy

Prex Illness: Pregnancy NOS,

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328728-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	08-Aug-2008	08-Aug-2008	0	15-Oct-2008	10-Feb-2009	NJ	WAES0808USA01814	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Information has been received from a certified medical assistant concerning a patient who on 08-MAR-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast), IM. On 08-AUG-2008, the patient received late the second dose of GARDASIL vaccine (yeast). The patient is not experiencing any known symptoms. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328729-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-Aug-2008	07-Aug-2008	0	15-Oct-2008	10-Feb-2009	MI	WAES0808USA02093	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	3	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Initial and follow-up information has been received from a medical assistant concerning a 12 year old female with attention deficit/hyperactivity disorder who on 23-APR-2007, 26-JUN-2007 and 25-OCT-2007 was vaccinated with a first, second and third dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). On 07-AUG-2008 the patient was vaccinated with a fourth dose of GARDASIL vaccine (yeast) (lot number 0152X) intramuscularly in the right arm and a dose of hepatitis A virus vaccine inactivated (HAVRIX) (lot number AHAVB0233A2) intramuscularly in the left arm. No adverse event was reported. It was unspecified if the patient sought any medical attention. Additional information is not expected.

Other Meds:

Lab Data: None

History:

Prex Illness: Attention deficit/hyperactivity disorder

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328730-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Dec-2007	27-Dec-2007	0	15-Oct-2008	10-Feb-2009	IL	WAES0808USA02131	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Initial and follow-up information has been received from a nurse concerning a 20 year old female patient who on 12-MAR-2007 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). On 27-DEC-2007 the patient was vaccinated with a second dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). On 13-AUG-2008 the patient was vaccinated with a third dose of GARDASIL vaccine (yeast) (lot number 0151X) in the deltoid (injection route not reported). No adverse symptoms. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328731-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	02-Nov-2007	02-Nov-2007	0	15-Oct-2008	10-Feb-2009	WA	WAES0808USA03228	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0388U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Information has been received from a certified medical assistant concerning a 16 year old black student female with no known drug allergies/reactions and no pertinent medical history reported who on 08-SEP-2006 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot# 653937/0637F) in the left deltoid. On 02-NOV-2007, the patient was vaccinated with a second dose of GARDASIL vaccine (yeast) (Lot # 657622/0388U) in the right deltoid. On 25-APR-2008, the patient was vaccinated with a third dose of GARDASIL vaccine (yeast) (lot # 659055/1522U) in the left deltoid. On 25-AUG-2008, the patient was vaccinated with an extra dose of GAEDASIL vaccine (yeast) ((lot # 660374/0275X) - invalid) in the left deltoid. No adverse effect reported. This is one of two sibling reports received from the same source. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **328732-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
42.0	F	21-Aug-2008	21-Aug-2008	0	15-Oct-2008	11-Feb-2009	--	WAES0808USA03616	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Information has been received from a 42 year old female who on unspecified date, was vaccinated with the first dose of GARDASIL vaccine (yeast). On 21-AUG-2008 was vaccinated the second dose of with GARDASIL vaccine (yeast). No adverse events reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328733-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Oct-2008	11-Feb-2009	--	WAES0808USA03767	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a registered nurse concerning an unspecified number of patients who on an unspecified date was vaccinated with GARDASIL vaccine (yeast) (route and administrating site not reported). Subsequently, the patients experienced pain at the injection site. This one of several reports from the same source. Attempts made to obtain additional identifying information to distinguish the individual patients mentioned in the report were unsuccessful. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **328734-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	28-Dec-2007	28-Dec-2007	0	15-Oct-2008	11-Feb-2009	NY	WAES0808USA04467	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a licensed practical for the pregnancy registry for GARDASIL vaccine (yeast) concerning a 27 year old female with no pertinent medical history and no allergies who on 28-DEC-2007 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot # 659653/1448U). On 28-FEB-2008 the patient was vaccinated with the second dose of GARDASIL vaccine (yeast) (lot # 659655/1486U). On 26-JUN-2008 the patient was vaccinated with the third dose of GARDASIL vaccine (yeast) (lot # 660555/0279X). There was no concomitant medication. The patient became pregnant during the immunization schedule of vaccine. The "ultrascreen and blood test" were performed. The last menstrual period was 16-JUN-2008. The estimated due date is 23-MAR- 2009. Date of conception was three days before receiving the third dose. No adverse effects were reported. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound; diagnostic laboratory

History: LMP = 6/16/2008

Prex Illness: Pregnancy NOS

Prex Vax Illns:

Vaers Id: **328735-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Oct-2008	11-Feb-2009	--	WAES0808USA04694	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Medication error

Symptom Text: Information has been received from a registered pharmacist concerning a patient who on an unspecified date was vaccinated a dose of GARDASIL vaccine (yeast) which was stored improperly. The patient has not experienced any known symptoms. It was unspecified if the patient sought medical attention. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328736-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Oct-2008	11-Feb-2009	--	WAES0808USA05380	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site

Symptom Text: Initial and follow-up information has been received from an official concerning unknown number of patients who were vaccinated with GARDASIL vaccine (yeast) at the gluteal region. No symptoms were noted. It was not specified if the patients sought medical attention or not. Attempts are being made to obtain additional identifying information.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328737-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	06-Jun-2008	06-Jun-2008	0	15-Oct-2008	11-Feb-2009	KS	WAES0809USA00217	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning a 22 year old white female with asthma, rhinitis allergic, gastroesophageal reflux disease and depression who on 06-JUN-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number 658556/1060U) in the left deltoid (injection route not reported). Concomitant therapy included (ADVAIR), (NASONEX), (ACIPHEX), (ZOLOFT), (LOESTRIN) and (FERRUM). On 06-JUN-2008, also reported as within six hours after the vaccination, the patient experienced nausea. The physician reported that the patient had emesis four to five times per day for the next two to three days. The patient had no fever, no abdominal pain and no diarrhea. It was unknown whether the patient sought any medical attention. On 10-JUN-2008, the patient recovered from nausea and emesis. Additional information is not expected.

Other Meds: LOESTRIN, FERRUM, ADVAIR, NASONEX, ACIPHEX, ZOLOFT

Lab Data: None

History:

Prex Illness: Asthma, Rhinitis allergic, Gastrooesophageal reflux disease, Depression

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328738-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	29-Apr-2008	29-Apr-2008	0	15-Oct-2008	11-Feb-2009	TX	WAES0809USA00218	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Palpitations, Panic attack

Symptom Text: Information has been received from a health professional concerning a 23 year old white female who on 29-APR-2008, at 1:56 pm, was vaccinated in the left deltoid with a first dose of GARDASIL vaccine (yeast) (lot #659655/1486U). On the same day the patient experienced panic attack symptoms like heart racing and difficulty breathing. It was reported that the patient called the GARDASIL vaccine (yeast) hotline and no more vaccines were given to the patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328739-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	27-Aug-2008	27-Aug-2008	0	15-Oct-2008	11-Feb-2009	--	WAES0809USA00222	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Breast feeding

Symptom Text: Information has been received regarding a case in litigation concerning a 24 year old female with no relevant medical history or allergies who on 25-JUN-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). Concomitant therapy included vitamins (unspecified). On 27-AUG-2008 the patient was vaccinated with a second dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). On 27-AUG-2008, also reported as starting the day of her second shot of vaccine, the patient experienced hair falling out in handfuls. The patient also reported that she was breastfeeding her 6 month old daughter. The patient's daughter developed a rash on her face. No medical attention was sought. The patient's event persisted. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328740-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Aug-2008	19-Aug-2008	0	15-Oct-2008	11-Feb-2009	CA	WAES0809USA00234	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Pallor, Syncope

Symptom Text: Information has been received from other health professional concerning a 17 year old Hispanic female with no known medical condition or illness at time of vaccination, who on 19-AUG-2008, at 10:30, was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot #659655/1486U) via intramuscular on her right deltoid and varicella virus vaccine live (Oka/Merck) (MSD) via subcutaneous on her left deltoid. On 19-AUG-2008, at 10:30 the patient felt light headed, looked pale and fainted right after shots given. The patient recovered a few seconds after. The patient was monitored for half an hour. The patient stated that she was nervous prior vaccine administration and did not eat in the morning. Laboratory test were not performed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Nervousness

Prex Vax Illns:

Vaers Id: **328741-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	27-Aug-2008	27-Aug-2008	0	15-Oct-2008	11-Feb-2009	TX	WAES0809USA00284	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Dizziness, Nausea

Symptom Text: Information has been received from a licensed visiting nurse concerning a 23 year old female with penicillin allergy who on 27-AUG-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (Lot # 660612/0229X), 0.5 mL, IM. There was no concomitant medication. On 27-AUG-2008, the patient experienced diarrhea, nausea and dizziness 60 to 90 minutes following vaccination. The patient's diarrhea and nausea and dizziness persisted. The patient sought medical attention by a phone call. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Penicillin allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **328742-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
35.0	F	15-Feb-2008	29-Feb-2008	14	15-Oct-2008	11-Feb-2009	FL	WAES0809USA00308	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dermatitis, Erythema, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a licensed practitioner nurse concerning a 35 year old female who on 12-DEC-2007, was vaccinated with her first dose of GARDASIL vaccine (yeast). On 15-FEB-2008, was vaccinated with her second dose of GARDASIL vaccine (yeast). On approximately 29-FEB-2008, two weeks after the second vaccination, the patient experienced dermatitis. The patient reports that when she lightly scratches her skin she gets an erythema that rises up, that she referred to as "Graphic Dermatitis". The patient's "Graphic Dermatitis" was self diagnosed. The patient discussed the dermatitis on her routine office visit on 09-JUL-2008 and a follow-up visit on 06-AUG-2008. The patient's graphic dermatitis persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328743-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	29-Aug-2008		15-Oct-2008	11-Feb-2009	FL	WAES0809USA00316	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from a physician concerning an 18 year old female with no known drug reactions/allergies who on an unspecified date was vaccinated with a third dose of GARDASIL vaccine (yeast) (lot# 660620/0571X) IM. There was no concomitant medication. On 29-AUG-2008 the patient fainted, fell and hit her head. The patient was taken to the Emergency Room where she had a computed axial tomography (CT) done. The CT result came back negative. The patient was released. The patient did not faint after the first and second dose. Additional information has been requested.

Other Meds: None

Lab Data: computed Axial, 8/29?/08, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328744-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	02-Sep-2008	02-Sep-2008	0	15-Oct-2008	11-Feb-2009	MA	WAES0809USA00319	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Somnolence

Symptom Text: Information has been received from a registered nurse (RN) concerning a patient who on 09-JUL-2007 was vaccinated intramuscularly with the first dose of GARDASIL vaccine (yeast), on 10-OCT-2007 was vaccinated intramuscularly with the second dose of GARDASIL vaccine (yeast) and on 30-JAN-2008 was vaccinated intramuscularly with the third dose of GARDASIL vaccine (yeast). On 02-SEP-2008 the patient was vaccinated intramuscularly with the fourth 0.5 ml dose of GARDASIL vaccine (yeast). The patient was sleepy but arousable. At the time of reporting, the outcome was unknown. No product quality complaint was involved. At the time time of reporting, the outcome was unknown. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328745-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	02-Sep-2008	02-Sep-2008	0	15-Oct-2008	11-Feb-2009	NY	WAES0809USA00326	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Information has been received from a registered nurse (RN) concerning a female who in July 2007, was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL vaccine (yeast) and on 02-SEP-2008 was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL vaccine (yeast). No problems reported. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328746-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Oct-2008	11-Feb-2009	--	WAES0809USA00334	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Migraine

Symptom Text: Information has been received from a physician concerning her daughter with a history of migraine in past who on an unspecified date was vaccinated with GARDASIL vaccine (yeast). There was no concomitant medication. The physician's daughter said GARDASIL vaccine (yeast) aggravated her migraine condition. Subsequently, "within a day or two after receiving vaccination", the patient recovered from aggravated her migraine condition. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Migraine

Prex Vax Illns:

Vaers Id: **328747-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jun-2008	01-Jun-2008	0	15-Oct-2008	11-Feb-2009	NC	WAES0809USA00340	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse, for the Pregnancy Registry for GARDASIL vaccine (yeast), concerning a 15 year old female with no pertinent medical history or drug allergies who at the end of June 2008, was vaccinated with a dose of GARDASIL vaccine (yeast). The nurse did not have lot numbers or number of GARDASIL vaccine (yeast) doses received. There was no concomitant medication. It was reported the patient was pregnant. No adverse effect was reported. The patient sought unspecified medical attention via office visit. Additional information has been requested.

Other Meds: None

Lab Data: None

History: LMP = 05/05/2008

Prex Illness: Pregnancy NOS

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328748-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	07-Mar-2008	25-Apr-2008	49	15-Oct-2008	05-Jan-2009	FL	WAES0809USA00353	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Back pain, Muscle spasms, Musculoskeletal discomfort

Symptom Text: Information has been received from a 24 year old female with no pertinent medical history and no allergies who on 02-FEB-2008 was vaccinated with the first dose of GARDASIL IM 0.5ml. On 07-MAR-2008 the patient was vaccinated with the second dose of GARDASIL IM 0.5ml. On 07-AUG-2008 (reported as 08/07/2007) the patient was vaccinated with the third dose of GARDASIL IM 0.5ml. There was no concomitant medication. On 25-APR-2008 the patient experienced severe joint pain after receiving her second dose. The patient's severe joint pain persisted. The patient sought medical attention. Additional information has been requested. 2/20/09 Received PCP medical records of 10/1/08-12/29/08. FINAL DX: none provided Records reveal patient experienced back pain, left paraspinal muscle spasms & bilateral hip pain. Tx w/meds, PT & referred for MRI.

Other Meds: None

Lab Data: None LABS: UA WNL, c/s neg. CMP WNL. T-spine x-ray WNL. LS spine abnormal & revealed lumbar spasm. Renal US neg. MRI spine 2/4/09 revealed straightening of t-spine & desiccation of intervertebral disc L4-L5.

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328749-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Oct-2008	11-Feb-2009	--	WAES0809USA00361	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site urticaria

Symptom Text: Information has been received from a practice manager concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). Subsequently the patient experienced hives at the injection site. It was unknown whether the patient sought any medical attention. The outcome was unspecified. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328750-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-May-2008	Unknown		15-Oct-2008	11-Feb-2009	--	WAES0809USA00369	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Information has been received from a female who in approximately May 2008, also reported as four months ago, was vaccinated with a first 0.5 ml dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). The patient reported that she would be getting her second dose soon. The patient did not have ill effects from this. No further information is available

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328751-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	02-Sep-2008	02-Sep-2008	0	15-Oct-2008	12-Feb-2009	TX	WAES0809USA00380	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event

Symptom Text: Information has been received from a office manager concerning a female who in June 2007, was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). On 02-SEP-2008 the patient was vaccinated with a second dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). No adverse effect reported. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328753-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Jan-2008	12-Feb-2008	39	16-Oct-2008	21-Oct-2008	FL		05-Nov-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1267U	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2545AA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AFWB218BA	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2544204	0	Right arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Activities of daily living impaired, Aggression, Agitation, Bipolar disorder, Constipation, Cough, Depression, Distractibility, Dysphonia, Gastritis, Gastrooesophageal reflux disease, Generalised anxiety disorder, Haemangioma of liver, Irritability, Nervousness, Oppositional defiant disorder, Oropharyngeal pain, Pharyngitis, Psychotic behaviour, Self injurious behaviour, Upper respiratory tract congestion, Weight decreased

Symptom Text: Chronic stomach pain onset after 5 weeks, Diagnosis of Gastritis after 7 weeks. Increased agitation,irritability, nervousness, distractability. Diagnosis of Bipolar Disorder, General Anxiety Disorder, Oppositional Defiance Disorder after 4 months. Patient has had 3 endoscopies, 2 ultrasounds and an abdominal CT scan. Patient continues (after 11 months) to complain of chronic abdominla pain. Patient has been treated with various acid blocking medicines. Patient has been Baker Acted to a locked facility 5 times and once voluntarily in the past 5 months due to psychotic, self- injurious, violent behavior. Patient was admitted to a Behavioral Residnetial treatment center for 8 weeks. Patient has been on various anti-depressants, anti-psychotic and mood stabilizers. Patient is at present still under psychiatric, psychological and gastrointestinal care. Prior to vaccinations, 12 year old patient showed no evidence of either gastrointestinal condition or mental illness. 11/4/08 Reviewed PCP medical records of 1/4-9/16/08. FINAL DX: none provided Records reveal patient experienced general good health on 1/4/08. RTC 2/6/08 w/cough, congestion, hoarseness & sore throat. Dx w/pharyngitis. RTC 2/15 w/abdominal pain, cough, constipation. RTC 2/22, had missed 2 wks of school w/persistent abdominal pain, 6 # weight loss. Admitted to hosp for peds GI consult. Dx w/gastritis & GERD. Tx w/meds. RTC 9/16/08 s/p admit for depression & bipolar disorder.

Other Meds:

Lab Data: 3 endoscopies w/ biopsy, abdominal CT and ultrasound. Various Lab tests: CBC,Heavy Metals Comp. Panel, Hummoral immunity Eval., Celiac Disease Comp Panel, CMP, Anti- Streptolysin. EEG(with abnormal findings),MRI of the Brain(normal). Stool

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **328766-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	16-Oct-2008	16-Oct-2008	0	16-Oct-2008	24-Oct-2008	TN		24-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	2	Right arm	Intramuscular	
	FLU	GLAXOSMITHKLINE BIOLOGICALS	AFLLA158AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Heart rate decreased, Syncope vasovagal

Symptom Text: Vasovagal syncope with subsequent fall hitting head; rapid return of consciousness. BP 86/70, pulse palpated as low as 40. ECG - HR = 55. Pulse ox = 98%.

Other Meds: Ortho-Tri-Cyclen Lo

Lab Data: ECG, pulse oximetry; 2D-echocardiogram scheduled

History: Sulfa allergy

Prex Illness: No

Prex Vax Illns:

Vaers Id: **328769-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Oct-2008	15-Oct-2008	0	16-Oct-2008	24-Oct-2008	TX		27-Oct-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLU	SANOFI PASTEUR	U2791BA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2658AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B027AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	M0072X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Feeling abnormal, Heart rate normal, Pallor

Symptom Text: Client received HPV #1 vaccine on right upper arm approximately at 5:15pm in company of her mother. Mother during assessment stated she had eaten "goodies" prior to vaccine and was ready to receive her "shot" although she appeared nervous. After informing patient/parent of the benefits of the vaccine and comfort measures, she stated she was ready for "shot". Approximately 2 minutes after administration, patient stated she didn't feel good and sat on her mother's lap. She leaned towards her mother resting her head on mother's chest. "I'll be alright, I just need some time" she added that she felt weak and needed to sit down on chair. She stood up and with my assistance she proceeded to sit in chair. I questioned mother on her pale color, to which she answered that it was her "normal color", she was always pale. Vital signs taken excluding temperature. P-66, R-12, B/P 108/80. Patient called on cell phone initiating a conversation. Mother stated she was fine and they needed to go, signing Vaers form that she could no longer stay. Patient left ambulating in company of mother and sister at approximately at 6:00 pm.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **328820-1** **Related reports:** 328820-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Jun-2008	Unknown		16-Oct-2008	08-Jan-2009	MN		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U		Right arm	Unknown	
	MNQ	SANOFI PASTEUR	62381AA		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: MENACTRA given in early pregnancy, GARDASIL given in early pregnancy.

Other Meds: ORTHOEVERA PATCH

Lab Data: Positive pregnancy test 7/1/08; US 8/12/08, - Date of conception 6/3/08

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **328820-2** **Related reports:** 328820-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Jun-2008	Unknown		17-Nov-2008	17-Dec-2008	MN	WAES0809USA04609	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Nausea

Symptom Text: Information has been received from a medical assistant for pregnancy registry for GARDASIL, concerning an 18 year old female with allergy to amoxicillin who on 17-JUN-2008 was vaccinated with her first and only dose of GARDASIL intramuscularly while pregnant. Concomitant therapy included meningoccoccal ANYN conj vaccine (dip toxoid) (MENACTRA). LMP was 22-MAY-2008. No adverse effect was reported. The patient sought medical attention. Follow up information has been received from a physician concerning the "healthy teenage female on ORTHO EVRA (enter generic name) patch" which was discontinued on 01-JUL-2008. The patient took B6 50 mg TID from June 2008 to July 2008 for nausea. She was also started on prenatal vitamins, 1 daily. An ultrasound was performed on 12-AUG-2008 for viability and dates and was normal. A maternal serum alph-fetoprotein (MSAFP) was done on 25-SEP-2008 and was normal. Another ultrasound was performed on 07-OCT-2008 for fetal survey and was normal. The patient had no other previous pregnancies. Additional information has been requested.

Other Meds: ORTHO EVRA

Lab Data: Ultrasound, positive; Diagnostic laboratory, "quad test", positive; Ultrasound, 08/12/08, normal; Ultrasound, 10/07/08, normal; Serum beta-human, positive; Serum alpha-fetoprotein, 09/23/08

History: Penicillin allergy

Prex Illness: Pregnancy NOS (LMP= 5/22/2008

Prex Vax Illns:

Vaers Id: 328837-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.5	F	27-Aug-2008	Unknown		15-Oct-2008	09-Dec-2008	--	WAES0809USA00440	05-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure via breast milk, Rash

Symptom Text: Information has been received regarding a case in litigation concerning a 6 month old female infant whose mother on 25-jun-2008 was vaccinated with a first dose of GARDASIL. Injection site and route not reported). On 27-AUG-2008 the mother was vaccinated with a second dose of GARDASIL. Injection site and route not reported). The mother reported that she was breastfeeding the baby. The baby developed a rash on her face. The mother took the baby to the pediatrician to see if it was vaccine-related. The outcome of the baby was unspecified. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328838-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		15-Oct-2008	12-Feb-2009	--	WAES0809USA00446	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Musculoskeletal pain

Symptom Text: Information has been received from a pharmacy student concerning a 15 year old female who was vaccinated with GARDASIL vaccine (yeast). The patient had knee, elbow and shoulder pain since she was given GARDASIL vaccine (yeast). The reporter did not know how many doses the patient was given. The outcome was unknown. It was unknown if the patient sought medical attention or not. The reporter stated that she was only asked to research the information but was no further information on the patient. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328839-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	28-Aug-2008	29-Aug-2008	1	15-Oct-2008	12-Feb-2009	TN	WAES0809USA00447	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Rash

Symptom Text: Information has been received from a nurse concerning a 22 year old female with sulfonamide allergy and allergic reaction to (CLEOCIN) who on 28-AUG-2008 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL vaccine (yeast) (lot no. 659180/1758U). Concomitant therapy included (ORTHO EVRA) and (ANAPROX DS). On 29-AUG-2008 the patient developed swelling of the first digit of her left hand and the second digit if her right hand. On 30-AUG-2008 the patient developed a rash on her right forearm. The patient self-treated with (ADVIL). On 02-SEP-2008 the patient contacted the office by phone stating that the symptoms had resolved. Additional information has been requested.

Other Meds: ORTHO EVRA; ANAPROX DS

Lab Data: None

History: Sulfonamide allergy

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **328840-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	27-Aug-2008	30-Aug-2008	3	15-Oct-2008	12-Feb-2009	OH	WAES0809USA00452	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Ear discomfort, Nasal congestion, Oropharyngeal pain, Urticaria

Symptom Text: Information has been received from a physician concerning a 21 year old female with hypothyroidism and hypercholesterolaemia and a history of hives in the past who on 27-AUG-2008 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL vaccine (yeast) (lot no. 659655/1486U). Concomitant therapy included (SYNTHROID), (MSD) and hormonal contraceptives (unspecified). On 30-AUG-2008 the patient developed hives on both upper and lower extremities, stuffy nose, sore throat and "a full feeling" in her ears. The physician stated that the patient was "cleaning out a friend's apartment on 29-AUG-2008 and was exposed to a lot of dust and mold at that time". The patient was examined in the office on 03-SEP-2008 and was prescribed topical steroid cream. At time of this report, the patient's symptoms persisted. Additional information has been requested.

Other Meds: hormonal contraceptives; SYNTHROID; ZOCOR

Lab Data: None

History: Hives

Prex Illness: Hypothyroidism; Hypercholesterolaemia

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328841-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		15-Oct-2008	12-Feb-2009	--	WAES0809USA00464	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female patient who on unspecified dates was vaccinated with the first and second dose of GARDASIL vaccine (yeast). The nurse reported that each time the patient received a dose of HPV vaccine, she experienced flu like symptoms for 3 to 4 days. At the time of the report, the patient had recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328844-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Oct-2008	12-Feb-2009	--	WAES0809USA00465	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	4	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect dose administered, No adverse event

Symptom Text: Information has been received from a nurse practitioner concerning a patient who on unspecified dates was vaccinated with 3 doses of GARDASIL vaccine (yeast) at another location. The nurse practitioner reported that her office did not realize that and started her on another series and administered 2 doses of GARDASIL vaccine. The patient received 5 doses of HPV vaccine in total. No adverse event reported. It is unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328845-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Oct-2008	12-Feb-2009	NH	WAES0809USA00466	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling abnormal, Malaise, Visual impairment

Symptom Text: Information has been received from an office manager concerning a female who "a very long time ago" was vaccinated with a dose of GARDASIL vaccine (yeast) and "that evening felt very strange, had trouble with vision, and just did not feel well". The father of the patient was concerned and the patient contacted doctor for medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328846-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	01-Mar-2008		15-Oct-2008	12-Feb-2009	--	WAES0809USA00467	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Injection site haematoma, Injection site swelling

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with no known pertinent medical history or drug reactions/allergies who on 06-AUG-2007 was vaccinated with a first dose of GARDASIL vaccine (yeast) 0.5 ml IM. On unspecified dates the patient received the second and the third doses of GARDASIL vaccine (yeast) 0.5 ml IM. Concomitant therapy included an unspecified vaccine. In March 2008, the patient experienced 50% loss of her hair. The patient also experienced bruising and swelling at the injection site on an unspecified date. The patient's 50% loss of hair persisted. The patient's physician had suggested that she should be tested for "heavy metals". The patient sought unspecified medical attention. No further information is available.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328847-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	06-May-2008	06-May-2008	0	15-Oct-2008	12-Feb-2009	--	WAES0809USA00484	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Vomiting

Symptom Text: Information has been received from a consumer concerning her daughter who on approximately 06-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast). Subsequently the patient experienced diarrhea and vomiting. The outcome of the patient was unknown. The patient did not seek medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328848-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	29-Jul-2008	12-Aug-2008	14	15-Oct-2008	12-Feb-2009	--	WAES0809USA00487	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Dyspnoea, Lip swelling, Oedema peripheral, Rash pruritic

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old white female who at 9 am on 29-JUL-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot# 660557/0072X) 0.5 ml IM in her left deltoid. Concomitant therapy included (DESOGEN). At 8 am on 12-AUG-2008 (also reported as 13 to 14th August) the patient noted a pruritic rash beginning on her trunk and extending down her legs and arms. Within 24 hours, her plantar surfaces were swollen and she developed a pruritic rash. Then the patient developed swollen lips and a dry cough with shortness of breath within 48 hours. The patient was prescribed 3 weeks course of Prednisone oral, an unspecified "antihistamine" and an Albuterol inhaler. The patient had a chest x-ray on an unspecified date which was negative. A pulmonary function test was performed on an unspecified date with a normal result. A Lyme disease enzyme-linked immunosorbent assay for "pulmonary edema" and her events were confirmed as an allergic reaction. The patient was recovered from the allergic reaction. The patient sought medical attention in the office. Additional information is not expected.

Other Meds: DESOGEN

Lab Data: chest x-ray, negative; pulmonary function tests, normal; Lyme disease assay, negative

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328849-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	03-Sep-2008	03-Sep-2008	0	15-Oct-2008	12-Feb-2009	--	WAES0809USA00490	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: Information has been received from a medical assistant concerning a female who in August 2007, was vaccinated with the first dose of GARDASIL vaccine (yeast). In November 2007, the patient was vaccinated with the second dose of GARDASIL vaccine (yeast). On 03-SEP-2008, "today", the patient was vaccinated with the third dose of GARDASIL vaccine (yeast). No adverse effect reported. It was unknown if the patient sought medical attention or not. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328850-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.1	M	03-Sep-2008	03-Sep-2008	0	15-Oct-2008	12-Feb-2009	--	WAES0809USA00494	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: Information has been received from a consumer concerning her 1 month old infant son who on 03-SEP-2008 was vaccinated with GARDASIL vaccine (yeast) instead of a hepatitis B virus vaccine. It was not product confusion but a nursing error due to location in the refrigerator. No adverse effects noted thus far. Medical attention was sought at office. No product quality complaint was involved. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328851-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	06-Jun-2008	20-Jun-2008	14	15-Oct-2008	12-Feb-2009	--	WAES0809USA00509	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse for the Pregnancy Registry for HPV vaccine concerning a 23 year old female who on 18-APR-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (lot#659182/1757U) IM. On 06-JUN-2008, was vaccinated with the second dose of GARDASIL vaccine (yeast) (lot#660389/1968U) IM. In September the patient was now pregnant. She had a positive pregnancy test. The patient's LMP was on 20-JUN-2008 and EDD 29-MAR-2009. No other symptoms were noted. Additional information has been requested.

Other Meds: Unknown

Lab Data: beta-human chorionic, positive

History: LMP = 6/20/2008

Prex Illness: Pregnancy NOS

Prex Vax Illns:

Vaers Id: **328852-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Aug-2008	01-Aug-2008	0	15-Oct-2008	12-Feb-2009	--	WAES0809USA00510	11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a physician assistant for the Pregnancy Registry for HPV vaccine concerning a 20 year old female patient with no known drug allergies, who on 01-AUG-2008, was vaccinated with the first dose of GARDASIL vaccine (yeast) (Lot # 660620/0571X) IM. On 03-SEP-2008, the physician reported that the patient was administered her first dose of HPV vaccine and was pregnant. The patient's LMP was on 22-JUL-2008 and EDD 29-APR-2009. No adverse effect was reported. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328853-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Oct-2008	12-Feb-2009	WA	WAES0809USA00517	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with GARDASIL vaccine (yeast). Subsequently the patient experienced a serious adverse event. There were no specifics provided regarding the adverse experience. It was not specified whether the patient sought medical attention. Upon internal review, the "serious" adverse event was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328854-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	31-Jul-2008	02-Sep-2008	33	15-Oct-2008	10-Feb-2009	TN	WAES0809USA00525	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	HEP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Facial pain, Hypoaesthesia facial, Skin discolouration, Swelling

Symptom Text: Information has been received from a registered (x-ray) technician (RT) concerning her 11 year old daughter with allergic reaction to AMOXICILLIN (+) (AUGMENTIN) and no other pertinent medical history who on 31-JUL-2008 was vaccinated with the first dose of GARDASIL (yeast) (the lot number was not known). Concomitant therapy included other booster vaccines (unspecified by reporter) and hepatitis B virus vaccine (unspecified) (manufacturer unknown). On 02-SEP-2008 the patient developed intermittent numbness on the right side of her face and swelling and other children at school noticed that her face got purple. The patient described it as "a feeling she got after a shot at the dentist's office". She also stated the area was sore and she experienced abdominal pain. At the time of reporting, the patient did not recover. Medical attention was sought via telephone. No product quality complaint was involved. Additional information has been requested,

Other Meds:

Lab Data: None

History: Allergic reaction to antibiotics

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328855-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
34.0	F	03-Jul-2008	01-Sep-2008	60	15-Oct-2008	12-Feb-2009	NJ	WAES0809USA00530	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Information has been received from a physician concerning a 34 year old female who on approximately 03-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) in another office. In approximately September 2008, the patient had presented to the physician's office for the second dose of GARDASIL vaccine (yeast). No product quality complaint was involved. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328856-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	04-Sep-2008	04-Sep-2008	0	15-Oct-2008	12-Feb-2009	--	WAES0809USA00732	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: Information has been received from a nurse concerning an 18 year old female who in approximately September 2007, also reported as one year ago, was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). On 04-SEP-2008 the patient was vaccinated with a second dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). No adverse reactions were reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328857-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Oct-2008	12-Feb-2009	NJ	WAES0809USA00736	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date, was vaccinated with a dose of GARDASIL vaccine (yeast). The physician reported that the patient fainted and hit her head after receiving the dose of HPV vaccine. The patient sought medical attention at the physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328858-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Jun-2008	Unknown		15-Oct-2008	12-Feb-2009	MD	WAES0809USA00738	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site urticaria, Urticaria

Symptom Text: Information has been received from a physician concerning a 14 year old female with penicillin allergy and allergy to amoxicillin (+) (AUGMENTIN) who on 30-JUN-2008 was vaccinated with a dose of GARDASIL vaccine (yeast) intramuscularly in the arm (lot number not reported). Concomitant therapy included hepatitis A vaccine (inactive) (HAVRIX). Subsequently the patient experienced hives on her arm, at the injection site and also on her leg (left or right unspecified). Unspecified medical attention was sought. These symptoms lasted about one week. Subsequently, the patient recovered from the event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy; Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328859-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	04-Sep-2008	04-Sep-2008	0	15-Oct-2008	12-Feb-2009	--	WAES0809USA00741	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: Information has been received from a physician concerning a female who in approximately September 2007, also reported as about one year ago, was vaccinated with a first dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). On 04-SEP-2008 the patient was vaccinated with a second dose of GARDASIL vaccine (yeast) (lot number, injection site and route not reported). No problems reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328860-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Aug-2008	06-Aug-2008	0	15-Oct-2008	12-Feb-2009	FL	WAES0809USA00750	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a 15 year old female with drug allergy (she had rash on her body after Amoxicillin at age 1), who on 15-MAR-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) and she had no reaction to this dose. On 06-AUG-2008 the patient was vaccinated with the second dose of GARDASIL vaccine (yeast), Lot # 660612/0229X, 0.5 mL, IM. It was reported that within an hour or 2 after vaccination, the patient had rash on her chest and back. Patient was given (SOLU-MEDROL) and (MEDROL DOSEPACK) and told to start (BENADRYL). The patient's outcome is unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Rash

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **328861-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Oct-2008	12-Feb-2009	TX	WAES0809USA00754	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Autoimmune disorder

Symptom Text: Information has been received from an office staff member who reported their local health department contacted her concerning a female patient who on an unspecified date, was vaccinated with GARDASIL vaccine (yeast), Lot not provided. It was reported that the patient had an autoimmune disorder from GARDASIL vaccine (yeast). The patient's outcome was unknown. It was unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328862-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	22-Aug-2008	26-Aug-2008	4	15-Oct-2008	12-Feb-2009	--	WAES0809USA00755	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaginal haemorrhage

Symptom Text: Information has been received from a physician's assistant concerning a 25 year old female with a history of unspecified pelvic complaints, who on 22-AUG-2008 was vaccinated with her first dose of GARDASIL vaccine (yeast), Lot # 0152X. It was reported that on 26-AUG-2008, the patient had one episode of vaginal blood clots. On 26-AUG-2008, the patient recovered from vaginal blood clots. The patient sought medical attention, by phone. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Pelvic discomfort

Prex Illness:

Prex Vax Illns:

Vaers Id: **328863-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	26-Jun-2008	26-Jun-2008	0	15-Oct-2008	12-Feb-2009	NY	WAES0809USA00765	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pruritus generalised

Symptom Text: Information for the Merck Pregnancy registry for GARDASIL vaccine (yeast) has been received from a 20 year old female with urinary tract infection and not known allergies, who on 26-JUN-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast). Concomitant therapy included medications for urinary tract infection. The patient reported that she did not know that she was pregnant at the time of administration of the vaccine. On 29-JUN-2008, three days after vaccination, the patient experienced "itching all over". Subsequently, the patient recovered from the itching. Laboratory studies were not performed. At the time of reporting, the patient was 2 months and 2 weeks pregnant. Additional information has been requested.

Other Meds: therapy unspecified

Lab Data:

History: LMP = Unknown

Prex Illness: Pregnancy Nos; Urinary tract infection

Prex Vax Illns:

Vaers Id: **328864-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Nov-2006	20-Nov-2006	0	15-Oct-2008	12-Feb-2009	--	WAES0809USA00777	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a certified nurse midwife concerning an 18 year old female who on 20-NOV-2006 was vaccinated with her first dose of GARDASIL vaccine (yeast) (Lot#653937/0637F). Concomitant therapy included (PREVACID), acetaminophen (+) (ULTRACET), (MSD), (ZOLOFT), (CLARINEX) and (YASMIN). On 20-NOV-2006, a few minutes later after the vaccination, the patient fainted in the office. The patient was fully recovered from fainting a few minutes later. The patient later completed the series without any other symptoms. The patient seek medical attention. Additional information has been requested.

Other Meds: ULTACET, CLARINEX, YASMIN, PREVACID, SINGULAIR, ZOLOFT

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328865-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Oct-2008	13-Feb-2009	--	WAES0809USA00782	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Genital haemorrhage, Metrorrhagia

Symptom Text: Information has been received from a nurse concerning a teenager female patient who on an unknown date, was vaccinated with a dose of GARDASIL. The nurse reported that the patient experienced vaginal break through bleeding and spotting after receiving GARDASIL vaccine. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328866-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		15-Oct-2008	13-Feb-2009	--	WAES0809USA00789	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Human papilloma virus test positive, Smear cervix abnormal

Symptom Text: Information has been received from a consumer concerning her daughter, a 19 year old female with no pertinent medical history or drug reactions/allergies, who recently was vaccinated with her second dose of GARDASIL. On the same days she had a PAP smear which was positive for HPV. There was no concomitant therapy. As of 04-SEP-2008 the positive HPV persisted. The patient sought unspecified medical attention. Additional information is not expected.

Other Meds: None

Lab Data: Pap test - positive

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **328867-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Feb-2008	22-Feb-2008	0	15-Oct-2008	13-Feb-2009	NJ	WAES0809USA00801	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a certified medical assistant concerning a 14 year old female patient who on 22-FEB-2008, was vaccinated with a dose of GARDASIL. On 22-FEB-2008, just after being vaccinated, the patient fainted. The patient recovered shortly after she fainted. No other symptoms were noted. The patient sought medical attention in the physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328868-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	14-Aug-2008	14-Aug-2008	0	15-Oct-2008	13-Feb-2009	--	WAES0809USA00813	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a 19 year old female with no pertinent medical history or drug reaction/allergies, who on 14-AUG-2008 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. The patient found that she was pregnant 2 weeks ago on approximately 31-JUL-2008. As of 04-SEP-2008 the patient was 7 weeks gestation. The patient's LMP was 14-JUL-2008 and EDD 21-APR-2009. She had three pregnancy tests. The patient saw the physician in the office. No adverse event reported. Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic - pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 7/14/2008)

Prex Vax Illns:

Vaers Id: **328869-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	17-Jun-2008	24-Jun-2008	7	15-Oct-2008	13-Feb-2009	FL	WAES0809USA00824	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: Information has been received from a physician concerning a female with a history of thyroid cyst who on 17-JUN-2008 was vaccinated with the first dose of GARDASIL. On approximately 24-JUN-2008, "a week after receiving" the vaccine, the patient developed symptoms of "receding small reactive lymph node in her lower LAC section". Per physician patient will hold off in getting the succeeding GARDASIL. The patient sought medical attention. On an unspecified date, the patient recovered. Additional information has been requested. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Thyroid cyst

Prex Illness:

Prex Vax Illns:

Vaers Id: **328870-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Aug-2007	03-Sep-2007	31	15-Oct-2008	13-Feb-2009	--	WAES0809USA00845	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician and the patient's mother concerning a 15 year old female with no pertinent medical history who in approximately 03-AUG-2007, was vaccinated with her first dose of GARDASIL. Concomitant therapy included unspecified birth control. On 03-SEP-2007 (1 month after 1st dose) the patient began experiencing episodes of passing out. These episodes occurred just about every other day. There were "tons of episodes" which lasted until November 2007. In approximately 02-OCT-2007, she received her second dose of GARDASIL. In November 2007, therapy with birth control was discontinued. There were no other known reactions to the birth control, but it was discontinued since they did not know reason for repeated episodes of passing out. On 23-NOV-2007, the frequent episodes stopped. Since November of 2007, the patient has had 5 episodes of passing out. Patient was due for her third dose of GARDASIL in February, but did not receive it. The patient has had other test done, however, no cardiac abnormalities, or other causes noted. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **328871-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Oct-2008	13-Feb-2009	--	WAES0809USA00856	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site

Symptom Text: Initial and follow-up information has been received from an official concerning a female who was vaccinated with GARDASIL vaccine (yeast) at the gluteal region. It was stated that the girl was vaccinated this way because there was not enough muscle mass to vaccinate the intended way. No symptoms were noted. It was not specified if the patient sought medical attention or not. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328872-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Aug-2008	07-Aug-2008	0	15-Oct-2008	13-Feb-2009	IN	WAES0809USA00868	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1161F	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site pain

Symptom Text: Information has been received from a medical assistant concerning a 15 year old female patient with no known drug allergies or pertinent medical history who on 07-AUG-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast), Lot # 654540/1161F, 0.5 mL, intramuscularly in her left deltoid. Other concomitant medication included unspecified allergy medication. It was reported that the patient developed arm pain at the injection site, after receiving the first injection. The patient took Ibuprofen and applied ice and heat; however, the patient's arm pain worsened and the patient could not lift the arm to use a hair brush. On 21-AUG-2008 the patient was reported to have less pain. No other symptoms or treatment reported. At the time of the report the patient was recovering. The patient sought medical attention at physician's office. Additional information has been requested.

Other Meds: allergenic extract

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328873-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		15-Oct-2008	13-Feb-2009	IL	WAES0809USA00875	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Faecal incontinence, Headache, Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning a 25 year old female who was vaccinated with the second dose of GARDASIL vaccine (yeast). The patient developed nausea, vomiting and "loss of bowel control" about 19 hours after receiving the vaccination. This was followed by a headache that lasted for 3-5 days. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328874-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		15-Oct-2008	13-Feb-2009	MN	WAES0809USA00885	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a physician concerning a 20 year old female who was vaccinated with her second dose of GARDASIL vaccine (yeast). Subsequently the patient experienced 2 syncope episodes immediately post vaccination. Subsequently, the patient recovered from the 2 syncope episodes. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328875-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Oct-2008	13-Feb-2009	TN	WAES0809USA00887	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a registered nurse concerning a female with no allergies and no medical history reported, who was vaccinated with the first dose of GARDASIL vaccine (yeast) and two weeks later "broke out in hives". The patient was given a Prednisone Dose Pack. It is not known if the hives resolved. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **328876-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Oct-2008	13-Feb-2009	--	WAES0809USA00901	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a nurse who heard from a mother that her daughter was vaccinated with GARDASIL vaccine (yeast) and is now experienced hair loss. The hair loss looked like patches of "bold spots" down to the scalp. The patient's hair loss persisted. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328877-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	28-Aug-2008	29-Aug-2008	1	15-Oct-2008	13-Feb-2009	MI	WAES0809USA00908	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Pyrexia, Rash generalised

Symptom Text: Information has been received from a consumer concerning her 20 year old daughter with no allergies and no medical history reported, who on 25-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) and on 28-AUG-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast). Concomitant therapy included ZYRTEC and DEPO-PROVERA. Within 24 hours after second dose of GARDASIL vaccine (yeast), on 29-AUG-2008, the patient began to experience diarrhea and a rash on the back of her legs. The rash progressed up to the patient's back and to her arms and eventually covered approximately 50 percent of her body. On 04-SEP-2008, the patient developed a fever. Th physician's medical attention. Additional information has been requested.

Other Meds: ZYRTEC, DEPO-PROVERA

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **328878-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	21-Aug-2008	21-Aug-2008	0	15-Oct-2008	13-Feb-2009	NJ	WAES0809USA00917	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Juvenile arthritis, Pain in extremity

Symptom Text: Information has been received from a physician concerning an 18 year old female who on 21-AUG-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast) (Lot # 659184/0843X) and experienced pain in wrists, hands and arm. The physician diagnosed her with juvenile arthritis. The patient's events persisted. The patient sought physician's medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328879-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		15-Oct-2008	13-Feb-2009	NJ	WAES0809USA00919	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bedridden, Fatigue, Pain

Symptom Text: Information has been received from a physician concerning an approximately 18 year old female who on an unspecified date was vaccinated with the second dose of GARDASIL vaccine (yeast), IM and experienced aches and fatigue. The patient was "in bed for 3 days" due this. It was unknown if the patient sought medical attention. The patient outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328880-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		15-Oct-2008	13-Feb-2009	VA	WAES0809USA00928	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning an approximately 16 year old female with no known drug allergies and no medical history reported, who on an unknown date was vaccinated with the second dose of GARDASIL vaccine (yeast). There was no concomitant medication. On an unspecified date, 2 weeks after vaccination, the patient experienced syncope. The patient was also exercising at the time of adverse event. The patient recovered from syncope. The patient sought medical attention at the office. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 328881-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
32.0	F	19-Jul-2007	Unknown		15-Oct-2008	13-Feb-2009	--	WAES0809USA00931	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Arthralgia, Inappropriate schedule of drug administration, Menstruation irregular, Pain in extremity

Symptom Text: Information has been received from a 32 year old female patient with no pertinent medical history or drug reactions/allergies who on 18-JAN-2007, was vaccinated with the first dose of GARDASIL vaccine (yeast), on 19-MAR-2007 was vaccinated with the second dose of GARDASIL vaccine (yeast) and on 19-JUL-2007 was vaccinated with the third dose of GARDASIL vaccine (yeast) into her buttocks. There was no concomitant medication. In May or June-2007, the patient reported that her hair fell out in clumps, she experienced pain in the lower legs and sore joints (though not constant), after she was getting her second dose of HPV vaccine. Also she stated that her periods have gone from a steady every 28 days to between 28 and 50 days. She has not been on birth control for years. She has had no family history of female hair loss. The patient had also consulted a nutritionist and dermatologists. The blood work performed showed no vitamin or mineral deficiency. The patient's hair fell out in clumps, sore joints, pain in the lower legs and irregular menstrual cycle persisted. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory, no vitamin or mineral deficiency

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328882-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Oct-2008	13-Feb-2009	--	WAES0809USA00932	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a female patient who on an an unspecified date were vaccinated with GARDASIL vaccine (yeast). It was reported that the patient fainted within the 15 minute period following vaccination. No specifics known about the patient. At the time of reporting, the patient had recovered. The patient sought medical attention in office. This is one of several patients received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328883-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Sep-2007	01-Sep-2007	0	15-Oct-2008	13-Feb-2009	CA	WAES0809USA00939	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Information has been received from a health professional certified medical assistant concerning a patient who in February 2007, was vaccinated with the first dose of GARDASIL vaccine (yeast) IM. In September 2007 was vaccinated with the second dose GARDASIL vaccine (yeast) IM. No adverse event was reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328884-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		15-Oct-2008	13-Feb-2009	--	WAES0809USA00952	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a health professional concerning an under 26 year old female patient who was vaccinated with the first dose of GARDASIL vaccine (yeast) initially at another facility, but when she went into the physician's office for the second dose of GARDASIL vaccine, the reporter detected an abnormal PAP at this annual visit. This is one of two cases reported from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328885-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	19-Aug-2008	26-Aug-2008	7	15-Oct-2008	13-Feb-2009	NJ	WAES0809USA00955	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site swelling

Symptom Text: Information has been received from a nurse concerning a 20 year old female patient who on 27-JUN-2008, was vaccinated with the first dose of GARDASIL vaccine (yeast) IM into left deltoid, on 19-AUG-2008 was vaccinated with the second dose of GARDASIL vaccine (yeast) into left deltoid muscle. On 26-AUG-2008, the patient complained of swelling, itching and redness at the injection site. Nurse stated as far as she knew client recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **328886-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	23-Aug-2008	23-Aug-2008	0	15-Oct-2008	13-Feb-2009	MD	WAES0809USA00983	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Paraesthesia, Pruritus, Urticaria

Symptom Text: Information has been received from a physician concerning a 19 year old female patient who in June 2008, received the first dose of GARDASIL vaccine (yeast) IM. On 23-AUG-2008, the patient received the second dose of GARDASIL vaccine (yeast) IM. There was no concomitant medication. The patient experienced the following symptoms within 2 hours after receiving the second dose of GARDASIL vaccine (yeast): hives, swelling of the hands and redness of the hands, itching, tingling along nail and toe nail beds. Given BENADRYL which helped within 1/2 hour. Then put on CLARITAN for maintenance for 10-15 days. Had been off CLARITIN for 36 hours and all of the symptoms recurred. Symptoms are not severe, but hives and itching, swelling of the hands and redness recurred. Took another CLARITIN and BENADRYL. At time of reporting, the patient's adverse experiences were still being treated. No additional information is expected.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328887-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Jul-2008	01-Jul-2008	0	15-Oct-2008	13-Feb-2009	NY	WAES0809USA00985	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Chills, Pain, Pyrexia

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female who in July 2008, was vaccinated with the first dose of GARDASIL vaccine (yeast). In July 2008, two hours after vaccination, the patient experienced fever, chills, aches and joint pain. Subsequently, the patient recovered from fever, chills, aches and joint pain. The registered nurse reported that the patient did not seek any treatment for the symptoms. The symptoms had resolved within 24 hours. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328888-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		15-Oct-2008	14-Nov-2008	MN	WAES0809USA01000	14-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information Has been received from a nurse concerning a 19-20 year old female patient who around the end of 2007, was vaccinated with the first doe of GARDASIL. The patient had no medication history. The nurse reported that the patient experienced irregular menses after receiving GARDASIL. The patient sought unspecified medical attention.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328889-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Dec-2007	Unknown		15-Oct-2008	13-Feb-2009	MN	WAES0809USA01001	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a nurse concerning a 19-20 year old female patient who around the end of 2007, was vaccinated with the first dose of GARDASIL vaccine (yeast). Concomitant therapy included unspecified birth control. The nurse reported that the patient experienced irregular menses after receiving HPV vaccine. The patient sought unspecified medical attention. This is one of several reports provided by the same source. Additional information has been requested.

Other Meds: therapy unspecified

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328890-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-Aug-2008	28-Aug-2008	0	15-Oct-2008	28-Jan-2009	AZ	WAES0809USA01058	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X		Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Emotional distress, Loss of consciousness, Syncope

Symptom Text: Information has been received from a physician concerning a 13 year old female with a history of scoliosis (status post surgery) who on 28-AUG-2008 was vaccinated with an unspecified dose of GARDASIL (lot # 660612/0229X) in the left upper arm. Concomitant therapy included FLUZONE. At 4:00 PM, the patient went to the lobby after receiving her GARDASIL and FLUZONE shots, she was standing at the front desk and collapsed. She was unconscious for a few minutes and then woke up. Normal mental status when woke up except that she was upset. Additional information is not expected.

Other Meds:

Lab Data:

History: Scoliosis

Prex Illness:

Prex Vax Illns:

Vaers Id: **328891-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	03-Sep-2008	07-Sep-2008	4	15-Oct-2008	13-Feb-2009	PA	WAES0809USA01156	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Rash generalised, Urticaria

Symptom Text: Information has been received from a physician concerning an 18 year old female who on 25-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) and she had no reaction after her initial GARDASIL vaccine (yeast). On 03-SEP-2008, the patient was vaccinated with the second dose of GARDASIL vaccine (yeast). Four days post vaccination, on 07-SEP-2008, the patient developed what she described as a "hives". At the time of the report, the patient was "still itching with the hive/rash covering for whole body". She had been prescribed unspecified steroids to treat the reaction. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328892-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Aug-2008	01-Aug-2008	0	15-Oct-2008	13-Feb-2009	--	WAES0809USA01157	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a nurse concerning her daughter who in August 2008, was vaccinated with the first dose of GARDASIL vaccine (yeast) and it was painful. It was unknown if the patient sought medical attention. The patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328893-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	05-Aug-2008	05-Aug-2008	0	15-Oct-2008	13-Feb-2009	--	WAES0809USA01162	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site erythema, Injection site mass, Injection site swelling

Symptom Text: Information has been received from a nurse practitioner concerning a 19 year old female who on 05-AUG-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (therapy route and lot number not reported). Concomitant therapy included oral hormonal contraceptives (unspecified). On 05-AUG-2008 the patient experienced a lump, redness and swelling at the injection site after she received her first dose of GARDASIL vaccine (yeast). The patient's symptoms began immediately after she received the dose. The patient sought unspecified medical attention. The swelling and redness subsided but the lump has persisted and as of 05-SEP-2008 has become larger. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328894-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	11-Jul-2008	Unknown		15-Oct-2008	13-Feb-2009	WV	WAES0809USA01164	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a licensed practical nurse (LPN) concerning a 20 year old female with no pertinent medical history or known drug allergies who on 08-JAN-2008, 11-MAR-2008 and 11-JUL-2008 was vaccinated intramuscularly with her 0.5 ml first, second and third doses of GARDASIL vaccine (yeast) (all the lot numbers are 659180/1758U). Concomitant therapy included Ibuprofen, codeine and penicillin (unspecified). After administration of her third dose of GARDASIL vaccine (yeast), the patient developed a generalized rash intermittently on different parts of her body. The patient sought medical attention via telephone. No laboratory or diagnostics tests were performed. At the time of this report, the event persisted. Additional information has been requested.

Other Meds: codeine; ibuprofen; penicillin (unspecified)

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **328895-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		15-Oct-2008	13-Feb-2009	--	WAES0809USA01188	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Presyncope

Symptom Text: Information has been received from a physician's assistant concerning a 14 year old female who was vaccinated with GARDASIL vaccine (yeast). The patient was also given Adacel. Subsequently the patient turned white and almost passed out but did not. Subsequently, the patient recovered. No medical attention was needed. Additional information has been requested.

Other Meds: ADACEL

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328896-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-May-2008	13-May-2008	0	15-Oct-2008	13-Feb-2009	SC	WAES0809USA01193	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site swelling

Symptom Text: Information has been received from a nurse concerning a 17 year old female with exercised induced asthma and depression and a history of gastrooesophageal reflux disease who on 07-JAN-2008 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL vaccine (yeast) (lot # 654741/1208F). On 13-MAY-2008 the patient was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL vaccine (yeast) (lot # 659180/1758U). Concomitant therapy included hormonal contraceptives (unspecified), Albuterol and LEVSIN. On approximately 13-MAY-2008, after receiving her second dose, the patient developed round, red, raised, itchy bulls eye area on her arm, at the injection site. The area was raised in the center and on the outer edge. As of 08-SEP-2008, the patient's symptoms persisted. The patient sought unspecified medical attention via office visit. Additional information has been requested.

Other Meds: ALBUTEROL; hormonal contraceptives; LEVSIN

Lab Data: None

History: Gastrooesophageal reflux disease

Prex Illness: Asthma exercise induced; Depression

Prex Vax Illns:

Vaers Id: **328897-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Oct-2008	13-Feb-2009	IN	WAES0809USA01204	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the first dose of GARDASIL. Subsequently, the patient experienced vomiting and nausea. Subsequently, the patient recovered from vomiting and nausea. No product quality complaint was involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328898-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Oct-2008	17-Feb-2009	--	WAES0809USA01216	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a nurse concerning an unspecified number of females who were vaccinated with their second or third dose of GARDASIL. Subsequently the patients experienced episodes of prolonged arm pain. At the time of this report, the outcomes were unknown. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in its report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328899-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-Aug-2008	Unknown		15-Oct-2008	13-Feb-2009	KY	WAES0809USA01220	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Information has been received from a physician concerning a 13 year old female who on 27-AUG-2008 was vaccinated with the second dose of GARDASIL. The patient developed right side "body tingling" of the arm and leg. The symptoms resolved on their own. The patient sought medical attention by phone call. The physician did mention that he received conflicting information from the patient and her mother. No further information is available.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328900-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Sep-2008	03-Sep-2008	0	15-Oct-2008	13-Feb-2009	KY	WAES0809USA01225	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pyrexia

Symptom Text: Information has been received from a physician concerning a 11 year old female who on 03-SEP-2008 was vaccinated with a first dose of GARDASIL vaccine (yeast), (route and administration site not reported). Concomitant therapy on the same day included MENACTRA and ADACEL. On the day of the vaccination the patient did have an upper respiratory infection with no fever. Within 24 hours the patient experienced a 102 F fever and dizziness. The patient sought medical attention via a phone call. No further information is available.

Other Meds:

Lab Data: body temp, 09/03?/08, 102 F

History: Unknown

Prex Illness: Upper respiratory tract infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328901-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	05-Sep-2008	07-Sep-2008	2	15-Oct-2008	13-Feb-2009	--	WAES0809USA01238	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a licensed practicing nurse concerning a 25 year old female who in July 2008, was vaccinated with a first dose of GARDASIL (route and administration site not reported). On 05-SEP-2008 the patient was vaccinated with a second dose of GARDASIL (route and administration site not reported). On 07-SEP-2008 the patient developed a pinpoint rash on the neck and chest and a little bit on the arms and legs. The patient's pinpoint rash persisted. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328902-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Oct-2008	13-Feb-2009	--	WAES0809USA01364	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a certified medical assistant concerning a female who was vaccinated with a second dose of GARDASIL. "Recently" the patient was found out that she had papilloma viral infection. At the time of this report, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328903-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	13-May-2008	Unknown		15-Oct-2008	13-Feb-2009	--	WAES0809USA01368	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pruritus, Injection site rash

Symptom Text: Information has been received from a registered nurse concerning a female who on 07-JAN-2008 and 13-MAY-2008 was vaccinated with 05 ml first and second dose of GARDASIL (lot #654741/1208F and 659180/1758U), respectively. Subsequently the patient experienced a raised rash at the injection site. The rash was raised and looked like a "bull's eye". It was also noted that the patient experienced pruritus at the injection site. The patient was seen at the office. At the time of this report, the events persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328904-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		15-Oct-2008	10-Feb-2009	--	WAES0809USA01526	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a nurse concerning an under 26 year old female who was vaccinated with three shot series of GARDASIL. The patient went to the physician's office for her next annual visit and an abnormal PAP was detected. This is one of two cases reported from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328905-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Aug-2008	01-Aug-2008	0	15-Oct-2008	10-Feb-2009	--	WAES0809USA01631	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Information has been received from a nurse concerning her daughter who in August 2008, was vaccinated with the first dose of GARDASIL and it was painful. It was unknown if the patient sought medical attention. The patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328906-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Oct-2008	10-Feb-2009	--	WAES0809USA02510	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Presyncope

Symptom Text: Information has been received from a physician's assistant concerning a approximately 3 girls (no ages provided) who was vaccinated with GARDASIL. Subsequently the patients turned white and almost passed out but did not. The patients outcome were not reported. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328907-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Oct-2008	10-Feb-2009	--	WAES0809USA02511	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Pallor

Symptom Text: Information has been received from a physician's assistant concerning a female who was vaccinated with GARDASIL. Subsequently the patient turned white and passed out. The patient outcome was not reported. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328908-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		15-Oct-2008	10-Feb-2009	--	WAES0809USA04317	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information was received from a nurse practitioner reporting a patient fainted after receiving GARDASIL. The patient come up to the window to check out. She left light-headed and sat down on floor. The patient was monitored for 15-20 minutes and she was fine. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **328912-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	23-Oct-2007	29-Nov-2007	37	17-Oct-2008	20-Oct-2008	TX	WAES0801USA03118	03-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received via a pregnancy registry, from a registered nurse, concerning a 19 year old female patient with a history of abnormal papanicolaou (PAP) smears, who on 23-JUL-2007 was vaccinated IM, with the first dose, 0.5 ml (lot # 0469U) and on 23-OCT-2007 vaccinated IM with the second dose, 0.5 ml, of GARDASIL (lot # invalid). Concomitant therapy included prenatal vitamins (unspecified). On 29-NOV-2007 (currently 7 weeks and 6 days gestation), the patient was pregnant. The patient was seen in the office and the pregnancy was reported as normal (estimated date of delivery, 27-AUG-2008). In follow-up was reported that on 22-FEB-2008, at 14.6 weeks from LMP, the patient had an elective termination. Upon internal review, elective termination of pregnancy was considered to be an other important event. No further information is expected.

Other Meds: Vitamins (unspecified)

Lab Data: None

History: Papanicolaou smear abnormal

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328928-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	10-Oct-2008	10-Oct-2008	0	17-Oct-2008	09-Jan-2009	NY		09-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling hot

Symptom Text: Pt requested GARDASIL vaccine today. Order and Screening questionnaire reviewed and signed by Clinician. GARDASIL 0.5 ml IM administered in (L) Deltoid by clinic All VS WNL. 10 minutes after admin Pt c/o feeling warm and dizzy. Clinic Nurse helped Pt to lay down in Supine position and given an icepack for comfort. Checked VS BP 126/84, P:88. Injection site appears WNL. No redness, itching, pain or swelling. Pt monitored and instructed to rest for 5 to 10 minutes. VS rev after 10 minutes. BP 120/82; P: 82. Pt states feeling much better. Dizziness has subsided. Pt states she is well enough to leave clinic. Instructed Pt to monitor for allergic reaction (difficulty breathing, swelling, fever, pain, tachycardia). Pt verbalized understanding and will call or seek medical attn for above S&SX. No LOC

Other Meds: ORTHOTRICYCLEN

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328935-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Oct-2008	13-Oct-2008	0	17-Oct-2008	09-Jan-2009	PA		12-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Pt passed out about 10 min after receiving GARDASIL #3. Did not faint with other 2 GARDASIL vaccines.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **328936-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Oct-2008	13-Oct-2008	0	17-Oct-2008	09-Jan-2009	WI		12-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0572X	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B0240B		Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2670AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cyanosis, Gaze palsy, Muscle rigidity, Pulse abnormal, Tremor

Symptom Text: Within 1 minute of vaccine admin, eyes rolled back and had UE & LE shaking/tremors, unable to stop the tremors. This episode lasting approx 30 seconds, and was followed about 3 minutes later with eyes rolling back dusky color thready pulse with rigid contracting of her UES. This 2nd episode lasted about 1 minute total. EMS was activated, transported to hospital.

Other Meds: None

Lab Data: None0

History: None

Prex Illness: None

Prex Vax Illns: None~ ()~~0~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328938-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Sep-2008	22-Sep-2008	5	17-Oct-2008	15-Jan-2009	PA		15-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	2685AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0843X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised, Urticaria

Symptom Text: All over hive type body rash 5 days after vaccinations. Benadryl OTC prn.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **328990-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	13-Oct-2008	16-Oct-2008	3	17-Oct-2008	12-Nov-2008	TN		12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2768BA	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2768AA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Hypoaesthesia, Pyrexia, Rhinorrhoea

Symptom Text: History of Guillain-Barre' syndrome. Saw private provider 10/16/2008 with complaints of fever, chills, nasal drainage, lower back numbness. Given injection of depo-medrol, dexamethasone, and rocephin. RX for claritin.

Other Meds: Paxil

Lab Data:

History: History of Guillain-Barre

Prex Illness: No

Prex Vax Illns:

Vaers Id: **329017-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	17-Oct-2008	17-Oct-2008	0	17-Oct-2008	12-Nov-2008	IL		12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyskinesia, Fall, Muscle twitching, Unresponsive to stimuli, Urinary incontinence

Symptom Text: Gardasil administered in right deltoid and within approximately 1 minute, patient complained of feeling faintish. Around 1 1/2 minutes patient's head fell to the table and she began to twitch and jerk as if having a seizure and then urinated on the floor. This lasted about 15 seconds before she started responding to her name being called. No treatment was needed. Reported episode to her primary care physician for follow up.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329031-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	17-Oct-2008	17-Oct-2008	0	17-Oct-2008	12-Nov-2008	WA		12-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Crying, Injection site erythema, Injection site pain, Injection site swelling, No reaction on previous exposure to drug

Symptom Text: PAIN AT INJECTION SITE when given gardasil vaccine lot # 0072 excoriation was 10/24/2010 im - was 2nd gardasil -no adverse reaction from first vaccine - causing pt to cry, hold her arm, swelling at injection site 1/4 inch raised bump (declined within a seconds) redness that radiated to 1 1/2 inches from injection site (gone within 15 minutes) had pt lay down, monitor vital signs - stayed within normal limits except temp was 98.6, 15 minutes later was 99.0, got out emergency first aid benedryl but did not need it, pts color remained the same - ARNP check pt and injection site - pt remained in clinic for 30 minutes after injection - pain had decreased in arma and pt had mobility in arm and she left in good condition. Called pt at home 3 hours later and pt stated she felt much better and that her arm felt better than it had after her first gardasil vaccination after 3 hours.

Other Meds:

Lab Data:

History: vicodin - oral medication given for tx of injured wrist in 2006 - pt had rash on her face 2 days later

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329040-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Oct-2008	15-Oct-2008	0	19-Oct-2008	29-Oct-2008	PA		20-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1134X	1	Right arm	Intramuscular	
	TD	AVENTIS PASTEUR	U2022AA	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2549AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1487U	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2811AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal rigidity, Convulsion, Dyskinesia, Hypotonia, Immediate post-injection reaction, Paraesthesia, Syncope

Symptom Text: Pt. was given gardasil 10/15/08 at 1700 hrs, immediately fainted and body jerked once body went limp from fainting. I believe Pt. had a seizure. Within hours, suffered from severe abdominal pain where pt was guarding abdominal. Clinic contacted 1000 hours on 10/16/08. Instructed to return Pt to office at 1300 hrs. Pt was placed on bland diet and prescribed pedilite, and zantac 75 mg bid. 2330 hours, Pt. suffered severe abdominal pain and taken to hospital. Pain rated 9 out of 10. Given Lidocaine to numb pain, no labs were performed. Pt described pain as, "Pain is like when your foot falls asleep and you feel pins and needles in your foot. Only the pain is much worse, like 10 times worse." Pt. is still have abdominal pain. 10/24/08 office note received from PCP with vax rec. 11/10/08 ER record received for 10/16/2008 with Dx: Abdominal pain. Pt presented with c/o abdominal pain since receiving vax 1 day prior. Pt reportedly fainted after the HPV injection and then developed severe abdominal pain described as pins and needles. PE WNL. Tx with Maalox/Lidocaine po with improvement and d/c home.

Other Meds: non

Lab Data:

History: allergies: corn, wheat, soy, peanuts, pencillin,. HX, under developed CNS, tremors in hands, mood disorder, oppositional defiant disorder, PMH: Asperger Syndrome. multiple food allergies. PCN allergy. Allergic conjunctivitis. Muffled mood

Prex Illness: annual physical

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329076-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Oct-2008	16-Oct-2008	0	17-Oct-2008	12-Jan-2009	IL		12-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2624AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0575X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site warmth, Oral pruritus

Symptom Text: Redness warmth at GARDASIL injection site - Full tongue itchy HARDPALATE - NO SOB No Wheezing

Other Meds: LAMICTAL 100 mg bid

Lab Data:

History: Cerebral Palsy and Seizure Disorder

Prex Illness: None

Prex Vax Illns: 08/2008~HPV (Gardasil)~~12~In Patient

Vaers Id: **329083-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	30-Sep-2008	02-Oct-2008	2	17-Oct-2008	12-Jan-2009	CO		12-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2622AA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0991X	2	Left arm	Subcutaneously	
PPV	MERCK & CO. INC.	0958F	0	Right arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abscess, Induration, Pain, Skin warm, Swelling

Symptom Text: 3 days after receiving immunizations pt. presented with (L) sterile abscess 10 cm x 10 cm, warm to touch, swollen, and painful. Also (R) indurated area 4.5cm x 5cm, both corresponding to subcutaneous location of immunizations.

Other Meds:

Lab Data:

History: Bronchiolitis obliterans

Prex Illness: None

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329112-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		20-Oct-2008	21-Oct-2008	WA	WAES0810USA02664	07-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Uterine dilation and curettage, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician for the pregnancy registry for GARDASIL concerning a 26 year old female who on an unspecified date was inadvertently vaccinated with GARDASIL while pregnant. After the patient received GARDASIL, she had a spontaneous termination at 6 weeks and 5 days from the last menstrual period. The patient had FYA antibodies (noted to be abnormal antibodies indicative of an autoimmune disorder). She was antinuclear antibodies test (ANA) negative with this second termination. the patient was not hospitalized. Subsequently the patient recovered. She had dilation and curettage (D & C) following the spontaneous termination. The reporter didn't necessarily think it was linked but she could not understand the connection to GARDASIL, and she could not find any other reason for the termination. Upon internal review the patient's spontaneous termination was determined to be an other important medical event. The patient also had a first spontaneous termination after the vaccination at 13 weeks from the last menstrual period. (WAES# 0810USA01794) Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, FYA antibodies; serum ANA, positive, first termination; serum ANA, negative, second termination

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329113-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		20-Oct-2008	21-Oct-2008	--	WAES0810USA02003	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Blindness

Symptom Text: Information has been received from a physician concerning a 15 year old female who on an unspecified date was vaccinated with GARDASIL and lost her vision in "2007". The physician was not the patient's provider. The physician found this case out from a ski instructor who taught blind children. The event was reported as disabling. Attempts are being made to verify the existence of an identifiable patient and reporter have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329114-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		20-Oct-2008	21-Oct-2008	WA	WAES0810USA01794	07-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Uterine dilation and curettage, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician for the pregnancy registry for GARDASIL concerning a 26 year old female who on an unspecified date was inadvertently vaccinated with GARDASIL while pregnant. After the patient received GARDASIL, she had a spontaneous termination at 13 weeks from the last menstrual period. The patient had FYA antibodies (noted to be abnormal antibodies indicative of an autoimmune disorder). She was antinuclear antibodies test (ANA) positive with the first termination. The patient was not hospitalized. Subsequently the patient recovered. She had dilation and curettage (D &C) following the spontaneous termination. The reporter didn't necessarily think it was linked but she could not understand the connection to GARDASIL, and she could not find any other reason for the termination. Upon internal review the patient's spontaneous termination was determined to be an other important medical event. The patient also had a second spontaneous termination after the vaccination at 6 weeks and 5 days from the last menstrual period. (WAES# 0810USA02664). Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, FYA antibodies; serum ANA, positive-first termination; serum ANA, negative-second termination

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329115-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	22-Jun-2007	15-Jul-2008	389	20-Oct-2008	21-Oct-2008	CA	WAES0810USA01203	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician and a nurse, for the Pregnancy Registry for GARDASIL, concerning a 26 year old female consumer who in June 2007, was vaccinated with her first dose of GARDASIL, IM. Subsequently, she became pregnant. This was the patient's first pregnancy. She was hospitalized for a caesarean section due to "low transfer". On 03-JUN-2008 the patient delivered a healthy baby. Then on 15-JUL-2008 she received her second dose of GARDASIL (lot # 658560/1062U). On 07-OCT-2008 the patient has an intrauterine device insertion. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **329126-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	15-Sep-2008	15-Sep-2008	0	20-Oct-2008	21-Oct-2008	FR	WAES0810USA02048	21-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal pain

Symptom Text: Information has been received from the Health Authorities on 09-SEP-2008 (under the reference DHH2452N2008-42396): A 20 year old female patient received a dose of the GARDASIL (Lot # was not reported, site of injection and dose unknown) via intramuscular route on 15-SEP-2008. On 15-SEP-2008, she experienced pain in the shoulder and on 26-SEP-2008 she still felt pain in the shoulder, even worse. At the time of reporting, the patient had not recovered. The reporter felt that shoulder pain was an other important medical event. Other business partner numbers included: E2008-09402 and BGAR2008/129. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329137-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-Oct-2008	13-Oct-2008	0	20-Oct-2008	27-Oct-2008	NJ		14-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Concussion, Fall, Headache, Immediate post-injection reaction, Loss of consciousness, Syncope, Traumatic brain injury, Vomiting

Symptom Text: Syncope episode shortly after given, fell and sustained concussion. 12/2/08-records received for DOS 10/13/08-DC DX-Closed head injury/concussion. Admitted following a closed head injury from a syncopal episode. Loss of consciousness after vaccination. C/O pain and emesis. Coninued with emesis in ED as well as headache. Overnight observation.

Other Meds:

Lab Data: CT Scan head (-); Hospitalized overnight for observation. 12/2/08-records received- CT scan negative.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329163-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-Oct-2008	09-Oct-2008	1	20-Oct-2008	30-Oct-2008	MO		30-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	843X	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1134X	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2641AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site warmth

Symptom Text: 3 1/2 cm x 3 1/2 cm induration at vaccine site; warm to touch. BENADRYL 25 mg po q 6 hours ordered by Dr Bernhard

Other Meds: Polyethylene Glycol Rx Powder; Miralax Powder; Seroquel 300mg, 200mg and 100mg (Quetiapine); Erythromycin; Lithium CO3; Eskalith-CR; Peroxyl mouth rinse, Abilify

Lab Data:

History: Allergy grass

Prex Illness:

Prex Vax Illns:

Vaers Id: **329206-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Oct-2008	04-Oct-2008	3	20-Oct-2008	30-Oct-2008	PA		05-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0954X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Convulsion, Eye pain, Eyelid oedema, Headache, Malaise, Periorbital oedema, Rhinorrhoea, Syncope vasovagal, Vaccine positive rechallenge

Symptom Text: Siezures, eyelids swallen, could not see without experiencing headaches, feels ill when she wakes every morning. Very rarely does she feel well anymore, has been running a low grade temp off and on since the shot was administered and eyelids still puff up with headaches. 10/24/08-records received for DOS 10/1/08-2nd Gardasil vaccine received, vasovagal episode no post-ictal sequelae. Similar reaction to 1st Gardasil vaccine. Office visit 10/7/08-C/O eyelid edematous. Well until 3 days prior. Painful to move eye. Runny nose, headache, malaise. Day after vaccination returned to normal. Assessment: periorbital edema.

Other Meds:

Lab Data:

History: none

Prex Illness: eyelids, headaches, morning illness, week , low grade fever, fainted, and seizures

Prex Vax Illns: danielle~HPV (Gardasil)~2~16~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329214-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	26-Aug-2008	19-Oct-2008	54	20-Oct-2008	27-Oct-2008	IA		13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0053X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Deep vein thrombosis, Dysmenorrhoea, Oedema peripheral, Oral contraception, Orthostatic hypotension, Pain in extremity, Pulmonary embolism, Thoracic outlet syndrome

Symptom Text: Patient received Gardasil around 8/1/08 in left arm. While attending a forum for high school students, she presented to ER on 10/19/08 with left arm swelling and pain. Ultrasound demonstrated LUE DVT, and CT of chest showed small pulmonary emoboli. Only other risk factor for DVT is birth control pills. 12/04/08-records received for DOS 10/19-10/23/08-DC DX:Left upper extremity deep venous thrombosis with a few very small pulmonary emboli identified in right lung as well on chest computerized tomography. Transient orthostatic hypotension. Thoracic outlet syndrome on left likely contributing to deep venous thrombosis. Oral birth control pills started within last 4-6 months-now discontinued. Presented to ED with acute swelling of left upper extremity. 2/26/09-office visit note for DOS 8/26/08 received follow-up visit for dysmenorrhea now improved.

Other Meds: Birth Control Pills

Lab Data: CT chest on 10/19/08 showed several small pulmonary emboli. Ultrasound of left upper extremity, 10/19/08, showed extensive DVT. 12/4/08-records received-Ultrasound showed extensive deep venous thrombosis. WBC 13.4 84% neutrophils 11% lymp

History: 12/4/08-records received-Family history notable for upper extremity deep venous thrombosis.

Prex Illness:

Prex Vax Illns:

Vaers Id: **329216-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	15-Aug-2008	15-Sep-2008	31	20-Oct-2008	30-Oct-2008	PA		13-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site mass, Lipoma excision

Symptom Text: I received Gardasil Vac. on August 15, 2008. I received the injection in my upper left arm. A(back side) 30 Days later I went to my Family Doctor for a growth that was right where I recieved the injection. Upper left arm. (back side). September 18 2008, I went to a surgeon September 26 2008 MRI, and then October 3 2008 I had Surgury. October 14 2008 had follow up with surgeon. She told me to tell the doctor who gave the injection to me. I did and they contacted Merck. Now I am telling you because I was told to. 11/12/08-records received for DOS 10/3/08-DX: Left upper arm mass. Left upper arm mass excision with biopsy.

Other Meds: lithium seroquel

Lab Data: MRI Byopsy surgury 11/12/08-records received-Pathology report:focally large lymphoid cells, benign diagnosis, mature adipose tissue consistent with lipoma.

History: bipolar

Prex Illness: none

Prex Vax Illns:

Vaers Id: **329247-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Oct-2006	21-Oct-2006	1	20-Oct-2008	30-Oct-2008	NY		31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pyrexia

Symptom Text: High fever and significant nausea. Discontinued treatment (did not take the 2nd & 3rd doses).

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329269-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
30.0	F	06-Aug-2007	06-Aug-2007	0	17-Oct-2008	10-Feb-2009	MN	WAES0708USA03511	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Wrong drug administered

Symptom Text: Information has been received from a physician concerning a 29 year old white female with hypothyroidism and migraine headache and no previous pregnancy. In April-2007, the first ultrasound was performed for fetal survey. On 20-APR-2007, serum alpha-fetoprotein test was performed for screening and the result was normal. On 04-JUN-2007, the second ultrasound was performed for fetal survey. On 06-AUG-2007 the patient was vaccinated with a dose of GARDASIL when she was 29 weeks pregnant. The patient received the vaccine in error and was supposed to receive RHOGAM. Concomitant therapy included SYNTHROID and prenatal vitamins. On 16-AUG-2007 and 27-SEP-2007, separate ultrasound was performed. On 01-NOV-2007 the patient delivered a health normal baby boy at 41.2 weeks gestation. The weight of the baby was 8.0 pounds; the length was 21 inches; the Apgar score was 9/9. There was no congenital anomaly or complication with the baby. Additional information is not expected.

Other Meds: SYNTHROID; vitamins (unspecified)

Lab Data: ultrasound 04/???07, fetal survey;ultrasound, 06/04/07, fetal survey; ultrasound 08/16/07, fetal survey; ultrasound, 09/27/07, fetal survey; serum alpha-fetoprotein 04/20/07, normal

History:

Prex Illness: Pregnancy NOS (LMP = 1/15/2007); Hypothyroidism; Migraine

Prex Vax Illns:

Vaers Id: **329270-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	27-Jul-2007	27-Jul-2007	0	17-Oct-2008	10-Feb-2009	AZ	WAES0709USA01565	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Initial and follow-up information has been received from Merck pregnancy registry from a health professional and a 25 year old female with 1 previous pregnancy with full term delivery who on 27-JUL-2007 was vaccinated with a first dose of GARDASIL. There was no concomitant medications at the time of vaccination. Subsequently, she learned she was pregnant. The patient's last menstrual period was 20-JUL-2007 and estimated of delivery was 25-APR-2008. Ultrasound on 17-SEP-2007 and 18-DEC-2007 were within normal limits. Unspecified medical attention was sought. On 09-APR-2008, 37 weeks from LMP, the patient delivered vaginally a normal female (weight 7 pounds 15 ounces and length 20.5 inches). Follow up information reported that on 12-APR-2008, the newborn was seen in the office for jaundice. The physician reported that the newborn female was a healthy appearing, alert, normally nourished, developmentally normal, well hydrated child in no acute distress. The infant had skin symptoms of jaundice. Bilirubin levels were ordered and were as follows: Neonatal bilirubin was high at 12.3 and indirect bilirubin was high at 12. On 13-APR-2008 the physician reported that the patient had jaundice to the hips. Bilirubin levels were ordered and were as follows: Neonatal Bilirubin was high at 13.3 and Indirect Bilirubin was high at 12.9. On 14-APR-2008 the patient was evaluated at the office, and the child's mother stated "she looks less yellow today." The physician reported the patients status as improved. The child was to return to the clinic to follow-up in 2 weeks. The newborn was vaccinated with hepatitis B virus vaccine rHBsAg (yeast) on 09-APR-2008 at birth. (WAES0809USA03006). Other medication used during this pregnancy included pre-natal vitamins from 13-SEP-2008 to 09-APR-2008. Additional information is not expected.

Other Meds: None

Lab Data: ultrasound, 9/17/07, within normal limits; ultrasound, 12/18/07, within normal limits

History:

Prex Illness: Pregnancy NOS (LMP = 7/20/2007)

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329271-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	04-Sep-2007	04-Sep-2007	0	17-Oct-2008	17-Nov-2008	LA	WAES0710USA02663	17-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chlamydial infection, Drug exposure during pregnancy, Foetal disorder, Papilloma viral infection

Symptom Text: Initial and follow-up information has been received from a certified medical assistant, for the Pregnancy Registry for GARDASIL concerning a 19 year old female with a history of heart murmur and 1 previous pregnancy and 1 full term delivery who on 04-SEP-2007 was vaccinated intramuscularly with the first dose of GARDASIL during the first trimester of pregnancy. Concomitant therapy included prenatal vitamins and iron tablets. The patient sought unspecified medical attention in the physician's office. On 13-SEP-2007 routine ultrasound was performed and the result was normal. Follow-up information was received that during pregnancy, the patient developed papilloma viral infection and Chlamydia infection. On 27-January-2008, the patient was placed on ZITHROMAX, 1 gram, 1 dose for the treatment of Chlamydia infection. The outcome was unknown. During labor/delivery, the baby developed umbilical cord around neck. On 05-MAR-2008 the patient delivered a full-term, normal and healthy baby boy with no congenital anomalies. The weight of the baby was 7.4 pounds and the Apgar score was 9/9. Additional information is not expected.

Other Meds: iron (unspecified); vitamins (unspecified)

Lab Data: ultrasound, 09/13/07, normal; beta-human chorionic, positive

History: Cardiac murmur

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329272-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-Nov-2007	27-Nov-2007	0	17-Oct-2008	10-Feb-2009	SD	WAES0712USA07860	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received through the Merck Pregnancy Registry through a health professional concerning an 18 year old female with a history of attention deficit disorder, and mood swings, who on 27-NOV-2007 was intramuscularly vaccinated with her first dose of GARDASIL (Lot # 659437/1266U) and was subsequently determined to be pregnant (LMP=12Nov2007). Urine pregnancy test was positive. Concomitant therapy included CONCERTA, NORDETTE, LEVORA, and LEXAPRO. The patient sought medical attention during an exam in the office. No problems were reported. Follow-up information was received on 22-SEP-2008 from a registered nurse concerning an 18 year old white female who smoked daily before pregnancy and quit tobacco use when pregnant. Other medications used during pregnancy included LEXAPRO, 20 mg, once a day for the treatment of mood swings (stopped a 5 weeks pregnant), CONCERTA, 72 mg, once a day for the treatment of Attention deficit disorder (stopped at 5 weeks pregnant) and prenatal vitamin daily PO. On 22-AUG-2008, at 39 weeks from her LMP, the patient delivered a normal female baby weighting 7 pounds, 12 ounces. The baby's length was 19 inches and head circumference was 34 cm. The baby developed an elevated white blood cell count at birth and was treated intravenously with antibiotics for 10 days. The outcome of the baby was not reported. Additional information is not expected.

Other Meds: LEXAPRO 20 mg; NORDETTE; LEVORA; CONCERTA 72 mg; vitamins (unspecified)

Lab Data: urine beta-human, positive

History: Smoker

Prex Illness: Pregnancy NOS (LMP = 11/12/2007) Attention deficit disorder; Oral contraception; Mood swings

Prex Vax Illns:

Vaers Id: **329273-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-Jan-2008	07-Jan-2008	0	17-Oct-2008	10-Feb-2009	--	WAES0801USA04540	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chlamydial infection, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received from a mother and a licensed practical nurse for the Merck Pregnancy Registry for GARDASIL concerning her 17 year old daughter with no previous pregnancies who on approximately 07-JAN-2008 was vaccinated intramuscularly with a 0.5 mL dose of GARDASIL. The mother was calling to report that her daughter was pregnant after receiving the vaccine. Therapy was discontinued. The patient's mother reported that "they had no physician information because they have not found an OB/GYN in their area." The patient's mother advised that "once a doctor has been found they would call with the information." Medical attention was not sought. The patient's mother requested prescribing information. No product quality complaint was involved. On 29-JAN-2008 the patient was placed on therapy with ZITHROMAX (250mg once) for the treatment of chlamydia. Other medications taken during pregnancy included ZOFRAN and pre-natal vitamins. On 29-MAY-2008, the ultrasound was performed for rule out abruption and the result was normal. On 05-MAR-2008 the serum alpha fetoprotein test was performed as routine screen with negative result. On 09-AUG-2008 the patient delivered a normal female baby weighing 7 pounds 6 ounces at 38.5 weeks. There were no complications during pregnancy and labor/delivery. There were no congenital anomalies, other complications or abnormalities. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, 05/29/08, normal; beta-human chorionic, positive; serum alpha-fetoprotein, 03/05/08, negative

History:

Prex Illness: Pregnancy NOS (LMP = unknown)

Prex Vax Illns:

Vaers Id: **329274-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		17-Oct-2008	10-Feb-2009	UT	WAES0801USA04748	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Antepartum haemorrhage, Drug exposure during pregnancy

Symptom Text: Information has been received through the Merck pregnancy registry from a health professional concerning a 21 year old female who was vaccinated with her first dose of GARDASIL and it was subsequently discovered that the patient was pregnant. The patient's LMP=16-Nov-2007. Follow-up information has been received from a registered nurse. The patient experienced early pregnancy bleeding. The reporter was not aware of any other information that would inform the outcome of this pregnancy. Medications used during pregnancy included pre-natal vitamins (unspecified). There were no other complaints during pregnancy and labor/delivery. The prenatal labs, obstetrical procedure, serum alpha-fetoprotein test and ultrasound were performed. On 12-AUG-2008 the patient delivered a normal, health male baby weighing 7 pounds 6 ounces length 19.5 inch at 38 weeks with Apgar score "4/9/9." There were no congenital anomalies and no other complaints or abnormalities. Additional information is not expected.

Other Meds:

Lab Data: obstetrical procedure; ultrasound; laboratory test; serum alpha-fetoprotein

History:

Prex Illness: Pregnancy NOS (LMP - 11/16/2007)

Prex Vax Illns:

Vaers Id: **329275-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	07-Feb-2008	07-Feb-2008	0	17-Oct-2008	11-Feb-2009	CA	WAES0802USA04517	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Premature labour, Ultrasound scan, Vaginitis gardnerella

Symptom Text: Initial information has been received from a health professional and follow-up information was received from a physician, for the Pregnancy Registry for GARDASIL, concerning a 20 year old white female with depression, sciatica, drug hypersensitivity to PHENERGAN and amoxicillin and a history of 1 previous pregnancy (1 full-term delivery), cervical dysplasia, right ovarian cystectomy (2006), and loop electrosurgical excision of transformation zone procedure (LEETZ, in 2007). On 07-FEB-2008 the patient was vaccinated with the first dose GARDASIL (lot# not provided). On 13-FEB-2008 the patient had a positive blood test for pregnancy (LMP 15-JAN-2008) and an ultrasound on 27-FEB-2008 (IUP 8w5d). On approximately March 2008, the patient developed GARDNERELLA vaginitis. On 25-MAR-2008 the patient was placed on therapy with PROZAC, 20 mg, once a day, orally, for the treatment of depression and FLAGYL, 500 mg, twice a day, orally, for the treatment of GARDNERELLA vaginitis. On 30-JUN-2008 therapy with PROZAC was discontinued. On 01-JUL-2008 therapy with FLAGYL was discontinued. The outcome of GARDNERELLA vaginitis was unknown. On approximately 28-JUL-2008, the patient developed preterm labor at 30 weeks gestation. On 28-JUL-2008 the patient was placed on CELESTONE, 12 mg, every 12 hours, intramuscularly and magnesium sulfate, 2 gram every hour for the treatment of preterm labor. On 29-JUL-2008 therapy with CELESTONE was discontinued. On 30-JUL-2008 therapy with magnesium sulfate was discontinued and the patient was placed on terbutaline sulfate, 2.5 mg, every 4 hours, orally, for the treatment of preterm labor. On 11-AUG-2008 therapy with terbutaline sulfate was discontinued and the patient was placed on an unspecified medication, 10 mg, every 6 hours, orally, for the treatment of preterm labor. On the same day, the unspecified medication was discontinued. On 09-SEP-2008 the patient delivered a 7 pounds 6 ounces normal boy. The baby was diagnosed with sleep apnea and gastric reflux. Additional information is not expecte

Other Meds: Prozac

Lab Data: ultrasound, 02/27/08, IUP; serum beta-human, 02/13/08, posit

History: Cervical dysplasia; Ovarian cystectomy; Loop electrosurgical excision procedure

Prex Illness: Pregnancy NOS (LMP = 1/15/2008); Drug hypersensitivity; Penicillin allergy; Depression; Sciatica

Prex Vax Illns:

Vaers Id: **329276-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jun-2007	23-Oct-2007	144	17-Oct-2008	30-Dec-2008	IL	WAES0803USA02179	31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received from a physician and a medical assistant for the Pregnancy Registry for GARDASIL concerning a 16 year old Hispanic female with anemia and a history of 0 pregnancies who in June 2007, was IM vaccinated with GARDASIL. Medications taken during pregnancy included pre-natal vitamins (unspecified). The patient became pregnant sometime during the vaccination series. On 06-MAR-2008 the maternal serum alpha-fetoprotein test (MSAFP) was performed with the negative result. A positive ultrasound for pregnancy was performed on 13-Mar-2008. It is suspected that the patient's LMP is 23-Oct-2007. The patient sought unspecified medical treatment with an office visit. On 30-May-2008, the patient threatened premature labor. On that same day, she was placed on therapy with terbutaline sulfate (5 mg Q4H until 36 weeks) and KEFLEX (500 MG QID). On 10-JUL-2008 the patient delivered a normal female baby with apgar score 8/9. There were no complications during labor/delivery. There were no congenital anomalies abnormalities or complications. Additional information is not expected.

Other Meds:

Lab Data: Ultrasound 03/13/08 - positive for pregnancy Serum alpha-fetoprotein 03/06/08 - negative Apgar score 07/10/2008 8/9 -

History:

Prex Illness: Pregnancy NOS (LMP = 10/23/2007) Anaemia

Prex Vax Illns:

Vaers Id: **329277-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	25-Jan-2008	25-Jan-2008	0	17-Oct-2008	11-Feb-2009	--	WAES0804USA01219	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Drug exposure during pregnancy, Gastrooesophageal reflux disease

Symptom Text: Information has been received from a nurse practitioner concerning a 21 old pregnant female with a history of 2 pregnancies (1 miscarriage and 1 to full term) who on 25-JAN-2008 was vaccinated IM with the first dose of GARDASIL (lot # 659437/1266U). A urine pregnancy test was performed yielding positive results. The last menstrual period was reported as 15-JAN-2008. Nurse practitioner reported she wishes to register the patient for pregnancy registry. Follow-up information was received from a nurse practitioner concerning the patient who was a smoker who in June 2008 developed gastrooesophageal reflux disease, and in September 2008 developed anemia. The patient delivered a normal, health male baby weighing 7 pounds 15 ounces on 14-SEP-2008 (weeks from LMP: 38.4 weeks). Length: 21.5 inches. APGAR score: 8/9. Head circumference: 13.5 centimeters. There were no congenital anomalies and no other complaints or abnormalities. No complication during pregnancy and labor/delivery. No diagnostic test and infections or illnesses during pregnancy. PREVACID and REPLIVA were used during this pregnancy to treat the gastroesophageal reflux disease and anemia, respectively. Additional information is not expected.

Other Meds:

Lab Data: urine beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/15/2008); Smoker

Prex Vax Illns:

Vaers Id: **329278-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	05-Mar-2008	05-Mar-2008	0	17-Oct-2008	11-Feb-2009	--	WAES0807USA00309	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Nausea

Symptom Text: Initial and follow up information has been received from a nurse practitioner through the Merck pregnancy registry concerning an 18 year old black female with rhinitis allergic and no significant past medical history and no other concurrent medical conditions, who on 10-JAN-2008 was vaccinated with the first dose of GARDASIL (lot# 659653/1448U). On 05-MAR-2008, the patient was vaccinated with the second dose of GARDASIL (lot 655655/1486U). Concomitant therapy included prenatal vitamins. The patient became pregnant. The last menstrual period was 20-FEB-2008. The estimated due date is 27-NOV-2008. On 30-MAY-2008, the patient developed nausea. She was treated with PHENERGAN. Additional information has been requested.

Other Meds: vitamins (unspecified)

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 2/20/2008) Rhinitis allergic

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329279-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	23-Jan-2007	08-Mar-2008	410	17-Oct-2008	11-Feb-2009	MD	WAES0807USA01449	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vomiting in pregnancy

Symptom Text: Initial and follow-up information has been received from a physician, for the Pregnancy Registry for GARDASIL, concerning a 21 year old black female with a history of 2 previous pregnancies, 1 full term delivery in 2005, and 1 elective termination, and no defects or complications in previous pregnancies, who on approximately 23-JAN-2007 was vaccinated with GARDASIL (lot # not reported) 0.5 mL IM. There was no concomitant medication. On 20-MAR-2008 the patient was vaccinated with a second dose of GARDASIL (Lot# 659962/1740U). The patient's last menstrual period was 08-MAR-2008, her estimated conception date was 22-MAR-2008, and her estimated delivery date was 13-DEC-2008. In follow up information was reported that on an unspecified date, the patient started prenatal vitamins, 1 dose, every day for pregnancy. On 12-MAY-2008, the patient started TERAZOL at bed time, 3 doses, for morning sickness. It was also reported that on 22-JUN-2008, a maternal serum alpha-fetoprotein test performed for routine, revealed negative results. On 30-JUN-2008 an ultrasound performed, to rule out any anomaly, with result 16 5/7 weeks. On 25-JUL-2008, the patient started PROMETHAZINE, 25 mg, every six hours, as needed, for morning sickness. Follow-up information indicated that the patient had left the practice and was being cared for by another health care professional office. Follow-up information was received which reported that the patient was no longer followed in physician's office. This is one of two reports from the same source. Follow-up information was received which reported that the patient was no longer followed in physician's office. This is one of two reports from the same source. Additional information is not expected.

Other Meds: None

Lab Data: ultrasound, 06/30/08, 16 1/2 weeks; serum alpha-fetoprotein, 06/22/08, negative

History:

Prex Illness: Termination of pregnancy-elective

Prex Vax Illns:

Vaers Id: **329280-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Jan-2008	02-Jan-2008	0	17-Oct-2008	11-Feb-2009	NY	WAES0809USA00346	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Inappropriate schedule of drug administration, Ovarian cyst

Symptom Text: Initial and follow-up information has been received from a licensed practical nurse for the pregnancy registry GARADASIL concerning a 14 year old white female with asthma and no allergies, no previous pregnancies and a history of appendicectomy who on 23-MAY-2007 was vaccinated with the first dose of GARDASIL, IM 0.5 mL (lot # 654535/0960F). On 02-JAN-2008 the patient was vaccinated with the second dose of GARDASIL, IM 0.5 mL (lot # 659055/1522U). On 09-APR-2008, the patient was noted to have a right ovarian cyst. On 07-MAY-2008 the patient vaccinated with the third dose of GARDASIL, IM 0.5 mL (lot # 659964/1978U). Concomitant therapy included FLOVENT and albuterol. The patient's last menstrual period was 17-MAY-2008. The estimated due date is 21-FEB-2009. The patient had a positive urine pregnancy test on 14-AUG-2008. The ultrasound was performed on 26-AUG-2008 for dates with the results of 11 week 2 day fetus. No problems reported. The patient sought medical attention in the office visit. Additional information has been requested.

Other Meds: albuterol; FLOVENT

Lab Data: ultrasound, 08/26/08, 11 week 2 day fetus; urine beta-human, 08/14/08, positive

History: Appendicectomy

Prex Illness: Pregnancy NOS (LMP = 5/17/2008); Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329281-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	07-Jul-2008	01-Sep-2008	56	17-Oct-2008	11-Feb-2009	KS	WAES0809USA01361	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Information has been received from a physician concerning an 11 year old female with no known pertinent medical history or drug reactions/allergies who on 07-JUL-2008 was vaccinated with a first dose of GARDASIL (lot# 660393/0067X) 0.5 mL IM. Concomitant therapy included a dose of ADACEL received on 07-JUL-2008. On 01-SEP-2008 the patient developed a BELL'S palsy. She has facial drooping on her right side. A magnetic resonance imaging was performed with a negative result. The patient was treated with acyclovir and prednisone. The patient was recovering from BELL'S palsy. The patient sought medical attention in the office. Additional information has been requested.

Other Meds:

Lab Data: magnetic resonance, 09/??/08, negative

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **329282-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		17-Oct-2008	11-Feb-2009	--	WAES0809USA01369	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a physician assistant concerning an approximately 20 year old female who was vaccinated the second dose of GARADSIL. A few days post the second dose the patient broke out in a rash all over her body. The patient sought medical attention. Treatment was BENADRYL, the patient recovered. The physician assistant indicated the patient would not be completing the vaccine series. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329286-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Apr-2008	27-May-2008	40	21-Oct-2008	22-Oct-2008	FR	WAES0810USA02773	22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Pain, Pain in extremity, Pyrexia, Rash

Symptom Text: Information has been received from a anesthesiologist, concerning an 13 year old female who on 17-APR-2008 was vaccinated with the first dose of GARDASIL, (Lot #, route and injection site not reported). 2 days post vaccination, the patient developed fever up to 39 degrees. On 26-MAY-2008 and 27-MAY-2008, the patient presented to a pediatrician due to fever up to 39.9 degrees. The pediatrician prescribed antibiotics due to presumed sinusitis. Antibiotics were discontinued after 5 days due to a rash. On 04-JUN-2008 the patient developed fever up to 39.9 degrees again, now with pain on the whole body. Physical examination was without any pathological findings. On 04-JUN-2008 leukocytes cell count revealed 15000 and serum C-reactive protein test (CRP) 115. On the same day, on 04-JUN-2008, the patient was hospitalized until 13-JUN-2008. Discharge diagnosis was fever of unknown genesis. Due to recurrent fever, pain in limb and headache the patient was hospitalised again from 14-AUG-2008 to 20-AUG-2008. Suspicion of Juvenile idiopathic arthritis (Morbus Still) was established. At the time of reporting the patient had not recovered and still complained about fever (in the mornings), pain and changing rashes. Due to the unclear diagnosis, further diagnosis were initiated (no otherwise specified), the results were pending at the time of reporting. The reporter considered that a causal relation to the vaccine can not be excluded. Other business partner numbers included: E2008-09494. Additional information has been requested.

Other Meds: Unknown

Lab Data: Physical examination, 04Jun08, without any pathological findings; Body temp, 19Apr08, 39.0 C; Body temp, 27May08, 39.9 C; WBC count, 04Jun08, 15000; Body temp, 04Jun08, 39.9 C; Serum C-reactive protein, 04Jun08, 115

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **329287-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Aug-2008	26-Aug-2008	11	21-Oct-2008	22-Oct-2008	FR	WAES0810USA02065	22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Multiple sclerosis, Sensory disturbance, Somatosensory evoked potentials, Visual evoked potentials

Symptom Text: Information has been received from a health professional on 10-OCT-2008. A 17-year old female patient with no relevant familial or personal medical history reported received the first dose of GARDASIL (Lot # was not reported, site of injection and dose unknown) approximately on 15-AUG-2008. By the end of AUG-2008, approximately on 26-AUG-2008 the patient experienced numbness in her first right toe which resolved in 24 hours. Then by the end of SEP-2008-beginning of OCT-2008 she consulted at hospital for anomaly of sensation of left hemicorpus during 24 to 48 hours. Clinical examination was not detailed. A work-up was performed: cerebral MRI showed 2 hypersignals of T2 localized at frontal level. Result of visual evoked potential and somatosensory evoked potential were not available but visual evoked potential were long. The neurologist has not considered of performing a lumbar puncture. Another MRI was scheduled in 3 months. Evoked diagnosis was multiple sclerosis. At time of reporting the patient had not recovered. The reporter felt that the adverse event was an other important medical event. Other business partner numbers included: E2008-09472. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 2 hypersignals of T2 localized at frontal level

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329300-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Oct-2008	09-Oct-2008	0	21-Oct-2008	22-Oct-2008	FR	WAES0810USA02204	22-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1115U	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hypoaesthesia, Muscle twitching, Pyrexia

Symptom Text: Information has been received from a hospital neurologist concerning an 18 year old female patient who on 09-OCT-2008 was vaccinated with the third dose of GARDASIL (batch #NH33310, lot #1115U). On 09-OCT-2008 ("in the evening p.v.") the patient developed twitching of the whole body, numbness in the hands and feet and fever. The patient was hospitalized during the night. The outcome was not reported. Other business partner numbers include E200809449.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329307-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Oct-2008	04-Oct-2008	1	21-Oct-2008	30-Oct-2008	NY		31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	UF452AA	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	1145X		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site swelling

Symptom Text: Site erythema, swelling, firm, increasing in size. Went to Emergency Room 10/5/08. *Obese girl.

Other Meds: None

Lab Data: None

History: Asthma as child

Prex Illness: No

Prex Vax Illns:

Vaers Id: **329310-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Oct-2008	14-Oct-2008	0	21-Oct-2008	30-Oct-2008	CO		31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0539X	1	Left leg	Subcutaneously	
	HPV4	MERCK & CO. INC.	0279X	0	Right leg	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHABB238AA	0	Left leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Rash, Swelling

Symptom Text: Vaccines were administered on 10/14/08. Pt is on Enbrel; now having rash, itching, swelling.

Other Meds: Enbrel

Lab Data:

History: Rheumatoid Arthritis

Prex Illness: Rheumatoid Arthritis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329313-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Jun-2008	12-Jun-2008	0	21-Oct-2008	30-Oct-2008	WI		31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Dizziness, Dyspnoea, Feeling abnormal, Pyrexia

Symptom Text: 8 hours after vaccination developed chills, fever 101, dizziness, c/o short of breath, uneasy feeling. Lasted 1 1/2 hours and went away with no interventions.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 329322-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	16-Oct-2008	16-Oct-2008	0	21-Oct-2008	31-Oct-2008	HI		31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal dreams, Dizziness, Moaning, Musculoskeletal stiffness, Syncope vasovagal, Unresponsive to stimuli

Symptom Text: 11:40 am Injection given, 11:45 pt felt dizzy/faint. Then pt ? vaso-vagal response - (30-45s) mouth open/eyes open, stiffened, unresponsive to ammonia capsules x 3, moaning. Then pt awakes feeling dizzy, mentions weird dreams - is coherent 13:00 pt d/c; A+Ox3.

Other Meds: Levoxyl, Yasmin

Lab Data:

History: Hypothyroidism

Prex Illness: None

Prex Vax Illns:

Vaers Id: **329330-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-Oct-2008	08-Oct-2008	1	21-Oct-2008	31-Oct-2008	OR		31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	0843X	2	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	AHAVB246AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Mother called UCHD on morning of 10/8 and reported daughter had started running a fever during night: 101-102 F. Mom treating with TYLENOL and Ibuprofen which "has helped". Mom denies any local reaction at site of injection.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329353-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	07-Jul-2007	09-Jul-2007	2	21-Oct-2008	31-Oct-2008	MN		05-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Cervical dysplasia, Cervicitis, Colposcopy, Condition aggravated, Cough, Dyspareunia, Hyperhidrosis, Influenza like illness, Injection site haemorrhage, Injection site swelling, Insomnia, Migraine, Nausea, Palpitations, Papilloma viral infection, Photophobia, Rhinorrhoea, Sneezing, Tinnitus, Upper respiratory tract congestion, Vaccine positive rechallenge, Vomiting, Wheezing

Symptom Text: Bleeding and swollen @ injection site on 1st injection. Flu like symptoms after injection for about 1 week with both injections persistent unbearable migraine headaches- have not stopped since 1st injection, suffer about 1 a week that last 2-5 days- require urgent care visits. 11/4/08 Reviewed clinic records of 7/7-10/23/2008. FINAL DX: migraine headaches Records reveal patient experienced no improvement in HA symptoms on contraception & had stopped it approx 7 mo prior to 7/7/08. Periods were irregular w/mild dysmenorrhea & PMS s/s. Started on new contraceptive. RTC on 7/22 w/increased anxiety s/s of sweaty palms, heart racing, difficulty sleeping. Tx w/meds. RTC 8/22 w/allergic complaints of sneezing, cough, wheezing, runny nose, congestion, ears clicking. Tx w/meds. RTC 9/6 w/migraine x 1 day w/nausea. Improved w/meds. RTC 9/10 w/recurrent migraine HA awakening pt from sleep w/pain, nausea, vomiting, photophobia. Improved w/meds. RTC 9/16 for colposcopy for (+) HPV pap smear. RTC 10/9 for cervicitis, migraine HA & pain w/intercourse. Results from copposcopy were CIN I & chronic cervicitis. Tx w/meds. Had stopped new contraceptive due to increase in migraines. Started new contraceptive & tx w/cervicitis. RTC 10/23 w/migraine hA. Tx w/meds & referred to neuro.

Other Meds: None

Lab Data: LABS: abnormal pap smear 2007, (+) HPV

History: Seasonal allergies, High cholesterol PMH: colposcopy. migraine HAs tx w/contraception. Left eye optic nerve disorder. TMJ. Depression, anxiety, hyperlipidemia, Allergy: naprosyn, allergic rhinitis, allergy to cats. Family hx: alcoholism, hep C, bipolar, Hodgkins, HTN, MI, lung cancer, eye problems.

Prex Illness:

Prex Vax Illns:

Vaers Id: **329354-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	26-Sep-2008	Unknown		21-Oct-2008	31-Oct-2008	CA		23-Mar-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0843X	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024DB	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2637AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Eye pain, Headache, Inflammation, Optic nerve disorder, Optic neuritis, Sinusitis, Vision blurred

Symptom Text: Optic Neuritis - referred to ophthalmology for work-up. Symptoms started after vaccination. Unclear specific day/time. 1/30/09 Received PCP medical records of 9/26-11/3/2008. FINAL DX: Optic neuritis Records reveal patient in usual state of good health on 9/26/08 when received vaccinations & depoprovera. RTC 10/13 w/eye pain w/movement x 1.5 wk, peripheral blurry vision, seeing white spots, frontal HA, bilateral knee pain. Referred to Ophtho but no report available.

Other Meds:

Lab Data: Optic Neuritis LABS: CBC WNL. MRI brain abnormal w/focal inflammatory changes in posterior right optic nerve & right maxillary sinusitis.

History: None PMH: dysmenorrhea & irregular periods.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **329427-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Mar-2008	12-Mar-2008	0	21-Oct-2008	18-Nov-2008	WY		20-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site scab, Skin discolouration

Symptom Text: Patient received two doses of Gardasil at the appropriate intervals on 3/12/08 and 5/14/08. On 9/10/08 she refused the third dose and showed us her right arm. She stated that the vaccine had "bleached her skin white". The patient is darker skinned. Her arm displayed a circular area at what would have been the site of injection that was the size of a quarter and was very light in color, markedly lighter than the surrounding skin. She denied pain at the site. She also stated that the injection site on the opposite arm did not "heal" well and displayed a 1-2 mm scabbed area at what would have been an injection site. This was several months after the injection was given. No treatment was initiated.

Other Meds:

Lab Data: none

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329429-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-May-2008	14-May-2008	0	21-Oct-2008	18-Nov-2008	WY		18-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Malaise, Tachycardia

Symptom Text: Patient received the first dose of Gardacil at a school vaccination clinic on 3/12/08. She received the second dose on 5/14/08. She claimed she became ill after receiving the second dose and after the Public Health nurse left the school. She stated the school called an ambulance and she was taken to the local health clinic. Patient's mother stated the girl experienced tachycardia, was seen and sent home. Public Health was informed about the above incident on 9/10/08 when we sheduled the third dose which was refused.

Other Meds:

Lab Data: unknown

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329452-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Oct-2008	20-Oct-2008	0	21-Oct-2008	14-Nov-2008	AZ		17-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0560X	0	Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	112005AA		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncopal episode following administration of HPV# 1 vaccine

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329453-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	27-Dec-2007	Unknown		21-Oct-2008	14-Nov-2008	MD		17-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal behaviour, Alopecia, Regressive behaviour

Symptom Text: Change in behavior (inappropriate laughing, maturity regression), hair loss. Reported to us 10-21-08. Status changes were noted approximately 2 weeks after vaccine administration.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329455-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	08-Oct-2008	10-Oct-2008	2	21-Oct-2008	14-Nov-2008	CA		17-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Disorientation, Fall, Rhinorrhoea, Upper respiratory tract infection, Visual impairment

Symptom Text: Patient presented 10/17/08 to c/o "fainting" on 10/10/08 pm - 2 days following GARDASIL 10/08/08. On 10/09/08 patient had URI type. Symptoms of runny nose - o/w well. On 10/10/08 patient was in bathroom, standing and starting to feel faint; she saw "stars" and fell to the floor. Negative LOC. Appeared "lost" for few minutes.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **329464-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-Oct-2008	15-Oct-2008	1	21-Oct-2008	18-Nov-2008	PA		18-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Livedo reticularis, Pruritus

Symptom Text: 18 hours past vaccination, developed skin mottling, itching, and headache persisted for 3 days. Improved after Prednisone IM, Hydroxyzine and benedryl.

Other Meds: Daily Vitamin

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329502-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	19-Nov-2007	19-Nov-2007	0	22-Oct-2008	12-Jan-2009	--	WAES0711USA04055	12-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Depression, Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed practical nurse, for the Pregnancy Registry of GARDASIL, concerning a 21 year old white female with factor V Leiden and a tobacco user with a history of 2 pregnancies and 1 live birth (one full-term delivery with deep venous thrombosis post delivery; and a tubal pregnancy with a miscarriage and oophorectomy) who on 19-NOV-2007 was vaccinated intramuscularly with 0.5 ml of GARDASIL. Concomitant therapy included prenatal vitamins with folate (manufacturer unspecified) and aspirin 81 mg daily for factor V Leiden. After the vaccination on the same office visit, a pregnancy test was performed and the result was positive. No other symptoms reported. On 21-NOV-2007, and ultrasound was performed and confirmed a yolk sac was present. The date of last menstrual period was 17-OCT-2007 and the estimated delivery date was 24-JUL-2008. During the pregnancy, the other medications included LOVENOX 40 mg daily from 26-FEB-2008 until delivery for factor V Leiden and WELLBUTRIN XL 300mg daily from 14-JAN-2008 until delivery for depression. On 04-FEB-2008, serum alpha-fetoprotein test (MSAFP) was performed and the result was negative. On 18-FEB-2008, an ultrasound was done with the normal result. On 22-JUL-2008, at 40 weeks the patient delivered a normal, healthy female baby weighting 7 pounds 7 ounces. The apgar scores were 8/8. There were no congenital anomalies and no other complications/abnormalities. Additional information is not expected.

Other Meds: aspirin 81 mg vitamins (unspecified)

Lab Data: Ultrasound 11/21/2007 yolk present Ultrasound 02/18/2008 normal beta-human chorionic 11/19/07 positive serum alph-fetoprotein 02/04/08 negative

History: Tubal pregnancy, Miscarriage; Oophorectomy; Deep vein thrombosis; Clot blood; Blood transfusion

Prex Illness: Pregnancy NOS (LMP = 10/17/2007) Factor V Leiden mutation; Tobacco user

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329503-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	31-Aug-2008	01-Sep-2008	1	17-Oct-2008	11-Feb-2009	FL	WAES0809USA02192	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Periorbital oedema, Stomatitis

Symptom Text: Information has been received from a health professional concerning a 22 year old female who on the evening of 31-AUG-2008 was vaccinated with the second dose of GARDASIL, IM into left deltoid. The patient had been treated (06-AUG-2008) for a URI with Z-PAK. The patient awoke in AM with periorbital oedema and mouth sores on 01-SEP-2008 (also reported as 03-SEP-2008, 3 days post injection). The patient was treated with famotidine (MSD) and BENADRYL. The patient had a appointment of eye doctor and allergist. A CBC and BMP were within normal limits. Additional information has been requested.

Other Meds:

Lab Data: complete blood cell, WNL; metabolic marker test, WNL

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329504-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-Aug-2008	20-Aug-2008	14	17-Oct-2008	11-Feb-2009	PA	WAES0809USA02250	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Stomatitis, Urticaria

Symptom Text: Information has been received from a patient's mother via medical assistant who reported that her 20 year old daughter with no pertinent medical history or no drug allergies who on 06-AUG-2008 was vaccinated with the first dose of GARDASIL (lot # 660393/0067X). Concomitant therapy included hormonal contraceptives (unspecified) (oral contraceptives). About two weeks after vaccination on approximately 20-AUG-2008 the patient developed rash, hives over her face and sores in her mouth. The patient's rash and hives over her face and sores in her mouth persisted. Medical attention was sought via calling office. No product quality complaint was involved. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329505-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	09-Sep-2008	09-Sep-2008	0	17-Oct-2008	11-Feb-2009	--	WAES0809USA02287	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Feeling hot, No reaction on previous exposure to drug, Pain

Symptom Text: Information has been received from a physician concerning a 25 year old female who on 03-APR-2008 was vaccinated with the first dose of GARDASIL well tolerated. On 03-JUN-2008, the patient was vaccinated with the second dose of GARDASIL well tolerate. On 09-SEP-2008 the patient was vaccinated with the third dose of GARDASIL. Approximately 6 to 8 hours after the third dose the patient developed chills, aches and felt warm but never really took her temperature. The patient was advised how to self-medicate for the chills and aches and there had been no other adverse events reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329506-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Sep-2008	15-Sep-2008	0	17-Oct-2008	11-Feb-2009	--	WAES0809USA02290	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Unknown	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Pallor, Syncope

Symptom Text: Information has been received from a nurse concerning a 11 year old female who on 15-SEP-2008 at about 1530 was vaccinated with the first dose of GARDASIL (lot # 660553/0070X). Concomitant therapy included meningococcal vaccine (unspecified) and diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid. About 2 min after vaccination, the patient said she felt dizzy, became pale , and fainted into mother's arms. The patient was placed on exam table with feet elevated and she spontaneously revived. The events lasted only minutes. The patient was given water to drink. No hospitalization required. The reporter spoke with mother at home and patient remained fine at this time. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329507-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		17-Oct-2008	11-Feb-2009	TX	WAES0809USA02389	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Rash

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who in the Spring of 2008 was vaccinated with the third dose of GARDASIL. The physician reported that about one and a half months after the 3rd dose of GARDASIL, the patient had a severe abdominal pain. The patient also developed a mild rash on one side of the hips that radiated to the knees. The patient was seen by both her primary physician and gynecologist. On an unspecified date, the patient had a CT scan that was negative. The symptoms were diagnosed as idiopathic. Outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: computed axial, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329508-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Sep-2008	09-Sep-2008	8	17-Oct-2008	11-Feb-2009	OH	WAES0809USA02395	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Migraine

Symptom Text: Information has been received from a physician concerning a female who "in the past few weeks," was vaccinated with a dose of GARDASIL. "Last Week," on approximately 09-SEP-2008 the patient experienced a migraine headache. On an unknown date, the patient recovered from migraine headache. The patient sought medical attention by phone. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329509-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Aug-2008	29-Aug-2008	2	17-Oct-2008	11-Feb-2009	NY	WAES0809USA02397	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash papular

Symptom Text: Information has been received from a registered nurse concerning a 20 year old female with no pertinent medical history or allergies who on 04-JUN-2008 and 27-AUG-2008 was vaccinated intramuscularly with her 0.5 mL first and second doses of GARDASIL (lot #660391/0063X, 660557/0072X), respectively. There was no concomitant medication. On 29-AUG-2008 the patient developed a small bump in her right axilla. Medical attention was sought via call by the patient's mother. No laboratory or diagnostics tests were performed. The bump resolved without treatment within 12 hours. On 04-SEP-2008 the patient developed a large bump in her left axilla which resolved without treatment in 2 days. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329511-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-May-2008	Unknown		17-Oct-2008	11-Feb-2009	FL	WAES0809USA02400	10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Infectious mononucleosis, Lymphadenopathy

Symptom Text: Information has been received from a physician concerning an 18 year old female who in May 2008, was vaccinated with her first dose of GARDASIL 0.5 mL, IM. In approximately May 2008, after receiving the vaccination, the patient experienced lymphadenopathy. The patient called the physician in August 2008, about 10 days before her schedule appointment to say her lymph nodes were swollen. The physician said to wait the 10 days and then come in for her second dose. She come in 10 days after her call but was still sick so the second dose was not given. The physician "ran a bunch of testing, including bloodwork, and ruled out mononucleosis." Patient came on 02-SEP-2008 for a follow-up, but the physician still has to send her for a biopsy. Additional information has been requested. On 03-Nov-2008, Dr reported that the patient was seen by Infectious Disease specialist, and was diagnosed with mononucleosis. The patient's status was reported as recovered.

Other Meds: Unknown

Lab Data: blood work and ruled out mononucleosis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329512-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Sep-2008	12-Sep-2008	1	17-Oct-2008	11-Feb-2009	IN	WAES0809USA02402	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Oropharyngeal pain, Pyrexia

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 11-SEP-2008, was vaccinated with her first dose of GARDASIL. Concomitant therapy included diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid (manufacturer unknown). On 12-SEP-2008, the day after vaccination the patient experienced fever, sore throat and headache. The parent of patient called office. At the time of reporting, patient's fever, sore throat and headache persisted. Patient will be seen in the office today. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329513-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	05-Jun-2008	Unknown		17-Oct-2008	11-Feb-2009	FL	WAES0809USA02417	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Fatigue

Symptom Text: Information has been received from a physician concerning a female who in March 2008, was vaccinated with the first dose of GARDASIL and on 05-JUN-2008, received the second dose of GARDASIL. There was no concomitant medication. When she came back for her second dose on 05-JUN-2008, the patient experienced fatigue and joint pain. She still received her second dose and was also told to see a rheumatologist. The rheumatologist told the patient it could be fibromyalgia or rheumatoid arthritis. The patient was told to follow-up with the physician on 28-JUL-2008, however the patient never came back, but rather called the office recently and stated that she saw on the news that GARDASIL caused arthritis. Additional information has been requested.

Other Meds: None

Lab Data: hematology

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329514-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		17-Oct-2008	11-Feb-2009	NY	WAES0809USA02433	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactic reaction

Symptom Text: Information has been received from a physician concerning a 11 year old female who was vaccinated with the first dose of GARDASIL and had an anaphylactic reaction. The patient was reported to be recovered. The physician does not plan to continue to vaccination series. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329515-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	11-Feb-2009	--	WAES0809USA02457	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a Physician's Assistant concerning a female patient who was vaccinated with GARDASIL (lot no., route, injection site not reported). A couple minutes later the patient fainted. Unspecified medical attention was required. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 329516-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-May-2008	01-May-2008	0	17-Oct-2008	11-Feb-2009	--	WAES0809USA02475	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Nausea, Pyrexia

Symptom Text: Information has been received from a nurse practitioner concerning an 18 year old female who in May 2008, was vaccinated with the second dose of GARDASIL. Subsequently, in May 2008, the patient experienced nausea, fever and back pain. Subsequently, the patient recovered from nausea, fever and back pain. The patient contacted a physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329517-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	14-Mar-2008	Unknown		17-Oct-2008	11-Feb-2009	TX	WAES0809USA02485	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning a 25 year old female who on 14-MAR-2008 was vaccinated IM with her first dose of GARDASIL and post vaccination, unknown when, the patient developed numbness of the hands and feet, which lasted for a couple of days. The patient vaccinated IM with her second dose of GARDASIL on 14-MAY-2008 and post vaccination developed numbness of hands and feet which lasted for a couple of days. Subsequently, the patient recovered. The patient sought medical attention and the nurse called her. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329518-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	28-Apr-2008	28-Apr-2008	0	17-Oct-2008	11-Feb-2009	--	WAES0809USA02590	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1263U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Nausea, Urinary tract infection

Symptom Text: Information has been received from a health professional for the Pregnancy Registry for GARDASIL, concerning an 21 year old Caucasian female with a history of 4 previous pregnancies and 2 live births and one spontaneous abortion at 12 weeks from LMP who on 28-APR-2008 was vaccinated with a second dose of GARDASIL (lot #658282/1263U). The patient's last menstrual period was 10-MAR-2008 and estimated delivery date is 15-DEC-2008. On 16-MAY-2008 and 17-JUL-2008 the patient underwent ultrasound and the result indicated within normal limits. On 06-AUG-2008 maternal serum alpha-fetoprotein screening was performed and the result was negative. Subsequently, on an unspecified date in June 2008 the patient experienced nausea and was treated with ZOFRAN 4 mg PRN. No out come was reported. Also, on an unspecified date in September 2008, the patient developed a UTI and was treated with MACRODANTIN 100 TID. No outcome was reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, 05/16/08, within normal limits; ultrasound 07/17/08, within normal limits; serum alpha-fetoprotein 08/06/08, negative

History:

Prex Illness: Pregnancy NOS (LMP = 03/10/2008)

Prex Vax Illns:

Vaers Id: **329519-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-Sep-2008	Unknown		17-Oct-2008	11-Feb-2009	CO	WAES0809USA02618	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	3	Unknown	Intramuscular	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a healthcare worker concerning an 18 year old female with no pertinent medical history or allergies who on 12-SEP-2008 was vaccinated intramuscularly with a 0.5 mL fourth dose of GARDASIL (lot #661530/0575X). The dates of administration and the lot numbers for the previous 3 doses of GARDASIL were unknown. Concomitant therapy included influenza virus vaccine (unspecified). Subsequently the patient experienced arm pain, in an unspecified arm. The patient was seen at the office, no laboratory or diagnostics tests were performed. At the time of this report, the outcome was unknown. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329520-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Aug-2008	25-Aug-2008	0	17-Oct-2008	11-Feb-2009	CA	WAES0809USA02644	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Lethargy

Symptom Text: Information has been received from a physician concerning a 14 year old female with exertional asthma and no allergies who on 25-JUN-2008 was vaccinated with the first dose of GARDASIL, IM 0.5 mL (lot # 659657/1487U). On 25-AUG-2008 the patient was vaccinated with the second dose of GARDASIL, IM 0.5 mL (lot # 660391/0063X). There was no concomitant medication. On 25-AUG-2008 the patient experienced headaches and lethargy since she received the second dose. The patient sought medical attention at the office. The patient's headache and lethargy persisted. The computed axial tomography, neurological exam and blood work were performed with no results provided. Additional information has been requested.

Other Meds: None

Lab Data: computed axial, neurological; diagnostic laboratory, blood work

History:

Prex Illness: Asthma exercise induced

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329521-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	11-Feb-2009	VA	WAES0809USA02645	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with GARDASIL. The patient experienced headache after vaccination. On an unspecified date the patient recovered from headache. The patient sought medical attention. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329522-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	11-Feb-2009	--	WAES0809USA02651	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information has been received from a registered nurse concerning a female who was vaccinated with GARDASIL. The patient developed warts on hands after vaccination. The outcome of the patient was unknown. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329523-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Jul-2008	16-Jul-2008	0	17-Oct-2008	11-Feb-2009	OR	WAES0809USA02652	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Immediate post-injection reaction, Visual impairment

Symptom Text: Information has been received from a nurse concerning an 11 year old female with no pertinent medical history who on 16-JUL-2008 was vaccinated with the first dose of GARDASIL. On 16-JUL-2008 the patient experienced dizzy, sweaty and her vision darkened right after injection. The patient sat down for a few minutes and the symptoms went away. The patient recovered from dizzy, sweaty and vision darkened. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329524-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	08-Sep-2008	08-Sep-2008	0	21-Oct-2008	19-Nov-2008	--	WAES0809USA02657	19-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Nuclear magnetic resonance imaging, Syncope

Symptom Text: Information has been received from a registered nurse concerning a 26 year old female with sulfonamide allergy who on 08-SEP-2008 was vaccinated IM with the second 0.5ml dose of GARDASIL (lot #: 660555/0279X). Concomitant therapy included CLARITIN and SEASONALE. On 08-SEP-2008 the patient fainted and hit her head after she received the second dose of GARDASIL. The patient was still at the physician's office when she fainted and received unspecified medical attention. The date of administration and the lot number for the first dose was unspecified. Magnetic resonance imaging was performed, the result was not reported. No further information is available.

Other Meds: SEASONALE; CLARITIN

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **329525-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jul-2008	06-Aug-2008	21	17-Oct-2008	11-Feb-2009	MN	WAES0809USA02661	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a mother and a certified medical assistant concerning the development of a rash by a twin sister following vaccination. A 18 year old female who on 16-JUL-2008 was vaccinated with GARDASIL. Concomitant therapy included TRI-SPRINTEC Birth Control and CLARITINE. On approximately 06-AUG-2008, 3 to 4 weeks after vaccination, the patient experienced a rash. Patient's rash is currently resolved. Her rash was described as similar to her twin sister's (WAES 0809USA01996) Additional information has been requested. This is one of several reports received from the same source.

Other Meds: TRI-SPRINTEC; CLARITIN

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329526-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	24-Aug-2008	24-Aug-2008	0	21-Oct-2008	04-Jan-2009	--	WAES0809USA02676	05-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Nausea, Pain, Pyrexia

Symptom Text: Information has been received from a physician concerning a 12 year old female with a history of delayed mixed immunodeficiency who on 24-AUG-2008 was vaccinated with the first does of GARDASIL (lot # unspecified). Concomitant therapy included diphtheria toxoid (+) pertussia whole cell vaccine (+) tetanus toxoid. On 24-AUG-2008, after she received her first dose of GARDASIL the patient experienced nausea, body ache, headache and low grade fever for two days. There was no lab diagnostics studies performed for the patient. The patient sought unspecified medical attention. Subsequently, the patient recovered from nausea, body ache, headache and low grade fever and recovered date was unspecified. Additional information has been requested.

Other Meds:

Lab Data: None

History: Immunodeficiency

Prex Illness:

Prex Vax Illns:

Vaers Id: **329527-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	07-Apr-2008	Unknown		17-Oct-2008	11-Feb-2009	--	WAES0809USA02678	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a patient's mother, an employee at the physician's office, concerning her 20 year old daughter who on 07-APR-2008, last day of her menstrual period, was first vaccinated with GARDASIL (dose was unspecified and route was injection). Concomitant therapy included NUVARING for birth control. When NUVARING was discontinued the patient still continued to have her menstrual periods. Subsequently the patient experienced amenorrhea since then. The following dose of GARDASIL (MSD) was not reintroduced. On an unspecified date the patient took pregnancy test via blood and urine and all tests were negative. The patient sought medical attention. At the time of report the patient's amenorrhea persisted. Patient didn't have medical history and drug allergies. Additional information has been requested.

Other Meds: NUVARING

Lab Data: serum beta-human, negative; urine beta-human, negative

History:

Prex Illness: Contraception

Prex Vax Illns:

Vaers Id: **329528-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-May-2008	Unknown		17-Oct-2008	11-Feb-2009	TX	WAES0809USA02736	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hallucination, Pyrexia, Tremor

Symptom Text: Information has been received from a nurse concerning a 11 year old female who on 15-MAY-2008 was vaccinated with the first dose of GARDASIL IM (lot # 660391/0063X). The patient did not stay for the 15 minutes shot check, however called the office later (time unspecified) and stated that she was hallucinating, shaky and had a fever. The patient came to the office for any follow-up. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329529-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	11-Feb-2009	NJ	WAES0809USA02978	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a female patient who completed the series for GARDASIL. On an unspecified date, the patient was HPV positive. The outcome of the patient was not reported. Additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329530-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	11-Feb-2009	--	WAES0809USA03010	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Hair disorder

Symptom Text: Information has been received from a licensed practical nurse concerning 2 girls who on an unspecified dates were vaccinated with an unspecified dose of GARDASIL. A patient's mother heard that they have had hair loss and hair brittleness after vaccination with GARDASIL. These 2 girls are athletes and wash their hair several times each day. Additional information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 329531-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Sep-2008	10-Sep-2008	0	17-Oct-2008	11-Feb-2009	--	WAES0809USA03011	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia oral

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female with allergy to horses who on 10-SEP-2008, was vaccinated with GARDASIL (lot no. 660553/0070X) 0.5 mL, IM. There was no concomitant medication. On 10-SEP-2008, about 90 minutes after vaccination, the patient experienced numbness of her tongue and roof of her mouth. Within an hours, the patient recovered without treatment. No laboratory tests were performed. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Allergy to animal

Prex Vax Illns:

Vaers Id: **329532-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	18-Sep-2008	18-Sep-2008	0	17-Oct-2008	11-Feb-2009	CO	WAES0809USA03163	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	
	HEP	MERCK & CO. INC.	NULL		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Back pain, Dizziness, Injection site coldness, Injection site pain, Pain in extremity

Symptom Text: Information has been received from a certified medical assistant concerning a 21 year old female with no pertinent medical history reported who on 18-SEP-2008 was vaccinated with the first dose of GARDASIL 0.5 mL, intramuscularly in the left deltoid. Secondary suspect therapy included RECOMBIVAX HB. Concomitant therapy included ADACEL. The certified medical assistant reported that the patient got lightheaded following vaccination with GARDASIL and then developed back, abdominal and arm pain. After 10 to 15 minutes of vaccination the patient felt light headed. The patient was given a cracker and instructed to sit down. The patient then developed lower back pain then wrapped around the abdominal area. The patient was then instructed to lie down. The patient then complained that her arm (injection site arm) was cold and sore. The patient recovered in a few minutes with the exception of the sore arm. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **329544-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	08-Aug-2008	08-Aug-2008	0	17-Oct-2008	11-Feb-2009	VA	WAES0809USA01373	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1740U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Pyrexia

Symptom Text: Information has been received from a medical assistant concerning a 13 year old female with no pertinent medical history, drug reactions or allergies who on 08-AUG-2008 was vaccinated intramuscularly in the right deltoid with a first 0.5 mL dose of GARDASIL (Lot #659962/1740U). Secondary suspect vaccination was VARIVAX. On 08-AUG-2008, "about an hour after receiving GARADSIL," the patient developed an unspecified fever and then experienced facial itching that resolved within an hour after onset. The patient sought medical attention by phone call and did not seek treatment for the symptoms. On 09-AUG-2008 the patient recovered from the events. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **329545-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	28-Aug-2008	28-Aug-2008	0	17-Oct-2008	11-Feb-2009	--	WAES0809USA01384	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vaginal haemorrhage

Symptom Text: Information has been received from a physician assistant, for the Pregnancy Registry for GARDASIL, concerning a 24 year old black healthy female with a history of 6 pregnancies and 3 live births and a history of spontaneous abortion and stillbirth at 17 weeks for fetal anomalies who on 28-AUG-2008 was vaccinated with her first dose of GARASIL (Lot number 659964/1978U). There was no concomitant medication. The patient was pregnant. She had a menstrual period in Jun 2008 and then had vaginal bleeding on 28-AUG-2008 which was assumed to be a menstrual period. The patient sought medical attention and had been seen in the emergency room. The pregnancy test was performed there and the result was positive. On 04-SEP-2008, an ultrasound was performed for vaginal bleeding and the result showed as live intrauterine pregnancy at 6 weeks 3 days. The date of last menstrual period was unknown and the estimated delivery date was 26-APR-2009. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound, 09/04/08, Live intrauterine pregnancy at 6 weeks 3 days; beta-human chorionic 08/28/08-positive

History: Abortion spontaneous; Stillbirth

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329546-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	19-Dec-2007	20-Dec-2007	1	17-Oct-2008	11-Feb-2009	--	WAES0809USA01386	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Genital herpes, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered nurse concerning a 26 year old female with an amoxicillin allergy and a history of genital herpes who on 19-DEC-2007 was intramuscularly vaccinated with the first 0.5 mL dose of GARADSIL (lot # 659439/1267U), on 11-MAR-2008 was intramuscularly vaccinated with the second 0.5 mL dose of GARDASIL (lot # 659182/1757U) and on 21-AUG-2008 was intramuscularly vaccinated with the third 0.5 mL dose of GARDASIL (lot # 66012/0229X). There was no concomitant medication. The patient developed a mild outbreak of her genital herpes about one day after being vaccinated with doses one and two of GARDASIL. About two weeks after her third dose of the series, the patient had a more severe outbreak that required treatment with VALTREX. The patient was seen in the office. At the time of reporting, the patient was recovering. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Genital herpes

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329547-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Sep-2008	05-Sep-2008	4	17-Oct-2008	12-Feb-2009	--	WAES0809USA01394	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from a physician concerning a female who at the beginning of September, on approximately 01-SEP-2008 was vaccinated with her first dose of GARDASIL. Four days after vaccination, on approximately 05-SEP-2008, the patient experienced tingling and numbness in all her extremities. The patient's tingling and numbness in all her extremities persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329548-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Jul-2008	01-Jul-2008	0	17-Oct-2008	12-Feb-2009	--	WAES0809USA01404	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	UNK	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a grandmother concerning her 11 year old granddaughter who in July 2008, was vaccinated with GARDASIL. Concomitant therapy included "other vaccines" (unspecified). In July 2008 the patient experienced injection site pain, redness at injection site and swelling at injection site. Subsequently, "2 weeks after the vaccine was received," the patient recovered from injection site pain, redness at injection site and swelling at injection site. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329549-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	07-Jul-2008	07-Jul-2008	0	17-Oct-2008	12-Feb-2009	--	WAES0809USA01410	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Muscular weakness

Symptom Text: Information has been received from a nurse concerning a female who on 07-JUL-2008 was vaccinated with a dose of GARDASIL, 0.5 mL, I.M. and experienced general weakness of extremities. The patient was referred to local emergency room. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329550-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	14-Jul-2008	14-Jul-2008	0	17-Oct-2008	12-Feb-2009	--	WAES0809USA01416	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a pharmacist concerning a female who on 14-JUL-2008 was vaccinated with GARASIL. The patient fainted 45 after receiving HPV vaccine. The patient was referred to the ER of a hospital. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329551-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	15-Aug-2008	15-Aug-2008	0	17-Oct-2008	12-Feb-2009	--	WAES0809USA01426	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site extravasation, Muscle spasms

Symptom Text: Information has been received from a certified medical assistant concerning a female who on 15-AUG-2008 was vaccinated intramuscularly with a dose of GARDASIL (Lot # 660387/1967U) 0.5 mL. It was reported by the certified medical assistant that the patient had a muscle spasm as she was being vaccinated with GARDASIL. Most of the vaccine dose leaked back out of the injection site. An additional dose was then administered. On 15-AUG-2008 the patient recovered from muscle spasm. The patient sought medical attention: In office. There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329552-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	12-Feb-2009	TN	WAES0809USA01432	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Contusion, Dizziness, Eye injury, Fall

Symptom Text: Information has been received from a nurse, concerning her daughter who on an unspecified date was vaccinated with the first dose of GARDASIL (Lot # not reported). Ten minutes later, the patient experienced dizziness. When the patient stood up, she fell over and had a bruise on her eye. On an unknown date, the patient recovered. The patient sought medical attention with the nurse. There was no product quality complaint. Additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329553-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	02-Sep-2008	02-Sep-2008	0	17-Oct-2008	12-Feb-2009	PA	WAES0809USA01434	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urinary tract infection

Symptom Text: Information has been received from a physician concerning a 20 year old female patient, who one week ago (approximately 02-SEP-2008) was vaccinated with the second dose of GARASIL (Lot # not reported). One week ago (approximately 02-SEP-2008), the patient experienced urinary tract infection after receiving the second dose of GARDASIL. The patient sought medical attention, seen by the physician. There was no product quality complaint. Additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329554-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Aug-2007	12-May-2008	280	17-Oct-2008	12-Feb-2009	MD	WAES0809USA01437	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Hair growth abnormal

Symptom Text: Information has been received from a nurse, concerning a 16 year old female patient with who on 06-AUG-2007 was vaccinated with the first dose of GARASIL IM. On 10-OCT-2007, the patient was vaccinated with the second dose of GARDASIL (Lot #654540/1209U) and on 13-FEB-2008 was vaccinated with the third dose of GARASIL (Lot # 659055/1522U). Concomitant therapy included an unspecified birth control discontinued in May-2008. On 12-MAY-2008, the patient stated that she was having hair loss on her head only. At some point, she noticed that there was a little hair regrowth. She was seen by a dermatologist, who ordered a set of labs for her, they came back normal. As of 09-SEP-2008, the patient did not recovered. There was no product quality complaint. Additional information is expected.

Other Meds: (therapy unspecified)

Lab Data: diagnostic laboratory, normal

History:

Prex Illness: Contraception

Prex Vax Illns:

Vaers Id: **329555-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	02-Sep-2008	03-Sep-2008	1	17-Oct-2008	12-Feb-2009	TX	WAES0809USA01453	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal distension, Diarrhoea, Dysphonia, Feeling hot, Injection site rash, Migraine, Oropharyngeal pain, Rash generalised, Rash pruritic

Symptom Text: Information has been received from a registered nurse concerning a 22 year old female with allergy to ZITHROMAX who on 02-SEP-2008 was vaccinated with the first dose of GARDASIL (lot # 660618/0572X), IM in the deltoid. There was no concomitant medication. On 03-SEP-2008 the patient experienced a rash at the injection site arm that went to the abdomen, legs and the all over her body. The rash was described as slightly itchy. The patient took over the counter BENADRYL which seemed to help. The patient also felt feverish, but never documented a fever. The patient also developed a hoarse voice and had a slight sore throat. The patient also reported "GI puffiness", loose stools and migraine. The rash was still present as of the date of the report, but the patient was not complaining about the other symptoms at the time. The patient had called the office on 09-SEP-2008. No diagnostic test were performed. No other information to report. At the time of reporting, the patient was recovering. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **329556-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	12-Feb-2009	--	WAES0809USA01530	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a registered nurse concerning a teenage female who on unspecified date was vaccinated with a dose GARDASIL. After receiving GARDASIL, the patient was lightheaded. The outcome of the patient was not reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329557-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	12-Feb-2009	--	WAES0809USA01531	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a registered nurse concerning a teenage female who on unspecified date was vaccinated with a dose of GARDASIL. After receiving GARDASIL, the patient was lightheaded. The outcome of the patient was not reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329558-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	12-Feb-2009	--	WAES0809USA01532	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a registered nurse concerning a teenage female who on unspecified date was vaccinated with a dose GARDASIL. After receiving GARDASIL, the patient was lightheaded. The outcome of the patient was not reported. This one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329559-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	12-Feb-2009	--	WAES0809USA01533	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a registered nurse concerning a teenage female who on unspecified date was vaccinated with a dose of GARDASIL. After receiving GARDASIL, the patient was lightheaded. The outcome of the patient was not reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329560-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	12-Feb-2009	--	WAES0809USA01534	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a registered nurse concerning a teenage female who on unspecified date was vaccinated with a dose of GARDASIL. After receiving GARDASIL, the patient was lightheaded. The outcome of the patient was not reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329561-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	12-Feb-2009	--	WAES0809USA01535	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a registered nurse concerning a teenage female who on unspecified date was vaccinated with a dose of GARDASIL. After receiving GARDASIL, the patient was lightheaded. The outcome of the patient was not reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329562-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	12-Feb-2009	--	WAES0809USA01551	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myalgia, Pyrexia, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning her daughter who on an unknown date was vaccinated with a first 0.5 mL dose of GARDASIL (lot number, injection site and route not reported). Subsequently the patient experienced fever, vomiting and muscle aches. Unspecified medical attention was sought. The outcome was unspecified. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329563-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	04-Sep-2008	04-Sep-2008	0	17-Oct-2008	12-Feb-2009	IA	WAES0809USA01557	04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	
	TDAP	SANOFI PASTEUR	UF452AA		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contusion, Loss of consciousness

Symptom Text: Initial and follow-up information has been received from a physician and a registered nurse concerning an 9 year old female, also reported as 11 year old, with no relevant medical history or allergies, who on 04-SEP-2008 was vaccinated with dose of GARDASIL intramuscularly in the right deltoid. Concomitant therapy included MENACTRA and ADACEL (UF452AA) intramuscularly in the left deltoid. On 04-SEP-2008 3-5 minutes after the vaccination, the patient passed out at the front desk. The patient was unconscious for a few seconds. Her vital signs were stable. The patient bruised her chin and cheek. The patient was sent home with an icepack with her mother. It was unknown if the patient sought any medical attention. On 04-SEP-2008, the patient recovered from the events. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329564-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Aug-2008	01-Sep-2008	19	17-Oct-2008	12-Feb-2009	FL	WAES0809USA01558	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site inflammation, Injection site mass, Injection site swelling, No reaction on previous exposure to drug

Symptom Text: Information has been received from an office staff at the doctor's office concerning an approximately 15 year old female who on 13-AUG-2008 was vaccinated with her third dose of GARDASIL (lot #659964/1978U). On 10-SEP-2008 the patient came in the office with injection site inflammation with a lump at the site and swelling. The patient had no adverse symptoms from the first and second dosed. At the time of this report, the events persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329565-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	03-Sep-2008	09-Sep-2008	6	17-Oct-2008	12-Feb-2009	OH	WAES0809USA01570	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a registered nurse concerning a 21 year old female with sulfonamide allergy and no medical history reported, who on 03-SEP-2008 was vaccinated with the first dose of GARDASIL (Lot # 660612/0229X), 0.5 mL, into the left deltoid. There was no concomitant medication. On 09-SEP-2008, the patient called the physician with complaint of hives on face. The patient was treated with over the counter oral BENADRYL. The patient's outcome was not reported. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: 329566-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-Dec-2007	18-Aug-2008	243	17-Oct-2008	12-Feb-2009	NY	WAES0809USA01582	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Human papilloma virus test positive

Symptom Text: Information has been received from a physician concerning a 19 year old female with no medical history, who on 17-MAY-2007 was vaccinated IM with a first dose of GARDASIL (655165/0137U), on 17-JUL-2007 was vaccinated with a second dose of GARDASIL (Lot # unknown), and on 19-DEC-2007 was vaccinated with a third dose of GARDASIL (Lot # 659441/1446U). Concomitant medication for birth control. The physician reported that the patient received all 3 doses of GARDASIL and recently had a PAP test done and it came positive for high risk HPV on 18-AUG-2008. The outcome of the patient was not reported. The patient did not seek for medical attention. There was no product quality complaint. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Pap test, positive for high risk HPV

History:

Prex Illness: Contraception

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329568-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-Oct-2008	09-Oct-2008	0	22-Oct-2008	23-Oct-2008	FR	WAES0810POL00011	23-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Sleep terror

Symptom Text: Information has been received from a physician concerning a 13 year old female who on 09-OCT-2008 was vaccinated with GARDASIL. After vaccination the patient experienced night terror. The patient referred to the doctor on 12-OCT-2008 and was admitted to the hospital due to night terror. The patient's mother felt that night terror were related with therapy with GARDASIL. The reporter stated that relationship between night terror and therapy with GARDASIL is unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329569-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	12-Feb-2009	VA	WAES0809USA01590	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Human papilloma virus test positive

Symptom Text: Information has been received from a Family nurse practitioner concerning a female who was vaccinated with GARDASIL (dose, therapy route and lot number not specified). It was reported, after receiving GARDASIL, the patient's pap test came back for high risk of HPV. Unspecified medical attention was sought. The outcome of the adverse event was not specified. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, Pap test came back for high risk HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329571-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	24-Apr-2008	14-Aug-2008	112	17-Oct-2008	12-Feb-2009	HI	WAES0809USA01591	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning a 26 year old female with no allergies who on 28-FEB-2008 was vaccinated with the first dose of GARDASIL (LOT #659182/1757U). On 24-APR-2008 the patient was vaccinated with the second dose of GARDASIL (lot # 660387/1967U). On the same day PAP smear test was performed. On 14-AUG-2008 the patient was vaccinated with the third dose of GARDASIL (lot # 660391/0063X). At the time she was informed of the results of the PAP smear test done on 24-APR-2008 which showed Low Grade Squamous Intraepithelial Lesion. There was no concomitant medication. The patient sought medical attention in the office. The patient was scheduled for follow-up and colposcopy. Additional information has been requested.

Other Meds: None

Lab Data: cervical smear, 04/24/08, LSIL

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329572-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	27-Jul-2008	27-Jul-2008	0	17-Oct-2008	12-Feb-2009	IL	WAES0809USA01603	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a physician concerning a female with no pertinent medical history or no drug allergies who on approximately 27-JUL-2008 was vaccinated intramuscularly with a 0.5 ml dose of GARDASIL (lot number was not known). There was no concomitant medication. On approximately 27-JUL-2008 the patient experienced pain in her arm around the site of injection. The patient's pain in her arm around the site of injection persisted. Medical attention was sought via telephone. No product quality complaint was involved. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329574-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	12-Feb-2009	FL	WAES0809USA01624	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Human papilloma virus test positive

Symptom Text: Information has been received from a physician, concerning a female patient who never was sexually active presented with positive Pap test with high risk of HPV after receiving all three doses of GARDASIL. The patient sought medical attention, she saw the physician. There was no product quality complaint. Additional information is expected.

Other Meds: Unknown

Lab Data: Pap test, positive Pap Test: high risk for HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329577-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Sep-2008	02-Sep-2008	0	17-Oct-2008	12-Feb-2009	PA	WAES0809USA01660	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urinary tract infection

Symptom Text: Information has been received from a physician concerning a 17 year old female patient, who one week ago (approximately 02-SEP-2008) was vaccinated with the second dose of 0.5 mL GARDASIL (Lot # not reported). One week ago (approximately 02-SEP-2008), the patient experienced urinary tract infection after receiving the second dose of GARDASIL. The patient sought medical attention, seen by the physician. There was no product quality complaint. Additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329578-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	26-Aug-2008	02-Sep-2008	7	17-Oct-2008	12-Feb-2009	TN	WAES0809USA01664	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus

Symptom Text: Information has been received from a Licensed Practical Nurse concerning a 25 year old female with hypertension, type 2 diabetes mellitus and no known drug allergies, who on 26-AUG-2008, was vaccinated with her first dose of GARDASIL (Lot # 660557/0072X) 0.5 ml IM right deltoid. Concomitant therapy included AVAPRO, metformin and prenatal vitamins (unspecified). On 02-SEP-2008, the patient experienced generalized pruritus without a rash a week after receiving her first dose. The pruritus was worse on her hands and face. The patient called the physician. The patient was instructed to take BENADRYL. The patient's generalized pruritus persisted. Additional information has been requested.

Other Meds: AVAPRO; metformin; vitamins (unspecified)

Lab Data: Unknown

History:

Prex Illness: Hypertension; Type 2 diabetes mellitus

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329580-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	24-Sep-2008	24-Sep-2008	0	22-Oct-2008	23-Oct-2008	NY	WAES0810USA02469	23-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for the Pregnancy Registry for GARDASIL, concerning a 20 year old female who on 24-SEP-2008 was vaccinated with GARDASIL 0.5ml IM (Lot# 661044/0548X) (therapy site unknown). The patient was pregnant and sought medical attention. On 08-OCT-2008 the pregnancy was terminated. The pregnancy was not terminated because of complications but rather personal choice. The patient had no medical history and drug reactions/allergies. Concomitant therapy included AUGMENTIN. Her last menstrual period was 29-AUG-2008. The patient outcome was unknown. Additional information has been requested.

Other Meds: AUGMENTIN

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 8/29/2008)

Prex Vax Illns:

Vaers Id: **329581-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Sep-2008	15-Sep-2008	0	22-Oct-2008	23-Oct-2008	FR	WAES0810USA02770	23-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0569U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Dizziness, Hyperhidrosis, Hypotension, Immediate post-injection reaction, Loss of consciousness, Nausea, Vision blurred

Symptom Text: Information has been received from a health professional concerning an 18 year old female, with no medical history reported, who was administered on 15-SEP-2008 the third dose of GARDASIL (Batch # NG39340/ lot #0569U), (site and route not reported). After vaccine administration the patient suffered hypotension, dizziness, blurry vision, sweating, abdominal pain and nausea. The patient recovered. It was reported the patient had no adverse event with the previous doses of GARDASIL. The patient suffered a loss of consciousness immediately after vaccine administration, that persisted for 10 seconds. The patient recovered from hypotension, dizziness, blurry vision, sweating, abdominal pain and nausea 10 minutes after symptoms' onset. The first and second doses of GARDASIL (batch #'s not reported) were administered on 14-MAR-2008 and 15-MAY-2008 respectively, both of them by intramuscular route on the deltoid. This case was considered as serious with other medically important condition as criteria. This is a group of 4 linked cases (E2008-9562 to E2008-9565). The case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: It was reported the patient had no adverse event with the previous doses of GARDASIL.

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329582-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-May-2008	01-Aug-2008	78	17-Oct-2008	13-Feb-2009	FR	WAES0810USA02771	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1049U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Coordination abnormal, Dysarthria, Fatigue, Nervousness, Weight decreased

Symptom Text: Information has been received from a gynaecologist concerning a 14 year old female who on 19-MAR-2007 was vaccinated with the first dose of GARDASIL (Lot # 0466U, Batch # NG46490) and was well tolerated. On 15-MAY-2008, the patient was vaccinated with the second dose of GARDASIL (Lot # 1049U, Batch # NG46500). On 11-SEP-2008, the patient was vaccinated with the third dose of GARDASIL (Lot # 1427, Batch # NH15200). Concomitant therapy included unspecified hormonal contraceptives. At the beginning of August 2008, the patient developed slurred speech and incoordinated movements. Also, she was nervous, tired and had weight loss of 5 kg. She did not mention these events at the time she received her third dose vaccination. Reportedly, she was hospitalized in a neurological department end of September 2008. Results and final outcome were not reported. Other business partner numbers included: E2008-09434. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 329583-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-May-2008	03-Jun-2008	27	22-Oct-2008	23-Oct-2008	FR	WAES0810USA02774	23-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Dyspnoea, Gait disturbance, Hyperventilation, Muscular weakness, Myalgia, Pain in extremity, Paraesthesia, Respiratory disorder

Symptom Text: Information has been received from the foreign health authority - ref NY20080646 (local reference BGAR 2008/113), concerning a 13 year old female with allergy to Alternaria tenuis and sensibilisation to this mold, who on 05-MAR-2008 was vaccinated with the first dose of GARDASIL, by intramuscular route. On 07-MAY-2008, the patient was vaccinated with the second dose of GARDASIL (Lot # unknown) by intramuscular route. On 03-JUN-2008 the patient experienced dyspnea and tingling in hands and feet. Auscultation was normal. On 04-JUN-2008 she experienced an aggravation of the dyspnea. Clinical examination: hyperventilation without functional anomaly or clinical provocation of asthma: EFR normal. She was symptomatically treated with corticoid, antihistaminica and bronchodilatator. On 05-JUN-2008 she experienced a sudden sensation of weakness and pain of the lower limbs. Clinical examination showed a disorder gait, a painful palpation of the muscles. No pyramidal or cerebellar syndrome, no sphincter dysfunction. Normal tendon reflexe. EMG showed no sign of neuropathy or myositis. F-wave latency delayed. On 09-JUN-2008, there was a favourable evolution concerning the respiratory problems. On 13-JUN-2008 persistence of difficulty of walking due to a weakness of the muscles. Since then favourable evolution. She recovered fully. According to the serious criteria the patient has been hospitalised but no further information received. Other business partner numbers included: E2008-09498. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, 04Jun08, EFR test: normal; Electromyography, 05Jun08, no sign of neuropathy or myositis

History:

Prex Illness: Mycotic allergy

Prex Vax Illns:

Vaers Id: **329584-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Dec-2007	01-Jan-2008	19	22-Oct-2008	23-Oct-2008	FR	WAES0810USA02776	23-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0278U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Demyelination, Diplopia, Multiple sclerosis, Optic neuritis retrobulbar, Visual acuity reduced, Visual disturbance

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 13-DEC-2007 was vaccinated with the first dose of GARDASIL (batch no. NF58150; lot no. 0278U) (route and site not reported). In January 2008 (two to three weeks post vaccination) the patient experienced visual disturbance, double vision and vision decreased. The patient was seen by an ophthalmologist, but not confirmed by diagnosis. Despite the events, the patient was given a second dose of GARDASIL (batch no. NG34890; lot no. 0466U) (route and site not reported) on 13-FEB-2008 and a third dose of GARDASIL (batch no. NH15200; lot no. 1114U) (route and site not reported) on 25-JUN-2008. In September 2008 the patient consulted a neurologist and retrobulbar neuritis was diagnosed. The patient was not hospitalized. A magnetic resonance imaging was performed that showed multiple demyelinating foci, and a cerebrospinal fluid puncture showed increased IgG synthesis. The diagnosis of multiple sclerosis was established. Treatment with interferon had not been given at the time of the reporting, but it was intended. The patient had not recovered. Multiple sclerosis, retrobulbar neuritis, visual disturbance, double vision and vision decreased were considered to be another important medical event. Other business company numbers included: E2008-09508. Additional information has been requested.

Other Meds:

Lab Data: Magnetic resonance imaging, ??08, multiple demyelinating foci; Spinal tap, ??08, increased IgG synthesis

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **329585-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	30-Aug-2008	10-Sep-2008	11	22-Oct-2008	23-Oct-2008	FR	WAES0810USA02777	23-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Glossopharyngeal neuralgia

Symptom Text: Information has been received from a health authority (ref. # ES-AGEMED-517630344) concerning a 25 year old female who on 30-AUG-2008 was vaccinated with a dose of GARDASIL IM. It was reported that on 10-SEP-2008 the patient suffered a glossopharyngeal neuralgia that was still ongoing. The patient was treated with carbamazepine, (details regarding this treatment not reported). In September 2008 an ultrasound, a magnetic resonance imaging and a computed axial tomography were performed and showed normal results. According to the reporter, the patient has been checked by both the otorhinolaryngologist and the maxillofacial doctor; they have discarded any other pathologies. Other business partner numbers included: E2008-09537. Additional information has been requested.

Other Meds:

Lab Data: Magnetic resonance imaging, ??Sep08, normal results; Computed axial tomography, ??Sep08, normal results; Ultrasound, ??Sep08, normal results

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329586-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-May-2008	17-May-2008	0	22-Oct-2008	23-Oct-2008	FR	WAES0810USA02779	23-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NG30400	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a health professional concerning a 14 year old female with no reported medical history, who was administered on 17-MAY-2008 the third dose of GARDASIL (Batch No NG30400), intramuscularly into the deltoid. After vaccine administration the patient experienced loss of consciousness. The event lasted for a few seconds. The patient recovered. Additional information was received through telephone contact with the healthcare professional: GARDASIL was administered on the deltoid by intramuscular route (Batch # confirmed NG 30400). It has also been reported that the patient received the second dose of GARDASIL (Batch # not reported) by intramuscular route on her deltoid. The patient didn't receive any treatment for the adverse event. No other information has been reported. The case was reported by the Health Authority as serious with other medically important condition as criteria. This is a case of 4 linked cases (E2008-09562 and E2008-09565). The case is closed. Other business partner numbers included: E2008-09562. No further information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329587-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Sep-2007	Unknown		22-Oct-2008	23-Oct-2008	IL	WAES0810USA02781	23-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Complication of pregnancy, Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received from a consumer for the pregnancy registry for GARDASIL, concerning her 17 year old daughter with no medical history and no drug allergies reported, who on 09-JUL-2007 was vaccinated with the first dose of GARDASIL and on 21-SEP-2007 was vaccinated with the second dose of GARDASIL while she was pregnant. The patient did not know at the time of vaccination that she was pregnant. The patient gave birth two months early on 14-DEC-2007. The patient was hospitalized twice during the pregnancy due to unspecified complications. The patient received the third dose of GARDASIL after giving birth but it was unknown if the vaccine was given late. There was no concomitant medication. The patient's LMP was unknown. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **329588-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	U	Unknown	Unknown		22-Oct-2008	23-Oct-2008	--	WAES0810USA03315	23-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Deep vein thrombosis

Symptom Text: Information has been received from a physician concerning an 18 or 19 year old patient with no family history of deep vein thrombosis (DVT) and previously healthy who was vaccinated with a first dose of GARDASIL. 5 days after the vaccination, the patient came in the hospital with a right upper extremity DVT that required "Lyticx". At the time of this report, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329597-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	13-Feb-2009	--	WAES0809USA01727	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Muscular weakness

Symptom Text: Information has been received from a physician assistant concerning a female who was vaccinated the first dose of with GARDASIL and experienced numbness and weakness in one of her legs. The patient sought medical attention. The patient "got better". The physician assistant indicated the patient would not be completing the vaccine series. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329598-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		17-Oct-2008	13-Feb-2009	--	WAES0809USA01787	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Infectious mononucleosis, Splenomegaly

Symptom Text: Information has been received from a consumer concerning her approximately 14 year old grandaughter with no pertinent medical history of drug reactions/allergies, who "about two years ago" in approximately 2006 received the three doses of GARDASIL 0.5 mL. There was no concomitant medication. The reporter stated that the patient either a month after receiving her first or third dose, experienced mononucleosis as well as an enlarged spleen. Caller knew that patient received all three doses of the series, however it was unknown after which one the symptoms occurred. Patient also experienced fatigue. Last blood test was "about 6 months ago" in approximately March 2008. The patient sought unspecified medical attention. At time of report, the patient had not recovered. Additional information is not expected.

Other Meds: None

Lab Data: Diagnostic laboratory, 03/??/08

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **329599-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	13-Feb-2009	TX	WAES0809USA01805	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a female who was vaccinated with a dose of GARDASIL (lot # not available). The reporter stated that the patient had not eaten prior to receiving the vaccination, and fainted for 3 minutes after receiving the shot. The patient sought medical attention and saw the physician. At time of report, the patient was recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329600-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	12-Feb-2009	UT	WAES0809USA01817	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dermatitis contact

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with GARDASIL (route, site and lot number not reported). Subsequently the patient experienced contact dermatitis from the GARDASIL band-aids. The skin affected was the shape of the band-aids. The patient came in the day after the band-aid was applied to report the reaction. There was no additional information at that time. Further information was received from the office manager. It was reported that "several girls" mentioned that the band aids "should not be used." The patient information was not recorded at the time, and therefore, the office had no way of knowing "who made the comments."

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329601-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Feb-2008	13-Feb-2008	0	17-Oct-2008	12-Feb-2009	PA	WAES0809USA01827	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injection site nodule

Symptom Text: Information has been received from a emergency medical technician and a patient's mother concerning an 18 year old female with KEFLEX allergy who on 24-SEP-2007 (previously reported as "6 months ago") was vaccinated with the first dose of GARDASIL (lot# 658558/1061U). On 13-FEB-2008, she was vaccinated with a second dose of GARDASIL (lot # 659439/1267U). On 19-AUG-2008 (previously reported as "week of 11-AUG-2008") the patient was vaccinated with a third dose of GARDASIL (lot #660612/0229X), 0.5, I.M. Shortly, after receiving her third dose, on 19-AUG-2008, the patient experienced a 30 mm nodule at the injection site (previously reported as a lump at the injection site, the size of a "half dollar"). The patient sought medical attention calling the practice. The nodule persisted for 7-10 days, then resolved. The nodule returned at the same area in September 2008. At the time of reporting, the patient had not recovered from the nodule at the injection site. Additional information has been requested.

Other Meds: MENACTRA

Lab Data: None

History:

Prex Illness: Drug Hypersensitivity

Prex Vax Illns:

Vaers Id: **329602-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	11-Sep-2008	11-Sep-2008	0	17-Oct-2008	12-Feb-2009	MO	WAES0809USA01842	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a female who on 11-SEP-2008 was vaccinated with the first dose of GARDASIL Lot # was not available. Per nurse, the patient fainted after receiving the first dose of GARDASIL. The same day the patient recovered from fainted. The patient was seen by the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329603-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	12-Feb-2009	--	WAES0809USA01846	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass

Symptom Text: Information has been received from a registered pharmacist concerning a college student female who on an unspecified date was vaccinated with the first dose of GARDASIL and experienced a big lump at the injection site (50-60 millimeter in diameter). The pharmacist also mentioned that there was no shortness of breath and the lump resolved in 2 weeks. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329604-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	09-Sep-2008	10-Sep-2008	1	17-Oct-2008	12-Feb-2009	--	WAES0809USA01858	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a nurse practitioner concerning a 12 year old female with penicillin allergy and no pertinent medical history who on an unknown date, was vaccinated with the first dose of GARDASIL 0.5 mL, IM. The patient did not experience any difficulties. On 09-SEP-2008, the patient was vaccinated with the second dose of GARDASIL 0.5 mL, IM. There was no concomitant medication. On 10-SEP-2008, the patient experienced over all body rash. The patient's over all body rash persisted. No laboratory tests were performed. The patient was seen in the physician's office (not further specified). The patient sought medical attention by a doctor's office visit. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **329605-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	11-Sep-2008	11-Sep-2008	0	17-Oct-2008	12-Feb-2009	CA	WAES0809USA01861	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 23 year old female who on 11-SEP-2008 was vaccinated with GARDASIL (lot no. and route of administration were not reported). On 11-SEP-2008, the patient fainted after receiving GARDASIL at the doctors office. The physician reported that the patient had not eaten any meals prior to vaccination. As of 11-sep-2008, the patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329606-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	06-Mar-2007	07-Mar-2007	1	17-Oct-2008	12-Feb-2009	--	WAES0809USA01915	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Pain

Symptom Text: Information has been received from a consumer concerning her daughter, an 18 year old female patient with a history of "asthma as a child," who on 06-MAR-2007 was vaccinated with the first dose of GARDASIL (lot #, route and injection site not reported). According to the consumer, on 07-MAR-2007 her daughter had "terrible pain and abdominal cramping" after receiving her first dose of GARASIL. The patient contacted doctor and went to the emergency room on 08-MAR-2007 (reported as 08-MAR-2008). CT scan of pelvis and abdomen, wet smear, urinalysis, blood count, Gram smear, gonorrhea and Chlamydia tests were performed without results reported. It was reported that the patient was not hospitalized. The patient was placed on unspecified therapy and the event improved. At the time of the report, the patient was recovering from the event. Additional information is not expected.

Other Meds: None

Lab Data: CT scan of pelvis and abdomen; wet smear; urinalysis, blood count; Gram smear; gonorrhea and Chlamydia tests

History: Asthma

Prex Illness:

Prex Vax Illns:

Vaers Id: **329607-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Aug-2008	13-Aug-2008	0	17-Oct-2008	12-Feb-2009	FL	WAES0809USA01942	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site inflammation, Injection site mass, Injection site swelling

Symptom Text: Information has been received from a medical assistant and a health care worker concerning an approximately 15 year old female patient who on 01-AUG-2007 was vaccinated with the first dose of GARDASIL (lot #656050/0245U). On 05-OCT-2007, was vaccinated with the second dose of GARDASIL (lot #657006/0188U), and on 13-AUG-2008, was vaccinated with the third dose GARDASIL (lot 659964/1978U), all doses intramuscularly into her left arm. About three weeks after receiving the third dose of GARDASIL, on approximately 03-SEP-2008, the patient experienced injection site inflammation with a lump at the site and swelling. There was no adverse symptoms from the first or second doses. On 10-SEP-2008, the patient was seen at the physician's office. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329608-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	10-Sep-2008	11-Sep-2008	1	17-Oct-2008	12-Feb-2009	--	WAES0809USA01943	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Injection site vesicles, Nausea

Symptom Text: Information has been received from a 25-year-old female pharmacy technician who reported that on 10-SEP-2008, she received the second dose of GARDASIL (lot # not reported) 0.5 mL via intramuscular route in her left deltoid. Concomitant medication included ORTHO-CYCLEN. According to the reporter, on 11-SEP-2008 she developed two "fluid filled blisters on either side of the site of injection" after the second dose of vaccination. The patient also experienced nausea and diarrhea. She sought unspecified medical attention. At the time of reporting, the patient had not recovered from the events. The patient's received her first dose of GARDASIL on 03-JUN-2008. Additional information has been requested.

Other Meds: ORTHO-CYCLEN

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329609-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Aug-2008	15-Aug-2008	0	17-Oct-2008	12-Feb-2009	--	WAES0809USA01946	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a nurse concerning a 18-year-old female patient who on 15-AUG-2008 received the second dose of 0.5 mL GARDASIL (lot number, route and injection site not reported). On on 15-AUG-2008, after the vaccination the patient experienced a rash on one side of her body. She sought unspecified medical attention by calling the practice. On 15-AUG-2008 the patient recovered from the event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329610-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Apr-2007	Unknown		17-Oct-2008	13-Feb-2009	OH	WAES0809USA01952	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection, Smear cervix abnormal

Symptom Text: Information has been received from a consumer concerning her daughter a 19 year old female who on 04-OCT-2006 was vaccinated with the first dose of GARDASIL. In December 2006, the patient was vaccinated with a second dose of GARDASIL. In April 2007, she was vaccinated with a third dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). The patient received an abnormal pap smear. The abnormal cells were diagnosed as HPV. The patient sought unspecified medical attention. At the time of reporting the patient had not recovered from HPV. The patient's physician plans to retest in 3 months. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Pap test, HPV

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 329611-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	29-Aug-2008	29-Aug-2008	0	17-Oct-2008	12-Feb-2009	FL	WAES0809USA01953	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site induration, Injection site swelling

Symptom Text: Information has been received from a certified medical assistant concerning a female with no medical history and no know allergies who on approximately 29-AUG-2008 was vaccinated with a second dose of GARDASIL. There was no concomitant medication. The certified medical assistant reported that the patient developed swelling after injection on approximately 29-AUG-2008 and a hard knot days later around the injection site. It was reported that the patient exercised regularly and noticed that the knot at the muscle area was noticeable when she flexed her arm. At the time of reporting the patient had not recovered. Patient sought medical attention: was seen. There was no product quality complain. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 329639-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-Oct-2008	21-Oct-2008	0	22-Oct-2008	20-Nov-2008	WA		24-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2806AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0548X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2730AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0975X	1	Right arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C3027AA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cold sweat, Feeling cold, Hyperhidrosis, Pallor, Sluggishness, Syncope, Urinary incontinence

Symptom Text: Patient experienced a syncopal episode with possible generalized seizure activity, with urinary incontinence after receiving 5 vaccinations at approx. 4:45-5 p.m. on 10/21/08. She was immediately aroused with smelling salts by the RN and the supervisor was notified. After the incident the client was pale, slight diaphoretic,cool,clammy, and sluggish. Vitals signs after syncopy were BP 90/76, HR 70, RR 32 with repeat set after 15 mins. BP 90/76, HR 56, RR 32. Pt. was laid down, placed on 4-5L oxygen per mask, and observed for 30-45 mins. She then was alert, and oriented to person, place, and time, more verbal, and without balance problems. She was then referred to urgent care hours at her drs. office for follow up.

Other Meds: Unknown

Lab Data: n/a

History: None listed

Prex Illness: None

Prex Vax Illns: Unknown~ ()~~0~In Patient

Vaers Id: **329656-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Sep-2008	22-Sep-2008	7	22-Oct-2008	27-Oct-2008	CA		19-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2787EA		Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abnormal behaviour, Crying, Delusion, Irritability, Major depression, Mental status changes, Muscle twitching, Neurological examination, Psychotic disorder, Staring

Symptom Text: Pt had Gardasil and Fluzone vaccines on 9/15/08. 9/22/08 presented to the office crying with delusions about family members with lethal disease. Pt sent to Hospital to the ER for Neuro consult. EEG and labwork negative. 3 admits to Hospital and neuro work up. Inconclusive and unknown etiology. 11/14/08-records received for DOS 9/22-9/24/08-DC DX: Major deprssive disorder with psychotic features. Admitted due to changes in behavior and altered mental status. Increased irritability, staring with right sided twitching.

Other Meds: Maxalt 5 mg prn migraines

Lab Data: EEG, MRI, bloodwork 11/14/08-records received-CBC, CMP LFTs normal. UA negative, CK 53. EEG abnormal-generalized slowing of background.

History: Augmentin, Cefzil, Nuts, Zyrtec allergies. Spastic CP, Migraines, had Grp B Strep Meningitis as newborn 11/14/08-records received-PMH: anxiety, cerebral palsy, developmental delay secondary to neonatal group B streptococcal meningitis with seiuzres up to 6 monthg of age and no seizure from that point forward.

Prex Illness: 17 year well check visit

Prex Vax Illns:

Vaers Id: **329657-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Oct-2008	16-Oct-2008	0	22-Oct-2008	21-Nov-2008	TX		21-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypotension, Musculoskeletal stiffness, Syncope, Tremor

Symptom Text: immunization given, waited 10 min. left clinic,then fainted in car, was stiff and shaky. ambulance was called, transported to er via ambulance. was diagnosed with low blood pressure, had ct scan done at er

Other Meds: Zoloft, birth control pills

Lab Data: ct scan

History: none know

Prex Illness: none noted

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329669-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	18-Aug-2008	19-Aug-2008	1	17-Oct-2008	13-Feb-2009	--	WAES0809USA01982	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Dizziness, Fatigue, Nausea, Pyrexia, Vomiting

Symptom Text: Information has been received from a licensed practical nurse concerning a 19 year old female with penicillin allergy and sulfonamide allergy and history of tachycardia who on 18-AUG-2008 was vaccinated with the first dose of GARDASIL, 0.5 mL, IM. Concomitant therapy included metoprolol. Since 19-AUG-2008, the patient experienced fever, nausea, vomiting, chills, dizziness and fatigue. On 09-SEP-2008, the patient sought medical attention calling to the office because her symptoms had not resolved. Additional information has been requested.

Other Meds: metoprolol

Lab Data: None

History:

Prex Illness: Penicillin allergy; Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329670-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Jun-2008	20-Jun-2008	0	17-Oct-2008	13-Feb-2009	MN	WAES0809USA01996	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash erythematous

Symptom Text: Information has been received from a mother and a certified medical assistant concerning the development of a rash by a twin sister following vaccination. A 18 year old female who on 20-JUN-2008, was vaccinated with the first dose of GARDASIL. On 19-AUG-2008, was vaccinated with the second dose of GARDASIL. On 20-JUN-2008, the patient experienced rash after the first vaccination, but development or resolution was not available at the time of the report. The patient reported on 25-AUG-2008, that she developed a rash that started 10 days prior (4 days prior to the second vaccination). On 15-AUG-2008, the patient experienced 10 point erythematous rash all over her torso. At the time of reporting, the outcome was unknown. Her rash was described as similar to her twin sister's (WAES0809USA02661). Additional information has been requested. This one of several reports received from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: Rash~HPV (Gardasil)~~18~In Sibling

Vaers Id: **329671-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Jul-2008	03-Jul-2008	2	17-Oct-2008	02-Jan-2009	--	WAES0809USA02000	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acne, Alopecia, Blepharospasm, Contusion, Dyspnoea, Extraocular muscle paresis, Eyelid ptosis, Facial palsy, Gaze palsy, Headache, Lid lag, Malaise, Muscle contractions involuntary, Muscle fatigue, Muscle twitching, Muscular weakness, Musculoskeletal discomfort, Oropharyngeal pain, Pharyngitis streptococcal, Sinusitis, Viral infection, Vitamin B12 absorption test, Weight decreased

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female who on 01-JUL-2008 was vaccinated with the first dose of GARDASIL (lot no. 0250X) (route not reported). Concomitant therapy included birth control pills (unspecified), lithium (unspecified), SYNTHROID and CECLOR. On 03-JUL-2008, two days after vaccination the patient experienced eye twitching. The patient was testing for Lyme disease, thyroid dysfunction, vitamin B12 deficiency and the patient had a magnetic resonance imaging (MRI) done to rule out an aneurysm. No diagnosis was given. The patient sought medical attention by calling the physician. Additional information has been requested. 11/06/2008 Records received from OBGYN. Exam 7/1/08 with normal PE. Pt will not be getting 2nd HPV vax due to developing an eye twitch 2 days s/p 1st vax on 7/1/08. Has seen PMD, Neuro and endocrine with no dx. 12/19/2008 MR received from PCP beginning 7/18/-12/2/2008. Initially seen 7/18/08 with c/o of feeling unwell and intermittent eye twitch, lid lag and torso twitches. Seen in ER and dx: sinusitis-tx-abx. PE (+) for ptosis and R eye lateral and upward deviation, RUE and R upper eyelid weakness. Concern for MS or MG. DX: Palsy, parial 3rd nerve. Muscle fasculations. Referred to neuro who felt either sinusitis or psychiatric etiology. Returned 8/11/08 with c/o throbbing head pain/pressure on R side of head. Assessment: Muscle fasiculations. H/A etiology unclear. Ophth exam (=) for ptosis but no ocular componant to h/a. Seen in referral for 1 mon hx of eye twitching and muscular fatigue on exertion. ROS (+) for 18# wt loss, eye twitching, hip soreness, acne, hair loss and abnormal bruising. PE (+) for R eye lag. DX: Hypothyroidism. Muscle fasciculations. OV 9/19/08 in f/u. Dx: Infection, viral. Rx: Doxycycline. Flu vax 12/2/08. F/u for ER visit for SOB/sore throat. DX: Strep throat.

Other Meds: CECLOR; hormonal contraceptives; SYNTHROID; lithium sulfate

Lab Data: Unknown. Labs and Diagnostics: CT scan (+) for sinusitis. MRI brain (+) for L maxillary sinus disease. Lyme (-) x2, Babesia & Ehrlichiosis (-). TSH, T3, T4 all WNL. EBV IGG AB (+) 4.04. PAP (+) for ASCUS.

History: Unknown. PMH: Bipolar d/o. Hypothyroid. Allergies: Cefaclor.

Prex Illness:

Prex Vax Illns:

Vaers Id: **329672-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	29-Feb-2008	29-Feb-2008	0	17-Oct-2008	13-Feb-2009	UT	WAES0809USA02004	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysgeusia, Epistaxis, Parosmia

Symptom Text: Information has been received from a 23 year old female with penicillin, metals, FLOXIN and bromafid allergy, who on 29-FEB-2008, was vaccinated with the first dose of GARDASIL (lot no. 655327/1287U) 0.5 mL, IM. On 12-MAY-2008, was vaccinated with second dose of GARDASIL (lot no. 0152X) 0.5 mL, IM and on 12-SEP-2008 was vaccinated with the third dose of GARDASIL (lot no.660557/0072X) 0.5 mL, IM. The nurse reported that the patient experienced a metallic taste and smell of ammonia after each vaccine. The patient had nose bleed 2 hours after vaccination with first and second dose of GARDASIL that lasted for a few minutes. The nurse reported that no treatment was required. No laboratory tests were performed. The patient sought medical attention at the doctor's office. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy; Allergy to metals; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **329673-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	11-Sep-2008	Unknown		17-Oct-2008	13-Feb-2009	MA	WAES0809USA02022	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a 22-year-old female patient who on 11-SEP-2008 received the first dose of 0.5 mL GARDASIL (lot number and injection site not reported) via intramuscular route. On an unknown date after the vaccination, the patient developed a rash on her abdomen. No itching was noted. She sought unspecified medical attention through phone call. At the time of reporting, the patient was recovering from the event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329674-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	13-Feb-2009	UT	WAES0809USA02066	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dermatitis contact

Symptom Text: Information has been received from a physician concerning two patients who were vaccinated with GARDASIL (route, site and lot number not reported). Subsequently the patients experienced contact dermatitis from the GARDASIL band-aids. The skin affected was the shape of the band-aids. There was no additional information at that time. Further information was received from the office manager. It was reported that "several girls" mentioned that the band aids "should not be used." The patient information was not recorded at the time, and therefore, the office had no way of knowing "who made the comments."

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329675-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	14-Aug-2008	15-Aug-2008	1	17-Oct-2008	13-Feb-2009	--	WAES0809USA02084	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Streptococcal infection

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female who on 14-AUG-2008 was vaccinated with the third dose of GARDASIL. On approximately 15-AUG-2008 the patient developed a "strep infection" and was placed on steroids. The patient recovered without incidence. The patient sought medical attention at the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 329676-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		17-Oct-2008	13-Feb-2009	--	WAES0809USA02100	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Smear cervix abnormal

Symptom Text: Information has been received from a certified nurse midwife concerning her daughter's friend a 26 year old female with no pertinent medical history reported who on unspecified dates was vaccinated with the first and second doses of GARDASIL. After 2 doses of GARDASIL, the patient experienced an atypical squamous cells of undetermined significance. A PAPANICOLAOU test was performed which was positive for HPV. The friend's physician has recommended a cervical biopsy. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, positive for HPV

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329679-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Jul-2008	07-Sep-2008	41	17-Oct-2008	13-Feb-2009	PA	WAES0809USA02113	30-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2657AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Condition aggravated, Cough, Eczema, Fatigue, Joint swelling, Malaise, Migraine, Nausea, Phonophobia, Photophobia, Pyrexia, Rash, Urinary tract infection, Vomiting

Symptom Text: Information has been received from a licensed practical nurse concerning a 17 year old female with penicillin allergy and drug hypersensitivity to CECLOR who on 28-JUL-2008 was vaccinated with the first dose of GARDASIL (lot # 660553/0070X). Concomitant therapy included MENACTRA. "A couple weeks ago" the patient developed swollen ankles, rash on her legs and arms and night time fevers after her first dose of GARDASIL. Her ankles were swollen to the size of grapefruit. She also had an unproductive cough for 2 weeks and general malaise. The patient was seen in the office. At the time of reporting a chest X-ray and a blood tests were performed but results were pending. At the time of reporting the patient had not recovered from swollen ankles, rash on her legs and arms and night time fevers. Additional information has been requested. 3/27/09 Received PCP vaccine & medical records of 12/21/2006-2/26/2009. FINAL DX: none provided Records reveal paitent experienced general good health on 7/28/08 & also received MCV4 same day. Ongoing psych counseling for eating disorder. RTC 9/11/08 for rash, fever, cough x 2 wk, bilateral ankle swelling w/pain x 4 days, eczema flareup & fatigue. RTC 1/12/09 w/intermittent abdominal pain. Dx w/UTI & tx w/antibiotics. RTC 2/26/09 w/migraine HA x 4 days w/phonophobia, photophobia, N/V & had missed school. Tx w/meds.

Other Meds:

Lab Data: Chest X-ray; blood tests LABS: CBC & CMP WNL.

History: PMH: anorexia/bulimia, weight loss, irregular periods, nephrolithiasis, pyelonephritis, allergic rhinitis, eczema, rhinoplasty for nasal septal deviation s/p fracture, MVA w/back & hip pain. Allergy: PCN, ceclor, amoxicillin(rash). Family hx: migraine HAs.

Prex Illness: Penicillin allergy; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: 329680-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	06-Mar-2007	01-Sep-2007	179	17-Oct-2008	13-Feb-2009	NY	WAES0809USA02114	13-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0146U	2	Right leg	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Cerebral venous thrombosis, Chest pain, Fatigue, Headache, Migraine, Pain, Tremor, Vaginal infection

Symptom Text: Information has been received from a nurse and office manager for the pregnancy registry for GARDASIL a 27 year old Caucasian female who on 28-SEP-2006 was vaccinated with the first dose of GARDASIL. On 31-OCT-2006, the patient was vaccinated with a second dose of GARDASIL. On 06-MAR-2008, she was vaccinated with a third dose of GARDASIL. Concomitant therapy included a first influenza virus vaccine (unspecified) on 23-JAN-2006 and a second dose on 17-OCT-2007 and vitamins (prenatal vitamins). In September 2007, approximately 6 months after the third dose the patient became pregnant. When she was 15 weeks pregnant she experienced headaches and in the 18th week of pregnancy she was diagnosed with venous sinus thrombosis. The patient's family history and genetic relation of blood disorder that out after delivery. Since then, the patient has had a live birth female who was healthy and was born at 39 weeks from the LMP on 26-APR-2008 with a weight of 7 pounds and 1 oz and the length was 21.5 inches (LMP = approximately 26_JUL-2007, EDD - approximately 03-MAY-2008). Additional information is not expected. 3/10/09-records received for DOS 12/7-12/8/07-DC DX: Venous sinus thrombosis. Presented with C/O headaches at time 18 weeks pregnant. Office note 11/19/07 seen for evaluation of worsening headaches. During course of first trimester of pregnancy had increasing and severity of chronic headaches which began at age 8 or 9. Throbbing pain and sensationof nasal congestion. Assessment:mirgraine headaches. Office visit 2/14/08-follow up visit after hospitalization. Assessment:right cerebral transverse sinus thrombosis. 3/12/09-office records received office visit 6/20/07-annual exam WNL- 7/30/06-C?o fatigue and discharge, vagninitis. 9/28/06-1st Gardasil vaccine Lot #0955F, left deltoid. 10/31/06-2nd Gardasil vaccine received. 1/19/07-C/O feelings of anxiety, chest pain, shaking. 3/6/07-3rd Gardasil vaccine given Lot #0146U.

Other Meds: vitamins (unspecified)

Lab Data: magnetic resonance, venous sinus thrombosis; hematology; venous sinus thrombosis 3/10/09-records received-MRI and MR venogram showed venous sinus thrombosis. Office visit 6/13/08-MRI shows dimished size of right transverse thrombis.

History: 3/10/09-records received-chronic headaches which began at age 8 or 9

Prex Illness: Pregnancy NOS (LMP = 07/26/2007)

Prex Vax Illns:

Vaers Id: **329683-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	31-Jul-2008	Unknown		17-Oct-2008	13-Feb-2009	--	WAES0809USA02115	04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Genital lesion

Symptom Text: Information has been received from a 19 year old female patient with no pertinent medical history or allergies who on in the end of July, approximately 31-JUL-2008 who completed the 3 dose series and was vaccinated with GARDASIL (dose and route not reported). Concomitant therapy included birth control (unspecified). A couple of weeks ago in approximately September 2008, the patient experienced a little bump on the genital area that had not gone away, she has not experienced itching or pain. The patient stated she had had the same boyfriend for eight months. The vaccine was administered in one state and she is now in school in another state and the patient had no physician. As of 15-Sep-2008, the patient had not recovered. No laboratory test was performed. The patient did not seek medical attention. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **329686-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-May-2008	01-May-2008	0	17-Oct-2008	17-Feb-2009	NY	WAES0809USA02124	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a consumer concerning her 14 year old daughter who had no pertinent medical history or allergies who in November 2007, was vaccinated with the first dose of GARDASIL and in May 2008, was vaccinated with the second dose of GARDASIL . Concomitant therapy included ALLEGRA. In June 2008, the mother reported that her daughter started losing her hair, where her hair was thinning and she had bald spots on the front of her head and in other specific areas. The mother's patient also reported that the patient had seen her physician and was diagnosed with alopecia. It was reported that the physician did full blood work which were negative. The mother stated that her daughter looked like a man balding with hair plugs. It was reported that physician gave her a medicated shampoo, just in case of fungus on her scalp, which she was almost finished and she was starting to see some regrowth, but her hair was still thin. The mother also reported that in November 2007 the patient had stopped therapy with fexofenadine hydrochloride when she received her first dose of GARDASIL. The patient was also received routine vaccines (names and manufactures unspecified), before going back to school. The HPV vaccine series was discontinued (last dose May 2008). Additional information has been requested.

Other Meds: ALLEGRA

Lab Data: Diagnostic laboratory, blood work which was negative.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329690-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Mar-2008	Unknown		17-Oct-2008	17-Feb-2009	OH	WAES0809USA02127	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Back pain, Faeces discoloured, Headache, Muscular weakness, Pain in extremity, Somnolence, Vaginal discharge

Symptom Text: Information has been received from an office manager concerning a 17 year old female with penicillin allergy and a history of tonsillectomy (1994) who on 12-MAR-2008 was vaccinated with the first dose of GARDASIL 0.5 ml, IM and on 15-MAY-2008 was vaccinated with the second dose of GARDASIL 0.5 mL, IM. The patient had not yet received the third dose. Concomitant therapy included DEPO-PROVERA. The office manager reported that in 2008, the patient experienced stomach pain, leg pain, back pain and her leg had been "sour" and limp. The patient also had sleepy feeling. The patient was also experienced increased incidence of headaches and she also had a thin white discharged in the vagina. On 11-SEP-2008 the patient experienced green pink stool. She had no diarrhea and constipation. As of 15-SEP-2008 the patient experienced green pink stool. She had no diarrhea and constipation. As of 15-SEP-2008 the patient had not recovered from the symptoms. A vaginal specimen analysis was performed that were negative for vaginitis. The patient sought medical attention by seeing the physician. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: Vaginal specimen, negative for vaginitis

History: Tonsillectomy

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329692-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-May-2008	01-May-2008	0	17-Oct-2008	17-Feb-2009	NY	WAES0809USA02136	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a 24 year old female who in May 2008, was vaccinated with the third dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). Subsequently, after vaccination the patient experienced generalized urticaria. As of 15-SEP-2008, generalized urticaria persisted. The patient sought medical attention. She was seen by the physician. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329694-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	11-Aug-2008	Unknown		22-Oct-2008	14-Jan-2009	MN		14-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B021AA	5	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1978U	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	010X	1	Left arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U2565AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Atrophy

Symptom Text: DTaP, Varicella given in left arm. HPV and Meningococcal given in rt. arm on 8-11-08. Presents on 10-22-08 with atrophy of left arm noticed very recently.

Other Meds:

Lab Data:

History: Asthma

Prex Illness: None known

Prex Vax Illns:

Vaers Id: **329695-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-Mar-2008	11-Mar-2008	0	17-Oct-2008	17-Feb-2009	PA	WAES0809USA02173	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Road traffic accident

Symptom Text: Information has been received from a physician concerning a 17 year old female with low blood pressure who on 11-MAR-2008, 12-MAY-2008 and 13-SEP-2008 was vaccinated with a first, second and third dose of GARDASIL. Respectively, no concomitant medication was reported. The physician mentioned that after the first dose on 11-MAR-2008 the patient passed out in the office. No injuries were sustained and the patient was discharged home. The physician reported that three hours after receiving the second dose on 12-MAY-2008 the patient passed out while driving and hit another vehicle. No injuries were sustained. The physician reported that there were no adverse effects after the third dose. The outcome of the patient was not reported. The patient sought medical attention: in the office. There was no product quality complaint. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Low blood pressure

Prex Illness:

Prex Vax Illns:

Vaers Id: **329701-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	04-Mar-2008	Unknown		17-Oct-2008	17-Feb-2009	MT	WAES0809USA03582	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0755U		Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received from a registered nurse concerning a female with an estimated age of 20 year old with cheese allergy who on 04-MAR-2008 was vaccinated with a dose of 0.5mL GARDASIL (lot# reported as 658219/0755U) intramuscularly in the deltoid. Concomitant therapy included VALTREX. After receiving GARDASIL, the patient developed a "fever of 106 F" and was hospitalized for an unspecified period on time. The fever lasted two weeks and subsequently recovered. The patient told the physician of the fever at an office visit on 19-Sep-2008. No other symptoms or information about treatment reported. Additional information has been requested.

Other Meds: VALTREX

Lab Data: Unknown

History: Food allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **329702-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Jul-2008	01-Aug-2008	4	17-Oct-2008	13-Feb-2009	MI	WAES0809USA03531	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U		Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia

Symptom Text: Information has been received from a physician (also reported as medical assistant) concerning a 16 year old female with no known allergies or medical history, who on 28-JUL-2008 was vaccinated with a first, 0.5 mL dose of GARDASIL (LOT# 659964/1978U), intramuscular. There was no concomitant medication. Five or four days later the patient experienced joint pain. The patient is a golfer and indicated that her joints are so painful at the end of a golf game that she has to rest for the reminder of the time. At the time of the report, the patient had not recovered. She mentioned that she tried ice and BIO-FREE, but only ADVIL made it tolerable. The patient sought medical attention, she was seen. The patient's joint pain was considered to be disabling. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **329703-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	13-Feb-2009	FL	WAES0809USA03176	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL. The reporter states that the patient had "a tingling sensation in both her arms and hands" right after getting vaccination. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329704-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Dec-2007	01-Dec-2007	0	17-Oct-2008	13-Feb-2009	--	WAES0809USA03205	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injection site pain

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female who in August 2007, was vaccinated with her first dose of GARDASIL and she received her second dose of GARDASIL in December 2007 at another office. Subsequently, the patient commented the second dose was more painful than the first. No specifics known as given at another practice. The patient sought medical attention at office. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **329705-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-Sep-2008	11-Sep-2008	0	17-Oct-2008	13-Feb-2009	MA	WAES0809USA03208	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling of body temperature change, Flushing, Headache, Hypoaesthesia facial, Paraesthesia, Paraesthesia oral, Swelling face

Symptom Text: Information has been received from a registered nurse concerning a 12 year old female with allergic rhinitis, allergies to amoxicillin, AUGMENTIN, CEFZIL and dust mites allergies, who on 11-SEP-2008 was vaccinated with the first dose of GARDASIL (Lot # 659184/0843X), 0.5 mL, I.M. Concomitant therapy include MENACTRA. About 5 hours after the receiving vaccination, the patient developed a "prickly feeling" and numbness on her face. She also experienced sensations of hot and cold on her face. The numbness increased the next day and included a "tingling" sensation of her lips. The patient's mother reported to the nurse that her daughter's cheeks looked puffy and "flushed." The patient also developed a headache. The patient was treated with BENADRYL and on 13-SEP-2008 recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: None

History:

Prex Illness: Rhinitis allergy; Penicillin allergy; Allergic reaction to antibiotics; House dust mite allergy; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **329706-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Sep-2008	17-Sep-2008	0	17-Oct-2008	13-Feb-2009	MA	WAES0809USA03223	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Skin laceration, Syncope

Symptom Text: Information has been received from a nurse concerning a 16 year old female with sulfonamide allergy and no medical history reported who on 20-JUN-2008 was vaccinated with the first dose of GARDASIL (Lot # 660553/0070X), 0.5 mL, I.M. and on 17-SEP-2008 was vaccinated with the second dose of GARDASIL (Lot # 659184/0843X). Concomitant therapy included (OCELLA). After receiving her second dose, the patient fainted, fell and received a jagged laceration on her head about one inch in length. The patient was treated in an emergency room, where she received "7 sutures" to the laceration site. The patient was recovering from the events. The patient sought medical attention at the office. This is one of two reports received from the same source. Additional information has been requested.

Other Meds: drospirenone (+) ethinyl

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329707-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	04-Sep-2008	04-Sep-2008	0	17-Oct-2008	13-Feb-2009	PA	WAES0809USA03228	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a physician concerning a female who "two weeks ago" on approximately 04-SEP-2008 was vaccinated with her second dose of GARDASIL. There was no concomitant medication. Subsequently, the patient has continuing pain in her arm. The physician reported that the patient has been able to continue to work. The patient did not experience any problems after the first dose (date of administration not known). The patient has been taking MOTRIN for the discomfort results were not known. The patient's pain in her arm persisted. The patient has an appointment to see the physician on 22-SEP-2008. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329708-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	02-Jul-2008	02-Jul-2008	0	17-Oct-2008	16-Feb-2009	--	WAES0809USA03231	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site urticaria

Symptom Text: Information has been received from a nurse practitioner concerning a female who on 02-JUL-2008 was vaccinated with GARDASIL vaccine (yeast) 0.5 mL intramuscularly in the deltoid. On 02-JUL-2008, the patient experienced "hive like area near the injection site" after receiving the dose of GARDASIL vaccine (yeast). The patient sought treatment for adverse symptoms with an unspecified family physician. The patient was prescribed BENADRYL and cortisone cream. The symptoms resolved in "about one week". No other symptoms or treatment reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329709-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Oct-2008	16-Feb-2009	FL	WAES0809USA03445	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site reaction, Paraesthesia

Symptom Text: Information has been received from a physician concerning an unspecified number of patients who had no adverse reactions reported with GARDASIL vaccine (yeast) (MSD) (LOT# was unspecified) except for some tingling at the injection site. The physician did not specify the number of patients who had tingling. It was not reported if the patients sought medical attention. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329710-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	10-Sep-2008	10-Sep-2008	0	17-Oct-2008	16-Feb-2009	NY	WAES0809USA03448	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Heart rate irregular, Paraesthesia, Syncope

Symptom Text: Information has been received from a physician concerning a 24 year old female who on 10-SEP-2008 was vaccinated with a dose of GARDASIL vaccine (yeast) 0.5 ml IM. On 10-SEP-2008, the patient was at the doctors office and after receiving the dose of GARDASIL vaccine (yeast), she had blood drawn and fainted. The patient reported to the physician that she felt tingling "down her side" after fainting. An EKG was performed in the office, which showed and irregular heart rate. The patient was evaluated in an emergency room, and then she recovered and was discharged to home. Additional information has been requested.

Other Meds: Unknown

Lab Data: electrocardiogram, 09/10/08, irregular heart rate; blood test

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 329711-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	02-Sep-2008	02-Sep-2008	0	17-Oct-2008	13-Feb-2009	--	WAES0809USA03538	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Dizziness, Drug exposure during pregnancy, Musculoskeletal chest pain, Nausea, Tremor

Symptom Text: Information has been received from a nurse practitioner through a Merck pregnancy registry concerning a 25 year old female with allergy to Morphine who in approximately June was vaccinated with her first dose of GARDASIL vaccine (yeast) (lot # not provided). On 02-SEP-2008 the patient received the second dose of GARDASIL vaccine (yeast) (lot # not provided) and soon afterward found out she was pregnant. Her LMP was approximately 07-AUG-2008. Expected date of delivery was 14-MAY-2009, The patient had no medical history. Concomitant therapy include Pindolol, vitamins (unspecified) and CELEXA (reportedly being discontinued). In early September 2008, the patient experienced stomach pain, abdominal pain, rib pain, nausea, dizziness and shakiness. Therapy with GARDASIL vaccine was discontinued. At the time of the report, the patient had not recovered from the adverse experiences. The patient did not seek medical attention. Additional information has been requested.

Other Meds: CELEXA; PINDOLOL; vitamins (unspecified)

Lab Data: diagnostic laboratory; beta-human chorionic

History:

Prex Illness: Pregnancy NOS (LMP = 8/7/2008); Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329712-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Aug-2007	01-Aug-2007	0	17-Oct-2008	16-Feb-2009	--	WAES0809USA03551	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dyspepsia, Eating disorder, Gallbladder disorder, Intestinal functional disorder, Pyrexia, Vaccine positive rechallenge, Weight decreased

Symptom Text: Information has been received from a 19 year old female patient with allergy to codeine and no other medical history, who in August 2007, was vaccinated with GARDASIL 0.5mL. There was no concomitant therapy. On February 2008, the patient received the third dose of GARDASIL. After each shot her condition worsened. Since the beginning therapy, the patient experienced difficulty digesting food, loss of weight and energy, fever, problems with bowel movements, and at one time could not eat for 1.5 week. Her gall bladder is now not functioning and may have to be removed. The patient's mother, a registered nurse, stated that her daughter was sick almost most of summer especially with everything that contains fat. She was then eating a low fat diet. Ultrasound of the gallbladder was implemented and the results was negative for gall stones. At the time of report, the adverse events were ongoing. The patient sought medical attention. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound, gallbladder, negative for gall stones

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **329713-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-Aug-2008	14-Aug-2008	0	17-Oct-2008	17-Feb-2009	--	WAES0809USA03695	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 11 year old female with no pertinent medical history or drug reactions/allergies, who on 14-Aug-2008 was vaccinated with the first dose of GARDASIL (lot # 659655/1486U) I.M. into the right arm. Concomitant therapy included the first dose of MENACTRA (lot# 02560AA) IM into the left arm, the first dose of BOOSTRIX (lot# AC52B015AA) IM into the left arm, and the second dose of HAVRIX (lot# AHAVB245AA) IM into the right arm. After the patient was receiving HPV vaccine she waited in reception area for 10-15 minutes and with departure in hall and she vomited. No further information is available. It was reported that the patient's experience was considered non-serious. The original reporter was not provider. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **329714-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Jan-2008	Unknown		17-Oct-2008	17-Feb-2009	OH	WAES0809USA03739	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	1258U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Information has been received from a registered nurse concerning a 17 year old white female with allergic reaction to CECLOR and clindamycin who on 17-Jan-2008 was vaccinated with a first dose of GARDASIL (lot# 659439/1267U) IM in her left deltoid. Other suspect therapy received on the same date included a first dose of VAQTA (lot# 569186/1258U) IM in her right deltoid. In January 2008, the patient experienced right knee pain, mostly anterior. On 25-Jul-2008 the patient was vaccinated with a second dose of GARDASIL (lot# 660553/0070X) IM in her left deltoid. Other suspect therapy received on the same date included a second dose of VAQTA (lot# 659186/1258U) IM in her right deltoid. Approximately 2 weeks after the vaccinations the patient experienced right knee pain, mostly anterior. On 08-Feb-2008 the patient was seen by an orthopedic and performed an X-ray with essentially normal result. As of 16-Sep-2008, the patient's right knee pain persisted without obtained knee injury. Additional information has been requested.

Other Meds: Unknown

Lab Data: lower extremity x-ray, 02/08/08, essentially normal

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329715-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	17-Feb-2009	NY	WAES0809USA03787	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lupus-like syndrome

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with GARDASIL. Subsequently the patient experienced lupus like reactions. No other information reported. This is one of several reports from the same source. Additional information requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329716-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	17-Feb-2009	NY	WAES0809USA03788	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lupus-like syndrome

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with GARDASIL. Subsequently the patient experienced lupus like reactions. No other information reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **329717-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	17-Feb-2009	NY	WAES0809USA03789	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lupus-like syndrome

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with GARDASIL. Subsequently the patient experienced lupus like reactions. No other information reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329718-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	17-Feb-2009	NY	WAES0809USA03790	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lupus-like syndrome

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with GARDASIL. Subsequently the patient experienced lupus like reactions. No other information reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329719-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	28-Aug-2008	28-Aug-2008	0	17-Oct-2008	17-Feb-2009	--	WAES0809USA03792	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2621AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1446U		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under freedom of information Act. A patient with no pertinent medical history or allergies who on 28-AUG-2008, was vaccinated with GARDASIL (lot# 659441/1446U) IM into the right arm and MENACTRA (lot# U2621AA) IM, into the left arm. There was no concomitant medication. On 28-AUG-2008 the patient complained of feet swelling, about double sizes after receiving the vaccine. The patient's mother stated that the patient had no pain in her feet. It was reported that her feet started swelling about 45 minutes after receiving the vaccines and the swelling went away 90 minutes. She denied another problem. No laboratory tests were performed. The original reporting source was not provided. The VAERS ID # is 324371-1. No further information is available.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **329720-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	20-Sep-2008	20-Sep-2008	0	17-Oct-2008	17-Feb-2009	IL	WAES0809USA03809	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pyrexia, Rash, Vomiting

Symptom Text: Information has been received from a mother concerning her 22 year old female daughter with colitis and allergies to Ceclor, who on 20-SEP-2008 was vaccinated with the second dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified) and ASACOL. The mother reported that her daughter developed a fever, nausea, vomiting and a rash on her chest about 8 hours after receiving her second dose of GARDASIL. The patient sought medical attention by a phone call. At the time of report the patient had not recovered. Additional information has been expected.

Other Meds: Hormonal contraceptives; ASACOL

Lab Data: None

History:

Prex Illness: Colitis; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: 329721-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Sep-2007	01-Sep-2007	0	17-Oct-2008	17-Feb-2009	--	WAES0809USA03850	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Drug administered at inappropriate site, Injection site haematoma, Injection site necrosis, Injection site scar

Symptom Text: Information has been received from the mother patient concerning a 16 year old female with a knee operation who in "Fall 2007" approximately in September 2007, was vaccinated with her first dose of GARDASIL 0.5mL in her hip, closer to the waist than the thigh. Concomitant therapy included hormonal contraceptives (unspecified). About two weeks after the first shot, at the injection site she developed a scar that is indented and bruised, and the physician said it was dead tissue. She had her second and third dose of HPV vaccine(yeast) in the same spot so that it would not scar her arm too. She had also experienced joint pain. The patient's adverse experience persisted. The patient sought medical attention. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: None

History: Knee operation

Prex Illness:

Prex Vax Illns:

Vaers Id: **329722-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Aug-2008	01-Sep-2008	20	17-Oct-2008	16-Feb-2009	TX	WAES0809USA03873	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Information has been received from a physician, concerning a 17 year old female patient who on 12-AUG-2008 was vaccinated with her first dose of GARDASIL from her school. Lot number not available at this time. A few days ago, she experienced symptoms of Bell's palsy with paralysis of her face. She phoned the doctor and will be seen in the office this week. As of 22-SEP-2008, the patient had not recovered. There was no product quality complaint. Additional information is expected.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329723-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	11-Sep-2008	Unknown		17-Oct-2008	16-Feb-2009	MD	WAES0809USA03883	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Incorrect route of drug administration, Injection site induration

Symptom Text: Information has been received from a medical assistant concerning a female patient who on 11-SEP-2008 was vaccinated with GARDASIL was administered subcutaneous instead of intramuscular into the right upper arm. On an unspecified date, the patient experienced knot at injection site post vaccination. In September 2008 the patient recovered from knot at injection site post vaccination. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329724-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Jun-2008	04-Sep-2008	79	17-Oct-2008	17-Feb-2009	CA	WAES0809USA03896	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Fatigue, Malaise

Symptom Text: Information has been received from a physician concerning a female who on 17-Jun-2008 was vaccinated intramuscularly with the second dose of GARDASIL (lot# 659180/1758U). Her first dose was on 31-Mar-2008. The patient has no concomitant conditions and medical history. She has no drug reactions or allergies either. Subsequently the patient experienced shortness of breath, dyspnea, malaise and fatigue. The patient has been several times at an urgent care center. She was last seen by physician on 04-Sep-2008 and the physician wrote in her notes "symptoms resolving, possible GARDASIL reaction". At this appointment the patient stated that she is experiencing transient dizziness that last for 1 minute. At the time of the report the patient had not recovered. No additional information is available. Additional information has been requested.

Other Meds: None

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 329725-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	19-Sep-2008	22-Sep-2008	3	17-Oct-2008	17-Feb-2009	--	WAES0809USA03899	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a 26 year old female with no medical history who on 19-Sep-2008 was vaccinated with second dose of GARDASIL (Lot number reported as 0152X). The patient received her first dose of GARDASIL in JUL (year unspecified). On 22-Sep-2008 the patient experienced rash. No lab diagnostics studies were performed for the patient. It was unspecified if the patient received any concomitant therapy. However, the patient did not experience any rash after the 1st dose. The physician told the patient to take BENADRYL for the rash. The patient informed the physician that once the BENADRYL wears off the rash come back. The patient did not recover from the rash. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329726-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	17-Feb-2009	CA	WAES0809USA03900	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with GARDASIL was given. Subsequently the patient did not have menstrual period 4 months after GARDASIL was given. The patient sought medical attention. Additional information has been requested. This is one of two reports received from the same source.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329727-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Sep-2008	19-Sep-2008	15	17-Oct-2008	17-Feb-2009	UT	WAES0809USA03910	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site vesicles

Symptom Text: Information has been received from a nurse concerning a 15 year old female who was intramuscularly vaccinated with a dose of GARDASIL (MSD) on 04-FEB-2208. Concomitant vaccination on 04-SEP-2008 included MENACTRA (manufacture unspecified) in the same arm at the same time. Approximately on 19-SEP-2008 ("about 3 days ago") the patient experienced blisters around the injection site after she received GARDASIL (MSD) and MENACTRA (manufacture unspecified). On 22-Sep-2008, the patient was schedule to come into the physician's office for a check-up. The patient was recovering at the time of report. No further adverse event information reported. The patient called the doctor to seek medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **329728-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Oct-2008	17-Feb-2009	--	WAES0809USA03919	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a vaccine nurse who noticed that children that are on attention deficit disorder (ADD) or attention deficit/hyperactivity disorder (ADHD) medication or with psychological needs experience syncope more often after receiving GARDASIL (lot# not provided). The patients sought unspecified medical attention. Follow-up information was received from the nurse. She said that the office had 3 or 4 patients faint after receiving GARDASIL. When they looked into it the patients were all on ADHD medicine of Psych medicine. The office decided to lay all the patients down after they received the vaccine to hopefully prevent the syncope. None of the patients were hospitalized. She did not have any patient identifiers because all of this happened over a year ago. Since they started laying patients down after the vaccinations over a year ago they have had no problems. Attempts are being made to obtain identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Therapy unspecified

Lab Data: Unknown

History:

Prex Illness: Attention deficit/hyperactivity disorder; Psychological disorder NOS

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329729-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	08-Sep-2008	15-Sep-2008	7	17-Oct-2008	17-Feb-2009	NY	WAES0809USA03931	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a 24 year old female who on 08-SEP-2008 was vaccinated with a first dose of GARDASIL (lot # 0152X). Concomitant therapy included ZOVIA. On 15-SEP-2008 the patient experienced a rash on her face. The patient did not seek medical attention but was told to take BENADRYL for the rash. There was no lab test. No further information was provided. Additional information has been requested.

Other Meds: ZOVIA

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329730-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	29-Apr-2008	29-Apr-2008	0	17-Oct-2008	17-Feb-2009	--	WAES0809USA04121	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Panic attack

Symptom Text: Information has been received from a medical assistant concerning a female patient who on 29-APR-2008 was vaccinated with the first dose of GARDASIL. The medical assistant reported that after arriving home on the same day of the vaccine the patient had a "panic attack", difficulty breathing. The patient choose not to get the other 2 doses of GARDASIL. At the time of the report the patient had recovered. No further information is expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329743-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Oct-2008	20-Oct-2008	0	23-Oct-2008	14-Jan-2009	CA		14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2669AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0067X	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024DB	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Injection site pruritus, Nausea

Symptom Text: Pt c/o h/a, dizzy, nausea and itchy injection site (RD), laid in supine pt in exam room.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329750-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	18-Aug-2008	18-Aug-2008	0	23-Oct-2008	14-Jan-2009	KS		15-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: About 7-8 hours after HPV #1 on 8/18/08, the patient noted lightheadedness, slumped to floor and fell asleep. Patient awoke 2-3 hours later alert and oriented. No seizure activity or residual limb weakness, or aphasia.

Other Meds: SOLIA

Lab Data:

History: PCN; Sulfa

Prex Illness: None

Prex Vax Illns:

Vaers Id: **329752-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Oct-2008	18-Oct-2008	0	23-Oct-2008	14-Jan-2009	AZ		15-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB284DA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0229X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2683AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024DB	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0994X	1	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Nausea, Pallor, Syncope

Symptom Text: Within 2 minutes of vaccine administration completion, pt became nauseous. Pt then passed out; fainted. Pt was pale, and out for about one minute. She was laid on the floor. Upon waking, or coming out of faint spell, pt was very coherent, no shivering, but did not remember passing out. She thought she'd went to sleep and had a dream. Pt was monitored for a time period not less than 20 mins after fainting and showed no other signs or symptoms. All vitals were with normal limits 10 mins after pt "woke up". Pt's 11 years old sister was also given the same immunizations as pt and suffered no effects whatsoever. (same lot #'s and everything).

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329764-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Feb-2008	01-Mar-2008	19	23-Oct-2008	15-Jan-2009	NY		15-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2561AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2481AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Reports bald patch at back of head - onset one month after receiving MENACTRA, Flu and GARDASIL 2/11/08, condition has worsened over past 5 months - seen 9/25/08 for this condition. Treated - Triamcinolone - referred to Dermatologist.

Other Meds: Triamcinolone topical

Lab Data: None

History: Exercise induced asthma

Prex Illness: Eczema

Prex Vax Illns:

Vaers Id: **329787-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	17-Oct-2008	17-Oct-2008	0	23-Oct-2008	24-Nov-2008	MI		24-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB264CA	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2745AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0250X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2620AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: NONE

Other Meds: none

Lab Data: urine pregnancy test POSITIVE done after imms given.

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329803-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	20-Oct-2008	20-Oct-2008	0	23-Oct-2008	24-Nov-2008	NH		24-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt given HPV vaccine, 5minutes after vaccine administered pt fainted.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **329805-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	12-Feb-2008	01-Jun-2008	110	23-Oct-2008	24-Nov-2008	MO		24-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle atrophy

Symptom Text: Deltoid muscle atrophy which was first noted by patient on approx 6/08 as a depression in Left shoulder muscle of approz 2cm x 2 cm

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **329880-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	20-Jun-2008	20-Jun-2008	0	23-Oct-2008	22-Jan-2009	NC	NC08102	23-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1486U	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2927AA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2582AA	0	Right arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBUB452AA	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Vision blurred

Symptom Text: 2:30 patient received immunizations and dad and child checked out. At the check out desk the child got very dizzy and felt like she was going to pass out. Everything looked blurry and then started getting black. Sat her down in a chair and called the RN. We applied cool compresses to her face and forehead. Gave her juice and peanut butter and crackers and observed her for 30 min. BP taken. She was escorted downstairs by RN and dad picked her up in car. She left with dad.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **329887-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-Oct-2007	22-Oct-2007	11	24-Oct-2008	27-Oct-2008	PA	WAES0711USA04440	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0171U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a licensed practical nurse through the pregnancy registry for GARDASIL concerning a 17 year old female with penicillin allergy who on 11-OCT-2007 was vaccinated intramuscularly in the left arm with her first dose of GARDASIL (Lot # 655620/0171U). There was no concomitant medication. On 19-NOV-2007, the patient had a blood work drawn in the office for a pregnancy test which was positive (LMP approximately 22-OCT-2007). It was reported that the patient was 3 to 4 weeks pregnant. The patient sought unspecified medical attention in the office. Follow-up information received indicated that on 25-JUN-2008 the patient vaginally delivered a "normal" infant. Upon a skeletal joint exam in the hospital the baby was found to have pes adductus (club feet). The baby's club feet were considered a congenital anomaly. No further information is available.

Other Meds: None

Lab Data: physical examination, a skeletaljoint exam, the baby had pes adductus; serum beta-human, 11/19/07, positive

History:

Prex Illness: Pregnancy NOS (LMP = 10/22/2007); Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329888-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Oct-2008	11-Oct-2008	10	24-Oct-2008	27-Oct-2008	FR	WAES0810POL00013	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NH5233P		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Apathy, Asthenia, Muscular weakness, Tremor

Symptom Text: Information has been received from a physician concerning a 13 year old female who in October 2008, was vaccinated with GARDASIL. On 11-OCT-2008 the patient experienced weakness, apathy, lower extremities weakness and hands tremor. On 11.50 p.m. the patient was admitted to the hospital on neurological ward. Subsequently, the patient recovered from weakness, apathy, lower extremities weakness and hands tremor. The reporter felt that weakness, apathy, hands tremor and lower extremities weakness were related to therapy with GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 329889-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Jul-2007	13-Nov-2007	126	24-Oct-2008	27-Oct-2008	--	WAES0810USA00419	13-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	0	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Dizziness, Fall, Headache, Memory impairment, Nausea, Odynophagia, Oropharyngeal pain, Photophobia, Vertigo, Visual impairment

Symptom Text: Initial and follow up information has been received from a nurse practitioner concerning a 14 year old female patient with no known drug allergies, who on 11-SEP-2007, was vaccinated with the first dose of GARDASIL. On 13-NOV-2007, the patient was vaccinated with the second dose of GARDASIL. In November 2007, the patient started to report dizziness, headaches, difficulty with memory and unsure if she actually had been doing the things she had been doing or simply just thought of them. The patient was a dancer and was unable to dance for a while. The nurse practitioner reported that the patient tried meclizine for the vertigo. On an unknown date, the patient had a normal brain MRI. The nurse practitioner reported that the mom felt 90% of her daughter's symptoms resolved by summer 2008. The patient and the mother declined to received the third dose of GARDASIL. The events were considered to be disabling. Additional information has been requested. 11/5/08-ED records received for DOS 8/28/08-MVA-C/O neck pain. X-rays unremarkable of cervical spine. Impression: acute cervical strain11/12/08-records received- Office visit 11/2/07-C/O dizziness and vertigo intermittently for several months and worse past week, also nausea and headache. Photophobia with headache with nausea. Vision changes. Falling at dance class. Visit 11/13/07-received 2nd Gardasil vaccine. C/O dizziness feels like in a fog. Daily headaches, difficulty with memory. Missing school. Physician concerned about possibility of abuse and depression. Visit 10/1/08-C/O sore throat with painful swallowing.

Other Meds: Unknown

Lab Data: Unknown 11/12/08-records received-MRI brain normal. rapid strep negative.

History: Unknown

Prex Illness: 11/12/08-records received-office visit 9/11/07-received first Gardasil vaccine at time of visit C/O 2 weeks hyperextends right w

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329890-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-Oct-2008	08-Oct-2008	0	24-Oct-2008	27-Oct-2008	FR	WAES0810USA02202	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1881U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Rash

Symptom Text: Information has been received from a Health Authority (case n. 90326) concerning a 11 year old girl with no medical history reported who on 08-OCT-2008 was vaccinated intramuscularly with the first dose of GARDASIL (Lot# 1881U, Batch# NJ03030). Concomitant therapy was unspecified. On 08-OCT-2008, the same day, about 10 minutes post vaccination, she presented with a severe reaction with loss of consciousness for a few seconds followed by the onset of a cutaneous rash. The child was laid in a supine position with her lower limbs raised, her blood pressure was taken (NOS) and she quickly recovered in a few minutes. The outcome is recovered on 08-Oct-2008. The loss of consciousness and rash were reported as other important medical events. The case is closed. Other business partner numbers included E2008-09486. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **329891-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-May-2008	28-May-2008	0	24-Oct-2008	27-Oct-2008	FR	WAES0810USA02959	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0311U	0	Unknown	Intramuscular	
	TD	SANOFI PASTEUR	A6335		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Nausea

Symptom Text: Information has been received from a health care professional concerning a 14 year old female who on 28-MAY-2008 was vaccinated with the first dose of GARDASIL (Batch n. NG30400/Lot n. 0311U) intramuscularly (site and route not reported). Secondary suspect therapy included DIFTAVAX (Batch n. A6335-1), route and site of administration not reported. On 28-MAY-2008, after vaccine administration the patient suffered dizziness, nausea and loss of consciousness. The events lasted for 30 seconds. On an unspecified date, the patient was vaccinated with a second dose of GARDASIL with no adverse events. At the time of reporting the patient had recovered. Case is closed. Other business partner numbers included: E2008-09563. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329892-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Sep-2008	11-Sep-2008	0	24-Oct-2008	27-Oct-2008	FR	WAES0810USA03157	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Hypoaesthesia, Nausea, Peripheral vascular disorder, Vaccine positive rechallenge

Symptom Text: Information has been received from a gynaecologist concerning a-15-year old girl who was vaccinated with a first dose of GARDASIL (lot # 0483U; batch # NG20160) IM into the upper arm on 22-JAN-2008 and a second dose of GARDASIL (lot # 1049U; batch # NG46500) IM into the upper arm on 29-APR-2008. The patient was vaccinated with a third dose of GARDASIL (lot # 1427U; batch # NH15200) IM into the upper arm on 11-SEP-2008. Subsequently, approximately 1 hour post vaccination, the patient developed circulatory disorder peripheral, dizziness, nausea and numbness of arms and legs. The patient was hospitalized from 11-SEP-2008 until 18-SEP-2008. The adverse event lasted for several days, but the patient had not yet fully recovered when she presented at the gynaecologist's practice on 26-SEP-2008. The patient had already developed in a mild form peripheral circulatory disorder, dizziness, nausea, numbness in the arms and legs after doses 1 and 2. Other business partner number include E200809540. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: The patient had already developed in a mild form peripheral circulatory disorder, dizziness, nausea, numbness in the arms and legs after doses 1 and 2.

Prex Illness:

Prex Vax Illns:

Vaers Id: **329893-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		24-Oct-2008	27-Oct-2008	--	WAES0810USA03362	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a nurse practitioner, for the Pregnancy Registry for GARDASIL, concerning a 17 year old female patient who was vaccinated with three 0.5 ml doses of GARDASIL on an unspecified date (lot number not provided). The patient became pregnant after getting all three doses of GARDASIL and delivered a baby on an unspecified date. Two months later, the baby died from "DNA trim". No additional information was provided. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 329894-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Oct-2007	01-Nov-2007	28	24-Oct-2008	27-Oct-2008	FR	WAES0810USA03382	27-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0251U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute tonsillitis, Condition aggravated, Pruritus, Psoriasis, Rash, Rash erythematous, Rash generalised, Skin exfoliation, Skin plaque, Stress

Symptom Text: Information has been received from a gynecologist concerning a 16 year old female with psoriasis vulgaris (known for 12 years) in stable condition who 04-OCT-2007 was vaccinated with a second dose of GARDASIL (lot # 0251U/batch # NF43780) site and route not reported. In November 2007, exact onset not reported, the psoriasis exacerbated with generalized extensive disseminated efflorescences including the scalp. The patient suffered from severe pruritus. Therapy was started with CALCIPORTRIL, corticosteroids and TAGEVIL. As symptoms remained, the patient was hospitalized from 07-MAR-2007 til 18-MAR-2008. Serum antistreptolysin O antigen test (ASL) and serum C-reactive protein test (CRP) were normal, no focus was found. According to the hospital physicians potential triggering factor could be severe psychic stress with mobbing at school. At the time of hospitalisation, disseminated multiple erythematous plaques (palm-sized) with desquamation spread over the whole body. The rima ani, the axillae and the scalp were strongly affected. Laboratory findings included on 08-MAR-2008 ALT/P/37 degrees: 26 P+ (<23) u/l and AST/P/37 degrees: 31 P+ (<21) u/l. On 11-MAR-2008 serum immunoglobulin E test (IgE) was normal. On 12-MAR-2008 HLA antigen test standardization (HLA-Cw6) was positive. Routine diagnostic laboratory test showed normal results. The patient received balneophtotherapy. Additionally the patient was treated with 8% dithranolsalicylic petroleum jelly with liquor carbonis detergens and 5% salicylic acid. The face was treated with CURATODERM and FUMADERM. At that time an acute tonsillitis was diagnosed by the ENT physician. Antibiotic therapy with erythromycin was initiated and the symptoms quickly improved. On 16-MAR-2008 the condition of the skin had improved significantly and the patient was discharged. Since 19-MAR-2008 the patient was further treated with on a day care basis. In the course, she recovered completely, exact duration was not reported. On 05-JUL-2008 the patient was vaccinated with a third dose of G

Other Meds: Unknown

Lab Data: diagnostic laboratory test, normal; plasma aspartate aminotransferase test, 08Mar08, see narrative; plasma aspartate aminotransferase test, 08Mar08, see narrative; serum immunoglobulin E test, 11Mar08, normal; whole blood HLA antigen test,

History: On 02-AUG-2007 the patient was vaccinated with a first dose of GARDASIL (lot # 1537F/ batch # NF42160) and was well tolerated.

Prex Illness: Psoriasis vulgaris

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **329907-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	13-Oct-2008	14-Oct-2008	1	24-Oct-2008	23-Jan-2009	AZ		26-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2806AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0570X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Fall, Malaise, Syncope, Tremor

Symptom Text: Few hours after vaccines, developed malaise - then had syncopal episode, collapsed to ground, then had seizure - was shaking x few seconds.

Other Meds:

Lab Data: None

History: None

Prex Illness: Mononucleosis

Prex Vax Illns:

Vaers Id: 329921-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Aug-2008	01-Oct-2008	49	24-Oct-2008	29-Oct-2008	MI		10-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Conversion disorder, Fall, Gait disturbance, Headache, Hypoaesthesia, Loss of consciousness, Muscular weakness, Neurological examination normal, Sensory disturbance, Syncope, Victim of child abuse

Symptom Text: Pt received GARDASIL - dose #3 on 8-13-08. Pt to ER 10-15-08 - passed out, lower extremity weakness, no fever, has had headache - lower extremity weakness had been present x 2 wks. Also decreased sensation in lower extremities. 12/5/08 Reviewed hosptial medical records of 10/16-10/24/2008. FINAL DX: Conversion disorder; history of abuse. Records reveal patient experienced LE weakness, numbness x 2-3 wks, difficulty walking, syncopal episode w/fall. Admitted to outlying hospital for neuro w/u which was completely WNL. Referred for psych & transferred for inpatient rehab. Progressed well & d/c to home w/continued outpatient PT & counseling.

Other Meds: None

Lab Data: CT scan (Brain); MRI (Spine); CBC with diff; CMP; Serum Pregnancy LABS: CT of head & MRI of head & spine WNL. CSF tests & CXR WNL.

History: None PMH: Smoker. Allergy: bactrim.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **330026-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Sep-2008	28-Sep-2008	5	24-Oct-2008	29-Oct-2008	IN		13-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal tenderness, Activities of daily living impaired, Back pain, Epigastric discomfort, Fatigue, Feeling cold, Headache, Malaise, Nausea, Night sweats

Symptom Text: my daughter had GARDASIL. The next day became very sick with headache and nausea and very tired. This is going on 3 weeks she is still sick from this. has seen two doctors and can't find anything causing this. They won't say it was the shot. but she was very healthy when I took her for her yearly check up. She has missed 3 weeks of school so far.11/5/2008 PCP records received OV 10/3/08 with c/o low back pain, abdominal pain, nausea, tiredness and feeling cold x 1 week. Abd pain is epigastric-(+) tenderness. Bland diet suggested. TC from parent re: nausea-phnergan prescribed. Pt extremely tired unable to attend school x 2 days. OV 10/10/08 F/U for stomach pain, queezy, night sweats. Assessment: Nausea, H/A, fatigue-possible viral etiology, doubts 2' to Gardasil. ER visit 10/15/08 for above sx-prescribed Nexium.

Other Meds:

Lab Data: Labs and Diagnostics: CBC & Chem WNL. Monospot (-).

History: has never had any sickness

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330061-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Oct-2008	Unknown		27-Oct-2008	06-Nov-2008	MI		06-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Client received HPV IM on 10/1/08 through clinic. Client called PHN on 10/15/08 to report she had a (+) preg test on 10/14 and 10/15; she also had a TBST 10/13/08 but that was not administered at health dept. Client's LMP 9/12 on 9/13/08. Has 1st prenatal appt scheduled for 11/5/08.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **330064-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	13-Oct-2008	21-Oct-2008	8	27-Oct-2008	29-Oct-2008	NY		29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion

Symptom Text: Pt suffers from petit mal seizures. Pt reports increased seizure activity after GARDASIL.

Other Meds: Lamictal, Trileptol, Folic acid

Lab Data: Recent Brain Surgery

History: Petit Mal seizures.

Prex Illness:

Prex Vax Illns:

Vaers Id: **330079-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		27-Oct-2008	28-Oct-2008	--	WAES0810USA03285	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Dyspnoea, Intensive care

Symptom Text: Information has been received from a medical assistant concerning a female who was vaccinated with a dose of GARDASIL. Subsequently, the patient experienced shortness of breath. She had a hard time getting out of bed for 2 days for unspecified reasons and was admitted to the ICU. The patient's shortness of breath persisted. No other details. Shortness of breath was considered to be immediately life-threatening by the medical assistant. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330080-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Aug-2008	08-Aug-2008	0	27-Oct-2008	28-Oct-2008	FR	WAES0810USA03627	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1145U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Influenza like illness, Pain, Pyrexia

Symptom Text: Information has been received from a health authority on 16-OCT-2008 (HA ref. DK-DKMA-20082030) concerning a 17 year old female who on 08-AUG-2008 was vaccinated IM with the third dose of GARDASIL (LOT# 1145U). On 08-AUG-2008 the patient experienced influenza like symptoms included high fever, uncharacterized body pain, and headache. The patient was admitted to hospital at 6:45 on 09-AUG-2008. The patient had no rash or neck stiffness. C-reactive protein was slightly increased (40mg/L), other paraclinic markers were normal (not specified). The patient was admitted for observation and improved spontaneously. The patient recovered from all symptoms and was discharged at 14:45 on 09-AUG-2008. Other business partner numbers included: E2008-09673 and 20082030. Additional information has been requested.

Other Meds: Unknown

Lab Data: serum C-reactive protein, 09Aug08, 40 mg/L, slightly increased

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330081-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Apr-2008	05-Apr-2008	2	27-Oct-2008	28-Oct-2008	FR	WAES0810USA03698	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	
	IPV	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, General physical health deterioration, Haematemesis, Headache, Myalgia, Pyrexia, Vomiting

Symptom Text: Information has been received from a general practitioner concerning a 17 year old female patient with medical history of migraine and painful menstrual periods who received the first dose of GARDASIL (batch number not reported) and an injection of REPEVAX on 03-APR-2008. On 06-APR-2008 the patient was hospitalized for cephalgia, fever at 39 degrees C, vomiting and haematemesis. Hospital report mentioned facts described by the patient to the physicians: since 05-APR-2008 the patient had myalgia and haematemesis with black blood. Clinical examination found the patient with mediocre general condition, pulse rate at 115, abdominal pain without resisting at palpation. There was no (deglobulinisation). There was no other infectious point. Conclusion of hospital was a reaction post vaccination with GARDASIL. Lumbar puncture was normal. CT scan was normal. The patient had recovered and was discharged on 07-APR-2008 with treatment with paracetamol. Vaccine with GARDASIL stopped. As to her medical history the patient had ANTADYS for painful menstrual periods in DEC-2007, NSAID'S and VIDORA on 21-FEB-2008 during 5 days, antibiotics on 25-FEB-2008 for 5 days. Other business partner number include E2008-09727.

Other Meds: Unknown

Lab Data:

History: Pain menstrual; Migraine

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330082-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Oct-2008	01-Oct-2008	0	27-Oct-2008	28-Oct-2008	NY	WAES0810USA03974	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion

Symptom Text: Information has been received from a consumer concerning her daughter, a 20 year old female, with history of epilepsy who was vaccinated with the first dose of GARDASIL last week (in OCTOBER 2008). Concomitant therapy included LAMICTAL and TRILEPTAL, as well as VNS implant. While taking anti-seizure medications the patient had not had seizures in "quite a while", except for last week. The patient experienced half a dozen seizures within 2 hours after getting her first dose of GARDASIL. She contacted doctor for medical attention. At the time of report, the patient did not recover from this event. This is one of several reports of siblings. Upon internal review, "half a dozen seizures" was considered to be a other important medical event. Additional information ahs been requested.

Other Meds: therapy unspecified; LAMICTAL; TRILEPTAL

Lab Data: Unknown

History:

Prex Illness: Epilepsy

Prex Vax Illns: Pain; Arm Discomfort; Feeling unwell~HPV (Gardasil)~1~0~In Sibling

Vaers Id: **330094-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		27-Oct-2008	28-Oct-2008	FR	WAES0810USA03626	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epilepsy

Symptom Text: Information has been received from a general practitioner concerning a 22 year old female with no medical history of epileptic seizure who in 2008 was vaccinated with the first dose of GARDASIL (batch number not reported). 15 days later the patient experienced an epileptic seizure. At time of reporting a work-up was no-going and the patient had recovered. As of today the reporter did not see a relationship between adverse effect and vaccination. Upon internal review the event was considered medically significant. Other business partner numbers included: E2008-09678. Additional information has been requested. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330095-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-May-2008	08-May-2008	7	27-Oct-2008	28-Oct-2008	FR	WAES0810USA03433	28-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Status epilepticus

Symptom Text: Information has been received from a general practitioner concerning a female who in the first week of May 2008, was vaccinated with the third dose of GARDASIL (batch number not reported) via intramuscular. Seven days later, the patient experienced a mal epileptic status. On an unspecified date, the patient was hospitalized. At time of reporting the outcome was not specified. The patient had no concomitant treatment. Other business partner numbers include: E2008-09668 and E2008-05670. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330114-1** **Related reports:** 330114-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Apr-2008	23-Apr-2008	0	27-Oct-2008	31-Oct-2008	--		31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	17400	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Iris hypopigmentation

Symptom Text: Patient with congenitally brown eyes states with each of 3 GARDASIL injections right iris became increasing depigmented inferiorly (blue). Lower half of iris involved.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **330114-2** **Related reports:** 330114-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Nov-2007	01-Nov-2007	0	17-Oct-2008	17-Feb-2009	NY	WAES0810USA00072	17-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Iris hypopigmentation

Symptom Text: Information has been received from a optometrist concerning a female patient who in November 2007, was vaccinated with her first dose of GARDASIL, 0.5mL, IM. In January 2008, was vaccinated with her second dose of GARDASIL in May 2008, was vaccinated with her third dose of GARDASIL in November 2007. Since receiving the vaccine the patient experienced a depigmentation of the lower half of the iris of the right eye which has been progressive with each. A gonioscopy was performed which results normal. The patient had not recovered. The patient sought medical attention at the physician's office. The timing of the depigmentation was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Gonioscopy, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330119-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	09-Oct-2008	09-Oct-2008	0	27-Oct-2008	06-Nov-2008	FR		06-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	12676	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Wheezing

Symptom Text: Patient began wheezing and complaining of breathing problems. Started 10 minutes after vaccination. Patient given benadryl and Albuterol and recovered within about 20-30minutes.

Other Meds:

Lab Data: OZ sats is named above 95% vital signs blood pressure elevated however non life threatening.

History: History of asthma

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330155-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Mar-2007	Unknown		27-Oct-2008	06-Nov-2008	MI		19-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	088U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Loss of consciousness, Staring, Syncope, Tremor

Symptom Text: Syncopal episodes, increasing in frequency. Tremors of left hand that are worse when patient uses this hand. (she is left handed) 12/2/08 Reviewed PCP medical records of 7/29/2008. FINAL DX: headaches Records reveal patient experienced frequent left side frontal HA, staring spells, lightheadedness, blacking out for 30 sec-1 min x 6 mo & left arm/hand trembling uncontrollably & intermittently x 1 mo, lasting approx 1-2 hours each episode. Referred for EEG, EKG, labs, MRI brain. No results available.

Other Meds:

Lab Data: MRI of brain and spine- negative EEG-negative EKG-negative Multiple labs- all negative. Patient scheduled for ECHO and event monitor 10/30/08. Appointment with neurologist 11/26/08.

History: None PMH: ADHD, allergic rhinitis, reflux espohagitis, deviated nasal septum.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330163-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	27-Oct-2008	27-Oct-2008	0	27-Oct-2008	05-Nov-2008	MI		05-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2767AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0548X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: HPV Vaccine - Incorrect interval between doses. Patient had stated this was second dose but this was the third dose.

Other Meds: Nuvaring, Prozac, Vatrex

Lab Data: None

History: migraines, Depression

Prex Illness: No

Prex Vax Illns:

Vaers Id: 330224-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Oct-2008	Unknown		27-Oct-2008	06-Nov-2008	MT		23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB291AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect dose administered, No adverse event

Symptom Text: Patient was given Hep A 0.5 ml, right arm and Hep A 0.5 ml, left arm. Patient showed no signs of adverse effect. Parent was notified.

Other Meds: None

Lab Data: None

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330225-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	23-Sep-2008	23-Sep-2008	0	27-Oct-2008	06-Nov-2008	IL		07-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Witnessed syncopal event

Other Meds: Pamelor; Claritin; Yaz

Lab Data: Normal CBC; ECG: Normal signs rhythm, normal ECG

History: Migraine headaches and allergic to Demerol

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330230-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Oct-2008	15-Oct-2008	0	27-Oct-2008	06-Nov-2008	NY		07-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2817AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Nausea, Vomiting

Symptom Text: Patient feeling dizzy and nauseous - doctor spoke to mom 1st day close observation. Day 2 advised rest/push fluids/use Motrin for HA, if worsening to call back. Telephone call received from mother with the following information: 10/15 7 pm: feeling dizzy and nauseous a few hours after getting GARDASIL. Advised close observation and fluids tonight. Call in am to speak with PCP if persists. 10/16 9 am: spoke with mom this am to check on patient and she was not so great last night - woke up in middle of the night and vomited. This am had headache and went to school. Advised to follow up with PCP re future shots. Discussed that this is likely an intercurrent illness, not related to GARDASIL, but no way to know.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **330257-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	06-Aug-2007	06-Aug-2007	0	28-Oct-2008	29-Oct-2008	CO	WAES0708USA04844	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0929U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received from the Merck Pregnancy Registry via a registered nurse and a physician concerning a 26 year old female with anxiety and hay fever who on 06-AUG-2007 was vaccinated intramuscularly with a 0.5 ml first dose of GARDASIL (lot # 658282/0929U). There was no concomitant medication. On 24-AUG-2007 the patient was seen in the office for pregnancy. The patient's last menstrual period was on 29-JUN-2007 (previously reported as 15-JUN-2008) and the estimated date of delivery on 21-MAR-2008. The physician reported that the patient had a miscarriage at 8 weeks and 6 days, on 29-AUG-2007. An ultrasound was done at 10 weeks, approximately on 13-Sep-2007, which showed demise from 2 weeks prior. Upon internal review, miscarriage was considered an other important medical event. Additional information is not expected.

Other Meds: None

Lab Data: ultrasound, 09/13?/07 - demise from 2 weeks prior

History:

Prex Illness: Pregnancy NOS (LMP = 6/29/2007); Anxiety; Hay fever

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330259-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		28-Oct-2008	29-Oct-2008	--	WAES0810USA03307	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Convulsion, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who was vaccinated with GARDASIL for her second dose. Subsequently the patient experienced "seizure-like and fainting-like symptoms, including weakness". When on therapy the adverse effect improved. Subsequently, the patient recovered from seizure-like symptoms, fainting-like symptoms and weakness on unspecified date. The patient saw doctor for medical attention. Upon internal review, seizure like symptoms was considered an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330263-1** **Related reports:** 330263-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Mar-2008	01-Jun-2008	92	28-Oct-2008	29-Oct-2008	FR	WAES0810USA03870	29-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depression, Obsessive thoughts, Tremor, Vaccine positive rechallenge

Symptom Text: Information has been received from a foreign authority concerning a 19-year-old female who on an unspecified date was vaccinated with a first dose of GARDASIL and was administered on March 2008 the second dose of GARDASIL by intramuscular route, site of administration not reported. On June 2008, exact date not reported, the patient presented with shaky hands and feet, a clinical picture of depression and obsessive ideas. The patient was taken to the neurologist and was prescribed a medical treatment for these symptoms. No information had been reported regarding medicine used to treat adverse events. The patient improved. It was also mentioned that during JUL-2008, exact date not reported, the patient was vaccinated with the third dose of GARDASIL (batch number not reported, route and site of administration not reported). During SEP-2008, exact date not reported, the clinical features worsened. The patient was currently taking the prescribed neurologic treatment. No other information had been reported. The case was reported as serious by the Health Authority with other medically important condition as criteria. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330263-2** **Related reports:** 330263-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Mar-2008	01-Jun-2008	92	30-Oct-2008	31-Oct-2008	FR	WAES0810USA04233	07-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depression, Obsessive thoughts, Tremor, Vaccine positive rechallenge

Symptom Text: Information has been received from a health authority (reference number ES-AGEMED-520485241) concerning a 19 year old female with no medical history who on an unspecified date was vaccinated with the first dose of GARDASIL, and in March 2008, was vaccinated with the second dose of GARDASIL IM (batch number and site of administration not reported). In June 2008, the patient presented with shaky hands and feet, a clinical picture of depression and obsessive ideas. The patient was taken to the neurologist and was prescribed a medical treatment for these symptoms. No information has been reported regarding medication used to treat the adverse events. The patient improved. It was also mentioned that during July 2008, the patient was vaccinated with the third dose of GARDASIL (batch number not reported, route and site of administration not reported). During September 2008, the clinical features worsen. The patient is currently taking the prescribed neurological treatment. No other information has been reported. Case reported as serious by the Health Authority with other medically important condition criteria. Other business partner number included: E2008-09700. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **330267-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Feb-2008	02-May-2008	84	28-Oct-2008	03-Nov-2008	NY		20-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0524U	2	Right arm	Intramuscular	
HEPA	UNKNOWN MANUFACTURER	AHAVB215AA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Contusion, Cough, Disorientation, Fatigue, Headache, Mental status changes, Muscular weakness, Myalgia, Plasmapheresis, Pyrexia, Rhinorrhoea, Thrombocytopenic purpura, Upper respiratory tract congestion, Vomiting

Symptom Text: Pt in hospital until 1 week prior. Complain of total body myalgias and HA which worsened throughout week till arrival at ER with acute 2/19/09-records received for DOS 5/2/08. DC Thrombolic thrombocytopenic purpura. Plasmapheresis. Presented with altered mental stastus, fevers, myalgias and headche. One week ago C/O myalgias, fatigue and nonspecific diffuse muscle weakness and constant headache progressively worsened. Possible tactile fevers, arm numbness. Mild cough, congestion, rhinorrhea attributed to season allergies. New onset of bruising. Vomited in ED, disoriented and incoherent.

Other Meds:

Lab Data:

History: Obesity, DM type II, allergies to shrimp and peaches 2/19/09-records received- PMH: DM type II diagnosed 6 months ago, diet controlled.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330285-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Oct-2008	15-Oct-2008	0	28-Oct-2008	07-Nov-2008	WI		14-Nov-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2638AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1968U	2	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB285AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Loss of consciousness

Symptom Text: After receiving all three vaccine pt felt lightheaded and passed out while sitting in the upright position on the exam table for under ten seconds. After incident vitals were wnl. BP was 94/58

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330322-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	15-Oct-2008	15-Oct-2008	0	28-Oct-2008	07-Nov-2008	CO		07-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash pruritic, Urticaria

Symptom Text: Immunization given 10-15-08 in clinic at physical exam. No reaction W/N 20 min - left clinic RTC 10-16-08. Welts and rash randomly over arms, legs, throat and ABD (A+P). No sob or fever. Rash is pruritic. Instructed to use Benadryl 25 mg PO 4 - 6 hr.

Other Meds:

Lab Data:

History: Chlamydia - not treated yet at time of RW

Prex Illness: No

Prex Vax Illns:

Vaers Id: 330378-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Jun-2007	12-Jul-2007	22	28-Oct-2008	07-Nov-2008	MA		11-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0960F	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Carpal tunnel syndrome, Diarrhoea, Dysmenorrhoea, Hypoaesthesia, Joint swelling, Neuropathy peripheral, Pain in extremity, Paraesthesia, Tarsal tunnel syndrome

Symptom Text: patient received Gardasil vaccine on 12/20/06; 2/20/07; and 6/20/07.shortly after the last dose she has developed an pains in the ankles and feet, and numbness and tingling of the legs and hands. Evaluation by her current primary care doctor, neurologist and rheumatologist has yet to provide an explanation or treatment. Provisional diagnosis is neuropathy.consultant records received 11/18/08-C/O pain and swelling of both medial legs and ankles 7/07, pain worsened with weight bearing with swelling in ankles. Three weeks ago swelling and pain spontaneously improved. Assessment-possible that this represents a self limiting viral illness. Consultant visit 9/2/08-two months prior developed numbness, paresthesias and pain affecting bilateral plantar aspect of feet radiating to ankle and leg. Symptoms worse at night. Also right hand numbness. Assessment-bilateral feet pain consistent with neuropathic process likely bilateral tarsal tunnel. Right hand discomfort consistent with carpal tunnel syndrome. swelling in both feet. Started last summer. DX: peripheral neuropathy. Dysmenorrhea. Diarrhea.

Other Meds:

Lab Data: laboratory work, MRI, EMG, CXR 11/18/08-records received- EMG studies upper and lower extremities normal. Symptoms remain consistent with a generalized neuropathy and may reflect a small fiber neuropathy. CBC ESR ANA lyme titer negative. L

History: none 11/24/08-records received-Using Yaz birth control.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **330413-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	14-Jan-2008	22-Jan-2008	8	28-Oct-2008	26-Nov-2008	WI		26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Autoimmune disorder, Body temperature increased, Dizziness, Fear, Hallucination, visual, Injection site pain, Mental disorder, Presyncope

Symptom Text: Paige had her HPV shot on 1/14/08 at 3pm. Paige had started back on Adderall 10mg in January after taking a 6 month break. She got very light headed 1 hour after her shot and almost fell in the bathroom at home. A couple of days later, she had a temp of 104 degrees for 2 day. Tylanol was given every 4 hours with no real aid in dropping the fever. The 2nd night of the high temp, she had a vision of a boy standing by her bed in the middle of the night. The boy was not real. The temp broke that night. In March, Paige saw the vision of the boy by her bed in the middle of the night again. This continued to happen on an inconsistant bases, but by April she was seeing different visions of people during the day and night all of the time. She saw Dr. Dvorak (pediatrician) on April 15, 2008. She was told to stopped taking the Adderall. Paige was set up with an appointment with Dr.Jillian Brown(psychiatry) on April 23. Paige began Siraqual for her visions and numerous psychiatry appointments. After trying different doses, she continued on 1/2 pill per day until the end of May 2008. The visions went away after the second day of Siraqual. Paige also has a major fear of having any thing injected into her or taken out of her (example. immunizations and blood draws). She said the HPV shot hurt and you could feel the medicine go into your body. She had sessions to desensitizer her to have a blood draw done. The blood draw did show that her Auto-immune numbers were at 40. We have not followed up on this yet.

Other Meds: Adderall XR 10mg

Lab Data: 5/7/2008 EEG -(Showed spikes) 5/9/2008 MRI - ok After being off Seriqual for 1 month 7/9/2008 EEG - (no spikes) 7/23/2008 MRI - ok

History: ADD- short term memory & comprehension problems

Prex Illness: none

Prex Vax Illns:

Vaers Id: **330434-2 (S)** **Related reports:** 330434-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Sep-2008	17-Oct-2008	31	30-Oct-2008	31-Oct-2008	FL	WAES0810USA04488	06-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Dizziness, Dysstasia, Fall, Headache

Symptom Text: Information has been received from a physician concerning a 17 year old female with benign cyst in the breast, fungal infection behind the ears and no allergies who on 16-SEP-2008 was vaccinated intramuscularly with a first dose of GARDASIL (lot number 655604/0052X) (injection site not reported). There was no concomitant medication. On 17-OCT-2008 the patient experienced severe dizziness and headache and went to the emergency room. The ER found no factors relating to the symptoms. The patient continued to have severe dizziness and could not stand. Standing caused falling and so the patient was seen on 20-OCT-2008 by her primary physician. The patient was admitted to the hospital that day for 2 days. MRI, CT scan and blood work came back negative. The patient was seen by both a neurologist and cardiologist. The patient was then admitted to a hospital since 22-OCT-2008. The patient was given intravenous fluid because the physician did not find the cause for her symptoms. At time of this report, the patient's symptoms persisted. The patient's severe dizziness, headache, could not standing and standing which caused falling were considered to be disabling. Additional information has been requested.

Other Meds: None

Lab Data: magnetic resonance, 10/20?/08, negative; computed axial, 10/20?/08, negative; diagnostic laboratory, 10/20?/08, negative

History:

Prex Illness: Cystic disease of breast (benign); Fungal infection

Prex Vax Illns:

Vaers Id: **330439-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Sep-2007	29-Sep-2007	7	28-Oct-2008	20-Dec-2008	TX		22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2455AA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Asthenia, Hypoaesthesia, Obsessive-compulsive disorder, Paraesthesia

Symptom Text: Pt came for well visit on 10/13/08. At that time reported to me that when pt got her Gardasil #1 on 9-22-07 about 1 week later pt began to fall her legs were weak, she had decreased sensation. She also had experienced numbness and tingling. She has seen ortho and neuro. MRI of spin and brain normal. Better now some improvement, occas has symptoms 11/20/08-records received-office visit 10/10/07-At age 7 diagnosed with OCD is stable-repeats selft serveral times when worried. Rarely smiles or laughs. DC: Obsessive-Compulsive Disorder. Office visit 1/29/08-increasing ruminating thoughts and checking rituals have improved still some OCD thoughts. Anxious at times. Office visit 6/3/08-Doing well. 11/17/08-continues to do well overall.

Other Meds: Prozac, seoquel

Lab Data: MRI of brain and spine normal per her neurologist

History: OCD, scoliosis

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330445-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Oct-2008	27-Oct-2008	0	28-Oct-2008	29-Jan-2009	KS		29-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB245AA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2637AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0546X	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2997AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epistaxis, Erythema, Excoriation, Fall, Headache, Swelling face, Syncope, Vision blurred

Symptom Text: Client received vaccines and relaxed she felt okay - no complaints. Client left clinic and parent reports outside of clinic client fell onto lawn. Client reports had headache and blurry vision before she fainted and fainted and fell onto lawn. Noted: Nose bleed, abrasion beneath (L) Nostril, inner low lip, redness and swelling of (L) upper cheek area. Provided first aid, BP114/72 P-76 R-20. Provided crackers and water. Seen by Doctor here

Other Meds: None

Lab Data:

History: None

Prex Illness: None Known

Prex Vax Illns:

Vaers Id: **330453-1** **Related reports:** 330453-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Oct-2008	27-Oct-2008	0	28-Oct-2008	29-Jan-2009	AZ		29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2665AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0843X	1	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB245AA	0	Right arm	Intramuscular	
	HEP	MERCK & CO. INC.	1714U	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Face injury, Immediate post-injection reaction, Joint swelling, Syncope

Symptom Text: Patient fainted after receiving vaccines. Pt. was sitting and fell forward - hit nose on counter. Then; pt was layed back with legs elevated. Pt. came to in apprx 15-20 seconds *Pt immediately c/o (L) ankle pain, but ambulated out of clinic. Per mother, PT has swelling and aching in (L) ankle - starting later in the day. No trauma to (L) ankle @ time of visit.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330453-2** **Related reports:** 330453-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Oct-2008	27-Oct-2008	0	29-Oct-2008	02-Dec-2008	AZ	AZ0817	05-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEP	MERCK & CO. INC.	1714U	2	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0843X	1	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2665AA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB245AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Face injury, Fall, Joint swelling, Syncope

Symptom Text: Patient fainted after receiving vaccines. Patient was sitting and fell forward. Hit nose on counter. THen patient was layed back with legs elevated. Patient came to in approximately 15-20 seconds. Patient immediately c/o left ankle pain but ambulated out of clinic. Per mother, patient has swelling and aching in left ankle-starting later in the day.

Other Meds:

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330457-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-Oct-2008	28-Oct-2008	1	28-Oct-2008	29-Jan-2009	OR		30-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2617AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1758U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Dizziness, Pyrexia

Symptom Text: Mother- reports pt c/o fever/chills and lightheadedness today.

Other Meds: CLONIDINE 0.3 mg

Lab Data:

History: NKA

Prex Illness:

Prex Vax Illns:

Vaers Id: **330464-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Oct-2008	16-Feb-2009	CO	WAES0809USA04123	17-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a certified medical assistant concerning many patients that were vaccinated on unspecified dates with an unknown dose of GARDASIL and experienced sore arm after vaccination. Attempts are being made to obtain identifying information to distinguish the individual patients. This is one of two reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330465-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		29-Oct-2008	11-Feb-2009	VA	WAES0809USA04132	17-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with GARDASIL. The patient developed dizziness after vaccination. On an unspecified date the patient recovered from dizziness. The patient sought medical attention. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330466-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	16-Feb-2009	VA	WAES0809USA04133	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with GARDASIL vaccine (yeast). The patient developed dizziness after vaccination. On an unspecified date the patient recovered from dizziness. The patient sought medical attention. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330467-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	16-Feb-2009	--	WAES0809USA04135	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information has been received from a registered nurse concerning a female who was vaccinated with GARDASIL vaccine (yeast). The patient developed warts on hands after vaccination. The outcome of the patient was unknown. This is one of several reports from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330468-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Sep-2008	10-Sep-2008	7	17-Oct-2008	16-Feb-2009	--	WAES0809USA04139	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Hypertension

Symptom Text: Information has been received from a public school registered nurse concerning a 11 year year old female who on 03-SEP-2008 was vaccinated with a dose of GARDASIL vaccine (yeast) (unspecified whether the injection was the first or a subsequent injection in the series). After receiving GARDASIL vaccine (yeast), the patient developed hypertension (152/82) and "about a week after receiving GARDASIL vaccine (yeast)", the patient developed headaches. The hypertension was discovered as the reporter monitored the patient's blood pressure after a complaint of headache. No other symptoms or treatment were reported. On an unknown date, an unspecified blood work was performed (results not provided). The patient's status at the time of the report was not recovered. The patient sought medical attention at the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: blood pressure, 09/??/08, 152/8

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330469-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	15-Sep-2008	15-Sep-2008	0	17-Oct-2008	16-Feb-2009	IA	WAES0809USA04151	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Paraesthesia, Vision blurred

Symptom Text: Information has been received from a physician concerning a 26 year old female who was vaccinated the first 0.5ml dose of GARDASIL vaccine (yeast) (MSD) on 17-JUL-2008. On 15-SEP-2008 the patient was vaccinated the second 0.5 ml dose of GARDASIL vaccine (yeast((MSD) in the left arm. The patient took oral contraceptive (unspecified). A few hours later on 15-SEP-2008, the patient had a headache and blurry vision. The patient laid down and later woke up the tingling of right hand. The tingling resolved in 15 minutes. No treatment required. At time of report, the patient recovered on an unspecified date. The patient sought medical attention by phone. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History:

Prex Illness: Contraception

Prex Vax Illns:

Vaers Id: **330470-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		29-Oct-2008	11-Feb-2009	--	WAES0809USA04152	17-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Thrombosis

Symptom Text: Information has been received from a school receptionist concerning her daughter who was vaccinated with GARDASIL. Subsequently the patient experienced blood clots. The outcome is unknown. No further information is available. The patient sought unspecified medical attention. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330471-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	16-Feb-2009	CA	WAES0809USA04170	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstrual disorder

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with GARDASIL vaccine (yeast). Per the physician, the patient's mother reported that the patient used to have regular periods and now she is having periods every 2 weeks after receiving GARDASIL vaccine (yeast). AT the time of this report, the adverse event is ongoing. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330472-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	16-Feb-2009	PA	WAES0809USA04178	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Generalised erythema, Pruritus generalised, Urticaria

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with the second dose of GARDASIL vaccine (yeast). The physician reported that the patient received the HPV vaccine and experienced red, itchy welts head to foot. At the time of the report the patient had not recovered. The patient sought medical attention by phone. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330473-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-May-2008	15-Jun-2008	20	17-Oct-2008	20-Dec-2008	--	WAES0809USA04180	22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dermatitis contact, Leukocytoclastic vasculitis, Petechiae

Symptom Text: Information has been received from a registered nurse concerning her 14 year old niece with no pertinent medical history and no allergies or drug reactions, who on 29-MAY-2008 was vaccinated with the second dose of HPV 4L1 6 11 18 VLP vaccine (yeast). There was no concomitant medication. The nurse reported that in "mid June 2008", her niece experienced a generalized, "petechial-type rash". The above was diagnosed by a dermatologist as leukocytoclastic vasculitis. At the time of the report the patient had not recovered. Additional information has been requested. 11/5/08-records received-note of 9/23/08-Left leg superficial perivascular infiltrate of lymphocytes with erythrocyte extravasation consistent with progressive pigmentary purpura. No neutrophilic infiltrate or fibrinoid degeneration of vessels is identified to suggest a true vasculitis. Allergic contact dermatitis. 10/27/08-cancelled follow up appointment.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **330474-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	16-Feb-2009	PA	WAES0809USA04182	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning a female patient who on unknown dates, was vaccinated with the first and second dose of GARDASIL vaccine (yeast). The nurse reported that the patient experienced fever and dizziness after each dose of GARDASIL vaccine. The nurse would follow-up with medical services to see if she would give the patient her third dose. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330475-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Oct-2008	16-Feb-2009	MA	WAES0809USA04194	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a patient who was vaccinated with a dose of GARDASIL vaccine (yeast) and fainted, but was caught before she fell. It was unknown if the patient sought medical attention. This is one of two reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330476-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		17-Oct-2008	16-Feb-2009	CA	WAES0809USA04206	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse reaction

Symptom Text: Information has been received from a physician concerning an approximately 20 year old female patient who on an unspecified date, was vaccinated with the second dose of GARDASIL vaccine (yeast). The physician reported that the patient had an unspecified systemic reaction after receiving GARDASIL vaccine. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330477-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	16-Feb-2009	--	WAES0809USA04209	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from an office manager concerning a female who on an unspecified date was vaccinated with the first dose of GARDASIL vaccine (yeast). It was reported that on an unspecified date some time ago (also reported as some weeks ago) the patient passed out while standing at the check out after her first dose. The patient recovered. There were no emergency procedures; she was not injured and no pregnant. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330478-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-May-2008	04-May-2008	3	17-Oct-2008	16-Feb-2009	OH	WAES0809USA04214	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain

Symptom Text: Information has been received from a physician concerning a 23 year old female who in May 2008, was vaccinated with GARDASIL vaccine (yeast), 0.5 mL intramuscularly. Three days after receiving vaccination, the patient developed abdominal pain. The physician ran some laboratory tests but the results were negative. On an unspecified date, the patient recovered from abdominal pain. The patient sought physician's medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330479-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Sep-2008	17-Sep-2008	1	17-Oct-2008	16-Feb-2009	--	WAES0809USA04219	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy, Rash, Urticaria

Symptom Text: Information has been received from a physician's assistant concerning a 16 year old female who on 16-SEP-2008 was vaccinated with a dose of GARDASIL (lot # 660618/0572X) into the left deltoid. On 17-SEP-2008 the patient developed a rash on her groin and hives over the rest of her body. She also reported swollen lymph nodes in her left axillary area. She was treated topical steroids and antibiotics. No other information was available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330480-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	16-Feb-2009	CA	WAES0809USA04319	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated IM with GARDASIL vaccine (yeast). Subsequently the patient developed irregular menstrual periods after GARDASIL vaccine (yeast) was given. The patient sought medical attention. Additional information has been requested. This is one of two reports received from the same source.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330481-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	17-Aug-2008	20-Aug-2008	3	29-Oct-2008	29-Jan-2009	FL	WAES0809USA04328	29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oedema peripheral, Swelling

Symptom Text: Information has been received from a physician concerning a female who on 17-AUG-2008 was vaccinated with her first and only dose of GARDASIL. There was no concomitant medication. Within the 3-6 days after the vaccination, which is in approximately 20-AUG-2008 -23-Aug-2008, the patient developed swelling in hands and chin. She recovered from swelling in hands and chin at the time of the report. The patient sought medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **330482-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Apr-2008	01-Jun-2008	61	17-Oct-2008	16-Feb-2009	PA	WAES0809USA04340	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a consumer concerning his 12 year old daughter with no pertinent medical history, allergies or drug reactions who in April 2008, was vaccinated with the second dose GARDASIL vaccine (yeast) 0.5 ml (lot no. not reported). There was no concomitant medication. On an unknown date, the patient developed a bald spot on her head. Therapy with human papillomavirus vaccine was discontinued. The patient's bald spot on head persisted. In Jun 2008 a blood work was done (results not reported). The patient sought unspecified medical attention. No further information is available.

Other Meds: None

Lab Data: Blood work, results not reported

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330483-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	18-Aug-2008		17-Oct-2008	16-Feb-2009	--	WAES0809USA04347	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injection site pain

Symptom Text: Information has been received from a consumer concerning her daughter a 17 year old female with no known drug allergies/reactions and no pertinent medical history reported who on unspecified dates was vaccinated with the first and second doses of GARDASIL vaccine (yeast). On 18-AUG-2008, the patient was vaccinated with a third dose of GARDASIL vaccine (yeast) and experienced soreness at the injection site after receiving the vaccine. On 23-SEP-2008 the patient was vaccinated with a fourth dose of GARDASIL vaccine (yeast) 0.5 mL intramuscularly, and the patient's mother stated that the doctor's nurse accidentally administered the fourth dose. On 23-SEP-2008, soreness at the injection site reappeared after the 4th dose of GARDASIL vaccine (yeast). The patient sought unspecified medical attention. The patient recovered from soreness at the injection site on 23-SEP-2008. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330484-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	01-Sep-2007	01-Dec-2007	91	17-Oct-2008	16-Feb-2009	--	WAES0809USA04350	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received through the Merck pregnancy registry from a nurse who reported that on approximately 19-SEP-2008, a 2 week old old infant was born with an unspecified weakness to a mother who received the first dose of GARDASIL vaccine (yeast) about a year ago, approximately in September 2007. There was no concomitant medication. The patient is now receiving physical therapy. The patient sought medical attention with an office visit. At time of reporting, the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Muscular weakness

Prex Vax Illns:

Vaers Id: **330485-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	24-Sep-2008	24-Sep-2008	0	17-Oct-2008	16-Feb-2009	--	WAES0909USA04365	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea

Symptom Text: Information has been received from a nurse practitioner concerning a 25 year old female with no pertinent medical history and no allergies or drug reactions who on 23-JUL-2008, was vaccinated with the first dose of GARDASIL vaccine (yeast) 0.5 ml, intramuscularly. Concomitant therapy included YAZ. On 24-SEP-2008, the patient was vaccinated with the second dose of HPV vaccine (lot# 661044/0548X), 0.5 ml intramuscularly. The nurse practitioner reported that the patient developed intermittent nausea 1 and a 1/2 hours after receiving her second dose. The nausea was mild and intermittent, and had not caused emesis. At the time of the report, the patient had not recovered. The patient sought medical attention by phone. Additional information has been requested.

Other Meds: YAZ

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330486-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		17-Oct-2008	16-Feb-2009	--	WAES0809USA04390	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Visual impairment

Symptom Text: Information has been received from a physician assistant concerning hi daughter, a 13 year old female, who was administered her second dose of vaccination with GARDASIL vaccine (yeast) IM> Subsequently the patient experienced vision problems. The patient received a computed axial tomography (CAT) scan, and results were found to be normal. Subsequently, the patient recovered from vision problems. The physician assistant felt that vision problems are not related to therapy with GARDASIL vaccine (yeast). No further information is available.

Other Meds: Unknown

Lab Data: computed axial, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330487-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		29-Oct-2008	29-Jan-2009	--	WAES0809USA04397	29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a nurse practitioner concerning an 18 year old female who in October 2007, was administered her third dose of vaccination with GARDASIL, 0.5ml, IM. "About one month later" the patient experienced chronic head aches. Subsequently the patient was treated with NEURONTIN and Ibuprofen. The patient's chronic head aches persisted. The patient sought medical at the nurse practitioner's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330488-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jun-2008	16-Jun-2008	0	17-Oct-2008	16-Feb-2009	--	WAES0809USA04436	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Mouth injury, Suture insertion, Syncope, Unresponsive to stimuli

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female patient with no medical history who on 16-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (LOT# 659653/1448U) 0.5 ml intramuscular into the left arm. There was no concomitant medication. After receiving the injection the patient fainted and fell face first onto the the floor and was unresponsive for three minutes. Subsequently 911 notified and transported the patient to the hospital. The patient underwent a CT scan of the skull (no result was provided) and received 7 stitches to the upper lip. No other laboratory tests were performed. There were no other symptoms or treatment reported. Then the patient was released from the emergency room. At the time of this report, the patient's father reported that the patient was at home and feeling better. This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **330489-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	24-Jul-2008	24-Jul-2008	0	17-Oct-2008	16-Feb-2009	--	WAES0809USA04457	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning an 13 year old female patient with no medical history who on 24-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine (yeast) (LOT# 660557/0072X) 0.5 ml intramuscular into the left deltoid. There was no concomitant medication. Subsequently the patient fainted as she stood up after receiving GARDASIL vaccine (yeast). The fall was braced and the patient lowered to the floor without injury. The patient was monitored for 20 minutes and released to home with the patient's mother. No other laboratory tests were performed. At the time of this report, it was unknown if the adverse event was ongoing. The patient sought medical attention. This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **330490-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	16-Feb-2009	--	WAES0809USA04458	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a female patient who was vaccinated with GARDASIL vaccine (yeast). Subsequently the patient fainted. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330491-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-May-2008	Unknown		17-Oct-2008	16-Feb-2009	--	WAES0809USA04484	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Information has been received from a physician concerning a 16 year old female patient with no illness at time of vaccination who on 12-MAY-2008 was vaccinated with her third dose of GARDASIL vaccine (yeast) (therapy route, dose and Lot # unspecified). There was no concomitant medication. No lab diagnostics studies were performed for the patient. A couple of months after the vaccination, the patient experienced Bells Palsy. The patient sought medical attention in the emergency room but not admitted to the hospital. Subsequently, the patient recovered from Bells Palsy (recovered date unknown). Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **330492-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Sep-2008	24-Sep-2008	0	17-Oct-2008	27-Jan-2009	MD	WAES0809USA04486	27-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	1	Unknown	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Fall, Head injury, Hypotension, Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female who on 17-SEP-2007 was vaccinated with the first dose of GARDASIL vaccine 0.5 ml, IM, on 24-SEP-2008 was vaccinated with second dose of GARDASIL vaccine (lot no. 660618/0572X) 0.5 ml, IM. Concomitant therapy included MENACTRA and FLUMIST. On 24-SEP-2008. 5 minutes after vaccination, the patient passed out and fell to the floor hitting the head. The nurse also reported that the patient "had what looked like a little seizure", the patient was hypotensive. The patient was transferred to the emergency room. The head computed axial tomography performed was negative (head normal). The patient was not admitted in the hospital. The patient recovered and was discharged home. The emergency room diagnosis was syncope. Additional information has been requested.

Other Meds:

Lab Data: Computed axial - head normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **330493-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	11-Jul-2008	12-Jul-2008	1	17-Oct-2008	16-Feb-2009	DC	WAES0809USA04498	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a medical assistant concerning a 23 year old female who on 11-JUL-2008 was vaccinated with her dose of GARDASIL vaccine (yeast) (LOT# 660387/1967U). Concomitant therapy included GYNAZOLE and FEMCON. Approximately the following day on 12-JUL-2008, the patient experienced a generalized rash. The medical assistant also states that the patient began treatment with GYNAZOLE on 11-JUL-2008 for yeast infection. Subsequently, the patient recovered from generalized rash. Additional information has been requested.

Other Meds: GYNAZOLE 1; FEMCON FE

Lab Data: Unknown

History:

Prex Illness: Yeast infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330494-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	16-Feb-2009	--	WAES0809USA04515	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chronic fatigue syndrome

Symptom Text: Information has been received from a registered nurse, who was told by one of her patients that a female patient who an unknown date was vaccinated with a dose of GARDASIL vaccine (yeast). Subsequently, the patient developed chronic fatigue syndrome. At the time of reporting, the patient's chronic fatigue syndrome persisted. There was no product quality complaint. This is one of several reports provided by the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330495-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	09-Oct-2007	09-Oct-2007	0	17-Oct-2008	20-Dec-2008	IL	WAES0809USA04533	22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNK	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fibromyalgia, Migraine, Stress

Symptom Text: Information has been received from a pharmacist concerning to her 21 year old daughter with allergic reaction to cefaclor (CECLOR) and ovarian cyst, in the last year (in 2007) was vaccinated with three doses of HPV 4L1 6 11 16 18 VLP vaccine (yeast). Concomitant therapy included duloxetine hydrochloride (CYMBALTA) and lamotrigine)LAMICTAL). The patient developed fibromyalgia and more severe migraine headaches after received three HPV 4L1 6 11 16 18 VLP vaccine (yeast) injections "last year" (date unspecificed). The fibromyalgia was diagnosed in February 2008. Blood studies performed (results not provided). The patient was prescribed cyclobenzaprine HCL (FLEXERIL), gabapentin (NEURONTIN) and eletrptan hydrobromide (REPLAX). At the time of the reporting the patient was not recovered. The patient sought medical attention in office visit. There was no product quality complaint. Additional information is expected. 11/11/08-records received for DOS 10/9/07-C/O migraines times 1 week, body aches. Stress at school. Received 1st Gardasil vaccine 10/9/07-second dose 12/17/07 and 3rd dose 4/22/08-

Other Meds: CYMBALTA, LAMICTAL

Lab Data: Unknown 11/11/08-recodrs received-office visit 4/7/08 urine culture negative.

History: Ovarian Cyst. Allergic reaction to antibiotics. Fibromyalgia. Migraine

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **330496-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		17-Oct-2008	16-Feb-2009	TX	WAES0809USA04553	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Migraine

Symptom Text: Information has been received from a physician concerning a female patient between 18-26 years of age, who was vaccinated with her second dose of GARDASIL vaccine (yeast). The physician reported that the patient received her 2nd dose of HPV vaccine and developed migraine headaches. The patient had been taking TOPAMAX and the headache persisted. The physician reported that the patient was due for her third dose of HPV vaccine "soon" and was considering not receiving it due to her concern over the headaches. At the time of the report, the patient had not recovered. The patient sought medical attention at the physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330497-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Mar-2008	01-Mar-2008	0	17-Oct-2008	13-Feb-2009	NY	WAES0809USA04555	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lip swelling

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who six months ago, in approximately March 2008, was vaccinated with the first dose of GARDASIL (lot # 659657/1487U). Later that same day of administration, the patient's lips began to swell and her mother gave her child oral BENADRYL and the patient recovered. Approximately 4 months ago, in approximately May 2008, was vaccinated with the second dose of GARDASIL (LOT #660391/0063X). After the second vaccination, the patient's lips began to swell, oral BENADRYL was given and the patient recovered. No other medical follow-up was necessary. When the physician heard about the incident, he decided not to vaccinate the patient with the third dose of HPV vaccine. At the time of the report the patient had recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330499-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
49.0	F	01-Jul-2008	01-Jul-2008	0	17-Oct-2008	13-Feb-2009	NY	WAES0809USA04560	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Influenza like illness, Injection site pain

Symptom Text: Information has been received from a 49 year old female with seasonal allergy who on 01-JUL-2008 was vaccinated with an unspecified dose of GARDASIL. Concomitant therapy included SYNTHROID and unspecified allergy medications. On 02-JUl-2008, the patient experienced pain and soreness at the injection site and flu like symptoms. The patient did not seek medical attention. About 3 weeks after receiving shots, on approximately 22-JUL-2008, the patient recovered. Additional information has been requested.

Other Meds: (therapy unspecified); SYNTHROID

Lab Data: None

History:

Prex Illness: Seasonal allergy

Prex Vax Illns:

Vaers Id: **330500-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	27-Aug-2008	30-Aug-2008	3	17-Oct-2008	13-Feb-2009	--	WAES0809USA04564	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a 26 year old female who on 27-AUG-2008 was vaccinated with the first dose of GARDASIL. The patient had a menstrual period on 06-AUG-2008 and next period on 30-AUG-2008. Her periods are normally regular. The patient did not seek medical attention. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **330501-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	18-Sep-2008	18-Sep-2008	0	17-Oct-2008	13-Feb-2009	MN	WAES0809USA04567	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a female who "within the last week" on approximately 18-SEP-2008 was vaccinated with the first dose of GARDASIL. It was reported that "right after vaccination," the patient fainted after getting GARDASIL. It was unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330502-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	11-Sep-2008	12-Sep-2008	1	17-Oct-2008	13-Feb-2009	--	WAES0809USA04604	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness

Symptom Text: Information has been received from a physician concerning a 13 year old female who on 11-SEP-2008 was vaccinated with the first dose of GARDASIL (lot # not provided), intramuscular, 0.5mL. On 12-SEP-2008 the patient developed flu like symptoms. The patient sought for medical attention. Subsequently, the patient recovered from flu like symptoms. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330503-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Jul-2008	23-Jul-2008	0	17-Oct-2008	13-Feb-2009	FL	WAES0809USA04607	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Mass, Oedema peripheral, Pain, Pain in extremity

Symptom Text: Information has been received from a nurse concerning a 17 year old female who on 23-JUL-2008 was vaccinated with the first dose of GARDASIL (lot # 659964/1978U) via IM. Concomitant therapy included unspecified birth control pill. Later the same day, she experienced pain in her whole arm lasting for 2 weeks and swelling, a big throbbing lump, at site for a few days. She sought medical attention in office. No treatment required. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History:

Prex Illness: Contraception

Prex Vax Illns:

Vaers Id: **330504-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Oct-2008	13-Feb-2009	NY	WAES0809USA04623	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure orthostatic decreased, Dizziness, Headache, Nausea

Symptom Text: Information has been received from a nurse concerning a female patient between 9-26 years old who on an unknown date was vaccinated with the second dose of GARDASIL. Soon after the administration, the patient experienced dizziness, headache, nausea, and suspected drop in orthostatic pressure. Unspecified medical attention was given in the office. On the same date as the administration, the patient recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330505-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Feb-2008	Unknown		17-Oct-2008	13-Feb-2009	--	WAES0809USA04625	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	UNK	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety

Symptom Text: Information has been received from a nurse concerning an approximately 18 year old female who in approximately February 2008, "last spring" was vaccinated with a dose of GARDASIL (it is not known which dose it was in the series, lot number was not available). Concomitant therapy included "other unspecified vaccinations." It was reported that the patient experienced general anxiety after the shot was given. The patient sought medical attention. Additional information has been requested.

Other Meds:

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330506-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Jan-2008	01-Jun-2008	129	17-Oct-2008	13-Feb-2009	MA	WAES0809USA04631	10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	2	Unknown	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye pain, Vision blurred

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female who on 18-JUN-2007, 30-AUG-2007 and on 24-JUN-2008 was vaccinated IM with a 0.5 mL dose of GARDASIL. In approximately June 2008, a short time after the third dose, the patient experienced pain and blurry vision in her left eye. The symptoms have continued to the present. The patient had sought unspecified medical attention. A magnetic resonance imaging was done but the result was normal. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance, result normal

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330507-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		17-Oct-2008	13-Feb-2009	FL	WAES0809USA04640	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Nasopharyngitis, Pyrexia, Upper respiratory tract infection

Symptom Text: Information has been received from a physician for the pregnancy registry for GARDASIL concerning a 13 year old female who received her second dose of GARDASIL (lot no. 660620/0571X) "a few weeks ago." The patient come in the office on 26-SEP2008 with a fever, cold and was diagnosed with an upper respiratory infection. The patient also took pregnancy test on 26-SEP-2008 and it was confirmed she is 4 months pregnant. Physician referred patient to an obstetrician/Gynecologist and the third dose of GARDASIL will not be given. Additional information has been requested.

Other Meds: Unknown

Lab Data: beta-human chorionic, 09/26/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **330508-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	23-Sep-2008	24-Sep-2008	1	17-Oct-2008	13-Feb-2009	--	WAES0809USA04645	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0847X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Neck pain

Symptom Text: Information has been received from a nurse practitioner concerning a 25 year old female with no pertinent medical history and no drug reactions/allergies who on 16-FEB-2008 was vaccinated with the first dose of GARDASIL, on 14-APR-2008 was vaccinated with the second dose of GARDASIL, and on 23-SEP-2008, the patient was vaccinated with the third dose of GARDASIL into her left deltoid (Lot# 659968/0847X). There was not concomitant medication. On 24-SEP-2008, the patient developed severe pain radiating from the injection site (left deltoid) up into her neck. The patient's severe pain radiating from the injection site (left deltoid) up into neck persisted. It was reported that the patient sought medical attention: phone call. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330522-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	24-Oct-2008	24-Oct-2008	0	29-Oct-2008	27-Jan-2009	MD		27-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN	MEDIMMUNE VACCINES, INC.	5005411	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0229X	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1189X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Dry mouth, Pallor, Photopsia

Symptom Text: Feeling faint, pale skin color, dry mouth, seeing stars, feeling weak.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330524-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-Oct-2008	21-Oct-2008	0	29-Oct-2008	09-Feb-2009	GA		13-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Hypoaesthesia, No reaction on previous exposure to drug, Pharyngeal oedema, Rash

Symptom Text: Child received GARASIL #2 on 10-21-08 - 2pm. Mom gave Vit D p.o 9pm 10-21-08 - Started with skins rash, numbness, throat swelling. Treated at ED after syms started. IV steroid given with EPI-PEN. Dr at ED voiced felt it was allergic reaction to vit D, not GARDASIL. No reaction previous GARDASIL given 7-22-08.

Other Meds: Vitamin D later 10-21-08

Lab Data:

History: Sulfa

Prex Illness: None

Prex Vax Illns:

Vaers Id: **330546-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-Oct-2008	08-Oct-2008	0	29-Oct-2008	09-Feb-2009	GA		10-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0320X	1	Left arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B029AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1740U	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2620AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister, Pruritus, Vomiting

Symptom Text: Client vomited 1 1/2 hr. after receiving immunization then noticed had raised, clear fluid filled 17 mm + 10 mm oval on chin. 10/9/08 a round fluid filled area appeared on (R) side of neck. Every day or every other day they have noticed a new fluid filled circle/oval - (L) side neck, (L) under upper arm, (R) side of chest X 4, abd X 2. Mother has been applying an anti-itch cream & NEOSPORIN CREAM to areas. Client states areas were itchy when they first came up but then itching stopped & discontinued when creams applied. The last oval/circle area that has appeared was on 10/20/08.

Other Meds: None

Lab Data: None

History: allergic to peppermint (breaks out in hives)

Prex Illness: None

Prex Vax Illns: None~ ()~~0~In Patient|None~ ()~~0~In Sibling

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330547-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Oct-2008	Unknown		29-Oct-2008	02-Dec-2008	NY		02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548	3	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: None

Other Meds: Benzacin, Albuterol

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330548-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Oct-2008	Unknown		29-Oct-2008	11-Feb-2009	NY		17-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548	3	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: None

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330561-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	18-Sep-2008	19-Sep-2008	1	29-Oct-2008	11-Feb-2009	MO		25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Patient reported severe joint pain in hips, knees, and elbows starting within 24 hours of injection which is continuing.

Other Meds:

Lab Data:

History:

Prex Illness: none reported

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330566-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Oct-2008	16-Oct-2008	0	29-Oct-2008	10-Feb-2009	OH		10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2927AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2666AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pityriasis

Symptom Text: Pityriasis 2 hours after getting immunization.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **330567-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Oct-2008	28-Oct-2008	0	29-Oct-2008	11-Feb-2009	TX		25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness

Symptom Text: Patient received initial Gardasil 0.5 mL IM left deltoid and noted 10-15 second seizure with loss of consciousness.

Other Meds:

Lab Data: Had follow up with PCP 10/29/2008

History: None known

Prex Illness: None

Prex Vax Illns:

Vaers Id: 330580-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	17-Jun-2008	01-Aug-2008	45	29-Oct-2008	30-Oct-2008	CT	WAES0810USA04359	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Atelectasis, Back pain, Chest pain, Dyspnoea, Haemoptysis, Heart valve incompetence, Neck pain, Oral contraception, Patent ductus arteriosus, Pleural effusion, Pulmonary embolism

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female with no previous medical history or drug allergies reported who on 17-APR-2008 was vaccinated with the first dose of GARDASIL (Lot # 659653/1448U), 0.5 mL I.M. and on 17-JUN-2008 was vaccinated with the second dose of GARDASIL (Lot # 659962/1740U). Concomitant therapy included oral contraceptives (unspecified). After administration of the second dose, the patient developed a pain in her neck, chest and back area and was diagnosed with a pulmonary embolism. The patient was being treated with COUMADIN. On an unspecified date, the patient recovered. The patient sought medical attention at the office. Upon internal review, pulmonary embolism was determined to be an other important medical event. Additional information has been requested. 4/14/09 Received hospital medical records of 7/25-7/29/2008. FINAL DX: acute pulmonary embolism Records reveal patient experienced right side neck/chest pain since 7/18 which progressed to SOB & bloody sputum. Seen by PCP & CXR found to be abnormal. Sent to ER & found to have RLL PE assoc w/pleural effusion & atelectasis. Tx w/anticoagulants. Genetic testing done for possible predisposition for clotting was neg. Cardio consult done for abnormal echo. Improved & d/c to home on continued anticoagulant therapy w/PCP & cardio f/u w/additional clotting w/u to be performed as outpatient. /29/09 Received vaccine & GYN medical records of 4/17-10/23/2008. FINAL DX: pulmonary emboli Records reveal patient experienced good general health when seen for initial evaluation on 4/17 for HPV#1 & started OCP at that time as well. RTC 6/17/08 for HPV#2. D/C OCP 8/08 due to PE. Developed RLQ pain 10/08.

Other Meds: Hormonal Contraceptives

Lab Data: Unknown LABS: CTA chest c/w lower lobe branch of right pulmonary artery clot. US of LEs neg. Echocardiogram c/w trace mitral, tricuspid & pulmonis regurgitation as well as PDA. H/H 10.5/30.4(L), iron 21(L), iron sat 6(L). Retic count

History: None PMH: migraine HA w/nausea, sinusitis, abdominal cramps w/exercise x 3 yrs.

Prex Illness:

Prex Vax Illns:

Vaers Id: **330581-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		29-Oct-2008	30-Oct-2008	IN	WAES0810USA04309	30-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the first dose of GARDASIL. No lot number provided. Physician reported that a patient received her first dose of GARDASIL and shortly thereafter the patient experienced convulsions and had to be hospitalized (the length of the hospitalisation was unspecified). Physician reported that the patient was not going to received the second and third dose due to the experience. At the time of reporting the patient had recovered, and stated, "the patient is fine now." Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330587-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Oct-2008	25-Oct-2008	9	29-Oct-2008	10-Nov-2008	OK		14-Dec-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0947X	0	Right arm	Intramuscular	
FLU	NOVARTIS VACCINES AND DIAGNOSTICS	8788202	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Breast pain, Conversion disorder, Depression, Gait disturbance, Grip strength decreased, Hemiparesis, Sensory loss, Tremor, Vaginal erosion, Vomiting

Symptom Text: Patient was seen 10/16/08 for Well Teen Exam, given Gardasil and flu shot. Patient developed tremors, weaknesss, decreased sensation, hysteria on 10/25/08, went to ER had extensive lab, drug screening and CT of head - all WNL. Followed up with PCP on 10/27/08 - inital neuro exam showed decreased sensation bilateral hands and grip strength and abnormal gait. Patients right leg appeared weak with tremors primarily on right side. Patient appeared to be depressed. Patient has follow-up on 10/30/08, MRI of brain and neck pending, neuro consult also pending. 12/11/08-records received-office visit 11/8/07-requested testing for disease, vomited day before C/O breast pain left side times 2 days, C/O bumps in vaginal area times 2 weeks. Denies sexual activity. Assessment:URI. 10/16/08 C/O stuffy nose. 10/27/08C/O tremors shaking onset began Friday. DX hysteria with tremor. Dragging right foot. 10/20/08. Improved denies shaking weakness. Does not remember events of Friday.

Other Meds: None

Lab Data: CT of head, drug screen and lab - all WNL 12/11/08-records received-CT no abnormality. MRI of brain pending.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **330648-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Oct-2008	10-Oct-2008	0	29-Oct-2008	11-Feb-2009	CT		25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Dizziness, Flank pain, Nasal congestion, Nausea, Wheezing

Symptom Text: Nausea, dizzy, diarrhea, flank pain, nasal congestion, and wheezing.

Other Meds: Advair, Singulair, Flonase, Ventolin HFA

Lab Data:

History: Asthma, Eczema, multiple food allergies

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **330652-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jun-2008	Unknown		17-Oct-2008	13-Feb-2009	--	WAES0809USA04848	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a consumer concerning a 15 year old female with asthma and an allergy to BACTRIM who on 01-JUN-2008 was vaccinated with the first dose of GARDASIL. Concomitant therapy included montelukast sodium (MSD) and ZYRTEC. The patient developed hives after getting the vaccine. Medical attention was sought. On an unspecified date, she recovered. She was yet to receive her second shot. No further information is available.

Other Meds: ZYRTEC; SINGULAIR

Lab Data: Unknown

History:

Prex Illness: Asthma; Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330653-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	02-May-2008	Unknown		17-Oct-2008	13-Feb-2009	GA	WAES0809USA04652	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Skin papilloma

Symptom Text: Information has been received from a registered nurse concerning a 16 year old female with allergic reaction to minocycline, and warts, who on 02-MAY-2008 was vaccinated with the first dose of GARDASIL, 0.5 milliliter, intramuscular. The patient had one or two warts at the time of vaccination. Concomitant therapy included MENACTRA and diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid. Since the first vaccination with GARDASIL, the patient developed 40 leg warts and she sought medical attention to a dermatologist for the wart removal. No exact time frame for the development of the warts was available. The mother of the patient did not want her daughter to receive the second dose of GARDASIL and the patient had not received the second dose at the time of the report. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Allergic reaction to antibiotics; Wart

Prex Vax Illns:

Vaers Id: **330654-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	24-Sep-2008	25-Sep-2008	1	17-Oct-2008	13-Feb-2009	--	WAES0809USA04654	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Injection site erythema, Rash macular

Symptom Text: Information has been received from a physician concerning a 22 year old female with anxiety who on 24-SEP-2008 was administered the second dose of GARDASIL, 0.5 mL, IM (Lot# 659184/0843X). On 25-SEP-2008, the patient developed redness at the injection site, blotchiness and red streaks down her entire arm. Subsequently, the patient recovered from the symptoms on 25-SEP-2008. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Anxiety

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330655-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	26-Aug-2008	26-Aug-2008	0	17-Oct-2008	13-Feb-2009	WA	WAES0809USA04658	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Visual impairment

Symptom Text: Information has been received from a physician concerning a 23 year old health female who on 26-AUG-2008 was vaccinated with the first dose of GARDASIL (lot# 660555/0279X). Concomitant therapy included DEPO-PROVERA (not administered with GARDASIL). Later that day, on 26-AUG-2008, the patient had dizzy spells and vision changes lasting for 2 weeks. She had no headache. The patient's blood sugar was normal. She reported these symptoms to the physician after they had already resolved. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: blood glucose, normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **330656-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	08-Sep-2008	08-Sep-2008	0	30-Oct-2008	11-Feb-2009	--	WAES0809USA04665	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0573X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Musculoskeletal pain, Pain in extremity

Symptom Text: Information has been received from a registered nurse concerning a female with a history of hernia and no drug allergies reported who on 08-Sep-2008 was vaccinated with the first dose of GARDASIL (lot # 0573X), 0.5 mL, IM. There was no concomitant medication. On 08-Sep-2008, after vaccination, the patient experienced pain at injection site. On around 12-Sep-2008, the patient developed shoulder pain. At the time of the report, on 26-Sep-2008, the patient was having constant pain on right arm. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: NONE

Lab Data:

History: Hernia

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330657-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		30-Oct-2008	11-Feb-2009	--	WAES0809USA04674	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chronic fatigue syndrome

Symptom Text: Information has been received from a registered nurse, who was told by one of her patients that a female patient who an unknown date was vaccinated with a dose of GARDASIL. Subsequently, the patient developed chronic fatigue syndrome. At the time of reporting, the patient's chronic fatigue syndrome persisted. There was no product quality complaint. This is one of several reports provided by the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330658-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		30-Oct-2008	11-Feb-2009	--	WAES0809USA04675	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chronic fatigue syndrome

Symptom Text: Information has been received from a registered nursed, who was told by one of her patients that a female patient who an unknown date was vaccinated with a dose of GARDASIL. Subsequently, the patient developed chronic fatigue syndrome. At the time reporting, the patient's chronic fatigue syndrome persisted. There was no product quality complaint. This one of several reports provided by the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330659-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	08-Sep-2008	Unknown		17-Oct-2008	16-Feb-2009	--	WAES0809USA04689	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0573X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Limb discomfort, Pain in extremity

Symptom Text: Information has been received from a nurse concerning a 25 year old female who on 08-SEP-2008 was vaccinated with her first dose of GARDASIL (LOT#: 0573X) 0.5mL intramuscularly. Subsequently the patient experienced a severe pain and discomfort in the whole arm that the injection was given in. No treatment requirement. The patient's injection site severe pain and discomfort in the whole arm persisted. The patient sought medical attention in the office on 26-SEP-2008 with continued pain. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330660-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Sep-2008	26-Sep-2008	0	30-Oct-2008	11-Feb-2009	--	WAES0809USA04704	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Unknown	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Syncope

Symptom Text: Information has been received from a medical assistant concerning a 14 year old female patient, who on 24-Sep-2008 was vaccinated with the first dose of GARDASIL, 0.5 mL, IM. On 26-Sep-2008, the patient was vaccinated with the second dose of GARDASIL, Lot# 660557/0072X, 0.5 mL, IM, earlier than recommended and she fainted on the second dose. Approximately 10 minutes after the second dose, that patient briefly fainted. On 26-Sep-2008, the patient recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **330661-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Oct-2008	16-Feb-2009	FL	WAES0809USA04788	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a patient who on an unknown date, was vaccinated with the first dose of GARDASIL. On an unknown date, after receiving the vaccine, the patient fainted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330662-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	23-Sep-2008	Unknown		30-Oct-2008	11-Feb-2009	--	WAES0809USA04795	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Initial information was received from a consumer concerning her daughter who on 08-JUL-2008, was vaccinated with the first dose of GARDASIL. On 23-SEP-2008, the patient was vaccinated with the second dose of GARDASIL. The mother reported that her daughter received her second dose of GARDASIL due to being on antibiotics. The mother did not wish to document the experience. No farther information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330663-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Oct-2008	16-Feb-2009	--	WAES0809USA04813	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from an unspecified source concerning a patient who was vaccinated with a dose GARDASIL. Subsequently, the patient indicated that "the shot really does hurt! It hurts a lot going in, and then it fades quickly." No details on date of administration. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330664-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
33.0	F	01-Jul-2008	01-Jul-2008	0	17-Oct-2008	16-Feb-2009	OH	WAES0809USA04822	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Inappropriate schedule of drug administration, Migraine

Symptom Text: Information has been received from a health professional concerning a 33 year old white day care female with no known drug allergies/reactions and no pertinent medical history reported who on 01-JUL-2008 was vaccinated the first dose of with GARADSIL (lot # 660553/0070X) intramuscularly. There was no concomitant medication. On 02-JUL-2008, 4 hours after vaccination, the patient experienced migraine and headache. The patient did not seek medical attention. Subsequently, on 04-JUL-2008, the patient recovered from migraine and headache. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330665-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Jul-2008	24-Jul-2008	0	17-Oct-2008	16-Feb-2009	OH	WAES0809USA04823	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2421AA	0	Right arm	Unknown	
	DTAP	SANOFI PASTEUR	C2688AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1757U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injection site pain, Rash

Symptom Text: Information has been received from a health professional concerning a 14 year old white female who on 24-JUL-2008, at 10:30, was vaccinated with the first dose of GARDASIL Lot # 659182/1757U, into the left arm, DAPTACEL, Lot # C2688AA, into the left arm and MENACTRA, Lot # U2421AA, into the right arm. It was reported that on 24-JUL-2008 at 4:00 PM, the patient experienced rash down arm that had vaccine injected it lasted for several days. It was also pain at site of injection at the time of administration. On 26-JUL-2008, the patient recovered. Additional information is not expected.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **330666-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		17-Oct-2008	16-Feb-2009	--	WAES0809USA04854	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a physical therapist concerning a friend's daughter, a 19 year old female who was vaccinated with 3 doses of GARDASIL. It was reported that the patient had alopecia. The patient lost her eyebrows, eyelashes and was completely bald. At the time of the report the patient had not recovered. It was unknown if the patient sought medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330667-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
36.0	F	23-Jul-2008	23-Jul-2008	0	17-Oct-2008	16-Feb-2009	MA	WAES0809USA04859	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Immediate post-injection reaction, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a 36 year old female who on 23-JUL-2008 was vaccinated with her second dose of GARDASIL 0.5mL intramuscularly. "Immediately after dose" (on 23-JUL-2008) the patient reported hair loss. The patient's hair loss persisted. The patient did not seek medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330668-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	10-Sep-2008	11-Sep-2008	1	17-Oct-2008	11-Feb-2009	IN	WAES0809USA04850	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza

Symptom Text: Information has been received from a nurse concerning a 13 year old female who on 10-SEP-2008 was vaccinated with her first dose of GARDASIL 0.5ml, intramuscularly. On 11-Sep-2008, the patient's mother reported that the patient developed flu symptoms after vaccination. The outcome of the patient was not reported. The patient sought medical attention by phone. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **330669-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	07-Aug-2008	07-Aug-2008	0	30-Oct-2008	10-Feb-2009	WI	WAES0809USA04879	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Nausea

Symptom Text: Information has been received from an LPN for the Pregnancy Registry for HPV vaccine concerning a 24 year old female with attention deficit/hyperactivity disorder, who on 07-AUG-2008 was vaccinated with the first dose of GARDASIL (lot# 0250X). On 11-SEP-2008, the patient found out she was pregnant and on 26-SEP-2008, she confirmed that she was 10 weeks pregnant with a ultrasound performed that showed intrauterine pregnancy. The patient's LMP was approximately on 18-JUL-2008 and EDD 24-APR-2009. She subsequently took prenatal vitamins for pregnancy health and vitamin B for nausea. This was her first pregnancy. No further information is available.

Other Meds: Unknown

Lab Data: ultrasound, 09/26/08, Intrauterine pregnancy

History:

Prex Illness: Pregnancy NOS (LMP = 07/18/2008) Attention deficit/hyperactivity disorder

Prex Vax Illns:

Vaers Id: **330670-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	01-Apr-2008		17-Oct-2008	30-Dec-2008	--	WAES0809USA04910	31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Madarosis

Symptom Text: Information has been received from a medical assistant concerning her neighbor's 19 year old daughter who received 3 doses of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). In the spring of 2008, in approximately April 2008, her hair started to fall out. By August 2008, she was completely bald and had no eyelashes or eyebrows. He mother stated that the physician said that it may have been caused by GARDASIL. The daughter is not a patient at the practice where the medical assistant works. The patient sought medical attention. At the time of the reporting, the outcome of the patient was unknown. No further information is available.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330671-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Apr-2008	Unknown		17-Oct-2008	11-Feb-2009	AR	WAES0809USA04924	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Biopsy skin, Skin papilloma

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 23-APR-2008 was vaccinated with the third dose of GARDASIL. The physician reported that after the patient's last dose of GARDASIL the patient experienced skin warts that were all over her body cleared up. Biopsy of skin warts were performed. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330672-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jun-2008	01-Jun-2008	0	17-Oct-2008	11-Feb-2009	--	WAES0809USA04925	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Computerised tomogram normal, Head discomfort, Headache, Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from a nurse concerning a female who was vaccinated with the second dose of GARDASIL 0.5ml, and experienced some chest pain and some symptoms. In June 2008, the patient was vaccinated with the third dose of GARDASIL 0.5ml . After receiving the third dose, in approximately June 2008 the patient developed chest pain, headache, sharp pain behind her right ear and numbness and tingling on her head. A chest X-ray and CAT scan were performed but the results came back normal. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Chest X-ray - normal; Computed axial - normal;

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330673-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Aug-2008	01-Aug-2008	0	17-Oct-2008	11-Feb-2009	CA	WAES0809USA04942	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a physician concerning a 19 year old female with no known drug or food allergies who in August 2008, was vaccinated with the first dose of GARDASIL, and two days later experienced a generalized rash. The rash had not yet resolved. The patient was being treated with BENADRYL. The patient sought medical attention and called the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330674-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Aug-2008	Unknown		17-Oct-2008	12-Feb-2009	CA	WAES0809USA04950	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a physician concerning a 23 year old female who about 5 weeks ago, in approximately August 2008, was vaccinated with an unspecified dose of GARDASIL (lot#0250X), intramuscularly. Subsequently on an unspecified date, the patient experienced severe arm pain at the site of her last GARDASIL vaccination. The patient sought medical attention in the office. At the time of reporting her symptoms had continued. This is one of two reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330675-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jun-2008	19-Jun-2008	3	17-Oct-2008	12-Feb-2009	GA	WAES0809USA04952	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bronchial hyperreactivity, Constipation, Croup infectious, Cytomegalovirus infection, Fatigue, Hot flush, Leukopenia, Lymphadenopathy, Malaise, Myalgia, Petechiae, Pyrexia, Splenomegaly, Urticaria, Viral infection

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 14-APR-2008 was vaccinated with the first dose of GARDASIL. On 16-JUN-2008, the patient was vaccinated with a second dose of GARDASIL. Patient then went to the emergency room on 19JUN-2008. It was unspecified if the patient was hospitalized that day. The next day, on 20-JUN-2008, the patient came in the physician's office with petechial rash, hot flashes and muscle pain. The office did a complete blood count, high mono, and esosithil count, and a high alcoholine phosphate count. The next visit was on 21-JUN-2008; the patient had no bleeding but had a low white count and petechial rash on legs. On 23-JUN-2008, the patient's spleen tip was enlarged. The patient physician gave the patient a possible diagnosis of Ehrlichiosis. The patient was ordered a complete blood count(CBC), serum antinuclear antibodies test (ANA) and anti- DNA testing. The patient was tested for cytomegalovirus, rheumatoid factor, and Rocky Mountain spotted fever. A complete blood count showed low white count, negative serum antinuclear antibodies test (ANA) and normal rheumatoid factor (RF). Cytomegalovirus test (CMV) came back low white count; negative serum antinuclear antibodies test (ANA), and normal rheumatoid factor. Cytomegalovirus test (CMV) came back high, erichias, West Nile and Rocky Mountain spotted fever came back negative. Epstein-Barr came back high at 5.31. On 09-JUL-2008, the patient's rash was still present. On 14-JUL-2008, the patient had hives on her arms, constipation, and positive cytomegalovirus test. At this point the patient was referred to the infectious disease specialist. On 23-JUL-2008, the infectious disease physician ordered the patient not to receive the third dose of GARDASIL. The patient's history of persistent malaise, fatigue, and low platelet count had resolved by 09-JUL-2008. Additional information has been requested. 11/4/08 Reviewed PCP medical records of 6/16-7/29/2008. FINAL DX: none provided Records reveal patien

Other Meds: Unknown

Lab Data: Diagnostic laboratory 06/21/08 - low white count ; Diagnostic laboratory 06/20/08 - See narrative ; Diagnostic laboratory 06/23/08 - Erichiaa, West Nile and Rocky Mountain spotted fever negative ; Complete blood cell 06/20/2008 - no growth;

History: Unknown PMH: allergy: cephalasporin

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330676-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	24-Sep-2008	28-Sep-2008	4	17-Oct-2008	13-Feb-2009	--	WAES0809USA04963	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Nasal congestion, Nasopharyngitis, Pain, Pain in extremity, Pyrexia

Symptom Text: Information has been received from a 22 year old female patient with allergy reaction from to antibiotic, who on 30-JUN-2008 was vaccinated with the first dose of GARDASIL. On approximately 24-SEP-2008, the patient received her second dose of GARDASIL. There was no concomitant medications. On 28-SEP-2008, the patient woke up with stuffy nose, cough, fever, and general body aches. The patient did mention that her family recently had suffered from cold symptoms as well and she may have picked it from them. She did not had a similar reaction after the first dose of GARDASIL. The patient also stated that her arm was still a little sore. The patient sought unspecified medical attention. At the time of the report the patient had not recovered. No further information is expected.

Other Meds: None

Lab Data: None

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **330677-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Aug-2008	01-Aug-2008	0	17-Oct-2008	13-Feb-2009	NY	WAES0809USA04970	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a physician concerning a female who in August 2008, was vaccinated with the first dose of GARDASIL. In August 2008, the patient experienced pain for one month in the arm she received the injection. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330678-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Mar-2008	01-Mar-2008	0	17-Oct-2008	13-Feb-2009	--	WAES0809USA05038	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia, Underdose

Symptom Text: Information has received from a general practitioner concerning a 16 year female in good health with a history of blood pressure increased 2 years ago who in January 2008, was vaccinated with the first dose of GARDASIL. No adverse effect. In March 2008, the patient was vaccinated with a second dose of GARDASIL. 24 hours after the second dose of GARDASIL in March 2008, the patient experienced severe fever 40 deg C during two days. There was no associated symptoms. She had some Paracetamol. In March 2008, she also had blood pressure at 15/8. In September 2008, the patient received only half of the third dose of GARDASIL. There was an under dose. In September 2008, the patient had blood pressure at 15/9. she had no concomitant treatment. She had recovered on an unspecified date. Other business partner numbers included: EZ008-08727 and E2008-0B737. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Blood pressure increased

Prex Illness:

Prex Vax Illns:

Vaers Id: **330679-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-Jul-2008	09-Jul-2008	0	17-Oct-2008	13-Feb-2009	NY	WAES0810USA00028	04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	IPV	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0067X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Cold sweat, Myalgia, Pyrexia

Symptom Text: Information has been received from a physician concerning a 13 year old female patient with asthma, peanut allergy, shellfish allergy, Ipratropium (Atrovent) allergy, and ibuprofen (Motrin) allergy who on 09-Jul-2008 was vaccinated with the first dose of GARDASIL (lot# 660393/ 0067X). 0.5ml, intramuscularly. Concomitant therapy included unspecified asthma drug. The physician stated that on 09-Jul-2009, the patient developed muscle ache, weakness, clammy hands and was feverish for five hours after receiving GARDASIL. The physician reported that the patient received VERO, DTAP at the same office visit. No other symptoms reported. On 10-Jul-2008 the patient had recovered. Additional information has been requested.

Other Meds: Therapy unspecified

Lab Data: None

History:

Prex Illness: Peanut allergy; Shellfish allergy; Hypersensitivity ; Hypersensitivity; Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330680-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	16-Sep-2008	28-Sep-2008	12	17-Oct-2008	13-Feb-2009	TN	WAES0810USA00038	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	AHAVB289AA	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0573X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Joint effusion, Muscular weakness, Myalgia

Symptom Text: Information has been received from a mother of a 14 year old female patient with no known medical history and no known drug allergies, who on 16-Sep-2008 was vaccinated with the first dose of GARDASIL . Concomitant therapy included HEP A vaccine and Lisdexamfetamine Dimesylate. The mother reported that on the night of 28-Sep-2008, her daughter's knees felt very weak. The mother also reported that on 29-Sep-2008, her daughter went to school, then around 12:30 pm she had came home from school because the weakness moved from knees to her thighs and she felt like she didn't have knees and she was going to fall over. The mother reported that on 29-Sep-2008 her daughter went to her pediatrician who did strength test on her legs but her strength was fine, and she did say she had some fluid in her right knee but her knee was not hot. The mother reported that the physician was not sure what was causing the symptoms since the patients activities did not change, but stated to give it 72 hours and if nothing had changed the patient had come back and get blood work done. The mother also reported that on 29-Sep-2008 her daughter did stay home from school. The patient sought medical attention. At the time of the report the patient had not recovered. Additional information has been requested. 11/4/2008 PCP records received. Healthy with no problems noted at WCC 9/16/08. Vax given. Returned 9/29/08 with c/o joint/muscle pain and weakness. Tx ibuprofen and rest. Pt has recovered.

Other Meds: VYVANSE

Lab Data: Diagnostic procedure 09/29/08 - Strength was fine

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **330684-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	09-Sep-2008	Unknown		30-Oct-2008	31-Oct-2008	NY	WAES0810USA04493	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion

Symptom Text: Information has been received from a physician concerning a 20 year old female with seizures and a history of brain surgery within the past few months who on about 1 & 1/2 month ago (approximately 09-Sep-2008) was vaccinated intramuscularly with the first dose of GARDASIL (0.5 mL, lot# and injection site not reported). The patient informed office that she had an increased frequency of seizures post-GARDASIL. No information is available about any single occurrences. The patient informed the office of the seizures during a follow-up visit, when she may have received the 2nd dose of GARDASIL. Physician believes that the seizures are not related to GARDASIL. At the time of the report (24-Oct-2008) the symptom of seizures is stable. Upon internal review, seizures determined to be other important medical events. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Brain operation

Prex Illness: Convulsion

Prex Vax Illns:

Vaers Id: **330686-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		30-Oct-2008	31-Oct-2008	--	WAES0810USA04390	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who on unspecified dates was given all three dose of GARDASIL during pregnancy. Concomitant therapy included MENACTRA. The nurse practitioner was not informed of the pregnancy until the patient was 6 months pregnant. On an unspecified date, the patient had a miscarriage. It was not sure how far into the pregnancy when the miscarriage took place. Upon internal review, the miscarriage was considered to be an other important medical event (OME). Additional information has been requested.

Other Meds: MENACTRA

Lab Data:

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330687-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	20-Oct-2008	20-Oct-2008	0	30-Oct-2008	31-Oct-2008	TX	WAES0810USA04333	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse concerning a 19 year old female with no pertinent medical history, allergies or drug reactions, who on 20-OCT-2008 was vaccinated with the first dose of GARDASIL (lot no. 661044/0548X) 0.5 ml, IM. There was no concomitant medication. On 20-OCT-2008, two hours after vaccination, the patient had a seizure. The patient had no history of seizures. The nurse thought the patient may have gone to the emergency room. The physician had attempted to reach the patient's mother but has not gotten in touch with her yet. Upon internal review seizure was considered to be other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 330688-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Oct-2008	22-Oct-2008	0	30-Oct-2008	31-Oct-2008	--	WAES0810USA04308	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Consciousness fluctuating, Feeling cold, Heart rate decreased, Hypersensitivity, Immediate post-injection reaction, Inappropriate schedule of drug administration, Unresponsive to stimuli

Symptom Text: Information has been received from a physician concerning a 17 year old female patient with no previous medical history and allergies reported, who on 06-JUN-2007 was vaccinated with the first dose of GARDASIL 0.5 mL. On 22-OCT-2008, the patient was vaccinated with the second dose of GARDASIL (Lot # not provided) 0.5 mL. On 22-OCT-2008, the patient developed severe allergic reactions like unresponsiveness, in and out consciousness, heart rate down to 62 and cold immediately. On an unknown date, the patient recovered. The patient sought unspecified medical attention. The patient's adverse events were considered to be immediately life-threatening by the physician. Additional information is expected.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **330690-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Feb-2008	02-Feb-2008	1	30-Oct-2008	31-Oct-2008	FR	WAES0810USA04199	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Fatigue, Musculoskeletal chest pain, Pruritus, Skin lesion, Syncope, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a general practitioner concerning a 15 year old female who received the first dose of GARDASIL (batch number not reported) in February 2008. Twenty four hours after the injection the patient experienced syncope, arthralgia, vomiting, fatigue, intercostal pain and pruritus which turned into scratching lesions. Afterward, she presented with syncope or dizziness exercise induced. The patient partially recovered and on 06-MAY-2008 she received the second dose of GARDASIL (batch number not reported). She had the same symptoms 24 hours after the second dose of GARDASIL (on 07-MAY-2008). At the time of reporting the patient was recovering besides persisting intercostal pain. To be mentioned that the patient had to miss school to stay confined to bed to recover from fatigue. Cardiological, rheumatological and neurological work-up were negative. There was no prescribed treatment. The case was considered as serious by the reporter due to other medically important condition. Other business partner included: E2008-09832. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, cardiological, rheumatological and neurological work-up: negative

History: Syncope; Arthralgia; Vomiting; Fatigue; Intercostal pain; Dizziness; Pruritus

Prex Illness:

Prex Vax Illns:

Vaers Id: 330691-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Aug-2008	06-Aug-2008	0	30-Oct-2008	31-Oct-2008	ID	WAES0810USA04117	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Alopecia, Appendicectomy, Appendicitis, Arthralgia, Back pain, Cough, Fatigue, Vomiting

Symptom Text: Information has been received from a consumer, who is the mother of the patient, concerning her 14 year old daughter with sulfonamide allergy and a history of hypersensitivity who on 06-AUG-2008 or 08-AUG-2008 was vaccinated with GARDASIL for her first dose. Concomitant therapy included montelukast sodium, (MSD), allergy shots once a week and ZYRTEC. "A few days after receiving GARDASIL" the patient started to throw up once a week, was coughing and was losing her hair all over. Then the patient started to have knee and back pain and then had gone to the emergency room on 28-SEP-2008. At the hospital the patient was diagnosed with appendicitis and had emergency surgery to have her appendix removed. The patient had been in hospital from 28-SEP-2008 to the following Monday. The patient was still feeling tired, but she was recovering. No further adverse effect information was provided. Additional information has been requested.

Other Meds: Allergenic extract; ZYRTEC; SINGULAIR

Lab Data:

History:

Prex Illness: Sulfonamide allergy; Hypersensitivity

Prex Vax Illns:

Vaers Id: **330692-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Sep-2008	30-Sep-2008	0	30-Oct-2008	31-Oct-2008	CA	WAES0810USA03748	31-Oct-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Conjunctivitis, Drug exposure during pregnancy

Symptom Text: Information has been received, for the Pregnancy Registry for GARDASIL (lot number #660393/0067X), from a 15 year old female with a history of anxiety attacks and latent tuberculosis infection (+PPD, negative chest X-ray) and concurrent medical condition of cold who was vaccinated with the second dose of GARDASIL on 30-SEP-2008. Other medication used during this pregnancy included MOTRIN, POLYTRIM, ZOLOFT, SUDAFED and prenatal vitamins (unspecified). It was subsequently learned that the patient was pregnant at the time. Her LMP was 02-SEP-2008. A pregnancy test was performed. On 28-JUL-2008, urine HCG test was negative. On 17-OCT-2008 urine HCG was faint positive and serum HCG was positive (126.7). The patient experienced spontaneous abortion on 22-OCT-2008. The duration from LMP to abortion was more than 7 weeks. The patient sought unspecified medical attention. Follow-up information has been received from a physician who reported that the patient received the second dose of GARDASIL On 30-SEP-2008. It was reported that the patient had history of latent tuberculosis infection and concurrent medical condition of cold. The patient took isoniazid for the treatment of tuberculosis. During this pregnancy the patient took MOTRIN, POLYTRIM drops for the treatment of conjunctivitis, ZOLOFT for the treatment of depression, SUDAFED for the treatment of cold and prenatal vitamins (unspecified). On 22-OCT-2008 the patient experienced spontaneous abortion. Upon internal review, spontaneous abortion was considered to be a other important medical event. Additional information has been requested.

Other Meds: MOTRIN; POLYTRIM; ZOLOFT; SUDAFED; Prenatal Vitamins (unspecified)

Lab Data: Urine beta-human, 07/28/08, negative; Urine beta-human, 10/17/08, faint positive; Serum beta-human, 10/17/08, 126.7, positive

History: Anxiety attack; Latent tuberculosis

Prex Illness: Pregnancy NOS (LMP = 9/2/2008); Depression; Cold

Prex Vax Illns:

Vaers Id: **330702-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Oct-2008	22-Oct-2008	0	30-Oct-2008	27-Jan-2009	MT		27-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2806AA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Fainted after GARDASIL #1 within 5 min of admin - then moved from chair to bed without problems. Recovered within 20 min - no further problems reported.

Other Meds:

Lab Data:

History: None reported

Prex Illness: None reported

Prex Vax Illns: 10/22/2008~HPV (no brand name)~1~15~In Sibling

Vaers Id: **330703-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Oct-2008	22-Oct-2008	0	30-Oct-2008	27-Jan-2009	MT		03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2806AA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope

Symptom Text: Nearly fainted after GARDASIL #1 (After watching sister faint). Recovered within 10 min of laying down - Did not lose consciousness.

Other Meds:

Lab Data:

History: None reported

Prex Illness: None reported

Prex Vax Illns: 10/22/2008~HPV (Gardasil)~1~16~In Sibling

Vaers Id: 330730-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	07-Dec-2007	07-Dec-2007	0	30-Oct-2008	11-Feb-2009	CA	WAES0810USA00045	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for GARDASIL, concerning a 26 year old female with mild asthma, cervical dysplasia and migraine and no history of pervious pregnancies who on 10-SEP-2007 was vaccinated with the first dose of GARDASIL (lot# 657868/05230). On 07-DEC-2007, the patient was vaccinated with a second dose of GARDASIL. Concomitant therapy included prenatal vitamins (unspecified) daily for routine health maintenance. Subsequently, she became pregnant on approximately 20-NOV-2008 (LMP: 06-NOV-2007, estimated delivery date: 12-AUG-2008). On 05-FEB-2008, as routine screening a serum alpha-fetoprotein test (MSAFP) was performed at first trimester and the results showed low risk pregnancy. On 06-MAR-2008, as routine screening a modified serum MSAFP was performed and the result was negative. On 10-Mar-2008, was performed to the patient an ultrasound as routine screening which showed normal anatomy. On 29-JUL-2008, the patient delivered a normal, healthy female baby at 38 weeks from LMP. The baby had a face presentation at time of delivery (mal presentation). The baby's weight was 2977 grams, with a length of 18 inches, apgar score was 9/9 and a head circumference of 34. Additional information has been requested.

Other Meds: vitamins

Lab Data: ultrasound, 03/10/08, normal anatomy: routine screen; serum alpha-fetoprotein, 02/05/08, 1st trimester screen: low risk x 2. routine screening; serum alpha-fetoprotein, 03/05/08, modified MSAPP: Negative x 2. Routine screening

History:

Prex Illness: Pregnancy NOS (LMP = 11/06/2007); Asthma; Cervical dysplasia; Migraines; Routine health maintenance

Prex Vax Illns:

Vaers Id: **330731-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Apr-2007	23-Sep-2008	541	30-Oct-2008	11-Feb-2009	--	WAES0810USA00048	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a consumer concerning her 23 year old daughter who on an unknown dates was vaccinated with the three doses of GARDASIL was given in April 2007. There was no concomitant medications. On approximately 23-Sep-2008, the patient had a Papanicolaou test positive. As of 29-Sep-2008, the patient had not recovered. Further testing must be done pertaining to positive PAP test. The patient sought unspecified medical attention. No additional information is expected.

Other Meds: NONE

Lab Data: Pap test, 09/23/2008, positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330732-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		17-Oct-2008	11-Feb-2009	--	WAES0810USA00055	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash, Urticaria, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse practitioner concerning a 13 year old female who on an unknown dates was vaccinated with the three doses of GARDASIL. It was reported by the nurse that the patient developed reaction after each of the doses. On an unknown date, after the first dose the patient developed small rash at the injection site. On an unknown date, after the second dose, the patient developed a "bigger" reaction at the injection site. On an unknown date, after the third dose, the patient developed hives all over her body. The patient was given medication for the reaction. The patient was see by an allergist who determined that the reaction was due to the vaccine. On an unknown date, the patient recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330733-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	01-Aug-2007	09-Sep-2008	405	17-Oct-2008	11-Feb-2009	--	WAES0810USA00056	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysplasia

Symptom Text: Information has been received from a consumer concerning her 26 year old daughter who in 2007 was vaccinated with the three doses of GARDASIL third dose was in August 2007. There was no concomitant medication. On approximately 09-Sep-2008, the patient had a Papanicolaou test positive and revealed mild dysplasia. As of 30-Sep-2008, the patient had not recovered. The patient sought unspecified medical attention. No additional information is expected.

Other Meds: unknown

Lab Data: Pap test, 09/09/2008, positive, mild dysplasia

History: Unknown

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **330734-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	24-Sep-2008	25-Sep-2008	1	17-Oct-2008	17-Feb-2009	--	WAES0810USA00064	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Axillary pain, Injection site induration, Injection site swelling, Musculoskeletal pain, Pain in extremity

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female patient who on 24-SEP-2008 was vaccinated with the first dose of GARDASIL 0.5ml. There was no concomitant medication. On 25-Sep-2008, the patient experienced pain in the arm, also in her shoulder and axillary area. She was seen in the office, date not provided, with a hard lump and swelling at the site. No treatment required. The patient not had any labs test done. There was no product quality complaint. Additional information is expected.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330737-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Mar-2008	06-Mar-2008	2	17-Oct-2008	17-Feb-2009	NJ	WAES0810USA00091	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Feeling hot, Oedema peripheral, Rash, Urticaria

Symptom Text: Information has been received from a mother concerning her 16 year old daughter with allergy to Amoxicillin no pertinent medical history and no concomitant therapy reported, who on 04-Mar-2008 was vaccinated with the first dose of GARDASIL 0.5ml and experienced swelling, redness and feeling hot from her shoulder to elbow in the injection arm. On 09-May-2008 received her second dose of GARDASIL 0.5ml and experienced rash and hives which have not gone away. On 05-Sep-2008, received the third dose of GARDASIL 0.5ml and experienced her arm swelling again. The patient sought medical attention, physician. At the time of the reporting the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **330738-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Sep-2008	29-Sep-2008	2	17-Oct-2008	17-Feb-2009	NY	WAES0810USA00092	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Malaise, Nausea, Pyrexia, Vomiting

Symptom Text: Information has been received from a physician concerning a 20 year old female who is July 2008, was vaccinated with the first dose of GARDASIL (lot# 660555/ 0279X) and on 27-SEP-2008 was vaccinated with the second dose of GARDASIL (lot# 661044/0548X). On 29-Sep-2008 the patient began to feel unwell with fever of 101.3 F. She later developed nausea, passed out and vomited once or twice. The patient sought medical attention, in office. At the time of reporting the patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330739-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	22-Sep-2008	Unknown		17-Oct-2008	17-Feb-2009	CA	WAES0810USA00122	04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0573X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a physician concerning a 27 year old female who about 1 week ago, on approximately 22-Sep-2008, was vaccinated with an unspecified dose of GARDASIL (lot#0373X), intramuscularly. Subsequently on an unspecified date the patient experienced sever arm pain at the site of her last GARDASIL vaccination. The patient sought medical attention in the office. At the time of reporting her symptoms had continued. This is one of two reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330741-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Aug-2008	01-Aug-2008	0	17-Oct-2008	17-Feb-2009	NY	WAES0810USA00876	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a 11 year old female who in August 2008, was vaccinated with the first dose of GARDASIL. In August 2008, the patient experienced hives. Subsequently, the patient recovered from the hives. The physician reported that the patient had recovered. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330767-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	30-Oct-2008	30-Oct-2008	0	30-Oct-2008	03-Dec-2008	MA		03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site rash, Rash erythematous, Rash macular

Symptom Text: Upon administration of HPV(Gardasil) #3, pt developed lacey, red, flat rash on upper arm at site and extending across upper neck and involving opposite upper arm. Occurred within seconds of injection. Benedryl 25 mg given po. Redness/rash improved after approx. 20 minutes with no further complaints.

Other Meds: seasonale,inderal,skelatin

Lab Data:

History: allergy:codeine.has hx migraines

Prex Illness: allergies (nasal stuffiness)

Prex Vax Illns:

Vaers Id: **330788-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	20-Aug-2007	20-Sep-2007	31	30-Oct-2008	04-Dec-2008	IL		23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Arthritis, Asthenia, Back pain, Chest pain, Contusion, Depressed mood, Discomfort, Fatigue, Hypokinesia, Mood altered, Musculoskeletal stiffness, Nausea, Oropharyngeal pain, Pain, Polyarthritis, Pyrexia, Sleep disorder, Stomach discomfort

Symptom Text: In September of 2007, one month after receiving the third installment of the Gardasil vaccine, I began to have joint pain and body aches. The pain increased through October and November. The joints throughout my body were inflamed, I had a fever, disruption of sleep due to pain and discomfort, and severe restriction in movement. Tests revealed that I had severe inflammation. I was treated with Prednisone and Methotrexate as a preventative measure for arthritis. The inflammation decreased following medication treatment. However, when the medicines are reduced the inflammation of joints returns. There was also calcification in my wrist joints following the inflammation, causing restriction in joint flexibility. 1/16/2009 MR received from Rheumatologist. DX: Polyarthritis. Pt initially presented 11/26/07 with c/o abrupt onset of pain-joint pain: hands, knees, PIP, MCP, wrists, feet, hips, shoulders, lumbosacral spine and cervical spine, morning stiffness x 2 hrs, sleep disturbance, low energy and feeling moody and depressed. Initially thought to be RA with (-) markers. C/o sore throats, H/As and mild upset stomach 12/6/07. Tx with anti-inflammatories, Pred and Methotrexate with some improvement, however worsening with reduced doses. Reported chest pain, nausea and bruising 1/8/08. Increased H/A, neck pain and knee tightness 3/08. Increased fatigue despite sleeping well 11/08. Pain improved.

Other Meds: Kariva Birth Control, Fexofenadine

Lab Data: High levels of inflammation throughout the body. Labs and Diagnostics: CRP 10.7 (H). MRI L wrist (+) for mild flexor tenosynovitis and synovitis, no erosions. R wrist US (-). RF (-). ANA (-). CCP IgG Ab (-). ESR 1.0.

History: Allergies (pollen, dust, mold, cat and dog dander), eczema. PMH: HPV.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **330805-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Oct-2008	30-Oct-2008	2	30-Oct-2008	10-Feb-2009	OH		10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Headache, Nausea

Symptom Text: Headache, mild nausea and fatigue. Since evening of vaccine - 10/28/08.

Other Meds:

Lab Data: CBC with diff, ordered 10/30/08

History: Headache; glucose impairment; Acanthosis nigricans; Amenorrhea; sleep apnea; Hyperlipidemia; Metabolic Syndrome

Prex Illness: Heartburn; GERD

Prex Vax Illns:

Vaers Id: **330812-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Oct-2008	24-Oct-2008	0	30-Oct-2008	27-Jan-2009	CA		27-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X		Unknown	Unknown	
	FLU	SANOFI PASTEUR	U2757AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Myalgia, Pyrexia

Symptom Text: Myalgias. Fevers. Headache.

Other Meds:

Lab Data:

History: Pectus excavatum; bee sting allergy

Prex Illness: Wart treated

Prex Vax Illns:

Vaers Id: **330838-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Oct-2008	30-Oct-2008	1	31-Oct-2008	27-Jan-2009	PA		27-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2804AA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0571X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cough, Eye swelling, Throat tightness

Symptom Text: During a break from basketball she looked in mirror and noted swelling around her eyes. At the same time she developed some cough and a "full" feeling in her throat. These symptoms subsided within 30-40 minutes but eyes still swollen in am 10/31/08. (Also had contact with a dog before basketball)

Other Meds:

Lab Data: None

History: Allergic Rhinitis; history of asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330840-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Oct-2008	28-Oct-2008	0	31-Oct-2008	11-Feb-2009	TX		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling abnormal, Immediate post-injection reaction, Unresponsive to stimuli, Vision blurred

Symptom Text: 30 seconds after GARDASIL vaccine was administered she complained of feeling weird. While in seated position she slumped forward was unresponsive for less than 3 seconds. Then stated she had blurred vision. Felt faint, was reclined to lying position with lower extremities elevated. Became aware and responsive, she was monitored for 15 min. Left office without complications.

Other Meds: YASMIN BCP, ADDERALL PRN

Lab Data:

History: ADHD

Prex Illness: none

Prex Vax Illns:

Vaers Id: 330843-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	09-Oct-2007	09-Apr-2008	183	31-Oct-2008	11-Feb-2009	CA		16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1264U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Activities of daily living impaired, Anorexia, Asthenia, Disturbance in attention, Epistaxis, Gastrooesophageal reflux disease, Hiatus hernia, Migraine, Nausea, Pain in extremity, Rash generalised, Thirst decreased, Vaccine positive rechallenge, Visual impairment, Vomiting

Symptom Text: My daughter became ill on April 9th, 2008, 4 months after her second vaccine of GARDICIL vaccine, with a rash all over her body. The following week, she began vomiting multiple times per day for over four weeks. From April 9th through June 28, 2008 she experiences severe migraines, bloody noses, complete lack of energy, loss of appetite, nausea, acid reflux, weak and ache legs, constant stomach pain, trouble with vision. She has has chest x-ray, abdominal ultrasound, CT of abdomen with contract, MRI of brain with contrast, upper GI, endoscope, BRAVO, EEG and colonoscopy. She was in the ER department due to nausea and unable to eat and drink. She was sent home after numerous tests that showed nothing. She was unable to attend school from April 21, 2008 through June 20, 2008 due to her is and was home schooled. She is currently under the care of a pediatric neurologist, pediatric gastrointestinal physician and an immunologist who are truing to elevate her symptoms with various medications. All medical tests have come back normal except for her having a small hiatal hernia. As quickly as her symptoms came on, they stopped on June 28th. She received her third GARDASIL vaccine on July 29th, 2008. A week later on August 6, 2008, her symptoms returned again, severe pain in the abdomen, nausea, loss of appetite, difficulty with vision and concentration. I will begin the paperwork again this week with her doctor to have her home schooled as she hasn't been able to attend school for the past two weeks. I have also included copies of her physician reports for your review. Medicine she has taken or is currently taking: REGLAN, CARAFATE, TOPAMAX, PREVACID.

Other Meds: None

Lab Data: Endoscope, blood turine, Xray, CT, MRI, EEG, Bravo, upper GI, colonscopy

History: None

Prex Illness: None, very healthy

Prex Vax Illns:

Vaers Id: **330848-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		31-Oct-2008	11-Feb-2009	OH		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	
	TDAP	SANOFI PASTEUR	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling abnormal, Immediate post-injection reaction, Syncope vasovagal

Symptom Text: Pt had syncope/vagal response after GARDISIL #3 and ADACEL. I was in the room with pt. as she was in mid sentence saying "she felt funny". Pt sitting on exam table and laid down about 20-30 sec returned to NL. Alert and oriented x 2. BP WNL. Pt without breakfast. Pt waited 20 minutes and was with nl exam-left office d/t finished. Pt states she passes out with shots.

Other Meds: LEXAPRO; oral birth control pills

Lab Data: BP 100/60 after leaving

History:

Prex Illness: Sinusitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330901-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-Apr-2008	10-Apr-2008	1	31-Oct-2008	03-Nov-2008	FR	WAES0810AUS00154	03-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Pancreatitis

Symptom Text: Information was obtained on request by the Company from the agency, via a tabulation and Public Case Details Form, concerning a 13 year old female who on 09-APR-2008 was vaccinated with her third dose of GARDASIL as prophylactic vaccination. On 10-APR-2008, one day post-vaccination, the patient experienced persistent epigastric pain without vomiting, anorexia or fevers. Epigastric pain worsened after two weeks at which time the patient's serum lipase level was found to be elevated at 1272 U/L, later peaking at 5920 U/L. The patient's liver function tests were normal and an abdominal ultrasound was normal. Subsequently, in April 2008 the patient was hospitalised for 10 days and treated with nil by mouth and nasojejunal feeding. The patient was discharged on oral fluids and NJ feeds. In May 2008, three weeks later, the patient was readmitted to hospital with 3 to 4 days of worsening abdominal pain. Her serum lipase level was elevated at 7944 U/L. A diagnosis of acute-on-chronic pancreatitis was made and the patient was hospitalised for eight weeks. Treatment was NJ feeding and then a low-fat diet. On 14-JUL-2008 the patient recovered from upper abdominal pain and pancreatitis. All investigations for the cause of the patient's pancreatitis have been normal. The agency considered that upper abdominal pain and pancreatitis were possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Abdominal ultrasound, ??Apr08, normal; Diagnostic pathological examination, ??May?08, all investigations for cause of pancreatitis were normal; Hepatic function tests, ??Apr08, normal; Serum lipase test, 24?Apr08, 1272 U/L, elevated; Serum

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **330902-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	15-Jul-2008	15-Jul-2008	0	31-Oct-2008	03-Nov-2008	FR	WAES0810AUS00156	03-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Back pain, Hyperhidrosis, Pancreatitis, Pyrexia

Symptom Text: Information was obtained on request by the Company from the agency via a tabulation and a Public Case Details Form, concerning a 19 year old female, with normal alcohol use, who in May 2008, was vaccinated with her first dose of GARDASIL as prophylactic vaccination. On 15-JUL-2008 the patient was vaccinated with her second dose of GARDASIL, intramuscularly. Subsequently, in July 2008 "after injection" with GARDASIL, the patient developed a fever and sweating, followed a week later by back and abdominal pain. Subsequently, the patient was hospitalised for four days, with a final diagnosis of pancreatitis. In July 2008 a computed tomography (CT) scan showed no organic cause for the patient's pancreatitis. On 07-AUG-2008 the patient recovered from pancreatitis. The agency considered that pancreatitis was possibly related to therapy with GARDASIL. Vaccination with GARDASIL was discontinued. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Computed axial tomography, 15?Jul08, no organic cause found for pancreatitis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 330903-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	04-Aug-2007	15-Oct-2007	72	31-Oct-2008	03-Nov-2008	FR	WAES0810AUS00156	03-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Biliary colic, Chest pain, Cholelithiasis, Gastroenteritis viral, Pancreatitis

Symptom Text: Information was obtained on request by the Company from the agency, via a table and Public Case Details form, concerning a 26 year old female who on 04-AUG-2007 was vaccinated with her first dose of GARDASIL as prophylactic vaccination. Concomitant long-term therapy included multivitamins (unspecified). On 06-OCT-2007 the patient was vaccinated with her second dose of GARDASIL. Subsequently, on 15-OCT-2007, the patient experienced abdominal pain and chest pain. The patient's general physician diagnosed viral gastroenteritis and the patient was treated symptomatically. In January 2008 the patient started therapy with MARVELON as oral contraception. In February 2008, (125 days post-vaccination with GARDASIL), the patient experienced severe abdominal pain and chest pain and was hospitalised. There was a reported diagnosis of pancreatitis - no test results are available. The patient's abdominal and chest pain settled with analgesics and IV fluids. On 17-APR-2008 the patient was vaccinated with her third dose of GARDASIL. Subsequently, on 20-APR-2008, three days post-vaccination with GARDASIL, the patient again experienced severe abdominal and chest pain. She was found to have an elevated serum amylase of 792 U/L. The patient was hospitalised and diagnosed with pancreatitis. An ultrasound showed no gallstones. The patient saw a gastroenterologist post-discharge who diagnosed biliary colic with pancreatitis. In May 2008 a computed tomography (CT) cholangiogram showed normal biliary system with layering in gallbladder consistent with very small calculi. In May 2008 a limited viral screen showed hepatitis C negative; Hepatitis BsAg negative and hepatitis A Ab positive. In September 2008 the patient's serum calcium and lipids were normal. In October 2008 a magnetic resonance cholangiopancreatography (MRCP) was completely normal, showing no pancreatic parenchymal or ductal abnormality and intrahepatic and extrahepatic biliary tree normal. The patient had no prior history of illness, abdominal pains, gallstones or pancreati

Other Meds: desogestrel/ethinyl estradiol, Jan08 - Unk; vitamins (unspecified), Unk - Cont

Lab Data: Diagnostic pathological examination, 01Feb08, reported diagnosis of pancreatitis - no test results are available; Ultrasound, ??Apr08, no gallstones; Computed axial tomography, ??May08, cholangiogram - normal biliary system with layering in

History:

Prex Illness: Contraception

Prex Vax Illns:

Vaers Id: **330904-1 (S)** **Related reports:** 330904-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	23-Sep-2008	18-Oct-2008	25	31-Oct-2008	03-Nov-2008	IN	WAES0810USA04481	13-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Autonomic nervous system imbalance, Bradycardia, Cardiac murmur, Chest pain, Convulsion, Dizziness, Dyskinesia, Gait disturbance, Gaze palsy, Hypoaesthesia, Hypotension, Loss of consciousness, Malaise, Night sweats, Orthostatic hypertension, Orthostatic hypotension, Palpitations, Phonophobia, Photophobia, Pleuritic pain, Somnolence, Speech disorder, Syncope, Unresponsive to stimuli, Urinary tract infection

Symptom Text: Information has been received from a nurse concerning a 19 year old female with a history of penicillin allergy who on 22-JAN-2008 was vaccinated with the first dose of GARDASIL (lot # 659653/1448U) via IM route. On 03-APR-2008 she receive the second dose (lot # 659964/1978U) and on 23-SEP-2008 received the third dose (lot #661044/0548X), both via IM route. Concomitant therapy included hormonal contraceptives (unspecified). The patient was hospitalized for possible cardiac problems after administration of 3 doses of GARDASIL. On 18-OCT-2008 the patient started to stagger and her speech became "funny" and 30 minutes later she passed out. The patient was transported to the hospital. Emergency medical technician determined patient developed bradycardia. She was admitted to hospital on 18-OCT-2008. As of the reporting time, she was still in the hospital. She was experiencing complex seizures and severe orthostatic hypertension. She was diagnosed with possible cardiac arrest and may need an implantable cardioverter defibrillator. On an unspecified date, the magnetic resonance imaging (MRI) showed normal results, electrocardiogram showed normal slow and toxicology screen was negative. The patient had not recovered. The reporter considered the events to be disabling, immediately life-threatening and to be other important medical events. A lot check has been requested. Additional information has been requested. 1/27/09 PCP records received including multiple diagnsotic studies from 10/2008 for syncope/unresponsiveness/bradycardia. In for annual exam 11/5/08. ROS note states "Drs think the problems she had were from a blood vessel in brain and reaction to meds" Not sure if Gardasil started the whole thing off. Exam WNL. 2/11/09 Tag2 received. 2/20/09 MR received for DOS 10/20-26/2008 with no definitive DX as pt was transferred to higher level of care for further w/u. Had been admitted with admission dx of syncopal episode with orthostatic hypotension and bradycardia. ER visit 12/2/08 with dx: seizure. Pt presente

Other Meds: hormonal contraceptives

Lab Data: magnetic resonance, normal; electrocardiogram, normal slow; blood drug screen, negative. Labs and Diagnostics: Head CT WNL CXR (+) for b/l upper lobe infiltrates/atelectasis. Transthoracic Echo (+) for trace mitral, tricuspid and pulmonic

History: PMH: appendectomy. recent stress. RSD R ankle. EIA. allergy to PCN

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **330904-2 (S)** **Related reports:** 330904-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	23-Sep-2008	18-Oct-2008	25	10-Feb-2009	16-Feb-2009	IN		16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anorexia, Aphasia, Convulsion, Deafness, Dizziness, Dyspnoea, Eye disorder, Fatigue, Headache, Heart rate decreased, Hypersomnia, Hypotension, Loss of consciousness, Malaise, Pain, Pain in extremity, Syncope, Trismus, Unresponsive to stimuli

Symptom Text: Right after she recieved her last Gardasil shot patient felt sick, severe headaches, dizzy, ached all over, not hungry, extremely tired her arm hurt. This lasted for 2-3 weeks. She thought she felt better and tried to go to work. Patient collapsed at work, found unresponsive, extremely low blood pressure, low heart rate, unable to start IV. Once in Ambo. they were able to start IV on the way to hospital they had to give more medicine to keep heart rate going. Rushed to Medical Center. In ER they cut off clothes called for crash cart were able to start central line. They did all tox screens nothing found in blood work up. Heart rate at 37 she was transferred to Progressive Cardiac Care unit. They started her on 2 medications. She started having seizures that lasted 3-5 minutes she had at least 12 in one day.When she stood up her heart rate would go to 180 and she would pass out or have seizure. She had multiple EEG's and EKG's and a few other test towards the end of the week her seizures went to 25-55 minutes in length. She was transfered to clinic by a Medivac ambulance. Once there she went thru a battery of test they found that the seizures were none epilectic in nature. Her seizure state was glassy eyes, trouble breathing, couldn't hear, mouth would lock, unable to talk throat would move rapidly. When the seizure was done she would sleep for a long time. The only thing patient had was the Gardasil HPV shot. She still has difficulty with her left arm. She was a healthy 19 year old girl until she had the shot.

Other Meds: birth control YAZ

Lab Data: Multiple EEG's and EKG's and blood work up

History: allergic to penicillin

Prex Illness: no

Prex Vax Illns:

Vaers Id: **330905-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	09-May-2008	Unknown		31-Oct-2008	03-Nov-2008	FR	WAES0810USA04618	03-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Systemic lupus erythematosus

Symptom Text: Information has been received from a Health Authority on 23-OCT-2008 under reference 2008-02178. It was reported by a obstetrician-gynaecologist on 09-MAY-2008 that a female patient (initials and age unknown) with no past medical history or concomitant condition reported received a dose of GARDASIL, lot number, site and route of administration not reported) on an unspecified date. On an unknown date she experienced a systemic lupus erythematous. Concomitant medication included YASMIN (batch number not reported). The patient was taking YASMIN for a relatively short time of period (not further specified). At the time of reporting, the outcome was unknown. This case was considered as serious with other medically important condition as criteria. Other business partner numbers included: E2008-09878. Additional information has been requested.

Other Meds: YASMIN

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **330911-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-May-2008	06-May-2008	1	31-Oct-2008	03-Nov-2008	FR	WAES0810AUS00153	03-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hepatitis

Symptom Text: Information was obtained on request by the Company from the agency via a tabulation and a Public Case Details form, concerning a 14 year old female who on 05-MAY-2008 was vaccinated with her second dose of GARDASIL as prophylactic vaccination. On 06-MAY-2008 the patient developed severe hepatitis and was hospitalized. Subsequently, the patient's hepatitis settled spontaneously over two weeks. No cause was found for the patient's hepatitis. The agency considered that hepatitis was possibly related to therapy with GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **330963-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	15-Sep-2008	24-Oct-2008	39	01-Nov-2008	11-Nov-2008	WA		03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Abdominal pain, Abdominal pain lower, Amenorrhoea, Anorexia, Anxiety, Chest discomfort, Crying, Depression, Dizziness, Dyspepsia, Dyspnoea, Fatigue, Feeling cold, Flank pain, Heart rate irregular, Malaise, Nausea, Palpitations, Pelvic pain, Stomach discomfort, Tremor, Vertigo, Vomiting

Symptom Text: 9/21-missed period for the month. 3 weeks after receiving the shot I began feeling a tightness in my chest and abdomen this has continued ever since. 10/30/08- possible seizure. The following symptoms I have experienced since 10/24/08- My digestive tract does not seem to be working properly. I am not hungry and when I eat food does not get digested properly. My stomach feels like it is in a knot. My heart is beating irregularly, at times very fast, and there is a tightness around my chest and heart. It is difficult to breath. 11/03/08 Spoke with office MA. Seen 10/27/08 for amenorrhea and pelvic pain. 11/24/08 MR received from PCP for several OVs beginning 10/29/08 with c/o abdominal discomfort, ill feeling, and fatigue. PE (+) for tearfulness, poor eye contact. Assessment: Pain, abdominal, generalized, acute. Nausea w/ vomiting. Dizziness/vertigo NOS, acute. Depressive d/o. Returned 10/31/08 with c/o dizziness and feeling unwell x 5 days. Missed last period but currently menstuating. Feels dizzy after eating with slow digestion. Feeling cold, some nausea. Assessment: nausea, alone with dizziness. Etiology unclear. Returned 11/3/08 with for f/u with c/o feeling unwell x 2 months since HPV vax. Currently bilateral flank pain and bilateral lower abd pain. Feeling heartrate changes, slower then faster. HR = 110bpm. One episode last week of body shaking, no LOC. Tx by EMS with O2. Upon PE pt is anxious. Asessment: Pain, abdominal, generalized. Palpitations, acute.

Other Meds: none

Lab Data: 10/28/08 increased bilirubin counts. Labs and Diagnostics: Total bili 1.4. Bili indirect 1.10. Otherwise labs WNL.

History: none. PMH: herpes.

Prex Illness: none

Prex Vax Illns:

Vaers Id: 331036-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Mar-2008	01-Mar-2008	0	03-Nov-2008	04-Nov-2008	FR	WAES0810USA04883	04-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chills, General physical health deterioration, Inflammation, Oedema, Proteinuria, Pyrexia, Rash

Symptom Text: Information has been received from a pediatrician, concerning a female patient with no relevant medical history reported who received the first dose of GARDASIL (lot number not reported) in the beginning of March 2008. Five days later the patient developed a cutaneous eruption in her lower limbs associated to an oedema. Then she had fever, chills and a reduced general condition. At biological level there was proteinuria with CRP increased at 57. The patient was hospitalized on 14-MAR-2008 until the 18-MAR-2008 in pediatrics. Seric disease was only evoqued but diagnosis was an acute auto inflammatory episode. At time of reporting the patient had fully recovered (unspecified date) without any corticosteroid. The patient had no concomitant treatment. Additional information has been requested.

Other Meds: None

Lab Data: serum C-reactive protein, 57, increased

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **331037-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
32.0	F	Unknown	Unknown		03-Nov-2008	04-Nov-2008	--	WAES0810USA03831	04-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Diplopia, Hallucination, auditory, Inappropriate schedule of drug administration, Vision blurred

Symptom Text: Information has been received from a consumer concerning a 32 year old female patient with chronic fatigue syndrome and depression who on an unknown dates was vaccinated with the first and second dose of GARDASIL at a health department. Concomitant therapy included "anti-candida herbal remedy" [therapy unspecified]. The consumer reported that the patient on 01-AUG-2008 and 14-AUG-2008 said that she was hallucinating, seeing double, had blurry vision and heard voices". The consumer reported that the patient said that she "had these symptoms for 4 months which rendered her incapable to take care of her son". Additional information was not available.

Other Meds: [therapy unspecified]

Lab Data: Unknown

History:

Prex Illness: Chronic fatigue syndrome; Depression

Prex Vax Illns:

Vaers Id: **331052-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-Oct-2008	06-Oct-2008	0	03-Nov-2008	13-Nov-2008	FL		14-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthropod bite, Erythema, Oedema peripheral, Pruritus

Symptom Text: On 10/7/08 Pt called stated about 8 days after received vaccine Left hand became itchy, bright red and swollen index finger worse. Pt stated felt like "finger has a fever" - Pt was referred to urgent care clinic - was told she had a bug bite.

Other Meds: SYNTHROID; ZYRTEC D; YASMIN;

Lab Data: None

History: Hypothyroid; ulcer symptoms; seasonal allergies

Prex Illness: None

Prex Vax Illns:

Vaers Id: **331053-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Jun-2008	19-Jun-2008	2	03-Nov-2008	13-Nov-2008	FL		14-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Dizziness, Fatigue, Headache, Nausea

Symptom Text: Patient's mom states patient had a temperature, severe nausea, headaches, dizziness, and fatigue - starting 06/19/2008 - 2 days after injection of GARDASIL #1

Other Meds: None @ time.

Lab Data: None

History: Headache- non migraine

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331057-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Oct-2007	26-Oct-2007	3	03-Nov-2008	13-Nov-2008	NY		14-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1264U	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2391BA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2862AA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Dizziness, Fatigue, Headache

Symptom Text: Pt has H/O headache. 3 days after immunizations dizziness, fatigue, and increase in headaches. Pt seen in my office on several occasions, 2 separate neurologists and ENT. The pain is improving. Normal Blood work and CT Scan.

Other Meds: CYMBALTA; herbal supplements; CLARINEX; NASONEX.

Lab Data: NL CT Scan; Blood Work - Work-Up negative

History: Seasonal allergies, Acne, Scoliosis, headaches.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331066-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	10-Oct-2008	16-Oct-2008	6	03-Nov-2008	04-Dec-2008	NY		04-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Chest pain, Rash erythematous, Rash papular, Rash pustular

Symptom Text: Pt developed pain L upper chest and back a few days after receiving 2nd GARDASIL vaccine. Two days later developed rash in same area- papules/postules on erythematous base. Cx pos felt zoster. Treated with VALTREX. Resolving.

Other Meds: None

Lab Data: Herpes Zoster Culture - positive

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331067-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	M	27-Oct-2008	27-Oct-2008	0	03-Nov-2008	04-Dec-2008	MI		04-Dec-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2865AA	5	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2817AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	00724	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB252AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Feeling abnormal, Pallor

Symptom Text: Pt. received 4 injections at our clinic- Alert, walked to lobby to schedule return visit when c/o feeling funny sat in chair- sucker given, cool cloth to neck; cold cool water offered. Pale did not faint but feet weak. water offered- pale looks, did not faint but feel weak. pc 10/29/2008 2p- still looks pale but fine.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 331124-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	03-Nov-2008	03-Nov-2008	0	03-Nov-2008	12-Nov-2008	MD		12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Right arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood glucose normal, Convulsion, Fall, Gaze palsy, Heart rate decreased, Musculoskeletal stiffness, Oxygen saturation normal, Syncope

Symptom Text: PT RECEIVED GARDISIL(LOT 0548X EXP. 11/29/2010 MERCK) 0.5 ML IM RIGHT DELTOID WITHOUT DIFFICULTY. AS PATIENT WAS CHECKING OUT SHE FAINTED AND FELL AND WAS DESCRIBED AS HAVING SEIZURE SYMPTOMS(ARMS STIFF, EYES ROLLED IN BACK OF HEAD). BP 110/80, BS 89, PULSE 49-50 AND IMPROVED TO 70 BPM WITHIN MINUTES, PULSOX 98%. EMS WAS CALLED AND PT WAS TRANSPORTED TO THE HOSPITAL.

Other Meds:

Lab Data: NONE BY THIS OFFICE, UNKNOWN AT ER.

History: NKDA

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **331142-1 (S)** **Related reports:** 331142-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jul-2008	01-Oct-2008	92	03-Nov-2008	10-Nov-2008	MA		03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Arthralgia, Asthenia, DNA antibody positive, Encephalitis, Headache, Insomnia, Mental status changes, Nausea, Pain, Rash papular, Retrograde amnesia, Systemic lupus erythematosus, Vision blurred

Symptom Text: Patient developed arthralgias, change in mental status. Diagnosed with Systemic Lupus Erythematous on 10/23, based on +ANA and +dsDNA. Admitted to Hospital for changes in mental status, thought to be from lupus cerebritis. records received 11/14/08-presented to ED 10/28/08-C/O short term retrograde amnesia. Intermittent blurry vision. C/O joint pain, headaches nausea for 4 weeks. Left hand weakness. One and half months prior C/O pain in hands and feet, isolated papules. Difficulty sleeping. 12/1/08-DC summary received for DOS 10/28-11/6/08-DX:Lupus cerebritis. Change in mental status.

Other Meds: OCPs

Lab Data: 11/14/08-records received-ANA positive. CT sinusitis. MRI consistent with lupus cerebritis. Echocardiogram normal. WBC 22.4, absolute neutrophil count increased 18.82, ESR increased 87, CSF glucose low 59, oligo bands albumin , serum 3330

History: none 11/14/08-records received-PMH: recent diagnosis of lupus last week on prednisone.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **331142-2 (S)** **Related reports:** 331142-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jul-2008	01-Oct-2008	92	26-Jan-2009	27-Jan-2009	--	WAES0901USA01080	29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Arthralgia, Encephalitis, Headache, Insomnia, Mental status changes, Muscular weakness, Nausea, Retrograde amnesia, Systemic lupus erythematosus, Vision blurred

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. On 01-JUL-2008 a 16 year old female with no relevant medical history was vaccinated intramuscularly with a first dose of GARDASIL (lot number 660553/0070X) in the right arm. Concomitant therapy included oral contraceptive pills (unspecified). On 01-OCT-2008 the patient developed arthralgias, change in mental status. The patient was diagnosed with Systemic Lupus Erythematosus on 23-OCT-2008, based on antinuclear antibodies test positive and deoxyribonucleic acid antibodies test positive. It was reported that "last week" the patient was on prednisone. The patient was admitted to the hospital for changes in mental status, which was thought to be from lupus cerebritis. Medical records received on 14-DEC-2008 which showed that the patient was presented to the emergency department on 28-Oct-2008, and complained of short term retrograde amnesia. The patient also had intermittent blurry vision, complained of joint pain, headache and nausea for 4 weeks. The patient had left hand weakness. One and half months prior, the patient complained of pain in hands and feet and isolated papules. The patient had difficulty in sleeping. On 06-NOV-2008, the patient was diagnosed with lupus cerebritis, change in mental status. Laboratory tests showed antinuclear antibodies test positive, CT sinusitis, MRI consistent with lupus cerebritis, echocardiogram normal, white blood cell count 22.4, absolute neutrophil count increased 18.82, ESR increased 87, CSF glucose low 59, oligo band albumin, serum 3330. The listing indicated that one or more of the events required hospitalisation, was considered to be immediately life-threatening. No further information is available. The original reporting source was not provided. The VAERS ID # is 331142. A standard lot check investigation was performed. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investi

Other Meds: Hormonal contraceptives

Lab Data: Computed axial, sinusitis; Magnetic resonance, lupus cerebritis; Echocardiography, normal; Diagnostic laboratory, oligo bands albium, serum 3330; Serum ANA, positive; Deoxyribonucleic acid, positive; WBC count, 22.4; Absolute band, 18.82, i

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **331178-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Oct-2008	28-Oct-2008	0	03-Nov-2008	17-Feb-2009	SC		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Fall, Head injury, Loss of consciousness, Syncope vasovagal

Symptom Text: 340P pt had vasovagal syncope, fell and hit head after injection with prompt recovery. 6p-pt returned to have arm checked for fx and became weak and passed out while sitting, pt sent to ER.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 331197-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-May-2008	27-Jun-2008	42	04-Nov-2008	05-Nov-2008	FR	WAES0808USA01213	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Intra-uterine death, Uterine dilation and curettage

Symptom Text: Information has been received from a physician through the Sanofi Pasteur MSD GARDASIL Pregnancy Registry, concerning a 16 year old female who on 15-MAY-2008 was vaccinated with the first dose of GARDASIL and on 17-JUL-2008 was vaccinated with the second dose of GARDASIL. The patient started a spontaneous pregnancy approximately 3 weeks before receiving the second dose of GARDASIL (batch number not reported). The starting date of her last menstrual period was 13-JUN-2008. No adverse event reported. Estimated date of delivery 20-MAR-2009. Follow-up information received through the initial pregnancy questionnaire: Case upgraded to serious. Administration dates of vaccine were modified from 15-MAY-2008 into 16-MAY-2008 for the first dose of GARDASIL. Estimated date of conception was on 27-JUN-2008 and estimated date of delivery was 27-MAR-2008. On 08-SEP-2008 an echography revealed a foetal death and the patient had a curettage on 10-SEP-2008. At the time of reporting the outcome was not specified. To be mentioned that patient consent was provided. Foetal death and endometrial curettage were considered to be an other important medical event. Other business partner included: E2008-07519. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 13Jun08)

Prex Vax Illns:

Vaers Id: **331198-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Aug-2008	01-Oct-2008	61	04-Nov-2008	05-Nov-2008	MA	WAES0810USA04762	05-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cerebral disorder

Symptom Text: Information has been received from a pharmacist concerning a "college age" female who in August 2008 was vaccinated with GARDASIL (dose and duration not reported). Two months after vaccination, the patient developed cerebralitis and was hospitalized. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 331199-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		04-Nov-2008	05-Nov-2008	--	WAES0810USA04949	05-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a physician concerning an "approximately 18-20 years old" female who on unspecified date was vaccinated with the first dose of GARDASIL. Immediately after receiving vaccination, the patient had a convulsive seizure for 2 seconds and then fainted. The patient has recovered but the physician does not plan to administer the second or third doses to the patient. The patient sought unspecified medical attention. Upon internal review, convulsive seizure was considered to be an other important event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **331200-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Oct-2008	28-Oct-2008	0	04-Nov-2008	05-Nov-2008	CA	WAES0810USA05135	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Hypotonia, Presyncope

Symptom Text: Information has been received from a consumer concerning her 17 year old grand-daughter with allergy to penicillin and no pertinent medical history reported who on 28-OCT-2008 was vaccinated with the first dose of GARDASIL. Concomitant therapy included NUVARING, flu vaccine (unspecified) (also given on 28-OCT-2008) and unspecified antibiotic. After receiving her first dose of GARDASIL, on 28-OCT-2008, in the physician's office, the patient almost fainted and her head was flopping around. The consumer stated that she thought it looked like a seizure. At the time of reporting, the patient was recovering. Upon internal review, seizure was considered to be other important medical event. Additional information has been requested.

Other Meds: antimicrobial (unspecified); NUVARING; Influenza virus vaccine

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331201-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		04-Nov-2008	05-Nov-2008	--	WAES0810USA05158	05-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a health care worker who reported that one of their patient's mother stated that her niece, on an unknown date was vaccinated with the third dose of GARDASIL. The health care worker reported that the patient didn't go to their office. The patient's aunt reported that her niece shortly after received her third dose of GARDASIL had a seizure. The patient's aunt reported that the seizure happened different times of day and they still happening. She also reported that the patient did see her physician who said that the seizures could be due to GARDASIL. At the time of the report the patient had not recovered. Upon internal review seizure is considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **331204-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
44.0	F	17-Mar-2008	17-Mar-2008	0	04-Nov-2008	05-Nov-2008	FR	WAES0810USA05121	05-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1466F		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Hyperhidrosis, Inappropriate schedule of drug administration, Tachycardia

Symptom Text: Information has been received from a Health Authority (case n. 90964) concerning a 44 year old female who was vaccinated on 17-MAR-2008 with one dose of GARDASIL (batch n. NF22880). On the same day she started starving for air and presented with tachycardia and sweating. She was treated with URBASON 40 mg i.v. The outcome is recovered on 17-MAR-2008. The case was considered as serious based on the criteria "other medically significant condition". Other business partner numbers included: E2008-09819 and IT419/08. The case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331219-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Oct-2008	20-Oct-2008	4	04-Nov-2008	14-Nov-2008	TX		14-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	0570X	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	88635		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood immunoglobulin A increased, Cytomegalovirus test positive, Epstein-Barr virus antibody positive, Lymphadenitis

Symptom Text: Acute neck lymphadenitis x 1 week after the shot of HPV and FLUVIRIN. Given Augmentin after ENT consult and diagnosis of ? Cat scratch vs ? HPV shot allergy.

Other Meds: None

Lab Data: Other labs unremarkable. Labs + for EBV and CMV. Ab IgG only.

History: None except behavioral issues

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331239-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	28-Oct-2008	31-Oct-2008	3	04-Nov-2008	14-Nov-2008	MI		14-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blister, Eye swelling, Ocular hyperaemia, Pruritus, Urticaria

Symptom Text: On 10-31-08 this clt was seen in walk-in clinic because of hive reaction possibly from HPV vaccine given on 10-28-08. Clt reports on Friday am, she woke up with swollen, red eye. Later that day, foot started itching and noticed on set of hives on foot. C/o being itchy all day. Later that day, developed blister like hives on back. Was instructed to use OTC Benedryl and was given an RX for Prednisone plus ABX for bronchitis.

Other Meds:

Lab Data:

History: Allergies to Augmentin & Penicillin

Prex Illness: clt was diagnosed with bronchitis approx 3 days after vaccination.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 331243-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Oct-2007	25-Oct-2007	1	04-Nov-2008	11-Nov-2008	PA		28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Condition aggravated, Crying, Disturbance in attention, Feeling abnormal, Major depression, Overdose, Pharyngitis, Suicidal ideation, Suicide attempt, Syncope

Symptom Text: Kate was a perfectly healthy young woman prior to these events. The day after receiving the first shot of Gardasil on 10/24/2007, Kate experienced frequent fainting and crying spells. The possible connection to the vacine shot was not considered. Her pediatrician recommended a psychiatrist for an evaluation. The psychaitrist diagnosed severe depression and prescribed lexapro. 17 days later, Kate overdoses and is transported to the hospital. She is hospitalized for 4 days. She continues to be seen over the next 9 months for depression. Meds are frequently changed. She was plagued by various side effects. Her life ruined. 01/19/09 Reviewed hospital medical recods of 11/25-11/29/2007. FINAL DX: major depression, recurrent, severe, w/o psychotic features; pharyngitis on antibiotics; GAF on admit 25, on d/c 60. Records reveal patient had suicide attempt by overdose after worsening depression, decreased energy, decreased concentration, feelings of hopeless & worthless. No history of prior suicide attempts or prior psych hospitalizaations although had long history of depression. Had been started on Lexapro approx 2 wks prior to suicide attempt. Slowly improved & d/c to home with continued outpatient psych program. 1/19/09 Reviewed ER medical records of 11/25/2007. FINAL DX: overdose suicide attempt Records reveal patient took multiple drugs in suicide attempt. Had increased depression & suicidal thoughts lately. Under psych treatment & transferred to inpatient psych hospital.

Other Meds: NA

Lab Data: LABS: EKG, CBC, drug screen all neg.

History: NA PMH: depression.

Prex Illness: NA

Prex Vax Illns:

Vaers Id: 331253-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Oct-2008	16-Oct-2008	6	04-Nov-2008	10-Nov-2008	AZ		16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968 U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal distension, Abdominal pain, Abdominal tenderness, Decreased appetite, Dehydration, Diarrhoea, Hyperbilirubinaemia, Hypokalaemia, Hyponatraemia, Hypophagia, Iron deficiency anaemia, Jaundice, Ocular icterus, Pyrexia, Renal failure acute, Thrombocythaemia, Urine output decreased, Vomiting

Symptom Text: Fever, adominal pain and emesis .started 6 days after last dose of Gardasil.progressed to jaundice and dehydration. MANUFACTURER MERCK. 11/12/2008 MR received for DOS 10/23-11/4/2008 with D/C DX: Superior mesenteric venous thrombosis. Direct hyperbilirubinemia. Hyponatremia, Hypokalemia, Acute Renal Insufficiency, Thrombocytosis, Anemia (iron deficiency). Pt presented with a 1 week hx of fevers, emesis, decreased po intake, appetite and urine output, abdominal pain and one episode of diarrhea. Pt noted to be dehydrated and icteric on admission. On PE abdomen noted to be distended with some tenderness in the RuQ and epigastric regions. Started on Lovenox, coumadin, and abx. No resolution of thrombus but no further extension. LFTs improved. Creatinine improved with hydration. D/C for continued outpt f/u.

Other Meds: none

Lab Data: Ct scan positive for a superior mesenteric vein thrombosis. Labs and Diagnostics: CBC with WBC 14,200, Hgb 9.7, MCV 76. Ferritin high. AST 81. ALT 57. Creatinine 1.34. Alk Phos 306. Bilirubin total 6.6. Bili direct 4.4. GGT 161. Albumin

History: none. PMH: none.

Prex Illness: none

Prex Vax Illns: none~Vaccine not specified (no brand name)~~0~In Patient|N?A~ ()~~0~In Sibling

Vaers Id: 331290-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-Oct-2008	25-Oct-2008	3	04-Nov-2008	10-Nov-2008	NM		09-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0381X	0	Left leg	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B027AA	5	Right leg	Unknown	
MNQ	SANOFI PASTEUR	U2730AA	0	Right leg	Unknown	
VARCEL	MERCK & CO. INC.	0994X	0	Left leg	Unknown	
FLUN	MEDIMMUNE VACCINES, INC.	500560P	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Arthritis, Carditis, Joint range of motion decreased, Joint swelling, Mitral valve incompetence, Myalgia, Pharyngitis streptococcal, Pyrexia, Rash, Rash pruritic, Tricuspid valve incompetence, Urticaria

Symptom Text: Hives like rash at day 3-4D, Fever day 5, Joint and muscle pain debilitating by day 5, Admitted to hospital 10-28-08. WBC 32,000, ESR 70 - 124, CRP 7.3. 1/26/09 Reiceived hospital medical records for 10/28-10/31/2008. FINAL DX: not available on d/c summary available Records reveal patient experienced migratory joint pain, fever & migrating pruritic rash. Had recent strep throat. Tx w/IV antibiotics, NSAIDS & antihistamines. Improved by d/c to home on continued oral PCN & w/outpatient cardio & rheum consults. 2/3/09 Received Rheum & ID consults. Rheum consult of 11/14/2008: FINAL DX: arthritis, carditis, fever, ?Still's disease Records reveal patient exp (+)GABS 10/26 after rash developed on 10/24. Rash has waxed & waned since. Remained on PCN & NSAID. Exam revealed swollen wrists w/decreased ROM. Labs & x-rays ordered. Patient was being f/u by cardio. ID consult of 11/18/2008: FINAL DX: fever, arthritis, rheumatic fever doubtful Records reveal review of extensive medical records w/o definitive diagnosis. Referred back to cardio & rheum clinics.

Other Meds: None

Lab Data: ASO (-); Blood culture (-); RF (-); (+) Rapid test for strep; Many others LABS: Urgent care labs of 10/10/26/08: WBC 38,300, PMNs 92%. ESR 70(H). Hospital labs of 10/28-31/08: WBC 31,900, PMNs 93%. ESR 124(H). CRP 7.3(H). ASO neg.

History: None PMH: sibling w/(+)GABS 10 /18

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331309-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Mar-2008	17-Mar-2008	0	05-Nov-2008	06-Nov-2008	NY	WAES0803USA02784	06-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy, Nausea, Vomiting

Symptom Text: Information has been received from a physician, through the Pregnancy Registry for GARDASIL, concerning a 15 year old female who on 17-MAR-2008 was inadvertently vaccinated intramuscularly with GARDASIL (Lot # 659437/1266U). The patient has not experienced a menstrual cycle for 2 months and is experiencing nausea and vomiting. The physician suspected she was pregnant and performed a pregnancy test. On 18-MAR-2008, the serum pregnancy test results were positive. The patient sought unspecified medical attention in the office. No additional information is available. Follow up information was received from the physician who reported that the patient had termination of pregnancy (TOP) few days after she was given GARDASIL, approximately 19-Mar-2008. This was unwanted teenage pregnancy and the TOP was an already planned before she was given GARDASIL. Upon internal review, elective termination was determined to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: beta-human chorionic, 03/17/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **331310-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		05-Nov-2008	06-Nov-2008	FR	WAES0810ISR00019	06-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Haemoptysis, Pyrexia, Wegeners granulomatosis

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with GARDASIL. The patient was hospitalized due to fever and blood spitting. Subsequently the patient experienced Wegener's Granulomatosis. The patient was placed on therapy with prednisone for the treatment of Wegener's Granulomatosis for one week and then on therapy with cytotoxic drug (not reported). The outcome is unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Body temp, 41 Celsius

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **331344-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Oct-2008	29-Oct-2008	1	05-Nov-2008	09-Dec-2008	NE		09-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Haematuria

Symptom Text: Hematuria noted at 2:30 am on 10/29/2008. Patient had received 1st GARDASIL shot on 10-28-08 at 09:05am

Other Meds: None

Lab Data: Urogram- large amount of blood; UA with micro and calcium kreatonine peding

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331351-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Oct-2008	30-Oct-2008	2	05-Nov-2008	16-Dec-2008	FL		16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0702X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Pain in extremity, Paraesthesia

Symptom Text: GARDASIL given 10/28/2008 in Left arm. Gradual onset of numbness. tingling and pain in left arm beginning on the morning of 10/30/2008.

Other Meds: Prozac

Lab Data: MRI

History: Depression

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331354-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jul-2008	03-Jul-2008	1	05-Nov-2008	18-Dec-2008	MD		20-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Adverse reaction, Hypoaesthesia, Muscle spasms, Myalgia, Pain in extremity, Paraesthesia

Symptom Text: Tingling/numbness in legs. Started in lower legs & moved higher in both legs. Called dr 7/4/08 am and was told to go to urgent care. Urgent care on 7/4/08 with exam and lab work with follow-up on 7/6/08. Symptoms slowly diminished. 11/20/08 MR received for OV 7/4/2008 with DX: Adverse rxn to Gardasil. Pt presented with c/o 3 day hx of leg cramps which began 1 day after HPV vax. PE (+) for calf tenderness, otherwise WNL. Does not think GBS. F/U 7/6/08 with 80% resolution of muscle tenderness. No further c/o.

Other Meds: Vyvanse

Lab Data: Multiple lab tests on 7/4/2008. CBC, lytes, BUN, UA all WNL except platelets 447

History: Turners Syndrome NFI

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331403-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Nov-2007	14-Nov-2007	1	05-Nov-2008	30-Dec-2008	OH		31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL	0	Unknown	Intramuscular	
	TDAP	UNKNOWN MANUFACTURER	NULL	5	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Head injury, Loss of consciousness

Symptom Text: Felt very dizzy next morning and passed out hitting her head on door jamb.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 331407-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	24-Mar-2008	08-Apr-2008	15	05-Nov-2008	18-Dec-2008	IL		11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Diplopia, Dizziness, Facial pain, Fatigue, Feeling abnormal, Fibrocystic breast disease, Gait disturbance, Headache, Hemiparesis, Hypersensitivity, Hypoaesthesia, Malaise, Nasal congestion, Nausea, Palpitations, Paraesthesia, Presyncope, Rhinorrhoea, Sinusitis, Syncope, Tachycardia, Tremor, Visual impairment

Symptom Text: Fainting, left sided weakness and tingling, double vision for 3 months, prolonged fatigue, rigors, hypersensitivity, unsteady gait. All symptoms continue to persist. Placed on steroids on and off for three months. 11/20/08 Received GYN office records of 3/24-10/06/2008. FINAL DX: none provided Records reveal patient had fibrocystic breasts on 3/24 & BCP changed. US of breasts reviewed & WNL. T/C 6/26 pt reported having been seen in ER x 2, ENT, Neuro & had EEG, CT scan & MRI. Had faint feeling, numbnness in feet, visual changes x 1.5 mo. RTC 10/6/08 12/8/08 Received ER medical records of 5/1/2008. FINAL DX: pre-syncope & palpitations Records reveal patient experienced intermittent pre-syncope & palpitations x 3 weeks now with same plus tingling around mouth & hands, nausea x 2 wks, dizziness. No symptoms while in ER & d/c to home w/PCP f/u. 2/2/09 Received hospital clinic records for 6/25-8/8/2008. FINAL DX: none provided Records reveal patient w/lightheadness, fatigue, multiple episodes of felt faint, tachycardia, hand tremors, feeling foggy, intermittent tingling & weakness of legs, vision abnormal since 3/08 shortly after received HPV #1. 2/3/09 Reeived ENT medical records of 5/8/2008. FINAL DX: resolving sinusitis Records reveal patient experienced sinus infection s/s x 3 weeks of nasal congestion, malaise, HA, rhinorrhea, facial pain/pressure & dizziness. 2/9/09 Received ER medical records of 4/14/2008. FINAL DX: dizziness, etiology unknown Records reveal patient experienced dizziness & felt faint x 5 days. D/C home w/neg exam.

Other Meds: none

Lab Data: 2 ER visits due to near syncope. All lab tests negative. MRI and CT of the head negative. EEG negative. Retnal specialist exam negative as well as ENT scope negative. LABS: 2006 PAP smear abnormal w/inflammation; PAP smears WNL since. ECG

History: asthma (seasonal) PMH: dysmenorrhea, contraception, asthma, hypercholesterolemia, pneumonia, allergic rhinitis,sinus infection, GERD, ovarian cysts. Off contraception x few mo. Needle stick from HIV+ patient in 12/2007, meds x 2 mo, own HIV test neg. Family hx: MS.

Prex Illness: none

Prex Vax Illns:

Vaers Id: 331436-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	08-May-2007	09-May-2007	1	05-Nov-2008	11-Nov-2008	MA		23-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Complex regional pain syndrome, Cystitis, Facial palsy, Kidney infection, Menstruation irregular, Migraine, Neuralgia

Symptom Text: my daughter was perfectly healthly before she received the HPV vaccine - now she has severe migraine headaches, Reflex Sympathetic Dystrophy Syndrome, bladder and kidney infections, etc. records received 11/17/08-clinic notes for 6/17/08 C/O constant right sided temporal pain radiating throughout scalp abrupt onset 9/7/07 with Bell's palsy-at time of HPV4 vaccine and second dose of progesterone for irregular menses. Impression probably history of autoimmune induced peripheral facial weakness as well as new onset of neuralgic pain. clinic notes for DOS 9/8/08-right sided posterior occipital and temporal pain since an episode of idiopathic Bell's palsy. Pain now less. Increased neck pain now.

Other Meds:

Lab Data: She has had MRI's, CAT scans, ultrasounds, blood tests, etc at Hospital, other Hospital and Medical center 11/17/08-records received-MRI T2 abnormalities seen at trigone of left lateral ventricle. Could represent gliosis. Phospholipid anti

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 331476-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Oct-2008	28-Oct-2008	0	06-Nov-2008	07-Nov-2008	TX	WAES0810USA05093	07-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse concerning a 18 year old female who on 28-OCT-2008 was vaccinated with the first dose of GARDASIL (lot# 0947X). Concomitant therapy included multivitamins VI and calcium (unspecified). The patient had a seizure after vaccination and received medical attention while in the physician's office. Subsequently, the patient recovered from seizure. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: calcium (unspecified); vitamins (unspecified)

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **331477-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Dec-2007	Unknown		06-Nov-2008	07-Nov-2008	FR	WAES0810USA05317	24-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea, Drug administered at inappropriate site, Dysmenorrhoea, Menstruation irregular, No reaction on previous exposure to drug

Symptom Text: Information has been received from a general practitioner on 03-OCT-2008. A 17 year old female patient who was a sportswoman in good health and non smoking received the third dose of GARDASIL (lot number not reported) on an unspecified date. Since the summer in 2008 the patient experienced irregular period and altered menstrual flows. No aetiology was found. The patient had no nutritional disturbance, there was no risk of pregnancy and she had no sexual activity. At the time of reporting the outcome was not specified. The patient had no adverse effect after first and second dose of GARDASIL in 2007. Follow-up information received through the pharmacovigilance form on 28-OCT-2008: Case upgraded to serious by the reporter who assessed the events as medically significant because of functional prognosis. Case of misuse. Patient's date of birth was completed. The patient received the three doses via intramuscular route in her back which was an inappropriate injection site. She experienced dysmenorrhoea followed by amenorrhoea of moderate intensity since the beginning of 2008. At time of reporting the patient had not recovered. Other business partner numbers include E2008-09209. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **331485-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Mar-2008	Unknown		06-Nov-2008	07-Nov-2008	UT	200801142	07-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2548A		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1757U		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Pre-eclampsia

Symptom Text: This case was received from a health professional on 18 April 2008. Seriousness Criteria: Other-Medically Significant. A 15-year-old female patient, with a history of type I diabetes and sulfa allergy, received an intramuscular left arm injection of MENACTRA (lot number U2548AA) and an intramuscular right arm injection of GARDASIL (Merck, lot number 1757U) on 04 March 2008. The patient was pregnant at the time of vaccination, and date of last menstrual period was 07 December 2007. At the time of the report, the patient had not experienced any adverse effects. Follow-up information received on 27 May 2008 from a clinic. Per the reporter, the patient was not seen at their facility. The name of the facility where the patient was evaluated was provided. No other medical information was received. Follow-up information received on 08 September 2008 from a healthcare professional. It was confirmed that the patient had no adverse effects following vaccination and that the date of her last menstrual period was 07 December 2007. The patient's estimated date of delivery was reported to be 18 September 2008. Her obstetrical history included no previous pregnancies. The patient's health during pregnancy and risk factors were not known. Follow-up information was received from the health professional on 27 October 2008. Based on new information received, the case was determined to meet serious criteria. Seriousness Criteria: Other-Medically Significant. The patient underwent an ultrasound on 18 August 2008 and a fetal stress test on 28 August 2008; results of both tests were reported as normal. Pregnancy complications included pre-eclampsia, failure to descend, and non-reassuring fetal status. A male infant was born on 29 August 2008 via C-section at 37 weeks gestation. Birth weight was 7 pounds 12 ounces, and birth length was 21.75 inches. Apgar scores were 8/10 at one minute and 9/10 at five minutes, and the infant had no congenital anomalies. He was subsequently adopted, and no information regarding the infant or adoptive pa

Other Meds:

Lab Data:

History: History of Type I Diabetes, and allergy to sulfa.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331501-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-Oct-2008	27-Oct-2008	0	06-Nov-2008	17-Feb-2009	OH		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	007X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: HPV # 2 administered in left deltoid. Brief fainting immediately. Rested supine on exam table with feet/lower legs elevated. Given some candy. Left office about table with feet / lower leg's elevated. Given some candy. Left office about 15 minutes later.

Other Meds: OTC Cough syrup

Lab Data:

History: ADHD PTSO

Prex Illness: Upper respiratory illness

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331506-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Oct-2008	30-Oct-2008	1	06-Nov-2008	17-Feb-2009	WA		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0994X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0575X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: Recurrent vomiting for 2 days after vaccine given

Other Meds:

Lab Data:

History: Irritable bowel syndrome, allergic Chronitis

Prex Illness:

Prex Vax Illns: Vomiting~HPV (no brand name)~1~14~In Patient|~Hep A (no brand name)~1~0~In Sibling

Vaers Id: **331515-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Oct-2008	23-Oct-2008	0	06-Nov-2008	17-Feb-2009	MD		02-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash pruritic

Symptom Text: Patient states that she developed an itchy rash only on the arm where she received the vaccine. it developed the day after the vaccine and persisted for about two week

Other Meds: ASACOL

Lab Data:

History: M Ulcerative colitis

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331537-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	27-Aug-2008	Unknown		06-Nov-2008	24-Dec-2008	NY		24-Dec-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0279X	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B028AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0433X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Pt. reports hives for 1 week after adminstration of vaccines.

Other Meds: Humalog,NPH

Lab Data: None

History: IDDM

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331545-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	05-Nov-2008	05-Nov-2008	0	06-Nov-2008	24-Dec-2008	TX		24-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Drug exposure during pregnancy, Headache

Symptom Text: PATIENTS HUSBAND CALLED THIS MORNING STATED SHE IS APPROXIMATELY 3 WEEKS PREGNANT, COMPLAINS OF HEADACHE AND STOMACH ACHE

Other Meds: UNKNOWN

Lab Data:

History: UNKNOWN

Prex Illness: UNKNOWN

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331562-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Nov-2008	04-Nov-2008	0	06-Nov-2008	29-Dec-2008	MN		29-Dec-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0575X	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B012AA	5	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0989X	1	Right arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB297BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Injection site warmth

Symptom Text: RT ARM, REDDENED AND SWOLLEN, WARM TO TOUCH. 9CM LONG, 7CM WIDE

Other Meds:

Lab Data: NO

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331573-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Nov-2008	06-Nov-2008	0	06-Nov-2008	29-Dec-2008	OK		30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2727AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pruritus, Pruritus

Symptom Text: Pt. has had an adverse reaction the hepatitis B shot in the past that consisted of a rash with an onset of 10 minutes after administration. Pt. received HPV shot and meningoccal today. I waited 15 minutes between adminstration of each vaccine to check for reactions. The meningococcal vaccine was adminstered first with no reaction. After 15 minutes the HPV vaccine was adminstered and patient had some localized itching at the injection site and some slight itching on her face but did not report any problems swallowing or breathing. After 15 minutes the patient left the office with instructions to call if itching increased. After one hour the patient's mother called in complaining of increased itching by the patient. The patient was informed to come in and per Dr. a 4mg/ml 1 ml dose of dexamethasone sodium phospate was injected in the gluteus muscle. The patient was held at the office for one hour and reported feeling better with less itching. The patient was sent home with instructions to go to the ER if any signs of trouble breathing or swallowing were found.

Other Meds: none

Lab Data:

History: Hepatits B vaccination

Prex Illness: none

Prex Vax Illns: Rash~Hep B (no brand name)~2~4~In Patient

Vaers Id: 331588-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Jun-2007	12-Jul-2007	14	06-Nov-2008	07-Nov-2008	NY	WAES0710USA00854	07-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse for the Merck pregnancy registry for GARDASIL concerning a 16 year old female smoker with attention deficit/hyperactivity disorder and a history of a functional murmur and febrile seizure as a child who on 25-APR-2007 was vaccinated intramuscularly with the first dose of GARDASIL (655205/1426F). On 28-JUN-2007, the patient received the second dose intramuscularly of GARDASIL (657868/0523U). Following the second dose, the patient was confirmed to be pregnant by ultrasound with a conception date of 12-JUL-2007. Concomitant therapy included prenatal vitamins. The patient had been taking SEROQUEL, METADATE, and TOPAMAX for ADHD but had stopped medications prior to conception. Gestation on 28-SEP-2007 was 11 weeks and 1 day. The patient sought unspecified medical attention. Additional information received from telephone call (09-JUN-2008): The physician reported that the patient delivered a healthy, normal male baby on 21-APR-2008 at 40 weeks gestation. Apgar scores were 8 at 1 minutes and 9 at 5 minutes. Birthweight was 8 pounds, 5 ounces, length 20 3/4 inches, head circumference was 14 1/4 inches and he was blood type O positive. On 29-APR-2008 the baby was seen for a one week well child visit. The baby is a healthy appearing infant, well nourished, bottle feeding and alert. Weight is within normal range for stated age. No known drug allergies. On 02-JUN-2008 the baby was seen for congestion, crying for no reason, vomiting yellow x 2, coughing and fever for a few days. Acute otitis media was suspected and the parents were instructed to take the baby to the emergency room for a septic work up and he was admitted to the hospital. On 24-JUN-2008 the baby was seen for a 2 month well child visit. The parents had no concerns. The baby's ear, nose and throat exam was normal. Additional information is not expected. All medical records are available upon request.

Other Meds: METADATE; SEROQUEL; TOPAMAX; vitamins (unspecified)

Lab Data: Echocardiography, normal; Ultrasound, 09/28/07

History: Murmur functional; Febrile convulsion

Prex Illness: Pregnancy NOS (LMP = 7/12/2007); Attention deficit/hyperactivity disorder; Smoker

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331593-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Nov-2008	05-Nov-2008	1	06-Nov-2008	16-Feb-2009	SC		16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0791X	0	Right arm	Subcutaneously	
	TD	SANOFI PASTEUR	U1982DA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2688AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: Varicella given subq R arm on 11/4/2008 and it starting turning red and swelling on 11/5/2008 around late PM. Return to RN on 11/06/08 at 4PM, injection site red and swollen.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 331624-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	13-Dec-2007	13-Dec-2007	0	07-Nov-2008	10-Nov-2008	MO	WAES0802USA04171	10-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse for the Pregnancy Registry for GARDASIL concerning an 18 year old female who on 13-DEC-2007 was intramuscularly vaccinated with her first dose of GARDASIL (lot # 658554/0928U) and later found out she was pregnant. On 27-Dec-2007, the patient sought unspecified medical treatment with an office visit. A pregnancy test was performed and determined she was about 5-6 weeks pregnant (LMP approximately 11/17/07). No adverse events were reported. Follow-up information was received on 03-NOV-2008 from a physician indicating that the patient is a female with 0 previous pregnancies. The patient had no significant past medical history or concurrent medical conditions. In early January 2008, 7-8 weeks from her LMP, the patient had an spontaneous abortion. The products of conception were not examined. It was unknown if the fetus was normal. Upon internal review, the spontaneous abortion was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Beta-human chorionic, 12/27/07

History: Papanicolaou smear abnormal

Prex Illness:

Prex Vax Illns:

Vaers Id: **331625-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	17-Sep-2008	01-Oct-2008	14	07-Nov-2008	10-Nov-2008	MA	WAES0810USA04749	10-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Uterine haemorrhage

Symptom Text: Information has been received from a 22 year old female with no pertinent medical history or drug allergies, for the Pregnancy Registry for GARDASIL, concerning herself who was vaccinated with the first (0.5ml) and second (dose not reported) dose of GARDASIL on 29-JUL-2008 and 19-SEP-2008 respectively. There was no concomitant medication. She became pregnant after getting the GARDASIL vaccine. She also stated that her baby is sinking and she was having internal abnormal bleeding around her baby. The patient's LMP was 25-OCT-2008. The patient had a blood test. The patient sought medical attention. Upon internal review the internal abnormal bleeding around the baby was determined to be an other important medical event. Additional information received indicated that the office had no knowledge of this patient having GARDASIL. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 10/25/2008)

Prex Vax Illns:

Vaers Id: **331627-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		07-Nov-2008	10-Nov-2008	MI	WAES0810USA05256	10-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactic reaction, Dyspnoea, Throat tightness

Symptom Text: Information has been received from a physician concerning a 15 or 16 years old female patient who was vaccinated with the second dose of GARDASIL 0.5ml IM (therapy date, site unknown. Subsequently after the second dose, "In July or August, 2008", the patient experienced anaphylactic reaction. "Her throat started closing and she couldn't breathe." The patient was given BENADRYL and steroids (unspecified). The patient recovered that day. The doctor did not say if there was an AE with the first injection. Because of these events, the patient will not be completing the series. Upon internal review, the throat tightness and dyspnea were considered to be other important medical events. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331628-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	26-Apr-2008	Unknown		07-Nov-2008	10-Nov-2008	FR	WAES0810USA05318	24-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea, Dysmenorrhoea, Incorrect route of drug administration, No reaction on previous exposure to drug

Symptom Text: Case received from a foreign general practitioner on 03-Oct-2008. Case linked to non serious case number E2008-09209 (same reporter, same product, similar AE). A 15-year-old female patient who was a sportswoman in good health and non smoking received the third dose of GARDASIL (batch number not reported) on an unspecified date. Since the summer 2008 the patient had no periods anymore. No aetiology was found. Work-up performed was normal. The patient had no nutritional disturbance, there was no risk of pregnancy and she had no sexual activity. At time of reporting the outcome was not specified. The patient had no adverse effect after first and second doses of GARDASIL in 2007. She was asked to refer to a gynaecologist. Follow up information received through the Pharmacovigilance form on 28-OCT-2008. Case upgraded to serious by the reporter which assessed the events as medically significant because of functional prognosis. Case of misuse. Patient's date of birth was completed. The patient received the three doses via intramuscular route in her back which was an inappropriate injection site. She experienced dysmenorrhoea followed by amenorrhoea since the summer 2008. At time of reporting the patient had not recovered. Consultation with gynaecologist was scheduled. Diagnosis was secondary amenorrhea.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: General physical condition normal; Non-smoker

Prex Vax Illns:

Vaers Id: **331629-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		07-Nov-2008	10-Nov-2008	MO	WAES0811USA00065	14-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Fall, Haemorrhage intracranial, Head injury, Headache, Intensive care, Suture insertion, Syncope

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a 16 or 17 year old female who on an unspecified date was vaccinated with her first dose of GARDASIL. Subsequently, "somewhere in 2007", the patient fainted and literally fell on her head and had front and back cranial bleeding. The patient was brought to the hospital and was placed in the intensive care. The patient also had 27 stitches on her head. The nurse reported that the patient complained that she was still having headaches all the time. The outcomes of other events were not reported. The reporter considered the patient's adverse events to be disabling and immediately life-threatening. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331630-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Aug-2007	11-Sep-2007	28	07-Nov-2008	10-Nov-2008	FR	WAES0811USA00100	10-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1473F	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Coeliac disease, Colitis ulcerative, Diarrhoea, Haematochezia

Symptom Text: Information was received from a gynaecologist concerning a 14-year-old female patient whose parents and siblings are healthy, who on 14-AUG-2007 was vaccinated with a second dose of GARDASIL (lot # 1473F, batch # NF46730, route and injection site unknown): Approximately 4 weeks after the vaccination, the patient developed bloody stool and diarrhoea. She was hospitalized in October 2007 and again in December 2007. Ulcerative colitis and coeliac disease were diagnosed. She had specific treatment (not reported in detail) and her symptoms improved until summer 2008. However, the patient cannot be considered as recovered as she is still under medication. The 3rd dose of GARDASIL was not given. The first dose of GARDASIL (lot # 655671/1024F, batch # NE51790) given to the patient on 12-JUN-2007 was well tolerated. Other business partner numbers included: E200810046. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: The first dose of GARDASIL (lot # 655671/1024F, batch # NE51790) given to the patient on 12-JUN-2007 was well tolerated.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331631-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Nov-2007	Unknown		07-Nov-2008	10-Nov-2008	FR	WAES0811USA00168	10-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Autoimmune thyroiditis, Hypothyroidism

Symptom Text: Information has been received from a physician concerning a 15 year old female who in November 2007 and August 2008, was vaccinated with her first and third doses, respectively, of GARDASIL (batch number not reported). On an unspecified date the patient experienced autoimmune hypothyroiditis. At the time of the report, the outcome of the patient was unknown. Autoimmune hypothyroiditis was considered to be an other important medical event. Other business partner numbers include E2008-10085. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331632-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	25-Aug-2008	25-Aug-2008	0	07-Nov-2008	10-Nov-2008	OH	WAES0811USA00272	10-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Drug administered at inappropriate site, Mobility decreased, Pain, Rash erythematous, Rash papular, Rash pruritic

Symptom Text: Information has been received from a physician concerning a 26 year old female with penicillin allergy and no relevant medical history who on 25-AUG-2008 was vaccinated intramuscularly with a first dose of GARDASIL in the left arm (lot number not reported). At time of administration, the patient experienced pain. The pain became severe and impaired lifting the arm. The patient self-treated with unspecified non-steroidal anti-inflammatory medications and the pain resolved in 3 weeks. On 27-OCT-2008, the patient was vaccinated intramuscularly with a second dose of GARDASIL in the gluteus muscle (lot number not reported). Concomitant therapy included YASMIN. Within a few hours, the patient developed a red, raised, itchy rash on her torso and both arms. The patient self-treated with BENADRYL. The patient contacted the physician's office by phone the next day to inform them of the reaction and at that time, the rash was improved. According to the physician, the patient's events were considered to be disabling. Additional information has been requested.

Other Meds: YASMIN

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331633-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	17-Jun-2008	17-Jun-2008	0	07-Nov-2008	10-Nov-2008	CA	WAES0811USA00281	10-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Gaze palsy, Syncope vasovagal

Symptom Text: Information has been received regarding a case in litigation from a administrative assistant concerning a 26 year old female with no relevant medical history or allergies who on 15-APR-2008 was vaccinated intramuscularly with a first 0.5 ml dose of GARDASIL (lot number and injection site not reported). On 17-JUN-2008, the patient was vaccinated intramuscularly with a second 0.5 ml dose of GARDASIL (lot number 660553/0070X) (injection site not reported). Concomitant therapy included birth control pills (unspecified brand). After the vaccination, the patient became lightheaded. Her eye rolled back and she seemed to have a severe vasovagal response. According to the reporter, it seemed like the patient was going to have a seizure. The patient was sent to the emergency room. The patient was observed there and released on the same day fully recovered. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **331648-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-Oct-2008	08-Oct-2008	1	07-Nov-2008	16-Feb-2009	PA		16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myalgia, Skin burning sensation

Symptom Text: Severe muscle pain entire body described as feeling like fire neck, arms & legs.

Other Meds:

Lab Data:

History: hx Lyme disease age 5

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331680-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Nov-2008	05-Nov-2008	1	07-Nov-2008	16-Feb-2009	MA		16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain lower, Dizziness, Nausea

Symptom Text: Dizziness, lightheadedness, nausea, lower abdominal pain. Began in morning 11/5/08, symptoms subsided within 6 hours.

Other Meds: SINGULAIR

Lab Data:

History: Asthma

Prex Illness: None

Prex Vax Illns:

Vaers Id: **331710-1** **Related reports:** 331710-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Oct-2008	29-Oct-2008	7	07-Nov-2008	18-Dec-2008	FL		27-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	2	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Activities of daily living impaired, Drug intolerance, Fatigue, Haematochezia, Headache, Nausea, Sleep disorder

Symptom Text: NAUSEA, HEADACHE, STOMACH PAIN, AND FATIGUE START A WEEK AFTER INJECTION MOTHER STATE SHE TOOK CHILD FOR LAB WORK AND CT SCAN. MOTHER NOTIFY ME ON FRIDAY 11/07/2008 IN AM. 12/23/08 Reviewed PCP medical records from 6/08-11/08. FINAL DX: none provided Records reveal patient experienced intermittent nausea, epigastric abdominal pain, HA, fatigue, tiredness & hematochezia(NSAID induced) while out of country. No weight loss. Sleep disturbance w/pain. Missed several days of school. GI consult done.

Other Meds: N/A

Lab Data: LABS: CT of abdomen/pelvis, gastric emptying study, EGD all WNL. X-ray of c-spine slightly abnormal. (+)proteinuria. Sodium 133(L). EBV antibody (+).

History: N/A PMH: intermittent epigastric pain x 6 yrs. Allergy: bee sting, shrimp, drug allergies to antibiotics & hydrocodone.

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331710-2 (S)** **Related reports:** 331710-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	27-Oct-2008	28-Oct-2008	1	26-Nov-2008	01-Dec-2008	--	WAES0811USA02930	10-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Chest pain, Nausea

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter who in approximately May 2008, also reported as six months ago, was vaccinated with a first dose of GARDASIL (lot number, injection site and route not reported). On approximately 27-OCT-2008, the patient was vaccinated with a third 0.5 ml dose of GARDASIL (lot number, injection site and route not reported). Concomitant therapy included pain medication. 24 hours after receiving the third dose, on approximately 28-OCT-2008, also reported as about three weeks ago, the patient experienced chest pain, nausea and pain in her stomach. However there was no vomiting. Unspecified medical attention was sought. The patient's events persisted. The patient's events were considered to be disabling. No further information is available.

Other Meds: analgesic (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 331718-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Nov-2008	07-Nov-2008	0	07-Nov-2008	30-Dec-2008	TX		31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Consciousness fluctuating, Dizziness, Hypotension, Mydriasis, Pallor, Peripheral coldness, Speech disorder

Symptom Text: Patient at first fine, then complained of feeling light headed. After a few minutes head became wobbly. Eyes, became dilated, hands became very cold. Seemed to be going in and out of conciousness. Patient also became very pale. Speech became very quiet also. Checked blood pressure and was very low. Initial reading was 70/47. Then on second reading 77/58. Third reading 86/59, Final reading 91/67. Readings done over a 15 minute period. Did use ammonium salts to wake up patient. EMs was called at start of reaction. On arriving patient was looking better. She did get checked over by EMS and they cleared her.

Other Meds: voltaren gel, relafen, protonix

Lab Data:

History: Penicillin Alllergy, Bee sting allergy, Sjogrn's

Prex Illness: no

Prex Vax Illns:

Vaers Id: **331799-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Feb-2007	Unknown		10-Nov-2008	12-Nov-2008	--	WAES0810USA05365	12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner through a Merck pregnancy registry concerning a 24 year old female with a history of 3 live births prior to vaccination of GARDASIL, who in February 2007 (according to the patient) was vaccinated with the first dose of GARDASIL (lot number, route and injection site unknown) at a different facility, when she was 5 weeks pregnant. The patient had sought unspecified medical attention. On an unknown date she terminated her pregnancy. Subsequently, during 2007 the same patient became pregnant 3 more times and each pregnancy ended with spontaneous abortions (miscarriages) (WAES # 0811USA00647, WAES # 0811USA00648 and WAES # 0811USA00649). The patient became pregnant again and gave birth to a child in September 2008 (WAES # 0811USA00650). On 30-OCT-2008, the patient received the second dose of GARDASIL (lot number, route and injection site unknown). Upon internal review, elective abortion was considered to be other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331800-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	30-Oct-2008	Unknown		10-Nov-2008	12-Nov-2008	--	WAES0811USA00647	12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner through a Merck pregnancy registry concerning a 24 year old female with a history of 3 live births prior to vaccination of GARDASIL, who in February 2007 (according to the patient) was vaccinated with the first dose of GARDASIL (lot number, route and injection site unknown) at a different facility, when she was 5 weeks pregnant. The patient sought unspecified medical attention. On an unknown date she terminated her pregnancy (WAES # 0810USA05365). Later in 2007 the patient became pregnant again, which ended with spontaneous abortion. Subsequently, during 2007 the same patient became pregnant 2 more times and each pregnancy ended with spontaneous abortions (WAES # 0811USA00648 and WAES # 0811USA00649). There were a total of 4 pregnancies in 2007 (the one that was terminated and the 3 that miscarried). Afterward, the patient became pregnant another time and gave birth to a child in September 2008 (WAES # 0811USA00650). On 30-OCT-2008, the patient received the second dose of GARDASIL (lot number, route and injection site unknown). Upon internal review, spontaneous abortion was considered to be other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 331801-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	30-Oct-2008	Unknown		10-Nov-2008	12-Nov-2008	--	WAES0811USA00648	12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner through a Merck pregnancy registry concerning a 24 year old female with a history of 3 live births prior to vaccination of GARDASIL, who in February 2007 (according to the patient) was vaccinated with the first dose of GARDASIL vaccine (lot number, route and injection site unknown) at a different facility, when she was 5 weeks pregnant. The patient sought unspecified medical attention. On an unknown date she terminated her pregnancy (WAES # 0810USA05365). Afterward the same patient became pregnant which ended with spontaneous abortion (WAES # 0811USA00647). Later in 2007 the patient became pregnant again, which ended with spontaneous abortion for the second time. Subsequently, during 2007 the same patient became pregnant 1 more time and the pregnancy also ended with spontaneous abortion (WAES # 0811USA00649). There were a total of 4 pregnancies in 2007 (the one that was terminated and the 3 that miscarried). Afterward, the patient became pregnant another time and gave birth to a child in September 2008 (WAES # 0811USA00650). On 30-OCT-2008, the patient received the second dose of GARDASIL (lot number, route and injection site unknown). Upon internal review, spontaneous abortion was considered to be other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **331802-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	30-Oct-2008	Unknown		10-Nov-2008	12-Nov-2008	--	WAES0811USA00649	12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner through a Merck pregnancy registry concerning a 24 year old female with a history of 3 live births prior to vaccination of GARDASIL, who in February 2007 (according to the patient) was vaccinated with the first dose of GARDASIL (lot number, route and injection site unknown) at a different facility, when she was 5 weeks pregnant. The patient sought unspecified medical attention. On an unknown date she terminated her pregnancy (WAES # 0810USA05365). Afterward the same patient became pregnant twice which ended with spontaneous abortion (WAES # 0811USA00647 and WAES # 0811USA00648). Later in 2007 the patient became pregnant again and the pregnancy ended with spontaneous abortion for the third time. There were a total of 4 pregnancies in 2007 (the one that was terminated and the 3 that miscarried). Afterward, the patient became pregnant another time and gave birth to a child in September 2008 (WAES # 0811USA00650). On 30-OCT-2008, the patient received the second dose of GARDASIL (lot number, route and injection site unknown). Upon internal review, spontaneous abortion was considered to be other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **331831-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	17-Sep-2008	17-Sep-2008	0	10-Nov-2008	20-Nov-2008	WA		20-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Injection site haematoma, Injection site pain, Nausea, Paraesthesia, Pyrexia

Symptom Text: Fever and nausea several hours after the shot for 1 week. Injection site soar ness and bruising. Left arm continuing to tingle and go numb, even 1.5 months after injection.

Other Meds: None

Lab Data: None yet to date

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 331847-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Nov-2008	10-Nov-2008	0	10-Nov-2008	30-Dec-2008	NJ		31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	1522U		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	U2621AA		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy, Hypotonia, Pallor

Symptom Text: About 1 minute after receiving the MENACTRA (L arm) HPV vaccine (GARDASIL) (R) arm. Pt's eyes rolled back and she slumped over, no color, came to within seconds.

Other Meds: None

Lab Data: Neg; normal neuro exam

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331851-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	10-Nov-2008	10-Nov-2008	0	10-Nov-2008	30-Dec-2008	KS		31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2637AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0546X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Loss of consciousness, Pallor, Unresponsive to stimuli

Symptom Text: Pt became pale and diaphoretic about 5 mins after injection given. Pt passed out and became unresponsive but was breathing for 5 mins-after given cool cloth and cool water and placed on exam bed Pt became responsive - color improved and was released with Mom in 10 mins.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331857-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	04-Nov-2008	05-Nov-2008	1	10-Nov-2008	30-Dec-2008	PA		31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	1	Right arm	Intramuscular	FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Urticaria

Symptom Text: Patient developed hives / itching - face , neck and forearms. As of 11/10/08 patient has itching of forearms only.

Other Meds: Zoloft , Advair, Amitriptyline

Lab Data: None

History: Tape/ Band Aids

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331860-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	29-Dec-2006	01-Dec-2007	337	10-Nov-2008	18-Dec-2008	NY		16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0962F	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain lower, Arthralgia, Joint injury, Joint swelling, Lymphadenopathy

Symptom Text: Arthralgia involving both knees X 1 yr. Intermittent (R) Lower abdomen pain and interconcomitant glandular swelling neck area. 11/20/08-records received for DOS 11/7/08-C/O left wrist pain x 2 days, denies trauma but last evening collided with another person and hyperextended left wrist. C/O knee arthralgia and swelling since receiving Garadsil.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **331949-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	05-Nov-2008	05-Nov-2008	0	11-Nov-2008	18-Dec-2008	MI		22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Dehydration, Fatigue, Headache, Malaise, Neck pain, No reaction on previous exposure to drug, Pain, Pallor, Pyrexia, Syncope, Tachycardia, Tremor

Symptom Text: Patient had stayed up from working MN's and went to doctor to receive final HPV vaccine. Had been feeling 'fine' --other than the normal post MN feeling. Had the injection administered about 12:30 pm--went home had something to eat, then went to bed. awoke about 5:00 pm this same day, with a headache, low grade fever, achiness, neck pain , and abdominal discomfort. temperature at @ 6 pm = 99.2 orally.pt took advil x 1. went to work at 9 pm this same day. started to feel much worse, increased fever, headache, and neck pain and 'feeling just run down all over'. patient could not work her mn shift, and was going to be escorted home. pt works in an Ed department and upon arrival of parents to pick her up, pt had an syncopal episode, pallor skin --almost white, with mild tremors. pt required stat ed care, which included a ct, lab, ivf (pt very dehydrated) required 3 liters of fluid, hr =tachy with low bp. spinal tap was done to r/o meningitis. pt 's lab revealed wbc with slight elevation. other labs wnl. temperature spiked to 102.5 rocephin iv given, and cultures drawn. pt started to feel better, after antipyretics , ivf's, and comfort/ sleep. discharged to home after 7 hours in the ed. pt remains with mild --cluster type headache controlled with pain medication. final dx= ? viral meningitis. 11/19/08-records received-final HPV4 vaccine received on-11/5/08-C/O headache, fever, neck pain, abdominal discomfort. General malaise and pale. Passed out. Dehydration. Diagnosed with viral meningitis and discharged from ED. Continues to C/O mild headache and tiredness and slowly progressing. No C/O with 2 previous HPV4 vaccines.

Other Meds:

Lab Data: 11/19/08-records received-Seen in ED performed CT scan, lab work and spinal tap. WBC mildly elevated. Initial spinal fluid negative, culture both serum and spinal negative.

History: none

Prex Illness: none that we are aware of

Prex Vax Illns:

Vaers Id: **331961-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jun-2008	01-Jun-2008	0	11-Nov-2008	12-Nov-2008	FR	WAES0810CAN00084	12-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hypoaesthesia

Symptom Text: Information has been received from a physician concerning a 15 year old female who in approximately June 2008, was vaccinated with first dose of GARDASIL (lot # not provided). In approximately June 2008, the patient experienced feeling faint and numbness in left arm (site of injection) following first dose of GARDASIL. The physician reported that the reaction was within 10-30 minutes following injection and lasted approximately an hour following. No intervention was taken and symptoms disappeared. Subsequently, the patient recovered from feeling faint and numbness in left arm. Upon internal review numbness in left arm (site of injection) was considered other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331993-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Nov-2008	04-Nov-2008	0	11-Nov-2008	21-Nov-2008	OH		16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	05484	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Drug hypersensitivity, Dysmenorrhoea, Paraesthesia

Symptom Text: Pt c/o intermittent paresthesias beginning 24 hrs after vaccine. 11/19/08-records received for DOS 11/4/08-Allergies to sulfa. Diarrhea. DX: dysmenorrhea. No additional visits in record.

Other Meds: none

Lab Data: None

History: none 11/19/08-records received-PMH: migraine without aura. Pt is highly allergic toall tree nuts.

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331996-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	13-Oct-2008	22-Oct-2008	9	11-Nov-2008	21-Nov-2008	MT		24-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U9659AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	007CX	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Dizziness

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **331999-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Nov-2008	11-Nov-2008	0	11-Nov-2008	21-Nov-2008	CT		27-Mar-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0947X	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1280P	1	Right arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U2824AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dyskinesia, Loss of consciousness, Malaise, Pallor, Syncope

Symptom Text: PT. received #3 vaccines, approx 4 min later while sitting on exam table stated to nurse in room, "I'm not feeling well". Nurse put pt's legs on table laid her down, pt had jerking all 4 extremities 3-5 sec. had loc-then recovered quickly-alert, pale. MD in aattendance after synopal episode + syncopal seizure witnessed by nurse.

Other Meds:

Lab Data: None

History: Allergic to Amoxicillin

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332014-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Nov-2007	Unknown		12-Nov-2008	13-Nov-2008	FR	WAES0811USA00358	13-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0276U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depression

Symptom Text: Information has been received from a general practitioner concerning a 16 year old female who on 13-NOV-2007 was vaccinated with the first dose of GARDASIL (LOT# NF58550, Lot # 0276U). Subsequently, on an unknown date the patient developed severe depression. She presented in the physician's practice on 08-Jan-08. It was noted in the patient's record that the patient "was still depressive". Despite ongoing symptoms the patient was vaccinated with a second dose of GARDASIL (Lot# not reported) on 14-Jan-2008. The reporter assessed the case as serious. Outcome was not reported. Depression was considered to be an other important medical event. Other business partner numbers included: E2008-10074. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **332015-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Oct-2008	13-Oct-2008	0	12-Nov-2008	13-Nov-2008	WI	WAES0811USA00706	17-Nov-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who on an unknown date was vaccinated with a dose of 0.5 ml GARDASIL (lot number, route and injection site unknown). Concomitant vaccination included a dose of BOOSTRIX and MENACTRA. After receiving GARDASIL, the patient experienced a seizure. She was seen at the emergency room. Patient's outcome was not reported. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332016-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	05-Oct-2007	05-Oct-2007	0	12-Nov-2008	13-Nov-2008	NJ	WAES0710USA06658	13-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received, for the Pregnancy Registry for GARDASIL, from a nurse concerning a 24 year old female who on 05-OCT-2007 was vaccinated intramuscularly with her first dose of GARDASIL. Subsequently, the patient found out she was pregnant (LMP = 15-SEP-2007). According to the reporter, it is believed that the patient was about 5 to 8 days pregnant at the time of vaccination. The patient sought unspecified medical attention. No further information was provided. Follow-up information was received on 04-NOV-2008 via phone call from a person of a doctor's office indicating that the patient was given the vaccine elsewhere and she came in for one prenatal visit and returned stating she had terminated the pregnancy elsewhere. The reporter could not confirm the gestational age at the time of the pregnancy termination. The patient later moved to another state and they have no further information to provide. Upon internal review, pregnancy termination was determined to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 9/15/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332017-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-Jun-2007	09-Sep-2007	89	12-Nov-2008	13-Nov-2008	IN	WAES0710USA05791	13-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1425F	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Failed trial of labour, Premature labour

Symptom Text: Initial and follow up information has been received from a physician and nurse for the Pregnancy Registry for GARDASIL regarding a 19 year old female who on 12-APR-2007 was vaccinated intramuscularly with her first dose of GARDASIL (lot #655165/1425F). On 12-JUN-2007, the patient was vaccinated intramuscularly with her second dose of GARDASIL (lot #655165/1425F). There was no concomitant medication. On an unspecified date, the patient took an over-the-counter pregnancy test and the results were positive (date unspecified). The patient sought medical attention via telephone. As of 04-JUN-2008, the patient is 38 weeks + 1 day pregnant, her estimated due date is reported as 17-JUN-2008 (LMP estimated as 09-SEP-2007). Follow-up information was received on 05-NOV-2008 via phone call from a nurse indicating that the patient had an estimated delivery date of 16-JUN-2008 and went into spontaneous labor on 22-JUN-2008. She progressed well through the first stage and reached full dilatation, pushed for one and a half hours and had a cesarean section for a diagnosis of failure to descend. The patient delivered a healthy and normal baby girl, weighing 8.2 pounds, at 40 and 5/7 weeks RGA. The patient had a normal post-operation recovery and was doing well. Upon internal review, "failure to descend" was determined to be an other important medical event. Additional information is not expected.

Other Meds: None

Lab Data: Beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 9/9/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332018-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		12-Nov-2008	13-Nov-2008	MO	WAES0811USA00534	13-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a an office manager, concerning 2 to 3 female patients who on an unspecified date were vaccinated with a dose of GARDASIL, Lot number was not available. The office manager reported that there were 2 to 3 patients who had miscarriage around the time when they received GARDASIL. At the time of the report the patients' outcome was unknown. The patient sought medical attention, seen by the physician. Miscarriage was considered to be an other important medical event. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **332022-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		12-Nov-2008	13-Nov-2008	--	WAES0810USA05376	19-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Benign intracranial hypertension, Disturbance in attention, Headache, Meningitis, Musculoskeletal stiffness, Neurological examination abnormal, Papilloedema, Vision blurred

Symptom Text: Information has been received via a company representative who saw on a television news channel a mother who reported an AE on behalf of her 15 year old daughter. The patient developed headache and meningitis symptoms after getting GARDASIL. Lot# was not provided. The patient's headache and meningitis symptoms persisted at the time of the report. No further information is available. 01/14/09 Reviewed Neurology medical records of 10/24-11/04/2008. FINAL DX: pseudotumor cerebri; headaches Records reveal patient experienced severe frontal HA, blurry vision, decreased concentration x 3 days. Neuro exam revealed florid bilateral papilledema & upgoing toes. Developed spells of neck & extremities stiffness. Tx w/high dose steroids, antiseizure meds & diuretic. RTC 11/4/08 much improved, HA resolved. Revealed that pt had started minocycline for acne on same day as HPV vax given.

Other Meds: Unknown

Lab Data: Unknown LABS: MRI brain abnormal. CT brain WNL. LP done w/opening pressure of 570.

History: Unknown PMH: family hx: migraine, HTN, DM.

Prex Illness:

Prex Vax Illns:

Vaers Id: 332026-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-Jun-2007	10-Jul-2007	13	12-Nov-2008	13-Nov-2008	TX	WAES0711USA00479	14-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Initial and follow up information has been received from a physician and a licensed visiting nurse through the Pregnancy Registry for GARDASIL concerning an 18 year old female, with no previous pregnancies and no reported medical history who on 02-MAY-2007 was vaccinated intramuscularly with the first dose of GARDASIL (Lot # and site not provided). On 27-JUN-2007, the patient was vaccinated intramuscularly with the second dose of GARDASIL (Lot # and site not provided). Subsequently, it was reported that the patient was pregnant (LMP = 10-JUL-2007). On 31-AUG-2007, the patient had an ultrasound to confirm gestational age and the results were normal. Concomitant medications during pregnancy were prenatal vitamins (unspecified) and TYLENOL. On 10-APR-2008, the patient gave birth to a normal baby girl (8 lbs 10oz; 21.5 inches in length, and head circumference 13 inches). The infant's apgar scores were 9 and 9. There were no complications during pregnancy, or labor and delivery, and the infant had no congenital anomalies. Follow-up information indicated that the infant was seen on 14-APR-2008 and there was a concern that her feet were "turned in." The infant was assessed with bilateral feet inversion most likely from inutero positioning. The plan was to observe the infant over the next couple months and it was reported that it may take 6 to 12 months to fully correct. A orthopedic referral, evaluation, and possible splinting for this problem were all considered. The physician reported that there were no congenital anomalies. However, upon internal review bilateral feet inversion was considered to be a minor congenital anomaly. Additional information is not expected. Medical records are available upon request.

Other Meds: None

Lab Data: Ultrasound, 08/31/07, confirm gestational age; results normal

History:

Prex Illness: Pregnancy NOS (LMP = 7/10/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332053-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Oct-2008	30-Oct-2008	1	12-Nov-2008	24-Nov-2008	NH		16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Unknown	
	FLU	SANOFI PASTEUR	892973P	6	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2686AA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Body temperature increased, Dyspnoea, Ear pain, Erythema, Fatigue, Oral dysaesthesia, Pain, Pain in extremity, Peak expiratory flow rate decreased, Rash, Urticaria

Symptom Text: C/O back pain, pain in arms and legs "mouth feels funny" was given MENACTRA, GARDASIL and FLUZONE vaccines on same day. Sharp pains and redness to right leg. Temp 101 Generalized body aches and fatigue transient rash to underside of left upper arm that appears hive-like. Med difficulty breathing. Has hit of asthma. Peak flow decreased from 500- 370.

Other Meds:

Lab Data: none

History: Sulfonamides, Penicillin

Prex Illness:

Prex Vax Illns:

Vaers Id: 332061-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Aug-2008	08-Aug-2008	0	12-Nov-2008	24-Nov-2008	TX		20-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	AHAVB235BA	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1967U	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Breast pain, Headache, Hypoaesthesia, Meralgia paraesthetica, Migraine, Muscular weakness, Musculoskeletal pain, Neuropathy peripheral, Pain in extremity, Paraesthesia

Symptom Text: c/o weakness to left arm since GARDASIL vaccine given on 8/8/08. 11/24/2008 Office records received from PCP. WCC 8/8/08 with vax given. PE WNL except papular lesions on the face. Seen agin 9/15/08 with c/o L arm pain which radiates to L hand since receiving HPV vax. Assessment: Paresthesia. X-ray 9/16/08 for knee pain. Seen again 9/29/08 with pain sx now also to the shoulder and breast. Awaiting neuro appt. 1/7/09 Neuro consult received from PCP dated 11/11/2008 with DX: Left Ulnar Neuropathy Symptoms. Left thigh Meralgia Paresthetica. Tendency to Migraine. Pt presented with 3 month hx of L sided head pain, L hand numbness and L thigh numbness which began after receiving HPV vaccine. PE (+) for altered sensation in ulnar distribution of L hand and no sensitivity of the nerve at the elbow. Unable to see association to immunization.

Other Meds:

Lab Data: Paresthesia. Labs and Diagnostics: X-ray L knee WNL.

History: PMH: Facial rash-dermatitis. Asthma. Tonsillectomy. Ear tubes. Allergy to Ceclor. Env allergies.

Prex Illness: Dermatitis to face

Prex Vax Illns:

Vaers Id: **332094-1 (S)** **Related reports:** 332094-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jul-2008	28-Aug-2008	58	12-Nov-2008	14-Nov-2008	MI		06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	2	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Arthralgia, Chest X-ray abnormal, Chest pain, Cough, Dizziness, Dyspnoea, Hodgkins disease stage II, Melanocytic naevus, Myalgia

Symptom Text: Garadsil vaccine given on 12/4/2007, 2/29/2008 and 7/1/2008. On 8/28/2008 chest pain, shortness of breath, lightheadedness and dizziness occured. OSF saw her in the ER. Chest X-ray should a "fullness" by the heart. On 8/30/2008 a CAT scan was performed and early Stage II A Hodgkin's Lymphoma was the official diagnosis received on 9/24/2008. Patient is currently undergoing treatment at the clinic. Prior to the beginning of the 3 shot series of Gardasil vaccine, patient had a chest X-ray, and the cheset X-ray showed no signs of Hodgkin's Lymphoma. 11/13/08-records received for ED DOS 8/28/08-presented with C/O shortness of breath, difficulty taking a deep breath symptoms began 5 hours ago.ED visit 9/14/08-presented with sternal pain, shortness of breath onset with attending a competition. C/O cough, arthralgia, myalgia. DX: chest pain, lymphoma. 3/3/09-seen in clinic on 1/23/09-with stage II nodular sclerosing Hodgkin's disease status post radiation and chemotherapy. Presents with C/O change in nerves in right armpit.

Other Meds:

Lab Data: CAT Scan, PET Scan, Lymph Node Biopsy, Bone Marrow Biopsy, Blood Work 11/13/08-records received- Labs WNL. Chest x-ray PA & Lateral demonstrated soft tissue density at right heart border not seen on previous exam of 10/4/07. Also soft tiss

History: NKA

Prex Illness: N/A

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332094-2 (S)** **Related reports:** 332094-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jul-2008	28-Aug-2008	58	27-Jan-2009	28-Jan-2009	--	WAES0901USA01079	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Chest pain, Dizziness, Dyspnoea, Hodgkins disease stage II

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 17 year old female with no known allergy who on 01-JUL-2008 was vaccinated in the left arm with the third dose of GARDASIL (lot# 659180/1758U) (route of administration not reported). The patient was vaccinated with the first and the second dose of GARDASIL on 04-DEC-2007 and 29-FEB-2008 respectively. On 28-AUG-2008 the patient experienced chest pain, shortness of breath, lightheadedness and dizziness. The patient was accepted by emergency room. Chest X-ray test indicated a "fullness" by the heart. On 30-AUG-2008 a computerized axial tomography (CAT) scan was performed and early Stage 2 Hodgkin's lymphoma was the official diagnosis received on 24-SEP-2008. The patient was hospitalized. Patient is currently undergoing treatment at the clinic. Prior to the beginning of the 3 shot series of GARDASIL, the patient had a chest X-ray, and the chest X-ray showed no signs of Hodgkin's Lymphoma. Other lab tests also included positron emission tomography (PET) scan, lymph node biopsy, bone marrow biopsy and blood work. A standard lot check investigation was performed. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center for Biologics Evaluation and Research and was released. The reporter considered the adverse experiences to be life threatening. The original reporting source was not provided. The VAERS ID# is 332094. No further information is available.

Other Meds: Unknown

Lab Data: chest X-ray, 08/28?/08, a "fullness" by the heart; computed axial, 08/30/08, official diagnosis result was early Stage Hodgkin's lymphoma; chest X-ray, 07?, no signs of Hodgkin's lymphoma

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **332096-1 (S)** **Related reports:** 332096-2; 332096-3; 332096-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	06-Nov-2008	07-Nov-2008	1	12-Nov-2008	14-Nov-2008	NC		20-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	2	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB294BA	2	Right arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Facial pain, Facial palsy, Hypoaesthesia facial, Hypoaesthesia oral, Oral herpes, Sensory loss, Vaccine positive rechallenge

Symptom Text: After final dose of both Hepititis A Vaccine, and HPV Vaccine my daughter awoke the following morning; (less than 24hrs) with complete paralysis of the left side of her face. Unable to smile on left side, close left eye completely, unable to stick out tongue or move it side to side. Complained of numbness and pain on left side of face. Prior to this, after last doses; my daughter complained that she was having problems with her tongue and taste buds, had one incident of severe pain in her ear which lasted one day, complained of stomach pain unrelated to anything, general aches and pains, and headaches. I called the doctor's office after assessing the situation and brought her in to be evaluated. The doctor felt it was unrelated to the vaccines and diagnosed her with Bell's Palsy. She provided patient with a neuroligical examination and a prescription of Prednisone and Acyclovir. She took the Acyclovir for 5 days and is still taking the steroids with no benefits or improvements. She will be rechecked on 11/17/08. 11/19/08-records received-office visit 11/7/08-C/O tingling of tongue and can not move left side of face, cold sore left corner of mouth some decrease in sensation on left side of face. cannot completely close left eyelid. DX:Bell's Palsy. Possibly related to herpes. Office visit 11/14/08-after 2nd Gardasil vaccine C/O sudden onset of ear pain that resolved same night. Bell's Palsy appeared day after 3rd dose of Gardasil. At time of this office visit symptoms improving.

Other Meds: n/a

Lab Data: Neurological exam given by doctor.

History: Allergy to penicillin

Prex Illness: n/a

Prex Vax Illns: Bell's Palsy~HPV (no brand name)~~13~In Patient

Vaers Id: **332096-2** **Related reports:** 332096-1; 332096-3; 332096-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	06-Nov-2008	07-Nov-2008	1	14-Nov-2008	11-Feb-2009	NC		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	2	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB294BA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ageusia, Facial palsy, Oral herpes, Paraesthesia oral

Symptom Text: 11/07/2008 Pt c/o tingling of her tongue over the past week. Woke up this AM. Can not smile, taste, or completely close (L) eye. Pt's mother concerned b/c GARDASIL and HARVIX given 11/06/2008. The doctor documented that Pt with cold sores (L) corner of her mouth. Pt was Dx with Bell's Palsy and placed on Prednisone 40mg x 7days, Acycbovir 20mg x 7days, and Pt was to return to clinic in 1 week for a follow up. Some improvement in facial movement per Dr.

Other Meds: NONE

Lab Data: None

History:

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **332096-3** **Related reports:** 332096-1; 332096-2; 332096-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.9	F	06-Nov-2008	07-Nov-2008	1	19-Nov-2008	12-Feb-2009	NY	NC08109	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	2	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB294BA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ageusia, Facial palsy, Facial paresis, Oral herpes, Paraesthesia, Paraesthesia oral

Symptom Text: 11/7/08: Pt. c/o tingling of her tongue over the past week. Move up this arm, cannot smile, taste, or completely close (L) eye. Pt.'s mother concerned b/c GARDASIL + HAVRIX given 11/6/08. Dr. documented pt. with cold sores (L) corner of her mouth. Pt. was Dx with Bell's Palsy and placed on Prednisone 40 mg x 7 days, Acyclovir 20 mg x 7 days and pt. was to return to clinic in 1 week for a follow-up.

Other Meds: None

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **332096-4** **Related reports:** 332096-1; 332096-2; 332096-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	06-Nov-2008	07-Nov-2008	1	20-Nov-2008	11-Feb-2009	NC		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	2	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB294BA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ageusia, Facial palsy, Oral herpes, Paraesthesia oral

Symptom Text: 11/7/08 pt complained of tingling of her tongue over the past week, Woke up this AM, cannot smile, taste or completely close (L) eye. Pt's mother concerned because HPV and HEP A given 11/16/08. Doctor documented pt with cold sores (L) corner of her mouth. Pt was diagnosed Bell's Palsy with and placed on PREDNISONE 40mg for 7 days, ACYELAVIR 20mg for 7 days and pt was to return to clinic in 1 week for a follow-up.

Other Meds: None

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **332098-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Nov-2006	21-Nov-2006	20	12-Nov-2008	18-Dec-2008	PA		24-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0955F	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Epistaxis, Henoch-Schonlein purpura, Joint sprain, Joint swelling, Musculoskeletal stiffness, Purpura, Rash, Rash pustular, Skin ulcer, Vasculitis

Symptom Text: my daughter developed hsp vasculitis 21 days after injection.she know has a chronic form of hsp and is on methotrexate.severe purple lesions on legs,buttocks,and elbows.she also has abdominl pain. 11/24/08 PCP records received beginning 11/1/2006 with WCC with normal exam. Gardasil #1 given. Pt returned 12/14/06 with c/o rash on legs x 7 days. Assessment: Vasculitis. HSP. Referred to Rheum. Rheum consult 1/8/07 with DX: HSP. PE (+) for purpuric lesions, some ulcerated. Few recent nosebleeds reported. Tx with prednisone. F/u 2/27/07 with c/o abdominal pain. F/u 2/13/08 with c/o ankle problems/swelling. 15 yr WCC on 9/9/08 with c/o knee and abd pain and stiffness.PE (+) for pink papulopustular rash. Assessment; h/o vasculitis-no signs of active disease. Rash. Knee pain. 11/26/08 ER rec of 8/23/06 with DX: wrist sprain. Pt developed wrist pain after doing a handstand. No fx.

Other Meds:

Lab Data: blood work and urinaylsis as well biopsy Labs and Diagnostics: Complement C3,C4 WNL. IgA WNL 187. Sweat test (-). X-ray neck (+) mild adenoid enlargement. X-ray wrist WNL.

History: none PMH: None

Prex Illness: none

Prex Vax Illns: hsp~HPV (Gardasil)~1~14~In Patient

Vaers Id: **332100-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	05-Nov-2008	06-Nov-2008	1	12-Nov-2008	14-Jan-2009	MN		15-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion

Symptom Text: Patient has history of seizure disorder but had not had seizures since Spring of 2008. Gardasil recv'd at 3pm on 11/5 and between midnight and 4am of 11/6 had 5-6 seizures.

Other Meds: sertraline, zonisamide, lamotrigine, nordette, flovent, afrin

Lab Data:

History: seizure disorder

Prex Illness: None known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332109-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-Sep-2008	19-Sep-2008	8	12-Nov-2008	18-Dec-2008	CA		08-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anorexia, Contusion, Erythema, Pain in extremity, Skin exfoliation

Symptom Text: NO APPETITE, HEADACHE, HANDS HURT WHILE EXPOSED TO HOT WATER, DARK PURPLE OVAL BRUISE-LIKE MARKS ON BOTH ELBOWS, REDNESS AROUND BOTH FEET, PAIN IN LEFT ARM AND IN FEET WHEN STANDING UP. I TOOK MY DAUGHTER TO URGENT CARE AND PRIMARY DOCTOR WITHIN DAYS OF EACH OTHER. REFERRED TO DERMATOLOGY AND AWAITED BLOOD TEST RESULTS. A WEEK OR TWO AFTER THESE SYSTEMS, THE SKIN ON HANDS AND ELBOWS BEGAN TO PEEL OFF JUST SHREDD OFF AND ABOUT TWO WEEKS LATER THE SKIN ON THE FEET BEGAN TO PEEL OFF, JUST SHREDDING OFF AND PURPLE BRUISE-LIKE MARKS APPEARED ON BACK, ANKLES, BUTTOCK AREA. DERMOTOLOGIST TOOK BLOOD TESTS AND A BIOPSY. A STERIOD OINTMENT WAS GIVEN AND USED ON PEELING/PURPLE AREAS OF SKIN FOR 14 DAYS. MANY BLOOD TESTS WERE DONE, CHEST X-RAY, BIOPSY OF ELBOW AND FOOT AREA. REFERRED TO HOSPITAL. ANOTHER OINTMENT WAS ISSUED. 11/14/08 MR received for dematology consult dated 10/15/2008. Pt presented for eval of rash which began on the elbows, gluteal cleft, hands and feet. Itchy at first, now improved. Burning sensation noted in hot water. Tx with steroids with some improvement. Pt also reports elbow pain. PE (+) for diffuse, slighly waxy exfoliation on the bilateral plantar surfaces of the feet, mild erythema w/o scale on elbows, hyperpigmented scaly plaques on the posterior and medial ankles, scaling and exfoliation on palms, follicular hyperkeratosis on knees and pustule and papules (acne) on the face. Assessment: Localized variant of pityriasis rubra pilaris vs psoriasis.

Other Meds:

Lab Data: BIOPSY, BLOOD TESTS, CHEST XRAY. Labs and Diagnostics: Skin bx c/w pityriasis rubra pilaris.

History: ALLERY TO SULFA. PMH: ear infections, stomach aches. allergic to sulfa.

Prex Illness: NONE

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332113-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	07-Apr-2008	07-Apr-2008	0	12-Nov-2008	14-Jan-2009	UT		15-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Suture insertion

Symptom Text: Pt was dizzy after getting the injection of Gardasil and fell and needed sutures.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332141-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-Oct-2008	28-Oct-2008	0	12-Nov-2008	14-Nov-2008	CA		23-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	2	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2757AA		Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Fall, Immediate post-injection reaction, Mouth injury, Syncope, Tooth injury

Symptom Text: Patient was given Gardasil, Influenza Vac and PPD. Few minutes after the injections patient fainted and fell to the floor. Mother and the medical assistant were in room. Patient sustained a laceration to her left upper lip and her one incisor broke. Patient needed treatment for laceration at the emergency room after she was transported by paramedics. She also required dental treatment. Full dental treatment has not been done yet. She has seen the dentist, she had xrays. She needs a crown, a root canal in the affected tooth. 12/11/08-records received for DOS 10/28/08-immediately after receipt of vaccine fainted, fell and broke her upper lip and front left incisor. Fainting a second time. Seen in ED. 12/17/08-ER records received for DOS 10/28/08-syncope-lip laceration. loose teeth.

Other Meds:

Lab Data:

History: Patient is in special classes.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **332142-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Nov-2008	06-Nov-2008	0	12-Nov-2008	04-Feb-2009	CA		04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Right arm	Intramuscular	
	FLU	GLAXOSMITHKLINE BIOLOGICALS	AFLLA178AA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect dose administered

Symptom Text: NONE

Other Meds: NONE

Lab Data: ADMINISTERED ADULT ONLY

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **332160-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-Mar-2007	20-Mar-2007	15	12-Nov-2008	17-Nov-2008	CA		03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Back pain, Eye pain, Faecaloma, Foreign travel, Hypoaesthesia, Nausea, Neuromyelitis optica, Optic neuropathy, Pain in extremity, Rash, Vaccine positive rechallenge, Visual acuity reduced, Vomiting

Symptom Text: 12/06-1/12/07 abdominal pain, nausea, vomiting. 1/15/07 upper GI. 3/15/07 GARDASIL #1. 3/20/07 unknown rash. 5/7/07 GARDASIL #2. 5/26/07 unknown rash. 9/14/07 GARDASIL #3. 9/24/07 unknown rash. 11/27/07 unknown rash. 2/20/08 ATTACK...left optic neuropathy, treated with prednisone over several days. Test positive for NMO IgG. 2/28/08 MRI Brain scan to determine damage to optic nerve. 3/1/08-5/18/08 prednisone treatment plan. 3/27/08 diagnosis of NMO from clinic. Discussed treatment with RITIXIMAB. 4/10/08 MRI thoracic spine, lesion discovered. 4/14/08 chest x ray. 5/16/08 leg pain, numbness. 5/20/08 hospital visit confirm diagnosis of NMO. 6/15/08-6/17/08 ATTACK...back pain/numbness in right leg/stomach numbness. 6/18/08 MRI thoracic spinal lesion confirmed. 6/18-6/22 Infusion SOLU-MEDROL 1000 mg (home). 6/22/08 ATTACK..back pain/numbness right leg/stomach numbness. 6/23/08-8/9/08 MEDROL tablet started. 7/14/08 MRI thoracic (follow up). 7/16 Infusion SOLU-MEDROL 1000 mg (hospital). 7/30/08 Infusion SOLU-MEDROL 1000 mg (hospital). 8/20/08 back pain. 8/20/08 MRI thoracic lesion noted. 10/3/08 back pain. 10/6/08 ATTACK...back pain. 10/7/08 back pain. 10/7/08-10/11/08 Infusion SOLU-MEDROL 1000mg (hospital). 10/27/08 mild back pain. 10/27/08 Infusion SOLU-MEDROL 1000mg (home). The medical team's initial evaluation, at this time, leads them to believe than the GARDASIL vaccine was the "trigger" that caused the NMO to surface. 11/24/08-records received-Neurology consult 6/20/08-3-5 episodes nausea and vomiting December 2006, symptoms resolved. Rashes after 3 Gardasil vaccinations. In February while on vacation in Mexico developed pain and decreased vision in left eye. MRI demonstrated enhancing lesion in left optic nerve, neuraxis. DX neuromyelitis optica. Three weeks ago intermittent episodes low back pain and hospitalized for severe impaction. Now C/O recurrence of back pain and numbness below waist. C/O numbness in both lower extremities left greater than right.

Other Meds:

Lab Data: 1/15/07, upper GI; 2/28/08, MRI Brain scan to determine damage to optic nerve; 4/10/08, MRI thoracic spine, lesion discovered; 4/14/08, chest x ray; 6/18/08, MRI thoracic spinal lesion confirmed; 7/14/08, MRI thoracic (follow up); 8/20/08,

History: none 11/24/08-records received-PMH: constipation. Raynaud's phenomenon. Eczema.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **332180-1 (S)** **Related reports:** 332180-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Mar-2008	03-Nov-2008	230	12-Nov-2008	17-Nov-2008	--		02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anaemia, Back pain, Blood pressure increased, Eye swelling, Headache, Oedema peripheral, Pain in extremity, Rash macular, Renal artery stenosis, Renovascular hypertension, Takayasus arteritis

Symptom Text: Diagnosed with Takayasu arteritis (rare disease). Chronic back pain 3 months after 1st vaccination. Headaches in summer 2008. Elevated B/p in June 08. 11/20/08-records received-office note 11/20/07-C/O 3 month history of mid back pain. Impression mid back strain. 10/09/08-ambulatory BP monitor-hypertension.Major component stress and anxiety. 6/24/08-C/O headaches. DX: Takayasu arteritis. Hospitalized for lower extremity edema and blotchy legs on 11/3/08. 12/31/08-records received for DOS 11/3/08-admitted after just started amlodipine with C/O ankle swelling and blotchy rash, admitted for evaluation of vaculitis. Headaches begin in June 2008 and elevated blood pressure. Eye swelling, achy legs when walking. Mild anemia with hemoglobin 10. Renal doppler showed elevated velocities but no renal artery stenosis. CT scan showed renal artery stenosis. Impression:renovascular hypertension due to bilateral renal artery stenosis, Takayasu arteritis.

Other Meds:

Lab Data: CT angiogram thoracoabdominal aorta - moderate right subclavian and mild left subclavian artery stenosis. Severe narrowing of abdominal aorta, celiac, SMA, and bilateral renal artery stenosis. 11/20/08-records received-MRI spine unremarkab

History: Healthy female

Prex Illness:

Prex Vax Illns:

Vaers Id: **332180-2 (S)** **Related reports:** 332180-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	16-Jul-2007	19-Jul-2007	3	24-Nov-2008	25-Nov-2008	IL	WAES0811USA01803	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	0	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Autoimmune disorder, Back pain, Eye haemorrhage, Headache, Hypertension, Takayasus arteritis, Tuberculin test

Symptom Text: Information has been received from a physician concerning a 19 year old female patient, with allergic reaction to antibiotics, who on 16-JUL-2007 was vaccinated with a first dose of GARDASIL (lot # 658094/0524U, on 20-SEP-2007 she received the second dose of GARDASIL (lot # 657736/0389U), and on 18-MAR-2008 she received the third dose of GARDASIL (lot # 659964/1978U). The physician reported that the patient experienced "back pain" from the GARDASIL, and on approximately 19-JUL-2007 the patient experienced blood dripping from both eyes (just for one day) and she has been having bad headaches since then. The physician reported that the patient was diagnosed with high blood pressure and an autoimmune disease affecting the large arteries called "TAKAYASU". The physician reported that the patient had been hospitalized for about a week as a result of the condition. Physician recommended Ibuprofen for treatment. The back pain, blood dripping from both eyes, bad headaches, high blood pressure and autoimmune disease affecting the large arteries called "TAKAYASU" were considered immediately life-threatening. On 27-May-2008 a "TB test" was done as a laboratory diagnostic studied (results not provided). The patient had not recovered. According to the physician, the patient has been released from the hospital. The physician is concerned about the "weird" things that she heard are happening to patients around the time of the GARDASIL vaccination. According to the reporting physician, "complications resulting from chronic use of steroids" was considered to be disabling. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332192-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	28-Jun-2007	07-May-2008	314	12-Nov-2008	18-Dec-2008	TN		23-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0174609	2	Left arm	Intramuscular	
DT	SANOFI PASTEUR	41707BA707	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	42328AA708	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Migraine

Symptom Text: Patient C/O bilateral ankle, wrist and knee pain. 1/16/2009 MR received from PCP. Pt in for 11yr WCC and vaccines 6/28/07. Well child with normal G&D with Dx: Exercise Induced asthma. Several sick visits for asthma exacerbations and cough and sore throats that year. At 12 yr exam 5/7/08, reports H/As, bilateral wrist, knee, and ankle pain and swelling. PE WNL Impression: Migraine H/A.

Other Meds:

Lab Data:

History: Asthma. PMH: EIA

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332218-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Oct-2008	22-Oct-2008	0	13-Nov-2008	14-Nov-2008	FR	WAES0811USA00568	14-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Musculoskeletal stiffness, Myalgia, Pain in extremity

Symptom Text: Information has been received from a consumer concerning her 15 year old sister who was vaccinated with a first dose of GARDASIL (lot #, site and route not reported) in OCT-2008. Two hours after vaccination the patient developed dizziness, stiffness of hands and feet and pain in limb. The patient was hospitalized on an unspecified date. She has not recovered at the time of reporting. The physicians do not see a causal relationship with GARDASIL vaccination. Further information was received from the hospital physician on 05-Nov-2008: The patient was vaccinated with a first dose of GARDASIL on 22-OCT-2008. One to two days after vaccination, the patient developed severe muscle ache in both thighs. The patient was hospitalized for a day (exact dates not reported) in a department of internal medicine. After two days at home she was admitted to a neurological department where she is still staying at the moment. Neurological examination was normal as well as lab findings including CK and electrolytes. Also MRI of lumbar spine, electroneurography and electromyography were normal. No diagnosis was established to date. Other business partner number include: E2008-10182. No further information is available.

Other Meds: Unknown

Lab Data: Neurological examination, normal; Magnetic resonance imaging, normal; Electromyography, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 332220-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-May-2008	Unknown		13-Nov-2008	14-Nov-2008	FR	WAES0811USA00961	14-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Eczema, Lymphadenopathy, Malaise, Pyrexia, Spleen palpable

Symptom Text: Information has been received from a Health Authority (HA reference # PEI2008016765) concerning a 17 year old female patient with no medical history reported who on 06-MAY-2008 was vaccinated with GARDASIL (Lot # and site not reported) IM. Two to three days post vaccination, the patient developed slight malaise. Six days p.v., the patient developed fever up to 40 C. The patient was treated with antibiotics. Additionally, she developed eczema on the legs and the fever persisted for 6 days. After short convalescence she experienced again fever up to 40 C with asthenia. The patient was hospitalized on an unspecified date. Upon hospitalization the cervical lymph nodes were partly enlarged, the spleen was palpable. Laboratory findings: Hemoglobin, reticulocytes, leukocytes decreased. Triglycerides: 368 mg/dl and C-reactive protein: 54.3mg/l. Abdomen sonography showed enlarge liver and spleen. Due to indication to possible Epstein-Barr virus infection the patient was treated with cefuroxime (manufacturer unknown) and trobamycin (manufacturer unknown) as well as doxycycline (manufacturer unknown). Due to suspicion of haemophagocytic lymphohistiocytosis treatment with dexamethasone IV (manufacturer unknown) was administered. After the symptoms had improved the dose was gradually reduced and treatment with amphocerin B (manufacturer unknown), trimethoprim (manufacturer unknown) and sulfamethoxazole (manufacturer unknown) was initiated. Diagnosis: Suspicion of haemophagocytic lymphohistiocytosis post vaccination or in consequence of an Epstein-Barr virus infection respectively. File Closed. Other business partner numbers include E2008-10243. No further information is available.

Other Meds: Unknown

Lab Data: Abdominal ultrasound, enlarged liver and spleen; WBC count, decreased; Hemoglobin, decreased; Serum C-reactive protein, 54.3 mg/l; Serum triglyceride, 368 mg/dl; Blood reticulocyte count, decreased

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332221-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		13-Nov-2008	14-Nov-2008	WA	WAES0811USA01103	14-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with GARDASIL, 0.5ml (unspecified route). The physician reported that the patient experienced syncope or seizures after receiving the GARDASIL vaccine and on the same day, the patient recovered. The patient sought unspecified medical attention. Upon internal review, seizures were determined to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **332227-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	Unknown	Unknown		13-Nov-2008	14-Nov-2008	FR	WAES0811CAN00032	14-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gait disturbance, Paraesthesia, Paralysis

Symptom Text: Information has been received from a pharmacist concerning a 9 year old female patient who was vaccinated with GARDASIL (lot # not available). Concomitant therapy included TWINRIX. Subsequently the patient experienced difficulties in walking for a few days - temporary paralysis and paresthesia were mentioned. Subsequently, the patient recovered from difficulties in walking for a few days - temporary paralysis and paresthesia. Upon internal review, paralysis was considered to be an other important medical event and paresthesia was determined to be an important medical event based on foreign agency requirements. Additional information is expected.

Other Meds: Hepatitis A virus vaccine inactivated, +, Unk

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332264-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Nov-2008	12-Nov-2008	1	13-Nov-2008	21-Jan-2009	CA		21-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2571AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0652X	0	Left arm	Intramuscular	
FLU	NOVARTIS VACCINES AND DIAGNOSTICS	88636	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site swelling, Injection site warmth, Pyrexia

Symptom Text: 1 day Right upper arm with redness, warmth, swelling, and firmness-measured 16 1/2 cm x 14cm diameters and low grade fever 100.2 F measured at home x 1 day.

Other Meds: none

Lab Data:

History: asthma

Prex Illness: none

Prex Vax Illns:

Vaers Id: **332275-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	21-Oct-2008	21-Oct-2008	0	13-Nov-2008	14-Nov-2008	FR	A0755303A	14-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Monoplegia

Symptom Text: This case was reported by a pharmacist and described the occurrence of leg paralysis in a 9-year-old female subject who was vaccinated with TWINRIX (GlaxoSmithKline), GARDASIL. On 21 October 2008 the subject received unspecified dose of TWINRIX (unknown), unspecified dose of GARDASIL (unknown). On 21 October 2008, in the same evening after vaccination with GARDASIL and TWINRIX, the subject experienced paralysis at her legs which lasted for few hours. She had trouble moving her legs. This case was assessed as medically serious by GSK. On 21 October 2008, the events were resolved.

Other Meds:

Lab Data: UNK

History:

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332325-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	27-Jun-2008	Unknown		13-Nov-2008	11-Feb-2009	OR		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0930V	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dermographism, Erythema, Pruritus, Urticaria

Symptom Text: New-onset dermatographism- raised red welts on skin with minor scratching, last for 5 to 10 minutes, not pruritic

Other Meds: DESOGEN OCP

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332343-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Oct-2007	22-Oct-2007	0	14-Nov-2008	17-Nov-2008	--	WAES0802USA05706	17-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a health professional, for the Pregnancy Registry for GARDASIL concerning a 16 year old female who on 09-JUL-2007 was vaccinated intramuscularly with her first dose of GARDASIL (lot # 658094/0524U). On 22-OCT-2007 the patient was vaccinated intramuscularly with her second dose of GARDASIL (lot # 658563/1063U). The patient is now about 6 weeks pregnant with an estimated LMP of 12-JAN-2008 and a due date of 18-OCT-2008. The patient had a positive urine pregnancy test. Follow-up information has been received which indicated that on 14-MAR-2008, the patient underwent elective termination. Upon internal review, elective termination was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Urine beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/12/2008)

Prex Vax Illns:

Vaers Id: **332344-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Apr-2008	01-Jul-2008	74	14-Nov-2008	17-Nov-2008	--	WAES0811USA01071	03-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anogenital warts, Anorexia, Cervical dysplasia, Colposcopy, Fungal infection, Genital lesion, Malaise, Papilloma viral infection

Symptom Text: Information has been received from a mother and aunt concerning a 16 year old female patient with no known medical history, who was vaccinated with all three doses of GARDASIL by June 2008. Concomitant suspect vaccination included influenza virus vaccine (unspecified) (name and manufacturer unspecified). The consumer reported that her niece was HPV (unknown type) positive after getting all three doses of GARDASIL. The mother subsequently reported that about one month after receiving all three doses of GARDASIL her daughter had a yeast infection and then two weeks later had another infection. The patient was the due for her yearly checkup and so she went and had a pap test done and the test showed the patient had genital warts and a "large lesion on her insides". The mother stated that her daughter is going to a specialist and will have to get "some work done on her" for the lesions. The mother reported that the patient does not feel well and has a loss of appetite. It also reported that the patient received the flu vaccine and "wound up in the hospital" (specifics not provided). The patient sought unspecified medical attention. At the time of the report it was reported that the patient was not recovered. No further information is available. 1/28/2009 MR received for GYN visit 12/5/08 for colposcopy for (+) PAP smear. Final DX: Mild to moderate dysplasia with HPV.

Other Meds: Unknown

Lab Data: gynecological, the patient had genital warts and large lesion on her insides; Pap test, the patient had genital warts and large lesion on her insides. Labs: Pap smear (+) for low grade sqaumous intraepithelial lesion. HPV (+). Cervical

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 332345-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Jun-2008	22-Sep-2008	94	14-Nov-2008	17-Nov-2008	FL	WAES0811USA01059	05-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Chest pain, Dizziness, Fatigue, Headache, Hypersomnia, Inappropriate schedule of drug administration, Nausea

Symptom Text: Information has been received from a registered nurse concerning her 17 year old daughter with an allergy to antibiotics and no other pertinent medical history, who on 22-APR-2008 was vaccinated with a 0.5 mL first dose of GARDASIL intramuscularly. On 20-JUN-2008 the patient received the second dose of GARDASIL. Concomitant therapy included hormone contraceptives (manufacturer unspecified). On 22-SEP-2008 the patient experienced headache, dizziness, nausea, fatigue, chest pain and stomach pains. The patient had her first CT Scan of the abdomen and blood work that were negative. On 09-OCT-2008 the patient had another CT Scan of the abdomen and the pelvis due to increased pain; the results were negative. On 22-OCT-2008 the patient received the third dose of GARDASIL. Then on 03-NOV-2008, the patient had an upper GI that was negative. On 04-NOV-2008 the patient had gastric emptying studies that were negative. On 05-NOV-2008 the patient had X-rays and blood work that were negative. The mother reported that her daughter was now "incapacitated", sleeping most of the day and was unable to get out the bed. The pain in the patient's stomach and chest had persisted and continued to worsen. The mother stated that "she continues to go down every day". The patient had been out of school for the past week and was not able to participate in after school activities (the patient was a cheerleader). At the time of this report, the patient had not recovered. The patient's headache, dizziness, nausea, fatigue, "sleeping most of the day/unable to get out of bed", "out of school for the past week and not able to participate in after school activities", "continues to go down every day", chest pain and stomach pains were considered to be disabling. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: Computed axial, negative; Diagnostic laboratory, negative, blood work; Computed axial, 10/09/08, negative; Upper GI series X-ray, 11/03/08, negative; Gastric emptying study, 11/04/08, negative; X-ray, 11/05/08, negative; Diagnostic laborato

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: 332346-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	07-Apr-2008	29-Apr-2008	22	14-Nov-2008	17-Nov-2008	FR	WAES0811USA00926	17-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Hypoaesthesia, Hypoaesthesia facial, Hypothyroidism, No reaction on previous exposure to drug, Post lumbar puncture syndrome

Symptom Text: Information has been received from a gynaecologist concerning a 25 year old female patient who was vaccinated with a second dose of GARDASIL (Lot #, site and route not reported) on 07-APR-2008. Concomitant medication included unspecified hormonal contraceptives. On 29-APR-2008, she was hospitalized for numbness of the left arm and face (left half) for 6 days. Additionally, she complained of dizziness. Neurological findings showed hypoesthesia of the left half of the face and the left arm. Overall clinical examination was normal. Lab findings revealed TSH: 6.26 uIE/ml. Routine laboratory findings showed normal results. Thyroid sonography was normal. Diagnosis of latent hypothyroidism was established. CSF puncture on 30-APR-2008: cell count: 1/3, glucose 63 mg/dL, protein: 21 mg/dL, lactate: 1.7 mmol/L. Albumin and IgG/IgA/IgM (CSF and serum) showed normal values. TPHA screening procedure was negative, specific IgG and IgM antibodies to borrelia (CSF and serum) were negative. No oligoclonal bands detectable. No CSF-blood barrier disorder. ECG showed normal results. Cranial MRI on 29-APR-2008: Normal NMR tomography of the cranium, no indication of lesions typical for multiple sclerosis. Electrophysiology on 02-MAY-2008, SEP of median nerve (bilateral): normal findings. VEP on 05-MAY-2008: normal findings. MEP (arms) on 05-MAY-2008: normal findings. MEP (legs) on 05-MAY-2008: normal findings. On 01-MAY-2008, the patient experienced headache caused by lumbar puncture. The patient's condition improved under treatment with infusions, Ibuprofen and caffeine tablets and at discharge on 05-MAY-2008 she had completely recovered from headache. Outcome from hemihypaesthesia was not reported. The first dose of GARDASIL (Lot # not reported) was administered on an unspecified date and was well tolerated. Other business partner numbers included: E2008-10187. Additional information has been requested.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: magnetic resonance imaging, 29Apr08, Cranial MRI: normal NMR tomography of cranium, no indication of lesions typical of multiple sclerosis; cardiac electrophysiology, 02May08, SEP of median nerve (bilateral) normal findings; visual evoked p

History:

Prex Illness: Hypothyroidism

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332358-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Sep-2008	01-Sep-2008	0	14-Nov-2008	17-Nov-2008	FR	WAES0811USA00812	17-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bronchospasm, Cyanosis, Loss of consciousness

Symptom Text: Information has been received from a pharmacist concerning a 17 year old female patient with no relevant medical history reported who received the first dose of GARDASIL (batch number not reported) by the end of September 2008. Five minutes later, the patient experienced bronchospasm, she became blue and had a loss of consciousness. Adverse events were reported of moderate intensity. She had fully recovered in 15 minutes. She had no concomitant treatment reported. Vaccination with GARDASIL was stopped. The adverse events were considered as other important medical event. Other business partner numbers included: E2008-10351. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **332382-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-May-2008	10-May-2008	4	14-Nov-2008	11-Feb-2009	WA		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	ANAVB236AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menorrhagia, Menstruation irregular, Papilloma viral infection

Symptom Text: States she has GARDASIL (1) day & 2 days later she had HPV. Her period came early & heavy & lasted 7 days she then stopped & 2 wks later had a regular cycle. She feels it was due to both shots so close.

Other Meds:

Lab Data: N/A

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **332423-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	29-Aug-2008	05-Sep-2008	7	14-Nov-2008	11-Feb-2009	NJ		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Discomfort, Injection site atrophy, Injection site discolouration, Injection site swelling, Muscular weakness

Symptom Text: Swelling and discoloration of left shoulder. Weakness/discomfort of left arm. Atrophy of left deltoid.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332434-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
75.0	M	12-Nov-2008	Unknown		14-Nov-2008	11-Feb-2009	IA		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: None noted

Other Meds: None

Lab Data:

History: NA

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332440-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Oct-2008	29-Oct-2008	0	14-Nov-2008	11-Feb-2009	IA		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	?	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Blister, Dizziness, Headache, Hypotension, Immediate post-injection reaction, Nausea, Pyrexia

Symptom Text: 1st shot of Gardisil Patient became ill with headache stomache ache (cramping) & mother told her it was probably just the flu & it lasted 3 days. The second time she got the shot 3 months later patient was dizzy & nauseated within 10 to 15 minutes after shot & other symptoms included achey all over blisters on skin & low blood pressure & headache & low grade fever.

Other Meds: none

Lab Data: 10/31/08 Blood pressure taken by Dr. & confirmed allergic reaction.

History: allergic to neosporin

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332477-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		14-Nov-2008	11-Feb-2009	WA		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Patient was HPV neg. Was given series of 3 GARDISIL vaccines summer of 2008. Aug 2008 PAP ASCUS and positive for high risk HPV PAPs previously were normal HPV neg.

Other Meds: ZURTEC; ORTHO TRICYCLIN L.o

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332488-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	29-Sep-2008	03-Oct-2008	4	14-Nov-2008	11-Feb-2009	NY		12-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1487U	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2687AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC526021AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash papular

Symptom Text: Popular rash noted on both arms advised to observe.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332519-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	04-Nov-2008	Unknown		17-Nov-2008	01-Dec-2008	OR	0R200842	01-Dec-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0570X	0	Right arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52802AA	0	Left arm	Unknown	
FLU	SANOFI PASTEUR	U2807AA	0	Right arm	Unknown	
HEPAB	GLAXOSMITHKLINE BIOLOGICALS	AHABB08AC	3	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect dose administered

Symptom Text: Patient was given TWINRIX, instead of correct dosage for age. Misadministration.

Other Meds: None

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332521-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Oct-2008	29-Oct-2008	0	17-Nov-2008	01-Dec-2008	PA		09-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	05751	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depression, Hypoaesthesia, Pain in extremity

Symptom Text: Pt presented with numbness feeling in arm and leg on both sides of body. She is also experiencing pain in all extremities (since the shot.) 2/6/09 Received PCP office records of 11/11/2008. FINAL DX: numbness in extremities, depression Records reveal patient experienced UE & LEs numbness since 10/29/08. Right arm pain into hand. Pt referred for counseling & was to return should symptoms persist. No further records available.

Other Meds:

Lab Data: CBC with diff, CMP free TY & TSH LABS: CBC, chemistry & thyroid studies WNL.

History: Vasomotor instability, syncope,PVC's

Prex Illness: only above symptoms

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332548-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-Nov-2008	14-Nov-2008	0	17-Nov-2008	01-Dec-2008	IL		01-Dec-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1181X4037X	1	Right arm	Subcutaneously	
TDAP	SANOFI PASTEUR	2863AA	1	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	02656AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	19680	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVR319AA	2	Left arm	Intramuscular	
FLU	SANOFI PASTEUR	02829AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Swelling, Urticaria

Symptom Text: Pt rec'd 3 vaccines in R deltoid, MONACTRA. GARDASIL, VARIVAX. Within 3 seconds of given GARDASIL, dime size were formed with reddened swollen area 3" by 2." Dr. evaluated and given BENADRYL 25 MG p.o. per Dr. Called mom @ 5:20 pm. She stated it looked less white in center, still swollen.

Other Meds:

Lab Data:

History: Peanuts; Shellfish; Insect bites

Prex Illness: None

Prex Vax Illns:

Vaers Id: 332587-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	06-Nov-2008	08-Nov-2008	2	17-Nov-2008	17-Dec-2008	FL		09-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	89685		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0070X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Burning sensation, Intervertebral disc protrusion, Muscle spasms, Musculoskeletal pain, Neck pain, Pain in extremity, Rash, Sensation of heaviness, Sleep disorder, Soft tissue disorder, Tenderness

Symptom Text: CLIENT STATED THAT THE FIRST TWO DAYS AFTER THE FLU SHOT, SHE HAD "A RASH AND MY ARM FELT HEAVY. THERE WAS SOME PAIN, BUT NOT ALOT." SHE THEN GOES ON TO SAY THAT THE THIRD DAY AFTER THE FLU SHOT SHE HAD A SHARP BURNING PAIN THAT RADIATED UP HER RIGHT NECK AND DOWN HER RIGHT ARM. SHE SAID THAT SHE TOOK TYLENOL, USED THE COLD COMPRESSES, TOOK HOT SHOWERS, BUT DID NOT GET ANY RELIEF AND CANNOT SLEEP. SHE DID NOT TAKE HER TEMPERATURE SO SHE IS NOT AWARE OF A FEVER. SHE CALLED OUR OFFICE BEFORE GOING TO SEE A DOCTOR. ENCOURAGED HER TO SEE HER PRIMARY CARE PHYSICIAN. SHE SAID THAT SHE DOES NOT HAVE ONE SHE WOULD HAVE TO GO TO THE ER. 2/5/09 Received ER medical records of 11/21/2008. FINAL DX: cervicalgia; pain in limb Records reveal patient experienced right side neck & shoulder pain x several weeks. Exam noted sever muscle spasm of right posterior neck & severe soft tissue tenderness of right upper neck. Tx w/steroids & pain meds. Phone f/u revealed patient improved on 11/24/08.

Other Meds: ORTHO-TRICYCLINE LOW

Lab Data: NONE LABS: CT scan c-spine revealed disk herniation C5-C6; disk bulging C6-C7.

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **332635-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Nov-2008	17-Nov-2008	0	17-Nov-2008	23-Jan-2009	MA		26-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2734AA	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2766AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0279X	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B027AA	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Pt received 1st dose of GARDASIL. Pt began seizing in approx 3-4 seconds after receiving GARDASIL vaccine.

Other Meds:

Lab Data:

History:

Prex Illness: Seizure

Prex Vax Illns:

Vaers Id: **332655-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	06-Dec-2006	28-Oct-2008	692	18-Nov-2008	19-Nov-2008	FR	WAES0811USA01728	19-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Foetal disorder

Symptom Text: Initial information has been received from an investigator concerning a 0 day old neonate (birth weight: 3432 g) who was born from a mother who entered a clinical trial. Concomitant therapy included "ALIMAN" and "ZALUCS". On 06-JUl-2006, the subject received the first inoculation of GARDASIL or placebo, 0.5 ml, IM. as prophylaxis against HPV infection. On 05-SEP-2006, the subject received the second inoculation of GARDASIL or placebo, 0.5 ml IM, as prophylaxis against HPV infection. On 06-DEC-2006, the subject received the third inoculation of GARDASIL or placebo, 0.5 ml IM, as prophylaxis against HPV infection. On 23-JAN-2008, it was the date of the subject's last menstrual period. On 28-OCT-2008, the subject gave birth to a neonate. Congenital clubfoot developed. at the time of the report, outcome of congenital clubfoot was "ongoing". The investigator felt that the neonates congenital clubfoot was possibly related to the study drug. The investigator considered the neonates congenital clubfoot to be serious due to congenital anomaly. Additional information has been requested. Reporter's comment: Regarding the causal relationship to the study drug, it was assessed as "possibly related", as there were no grounds to deny the relation.

Other Meds: Dexamethasone valerate, 06Nov06 - 10Nov06; Mequitazine, 06Nov06 - 10Nov06

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 23Jan08); Dermatitis atopic

Prex Vax Illns:

Vaers Id: 332656-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Oct-2008	15-Oct-2008	0	18-Nov-2008	19-Nov-2008	FR	WAES0811USA01709	19-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Depressed level of consciousness, Dissociation, Fall, Pallor, Urticaria

Symptom Text: Information has been received from an agency concerning a 15 year old female who on 15-OCT-2008 was vaccinated with a first dose of GARDASIL intramuscularly in her left back. The patient was lying during the vaccination and for 1 minute after vaccination. One minute after vaccination, the patient felt fine and went to the general practitioner's waiting room where she sat for observation. Five minutes after vaccination, the patient became pale in face, on hands and feet. The patient was feeling remote and fell off the chair. While lying on the floor, the patient was conscious, but responded with latency when latency when replying to questions. Rash urticaria-like was observed on the patient's neck and right shoulder. Adrenalin (dose not reported) was given to the patient and an ambulance was called. On arrival to hospital, the patient had recovered from all symptoms. The patient was admitted to hospital for observation. No rash was observed. The patient was discharged on the same day. Other business partner numbers included E2008-10403. Additional information has been requested.

Other Meds: unknown

Lab Data: unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **332657-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Feb-2008	01-Sep-2008	199	18-Nov-2008	19-Nov-2008	FR	WAES0811USA01708	19-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0278U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Leukaemia

Symptom Text: Information has been received from a gynaecologist (via a company representative) through a foreign country (Manufacturer control # E2008-10392) concerning an 18 year old female with a history of wisdom teeth removal in MAY 2007 who on 15-FEB-2008 was vaccinated with the third dose of GARDASIL (lot # 0278U, batch # NF56940) IM into the upper arm. In September 2008, leukemia was diagnosed. The final outcome was not reported. P1 of GARDASIL (lot # 1339F, batch # NF23310) administered on 12-JUL-2007 and P2 of GARDASIL (lot # 1475F, batch # NF37120) on 12-OCT-2007 were well tolerated. The patient's leukemia was considered an other important medical event. Other business partner numbers include E2008-10392. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Wisdom teeth removal

Prex Illness:

Prex Vax Illns:

Vaers Id: **332658-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Apr-2008	01-May-2008	20	18-Nov-2008	19-Nov-2008	FR	WAES0811USA01706	19-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dyspnoea, Palpitations, Panic reaction, Psychiatric decompensation

Symptom Text: Information has been received from a Health Authority (HA reference # PEI2008015405) concerning a 14 year old female with hypersensitivity and a history of hay fever who was vaccinated with a second dose of GARDASIL on 19-AUG-2008. Concomitant therapy included hormonal contraceptives (unspecified). Post vaccination in the evening the patient developed dyspnea, heart racing and panic reaction. The patient recovered from these events after 2 days. In May 2008, the patient experienced psychiatric decompensation and was hospitalized in a psychiatric clinic for 12 weeks. The patient recovered completely from all symptoms. P1 of GARDASIL was administered on 11-APR-2008. Post vaccination in the evening the patient developed dyspnea, heart racing and panic reaction. The patient recovered from these events after 2 days. Other business partner numbers include E2008-10326. No further information is available.

Other Meds: Hormonal contraceptives (unspecified), Unk, Unk

Lab Data: Unknown

History: Hay fever

Prex Illness: Hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332659-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	04-Jun-2007	01-Oct-2007	119	18-Nov-2008	19-Nov-2008	FR	WAES0811USA01705	19-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Dizziness, Headache, Lymphoedema, Muscle spasms, Oedema peripheral, Peripheral coldness

Symptom Text: Information has been received from a Health Authority (HA ref. #PEI2008014574) through a foreign agency concerning a 13 year old female with a history of Raynaud's syndrome (requiring several hospital stays) and atopic eczema who was vaccinated with the first, second and third doses of GARDASIL (lot #, injection site not reported) on 08-MAY-2007, 04-JUN-2007 (IM) and 15-NOV-2007 (IM) respectively. In October 2007, the patient developed oedema of the right foot. On 21-JAN-2008, the patient was hospitalized and treated with nifedipine 3 x 10mg (from 21-JAN-2008 to 24-JAN-2008). Discharge date was not reported. On 14-FEB-2008 the patient experienced lymphedema of hands and feet. On 26-FEB-2008 the patient experienced severe abdominal pain, cramps, headache, dizziness and pain in the right knee. The patient had no fever. On 06-MAR-2008 the patient experienced coldness in the right leg up to the knee. Laboratory testing on 29-MAY-2008 revealed values of Hb 12.3 and MCH 25. The patient recovered completely within an unspecified time. P1 GARDASIL on 08-MAY-2007 was well tolerated. Case closed. Other business partner numbers include E2008-10324.

Other Meds: Unknown

Lab Data: Hemoglobin, 29May08, 12.3; Mean corpuscular hemoglobin, 29May08, 25

History: Raynaud's syndrome; Eczema

Prex Illness:

Prex Vax Illns:

Vaers Id: **332660-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Sep-2008	30-Sep-2008	2	18-Nov-2008	20-Nov-2008	FR	WAES0811USA01704	20-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0510U	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Depressed level of consciousness, Dysarthria, Dyspnoea, Electrocardiogram QT prolonged, Syncope

Symptom Text: Information has been received from a health care professional concerning a 15 year old female who on 28-SEP-2008 was vaccinated with the third dose of GARDASIL (lot #0510U, batch #NG22850, route and site of administration not reported). Two days after vaccination (on 30-SEP-2008) the patient was on a jogging tour and after 6 km she suddenly experienced dyspnea and syncope. She was hard to get contact with and when she answered her speech was slurry. After 3 hours she felt normal again. Examination by physician revealed normal glucose and ECG with a tendency of QTC prolongation. She was hospitalized for 4 days for follow-up tests. Following ECG, Cardiac ultrasound and EEG were all normal. No further information is available. Outcome is recovered. Case is closed. Other business partner numbers include E2008-10295.

Other Meds: unknown

Lab Data: electrocardiogram, with an tendency of QTC prolonged; echocardiography, normal; electroencephalography, normal; blood glucose, normal

History: unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332665-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
34.0	F	04-Sep-2008	04-Sep-2008	0	18-Nov-2008	19-Nov-2008	FR	WAES0811USA01717	19-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Dysphagia, Haematoma, Inappropriate schedule of drug administration, Lip swelling, Oedema peripheral, Pruritus, Swollen tongue

Symptom Text: Information has been received from a Health Authority (reference number ES-AGEMED-224056332) regarding a 34 year old female who was administered on the 04-SEP-2008 the second dose of GARDASIL by intramuscular route, site of injection not reported. It was reported that on the same day of vaccine administration, the patient started with lip, tongue and hands swelling, burning sensation on feet, itchy legs, distal hematoma and slight deglution alterations. The patient recovered in 4 days. Case reported as serious by the Health Authority with other medically important condition as criteria. No further information has been reported. Case is closed. Other business partner numbers included: E2008-10477.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **332666-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	12-Jun-2008	12-Jun-2008	0	18-Nov-2008	19-Nov-2008	FR	WAES0808USA01994	19-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0513U	0	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Circulatory collapse, Crying, Dyspnoea, Hypersensitivity, Pallor

Symptom Text: Information has been received from a health authority (HA reference no. PEI2008011406) concerning a 12 year old female with no history reported who on 12-JUN-2008 was vaccinated with the first dose of GARDASIL (Lot No. 0513U; Batch No NG34780) into the left upper arm. On 12-JUN-2008 the patient was admitted to hospital with suspicion of allergic reaction to vaccine, no symptoms reported. The patient was hospitalized till 14-JUN-2008. She recovered, duration was not reported. Follow-up received on 05-NOV-2008. Post vaccination the patient experienced sudden crying, pallor, dyspnea and circulatory collapse. The patient recovered. The case was closed. Other business partner numbers included: E2008-07561. No further information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332693-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	13-Oct-2008	14-Nov-2008	32	18-Nov-2008	18-Dec-2008	PA		18-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 332721-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Jan-2008	30-Jan-2008	7	18-Nov-2008	24-Nov-2008	AL		03-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1424F	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Amnesia, Anxiety disorder due to a general medical condition, Asthenia, Chills, Disturbance in attention, Dizziness, Fatigue, Fibromyalgia, Headache, Hemiparesis, Injection site pain, Lethargy, Migraine, Mood disorder due to a general medical condition, Muscle spasms, Muscle tightness, Myalgia, Nasopharyngitis, Nausea, Neck pain, Pain, Pharyngitis, Phonophobia, Photophobia, Polymyositis, Productive cough, Pyrexia, Sinusitis, Sleep disorder, Tension headache, Vomiting

Symptom Text: Gardasil shots - 1st shot (11/12/07) Painful at shot location and had a dull headache November through January. 2nd Shot (1/23/08)Pain at immunization site for a couple of weeks. Developed cold and sinus issues by the next day. Migraine type headache (very painful) began on 01/30/08. She began having major fatigue,dizziness, muscle pain, major sensitivity to light and sound, nausea and vomiting. We had several tests ran and trips to the emergency room. She had CT scans, MRI of head and neck, and lumbar puncture. She was out of school for 3 months unable to concentrate, short term memory loss, continuous pain (head and body). Improved enough after doctors, medications, massage therapists to return to school for the last month and a half. 3rd shot (06/03/08)with 3 other shots. She developed a cold sinus and her headache came back within a week to a worse level that before. Her headache has never went away since January 30th. She has muscle pain and spasms, short term memory loss, lethargic, dizziness, major sensitivity to light and sounds, nausea and vomiting. She has no energy and basically has had no life for the last 11 months of her life. 12/19/2008 MR received from PCP. Seen 11/12/07 for 1st HPV and Flu vax. Returned 11/27/07 with c/o chills, low grade fever, tight neck muscles. Dx: Nausea, Vomiting. 2nd HPV 1/23/08. Returned 1/30/08 with c/o fatigue. Dx: sinusitis/pharyngitis. Returned 2/5/08 with c/o h/a, neck soreness, productive cough and light sensitivity. Dx: H/A. F/U visit 6/3/08 for hospital stay for h/a and 3rd HPV, to f/u with neurologist. OV 8/8/08 with c/o muscle spasms on back with shooting pain down left. DX: Muscle spasm ? Polymyositis. Tx with Flexeril. OV 8/22/08 with c/o worsening H/A, nausea, and photo/phono phobia. DX: Tension H/a. To see neurologist. 1/12/09 MR received for 2 ER visits and one outpt visit. Pt presented to ER on 2/26/08 with c/o 3 1/2 week hx of constant frontal h/A with intermittent emesis. No releif with previously prescibed meds. (+) photophobi

Other Meds:

Lab Data: CT scan of sinus,MRI of Head and neck, Lumbar Puncture, Allergy testing, complete blood workups. Labs and Diagnostics: CPK increased. Recent CT scan head (-). MRI brain and cervical spine WNL. EEG WNL. CSF (+) RBCs no WBCs (rare WBCs o

History: none at that time. PMH: GERD. Migraine. Allergy to Augmentin

Prex Illness: None

Prex Vax Illns: none~ ()~~0~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332737-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Oct-2008	22-Oct-2008	0	18-Nov-2008	16-Feb-2009	WA		16-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2997AA		Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2683AA		Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	6570X		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Anorexia, Bacterial infection, Burning sensation, Cellulitis, Contusion, Crying, Dizziness, Erythema, Genital pain, Headache, Pallor, Pruritus genital, Rash, Skin discolouration, Swelling, Vulvovaginal discomfort

Symptom Text: 10/22/08 after my daughter received the vaccinations at a little after 10:00 AM, my daughter started to tell me that she was itching around her pelvic/vaginal area and on the same day as the shot early morning she had just got her PMS before going to the Dr.'s office. I did not think it was serious because I thought that it might of been the pad that was making her feel uncomfortable. I remembered seeing my daughter's face was very pale, but again I did not think of anything serious nor read the allergic reactions vaccination handouts that was provided to me from the Medical Assistant GRA 93777-initials. And after the appointment, she also had a dentist appointment on the same day and she had two fillings done & 2 sealants. It finally got my attention after hearing my daughter acting abnormal, like constantly scratching and crying because her itching was burning and I asked her describe to me what they look like. She told me it was red and color purple around her vagina and that it was bruising and swollen, also it was spreading all over her bottom everywhere, between her legs. I was very scared to look at it but I told her that I would make a Dr's appointment and I also asked her if she would like to be taken into the emergency room and she refused to because she could not handled the pain anymore. I called her Dr.'s office on 10/27/08 and asked for the earliest appointment available in the later afternoon so I can have her stepfather take her to see the Dr. I even mentioned to the gentlemen that it was very weird that she has all these rashes right after she received the vaccinations. So the appointment was scheduled on 10/30/08 4:45 p.m. to see the doctor and she diagnosed her as rash & nonspecific skin eruption and on the same day they offered her a flu shot which she agreed to have. The Dr. provided a rash cream for antifungal bacterial infection around the vagina. At the same time I've been so worried and feel very helpless to see my daughter having to go through this pain, especially having her to tell me

Other Meds:

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **332745-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	07-Nov-2007	26-Dec-2007	49	19-Nov-2008	20-Nov-2008	CA	WAES0802USA05865	01-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0929U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for GARDASIL concerning a 26 year old female with a history of polycystic ovaries, irregular periods, absence of menstruation (August 2007), Papanicolaou smear abnormal (low grade 2007) and biopsy (July 2007, showed no dysplasia) who on 07-NOV-2007 was vaccinated intramuscularly with a first dose of GARDASIL (Lot # 658282/0929U) and on 04-FEB-2008 was vaccinated intramuscularly with a second dose of GARDASIL (Lot # 659653/1448U). There was no concomitant medication. The physician reported that the patient received 2 doses of the vaccine and is pregnant. The patient had a negative pregnancy test on 02-FEB-2008. On 05-FEB-2008 she had a positive qualitative HCG test (LMP 26-DEC-2007). The patient was seen in the office for unspecified medical attention. The patient was given a slip on 25-FEB-2008 to have routine OB panel. On 25-FEB-2008 the ultrasound showed the fetus to be 7 weeks and 6 days. No product quality complaint was involved. Outcome unknown. Follow-up information has been received from the physician on 10-NOV-2008. It was reported that this was the patient's first pregnancy. Medication taken during pregnancy included duet DHA prenatal vitamin, daily and Fe supplement, daily, for 9 months of pregnancy. Prenatal testing included MSAFP for Down's syndrome, screen negative, on 24-APR-2008. Subsequently, a healthy female infant was delivered at 38.5 weeks from LMP by cesarean section due to compound presentation on 26-SEP-2008. Birth weight was 7 pound 12 ounce, length 21.5 inch. The cesarean section was recommended due to non-vertex presentation. The infant was normal and with no congenital anomalies; there were no complications during pregnancy. The patient's concurrent medical condition included obesity. No further information is available.

Other Meds:

Lab Data: biopsy, 07/??/07, showed no dysplasia; ultrasound, 02/25/08, fetus, 7 weeks 6 days; Pap test, ?/?/07, low, abnormal; serum alpha-fetoprotein, 04/24/08, screen negative; beta-human chorionic, 02/02/08, negative; beta-human chorionic, 02/05/0

History: Polycystic ovaries; Irregular periods; Absence of menstruation; Papanicolaou smear abnormal

Prex Illness: Pregnancy NOS (LMP = 12/26/2007); Obesity

Prex Vax Illns:

Vaers Id: **332746-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Aug-2008	27-Aug-2008	2	19-Nov-2008	20-Nov-2008	FR	WAES0809USA02954	20-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427U	0	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bradycardia, Liver function test abnormal, Syncope, Thrombocytopenia

Symptom Text: Information was received from a physician concerning a 17-year-old female patient who on 25-AUG-2008 was vaccinated with a first dose of GARDASIL (lot # 1427U, batch # NH15200, route unknown) into her left upper arm. On 27-AUG-2008, the patient experienced syncope and bradycardia. On 30-AUG-2008, she experienced thrombocytopenia; on 01-SEP-2008, she experienced increased liver value. ECG, blood sample and blood pressure measurement were performed without results reported. At the time of reporting, the patient had not recovered. Further information was reported by HA (HA reference no. PEI2008013687). On 28-AUG-2008 the patient presented to an outpatient department. Syncope had lasted for two minutes. The patient had a history of arterial hypotension. She was told to present to her general practitioner for a long ECG (electrocardiogram) and clarification of the thrombocytopenia. Laboratory results were sent. Routine laboratory on 29-AUG-2008 without pathological findings, except for decreased thrombocytes. Liver value was not sent. Outcome was not reported. Follow up information was reported by the physician on the phone: The patient had not recovered. She was still treated in a hospital (outpatient or inpatient department is not known). Other business partner numbers included: E200808294. No further information is available.

Other Meds: Unknown

Lab Data: electrocardiogram, 29Aug08; diagnostic laboratory test, 29Aug08; platelet count, 29Aug08, 56.53 /microl

History:

Prex Illness: Arterial hypotension

Prex Vax Illns:

Vaers Id: 332747-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-Nov-2008	20-Nov-2008	--	WAES0811USA02178	20-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain

Symptom Text: Information has been received from a dental hygienist concerning a female patient ("one of their office employee's daughters), whose first dose of GARDASIL was well-tolerated. On an unspecified date she was vaccinated a second dose of GARDASIL (lot number, route and injection site not reported). Sometime after the vaccination, she had developed severe abdominal pain. It was stated that the patient was hospitalized for severe abdominal pain (duration unknown). The patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Information has been received from a dental hygienist concerning a female patient ("one of their office employee's daughters), whose first dose of GARDASIL was well-tolerated.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332748-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-Nov-2008	20-Nov-2008	--	WAES0811USA02218	20-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner, for the Pregnancy Registry for GARDASIL, concerning a female who was pregnant and vaccinated with the third dose of GARDASIL, IM, 0.5ml. Subsequently the patient had a miscarriage. This occurred some time ago and the reporter does not have patient information at this time. The patient sought unspecified medical attention. Upon internal review, miscarriage was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **332758-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	13-Nov-2008		19-Nov-2008	11-Feb-2009	--		03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash pruritic

Symptom Text: Patient given 1st GARDASIL injection. 3 hours later patient developed pruritic rash on back and torso.

Other Meds: None

Lab Data:

History: NKDA, No tab or alcohol. No other medical problems except migraines, asthma.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332775-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	18-Nov-2008	18-Nov-2008	0	19-Nov-2008	11-Feb-2009	CT		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1193X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0651X	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB259AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site pruritus, Injection site swelling

Symptom Text: Pruritus at injection site (received vaccine @ 10 am). Developed @ 5pm 11/18/08. Swelling, induration.- Swelling 6 cm x 3 cm noted.

Other Meds:

Lab Data: None

History: No allergies or conditions

Prex Illness: No

Prex Vax Illns:

Vaers Id: **332779-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Nov-2007	Unknown		19-Nov-2008	11-Feb-2009	FL		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pregnancy

Symptom Text: Pt. got pregnant 2 mos. after 2nd GARDASIL injection. Last inj. 11/30/07 / LMP 1/1/08 - preg. mid Jan. 2008

Other Meds:

Lab Data: + preg test 2/21/08

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **332796-1** **Related reports:** 332796-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jun-2008	16-Jun-2008	0	19-Nov-2008	11-Feb-2009	TX		11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688F	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Amenorrhoea, Back pain, Dizziness, Fatigue, Loss of consciousness, Migraine, Neck pain, Pain, Paraesthesia, Somnolence, Thinking abnormal

Symptom Text: Severe Migraines,Dizziness,Blacked out vision, Fatigue, Body aches,Neck pain, Back pain, abdominal pain, Rash on scalp, hand and foot tingling/falling asleep. No menstrual cycle. Foggy thinking.

Other Meds: Depo Provera @ same time as first Gardasil injection

Lab Data: Thyroid- clear MRA-clear

History: migraines

Prex Illness: none

Prex Vax Illns:

Vaers Id: **332796-2** **Related reports:** 332796-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jul-2008	01-Jul-2008	0	17-Apr-2009	08-May-2009	TX	WAES0903USA01620	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Back pain, Chest pain, Disturbance in attention, Dizziness, Fatigue, Menstruation irregular, Migraine, Neck pain, Paraesthesia, Photophobia, Rash

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter, with no known drug reactions/allergies and with a history of migraine headaches, who on an unspecified date was vaccinated with the first dose of GARDASIL (Lot # 653735/0688F), intramuscularly and in July 2008, was vaccinated with the second dose of GARDASIL (Lot reported # 659776/0022X was valid for MMRII (HSA, not GARDASIL). There was no concomitant medication. The consumer reported that her daughter had experienced persistent migraine headaches since receiving her first dose of GARDASIL. The patient had also experienced back pain, abdominal pain, neck pain, chest pains, dizziness, fatigue, rash on her head and neck, photophobia, irregular menstrual cycle, difficulty concentrating and her hands and feet frequently "fell asleep". It was noted that these symptoms all began after receiving the first dose of GARDASIL vaccine and intensified after receiving the second dose. At the time of the report, the patient had not recovered. The patient sought medical attention and was seen by the physician. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Migraine

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332829-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	18-Nov-2008	18-Nov-2008	0	19-Nov-2008	11-Feb-2009	MA		12-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2720AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0650X	1	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1222X	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness

Symptom Text: Patient passed out and had two seizure like episodes about 1 minute and 3 minutes after immunizations.

Other Meds:

Lab Data: Sent to ER for testing.

History: Asthma

Prex Illness: None

Prex Vax Illns:

Vaers Id: **332845-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	26-Nov-2007	Unknown		20-Nov-2008	21-Nov-2008	FR	WAES0811USA01707	21-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Arthropathy, Finger deformity, Headache

Symptom Text: Case reported by Health Authority (HA reference no. PEI2008016273) on 05-NOV-2008. It was reported that a 13 year old female patient, with a medical history of headache and general discomfort, was vaccinated with a second dose of GARDASIL (lot#, route, injection site not reported) on 26-NOV-2007. After vaccination (onset date not reported), the patient developed aggravation of headache and general discomfort. In addition, the patient experienced joint disorder and pain without swelling, and finger deformity ("deviation of axis of finger of the distal phalanx"). There were no signs of rheumatism of similar diseases. MRT revealed no pathological findings. The patient was treated with analgesics. ON 08-APR-2008, the patient received GARDASIL (lot#, route, injection site not reported). The symptoms were ongoing. The physician did not see a causal relation to the vaccine. The mother wanted to report the case. The patient recovered with sequelae within an unspecified time. GARDASIL on 24-SEP-2008, toleration not reported. The reporter considered the adverse events to be other important medical events. Other business partner number included: E2008-10327. No further information is available. Case closed.

Other Meds: unknown

Lab Data: diagnostic radiology, revealed no pathological findings

History:

Prex Illness: Headache; General discomfort

Prex Vax Illns:

Vaers Id: 332846-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Aug-2008	01-Sep-2008	15	20-Nov-2008	21-Nov-2008	FR	WAES0811USA00962	21-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chest discomfort, Chest pain, Cough, Nasopharyngitis, Oropharyngeal pain, Painful respiration, Pyrexia

Symptom Text: Information has been received from a health authority (H.A Ref. 083471) concerning a woman who on 17-AUG-2008 was vaccinated with GARDASIL, (route unknown, batch number and site of administration not reported). Health authority reported chest pain with onset 10-SEP-2008. Concomitant medication was oral contraceptives (manufacturer unknown). In the beginning of September 2008 the woman had fever, sore throat and a cold. During an episode she was feeling better and started to work out. On 10-SEP-2008 she had chest pains and sore throat and was investigated at a care center which revealed a normal EKG. On 13-SEP-2008 she went for care in another part of the country due to worsened chest pains. She was hospitalized for further investigations and termination of the oral contraceptives was ordered. The woman had symptoms of dry cough and pain at deep breathing. Investigations revealed increased D-dimer 1.12 mg/L (ref 0.25 mg/L), a CT thorax performed on 14 September did not indicate any lung emboli or other noticeable. A lung scintigraphy showed a minimal segmental perfusion defect basal dorsal of left lung. No other perfusion defects were observed. During hospitalization the patient received INNOHEP, which terminated on 15-SEP-2008 after the arrival of X-ray results. The chest pain decreased after discharged. On 16-SEP-2008, she was out walking about 3 km and the following night she woke up with a pressure on the chest. Here after she had a constant mild pressure over the sternum and spine. There was no clear correlation to breathing or to movement. Saturation was 100%, no fever, no tachycardia, normal EKG. The woman was hospitalized due to suspected lung emboli. But an X-ray of the lungs did not show any parenchyma changes. A CT-pulmonary did not indicate any signs of lung emboli. She received a dose INNOHEP before the x-ray results arrived. PK, D-dimer, CRP were all normal as well as the heart enzymes CK, CKMB and troponin T. The chest pains were considered to be without any cardiac genesis and to be muscle-skeletal

Other Meds: hormonal contraceptives (unspecified), Unk - Unk

Lab Data: chest computed axial tomography, 14Sep08, normal; electrocardiogram, Normal; arterial blood O2 saturation, 100%; serum C-reactive protein, Normal; serum TnT, normal; serum creatine kinase, Normal; serum creatine kinase isoenzyme MB, normal;

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **332847-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	24-Oct-2008	24-Oct-2008	0	20-Nov-2008	21-Nov-2008	FR	WAES0811USA01711	21-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Eye disorder, Fall, Gaze palsy, Immediate post-injection reaction, Loss of consciousness, No reaction on previous exposure to drug, Speech disorder

Symptom Text: Information has been received from a paediatrician reporting that a 13 year old patient was vaccinated with a second dose of GARDASIL (Lot # not reported) IM into the upper arm on 24-OCT-2008. Ten to fifteen minutes post vaccination, the patient had a seizure (she could not speak properly for 10 seconds, contorted her eyes, fell down, lost consciousness and she developed synchronous convulsions of her extremities, without tongue bite or losing urine). This was her first seizure which lasted for approximately one and a half minutes. Thereafter the patient recovered. Electroencephalography (EEG) on the next day showed normal results. First dose of GARDASIL (Lot # not reported) administered on an unspecified date was well tolerated. Case is closed. Other business partner numbers include E2008-10397. No further information is available.

Other Meds: Unknown

Lab Data: electroencephalography, 25Oct08, normal results

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332848-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Sep-2008	01-Sep-2008	0	20-Nov-2008	21-Nov-2008	--	WAES0811USA02264	21-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Intra-uterine death

Symptom Text: Information has been received from a health professional, for the Pregnancy Registry for GARDASIL, concerning an 18 year old female who in September 2008, was vaccinated with a dose of GARDASIL (lot number, injection site and route not reported). Subsequently the patient was pregnant. The LMP was 22-AUG-2008. On 13-NOV-2008, at the 12 weeks of pregnancy, ultrasound showed fetal demise. The outcome of the patient's experience was unknown. Upon internal review, fetal demise was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Ultrasound, 11/13/08, fetal demise

History:

Prex Illness: Pregnancy NOS (LMP = 8/22/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332849-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		20-Nov-2008	21-Nov-2008	TX	WAES0811USA02307	08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dyskinesia, Syncope

Symptom Text: Information has been received from a physician concerning a female who was vaccinated intramuscularly with a first dose of GARDASIL 0.5 mL on unspecified date. "Recently" the patient experienced faint and had a "jerky moment" that was "seizure like". On the same day the patient recovered. The patient sought unspecified medical attention. The doctor said that the vaccine was given by her OB doctor. Upon internal review, the seizure-like was determined to be an Other Important Medical Event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **332906-1 (S)** **Related reports:** 332906-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Sep-2007	17-Aug-2008	335	20-Nov-2008	25-Nov-2008	GA		06-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0181U	2	Right arm	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Chemotherapy, Chest discomfort, Cough, Dermatitis contact, Dysmenorrhoea, Eczema, Haematochezia, Hodgkins disease, Lymphadenopathy, Musculoskeletal pain, Rhinorrhoea, Sinus congestion

Symptom Text: Patient dx'd with Hodgkins Lymphoma following the vaccine 1/20/09-records received for DOS 9/13/08-Hodgkin's Disease, nodular sclerosis of intrathoracic lymph nodes. Office notes for GYN visit 3/5/06 C/O left calf cramping. Subsequent visit 11/13/06 received first Gardasil vaccine C/O heavy and cramping periods. 8/5/08-sports physical exam enlarged group of cervical lymph nodes. Contact dermatitis and other eczema on visit 7/30/07. 1/8/08 C/O shoulder pain for 4 weeks. 2/14/08 presented with cough, chest tight, sinus congestion, hoarseness, runny nose, sore throat. 3/26/08 blood in BMs times 1 month. 4/22/08-insidious onset cervical pain referred to shoulder. 1/30/09-records received oncology records indicate date of diagnosis 8/20/08 Hodgkin's after routine physical exam 8/5/08 when large right cervical lymphnode discovered. Receiving chemotherapy.

Other Meds: Seasonique - Oral Contraceptive

Lab Data: Core Biopsy - August 11, 2008 1/20/09-records received-8/7/08-CT neck multiple enlarged lymph nodes in right neck. Abdominal and pelvis scan right supraclavicular right axillary mediastinal adenopathy. Small right pleural effusion.

History: allergy to PCN 1/30/09-records received-PMH:adopted, limited family history. Hemorrhoids/constipation.

Prex Illness: none

Prex Vax Illns: Hodgkins Lymphoma~HPV (Gardasil)~3~16~In Patient

Vaers Id: **332906-2 (S)** **Related reports:** 332906-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Sep-2007	17-Aug-2008	335	27-Jan-2009	28-Jan-2009	--	WAES0901USA01078	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0181U	2	Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Hodgkins disease

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. On 17-SEP-2007, a 15 year old female with penicillin allergy was vaccinated with the third dose of GARDASIL (lot#: 656371/0181U) in the right arm. Concomitant therapy included SEASONIQUE oral for contraception. On 11-AUG-2008, core biopsy was performed. On 17-AUG-2008 the patient was diagnosed with Hodgkins Lymphoma. Hodgkins Lymphoma was considered to be immediately life-threatening. It was also reported that the patient had a previous vaccine illness of Hodgkins Lymphoma in the patient. The original reporting source was not provided. The VAERS ID # is 332906. A standard lot check investigation was performed. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the center and was released. No further information is available.

Other Meds: SEASONIQUE

Lab Data: cardiac biopsy, 08/11/08, Hodgkins Lymphoma

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332916-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Nov-2008	11-Nov-2008	1	20-Nov-2008	11-Feb-2009	TX		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	2	Left arm	Intramuscular	FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Headache, Hypoaesthesia, Hypoaesthesia facial, Pain in extremity, Paraesthesia

Symptom Text: Patient given vaccine about 4:30 pm, some pain in arm, otherwise ok until about 1:30 am awoke with numbness and tingling in her legs, severe headache, and abdominal pain. She also developed tingling and numbness in the arms and face. No visable swelling or redness at injection site. Mother treated her with ibuprofen and bedrest. Symptoms resolved after about 24 hrs.

Other Meds: Asmanex: one inhalation daily (asthma controller therapy)

Lab Data:

History: Asthma, Allergic rhinitis (allergic to dust mite and cat dander), Penicillin allergic.

Prex Illness: No

Prex Vax Illns: Similar event to above~HPV (Gardasil)~3~~In Sibling1

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332920-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	U	20-Nov-2008	Unknown		20-Nov-2008	11-Feb-2009	OH		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB582AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0070X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: None

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **332932-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Nov-2008	20-Nov-2008	0	20-Nov-2008	11-Feb-2009	PA		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Right arm	Intramuscular	HEPA MNQ TDAP

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient received first immunization in series and within 15 minutes of administration, had syncopal episode

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **332970-1** **Related reports:** 332970-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Sep-2008	12-Nov-2008	44	21-Nov-2008	17-Dec-2008	NV		27-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthropathy, Gait disturbance, Joint swelling, Musculoskeletal pain, Oedema peripheral, Pain, Polyarthritis, Scoliosis, Urticaria

Symptom Text: (Shoulder pain, continues) body sore 2 weeks after shot migratory polyarthritis, swelling fingers and toes, walks slowly. 12/15/08-records received-presented 9/29/08 routine exam. 11/12/08-presented with C/O finger and toe swollen, joints pain. Since Gardasil shot arm hurting, whole body sore, fingers swelling, retaining fluid in arms and legs for week or two. Assesssment:idiopathic scoliosis. Arthropathy. 12/2/08-rheumatology consult-12/9/08-moderate joint swelling, hives. Inflammatory polyarthritis.

Other Meds:

Lab Data: CBC, RF, CRP, Sedrate, ANA, Uric Acid, all normal 12/15/08-records received-ANA negative, RF negative.

History: Acne: Takes Minocycline, Finarea cream & Allegra 12/15/08-records received-Allergies to Sulfa drugs.

Prex Illness: No

Prex Vax Illns:

Vaers Id: **332970-2 (S)** **Related reports:** 332970-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Sep-2008	29-Sep-2008	0	25-Nov-2008	26-Nov-2008	NV	WAES0811USA02790	06-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Arthritis, Discomfort, Muscular weakness, Musculoskeletal stiffness, Pain, Swelling

Symptom Text: Information has been received from a physician concerning a 14 year old female with acne and no known drug allergies who on 29-SEP-2008 was vaccinated with the first dose of GARDASIL, 0.5ml IM on the left arm. Concomitant therapy included minocycline, FINACEA, fexofenadine hydrochloride (manufacturer unknown) and unspecified face wash. Subsequently the patient experienced pain on the arm of the injection since vaccination. In the middle of October 2008 the patient has swelling of the fingers, legs, toes, both arms, stiffness of the body and difficulty moving. The patient also had arthralgias of her arms, legs and back. The patient has been missing school because of the discomfort. The patient couldn't close her hands. Every part of her body was aching. Minocycline (unspecified manufacturer) was discontinued on 14-NOV-2008 and the patient has been able to move since 17-NOV-2008. The patient still has pain, swelling, and arthritis-like symptoms. The patient's work-up revealed normal RF, CBC, CRP, SED rate, ESR, but increased ALT (341) and AST (224). The patient sought medical attention. At the time of the report the patient was recovering. Pain on the arm of the injection, swelling of the fingers, legs, toes, both arms, stiffness of the body and difficulty moving. Every part of her body is aching and arthritis-like symptoms were considered to be disabling. Additional information has been requested.

Other Meds: [therapy unspecified]; FINACEA; fexofenadine hydrochloride; minocycline

Lab Data: serum rheumatoid factor, normal; complete blood cell, normal; serum C-reactive, normal; plasma parathyroid, normal; erythrocyte, normal; plasma aspartate, 224, increased; plasma alanine, 341, increased

History:

Prex Illness: Acne

Prex Vax Illns:

Vaers Id: **332990-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Oct-2008	Unknown		21-Nov-2008	16-Feb-2009	CA		10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2683AA	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Teen received HPV #1 and MENACTRA on 10/29/08. + Urine pregnancy test on 11/4/08 (LMP 9/28/08). No treatment.

Other Meds: None

Lab Data: Urine Pregnancy test + 11/4/08

History: None

Prex Illness: Eczema Rash

Prex Vax Illns:

Vaers Id: 332998-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Aug-2007	09-Sep-2007	11	21-Nov-2008	25-Nov-2008	PA		19-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	2	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Atrial septal defect, Benign intracranial hypertension, CSF pressure increased, Diarrhoea, Eye pain, Fall, Gait disturbance, Headache, Hyperacusis, Intensive care, Nausea, Neurological examination normal, Ophthalmological examination normal, Photophobia, Surgery, Urinary tract infection, Vomiting

Symptom Text: few days after receiving vaccine occipital headache, light/sound sensitivity, nausea, several days after receivng 3rd dose of gardicil vaccine headache, light and sound sensitivity,vomiting, diarrhea for 2 days,went to primary dr. nausea,vomiting and diarrhea stopped. headache,sound and light sensitivity increased. went to the hospital several times. spinal taps performed. increase spinal pressure relieved. pain decreased before returning. multiple treatments tried. multiple admissions. doctors aware of vaccine. 12/5/08 Reviewed PCP medical record which was essentially just vaccination record. 1/19/09 Reviewed hospital medical records of 9/28-10/3/2007. FINAL DX: chronic daily headache Records reveal patient had persistent occipital HA w/pain in eyes & had missed several days of school. Initially HA was assoc w/nausea/vomiting & eye pain which began after swimming in ocean. Had been seen previously & dx w/pseudotumor cerebri due to LP opening pressure of 200. Tx w/multiple meds but HA worsened & admitted. Tx w/antibiotic for UTI & multiple oral & IM/IV meds for HA w/minimal improvement. Neuro exam was WNL. Reviewed hospital medical recods of 12/10-12/15/2007. FINAL DX: none provided. Narrative states atypical HA records reveal patient had drainage of spinal fluid approx 350cc. In PICU for monitoring. Had some improvement on meds & d/c to home. Reviewed ER medical records of 4/4/2008. FINAL DX: difficulty walking Records reveal patient experienced difficulty walking, falls, continuing daily occipital HA w/photophobia. Had been seen by multiple neurologists. Ophthalmology exam previously WNL. Now seen per neuro request for repeat LP which was done w/normal pressures. Referred for neurophthalmogy. Reviewed hospital medical records of 5/16-5/17/2008 FINAL DX: patent foramen ovale Records reveal patient experienced trivial amount of right to left shunting.

Other Meds: singular, zertec.

Lab Data: labs, mri's, spinal taps, cervical cath. multiple medications tried to relieve headache. LABS:CT scan & MRI brain & c-spine WNL. CBC & chemistry WNL. Urine c/s (+). ANA & CRP (-).EKG & CXR WNL. CSF rbc 21,000(H), protein 71(H), glu

History: asthma PMH: pseudotumor cerebri dx 9/2007. Family hx of paradoxical ambolic stroke & atrial septal defect.

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333001-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-Nov-2008	20-Nov-2008	1	21-Nov-2008	17-Dec-2008	MI		27-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1968U	0	Right leg	Intramuscular	FLU
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB257AA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2619AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	4	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Oedema peripheral, Oral contraception, Pain in extremity, Skin discolouration

Symptom Text: Call from staff 10 am 11/20 states "both patient's hands are swollen and turning white and her joints hurt". Saw Dr. and he recom to stop vaccines or only vaccinate one vaccine at a time. He ordered Solu-Medrol dose pack.2/24/09-records received-office visit 11/20/08 C/O edema located on hands, fingers and upper arms. Swelling begain hour after receiving vaccines. Right knee pain, onset months ago, years ago. Onset sudden sustained inury while active, hyperextension and no treatment. Falls at times with weight bearing activities. Ankle and foot symptoms date of onset uncertain. Oral contraception. Impression. dergangement knee. Return as needed. No additional visits noted.

Other Meds:

Lab Data:

History: allergies to bees 2/24/09-knee injury.

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333018-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	16-Sep-2008	16-Sep-2008	0	21-Nov-2008	11-Feb-2009	MN		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	12666	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: right arm pain for two months now since vaccine given

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333028-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-Nov-2008	20-Nov-2008	0	23-Nov-2008	02-Dec-2008	NY		03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Pallor, Presyncope, Sensation of heaviness

Symptom Text: Patient left the exam room and after leaving the lobby, felt very dizzy while she was standing by the elevator. Told mother her vision was going "white". Mother supported her upright and called for assistance. RN's from the unit brought her into an exam room and helped her lie down on the exam table. She was reportedly pale and sweaty.RN's checked vital signs; teen was stable. They had MD come to check her. Over course of 10-15' she felt well enough to leave. I called mother later in evening. She said that patient was still a little pale but was much better. mostly embarassed about almsot fainting.She was saying that her arm felt heavy all the way down. She had full motion and pink fingers. Reviewed on-call availability with mother.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333059-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Nov-2008	18-Nov-2008	1	21-Nov-2008	16-Feb-2009	AZ		16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2814AA	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0650X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hot flush, Pruritus, Urticaria

Symptom Text: 24 hrs. after vaccine MENACTRA, GARADSIL administered pt developed hives itching & hot flashes.

Other Meds: MOTRIN

Lab Data: None

History: Bilateral knee pain

Prex Illness: None

Prex Vax Illns:

Vaers Id: 333086-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	14-Sep-2007	14-Sep-2007	0	24-Nov-2008	25-Nov-2008	TX	WAES0801USA03772	25-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Breech presentation, Caesarean section, Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received from Merck pregnancy registry through a Nurse concerning a 21 year old female with no previous medical history, who on 14-SEP-2007 was vaccinated IM with a first 0.5 ml dose of GARDASIL. Concomitant medication included FOCALIN 15 mg QD intermittently just until pregnancy known for ADHD and ZOFRAN 4 mg TID PRN for nausea/vomiting. It was reported that the patient received the vaccination while she was pregnant. Medical attention was sought. In follow up the nurse stated that on 28-May-2008, the patient delivered a normal live born female infant weighing 8 lbs and 9 Oz with an apgar score 9/9. There were no complications or abnormalities and no congenital anomalies. There were no infections or illnesses during pregnancy. It was reported that patient had a caesarean section since the baby was in breech presentation. Pediatric medical records were received and reviewed and the following experience was identified. On 02-JUN-2008 baby came to doctor's office and was found to have jaundice. Baby's bilirubin was 16.7 mg/dL and she needed photo therapy. She was seen on 03-JUN-2008 and it was reported as physiologic jaundice and was admitted to the hospital. On 06-JUN-2008 the baby was seen in the doctor's office for follow up hospitalization for jaundice. It was reported that on examination baby had "?questionable hip dysplasia". A follow up phone call was made to the doctor's office and information was received that the baby was referred to an orthopedist. The nurse reported that as per the doctor's note the baby had an examination with the doctor. It was reported that "physical examination showed the hip to be slightly lax, but there was no evidence of any dislocation and it appeared the hip was tightening". The mother cancelled the follow up visit for the baby with the doctor but reported that the baby was doing well. On 11-JUN-2008 the baby went to the doctor's visit. In the record it was reported that the baby had eye drainage and diarrhea after amoxicillin. The bab

Other Meds: FOCALIN, mg; ZOFRAN, mg

Lab Data: Ultrasound, 10/16/07, Normal and routine; Ultrasound, 01/10/08, Normal and routine; Skull X-ray, 06/18?/08, Negative; Ultrasound, 03/25/08, Normal and routine; Beta-human chorionic; Serum alpha-fetoprotein, 01/10/08, Normal and routine; Tot

History:

Prex Illness: Pregnancy NOS (LMP = 8/28/2007); Attention deficit/hyperactivity disorder; Nausea

Prex Vax Illns:

Vaers Id: **333087-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	10-Jan-2008	08-Oct-2008	272	24-Nov-2008	25-Nov-2008	FR	WAES0803USA03986	25-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a health professional concerning a female who was vaccinated with a dose of GARDASIL (lot#, injection route and site not reported) on an unspecified date. There was no concomitant medication. At the time of vaccination, the patient was already pregnant. The last menstrual period and due date were unknown. Follow-up information received on 21-APR-2008 indicated that the patient was vaccinated IM into the upper arm on 10-JAN-2008. Follow-up information received on 12-NOV-2008 indicated that upon internal review this case was upgraded due to cesarean section as an other medically important event. It was reported by the gynaecologist that the patient gave birth to a normal newborn via cesarean section on 08-OCT-2008. The Apgar score of the child was 10/10. The postnatal of mother and child showed no pathologies. The patient recovered. Case closed. Other business partner numbers include: E2008-01757. No further information is available.

Other Meds: None

Lab Data: Apgar Score, ??Oct08, 10/10

History: Pregnancy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333088-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
32.0	F	05-Apr-2008	07-Apr-2008	2	24-Nov-2008	25-Nov-2008	FR	WAES0804CAN00065	25-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Coordination abnormal, Dyspnoea, Fatigue, Hypertension, Hypoaesthesia, Inappropriate schedule of drug administration, Malaise, Muscle twitching, Speech disorder

Symptom Text: Information has been received from a physician concerning a 32 year old female who on 05-APR-2008 was vaccinated with GARDASIL (dose and lot number not provided). The patient had no allergies and there was no concomitant medication. ON 07-APR-2008, two days following vaccination with GARDASIL the patient became ill. The physician reported that the patient had problems breathing due to pain in the left hemi thorax. She also suffered from muscle twitches, numbness in the fingers and toes, extreme fatigue, difficulty in speaking and difficulty with coordination. It was reported that the patient went to the emergency room and while there they discovered that her blood pressure was high. The patient underwent various tests while in the emergency room, but no diagnosis was made. The patient was not hospitalized. The physician reported that the patient is still suffering from problems breathing due to pain in the left hemi thorax, muscle twitches, numbness in the fingers and toes, extreme fatigue, difficulty in speaking and difficulty with coordination and her blood pressure was high. Numbness in the fingers and toes was determined to be an important medical event based on foreign agency requirements. No further information is expected.

Other Meds: None

Lab Data: blood pressure measurement, 07??Apr08, Blood pressure was high

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333090-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		24-Nov-2008	25-Nov-2008	TX	WAES0811USA02306	12-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse concerning a 13 year old female who was vaccinated with the second dose of GARDASIL, IM, 0.5ml. Subsequently the patient had a "seizure like" reaction. The patient was "back to normal in 2 to 3 minutes". The patient did not seek medical attention. Upon internal review, patient's "seizure like reaction" was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333091-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Oct-2008	20-Oct-2008	0	24-Nov-2008	25-Nov-2008	FR	WAES0811USA02415	25-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0467U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea, Pyrexia, Syncope, Vertigo

Symptom Text: Information has been received from a med agency from a physician concerning an adolescent female (6th level of education) who on 20-OCT-2008 was vaccinated with GARDASIL (lot #, site and route of vaccination not reported). The patient collapsed 10 minutes post vaccination and developed fever and headache. Latency for fever and headache was not reported. The outcome was not reported. Follow up information was received on 13-NOV-2008 from a foreign healthy authority, documentation # 29185. An 11 year old female patient was vaccinated with a GARDASIL vaccine (lot # 0467U; batch # NG14300, intramuscular, site not reported) on 20-OCT-2008. 10 minutes after vaccination she collapsed. 1 day later she developed fever up to 38.00C, headache, nausea and vertigo. 4 days later (it was not reported if after vaccination or onset of AEs) she recovered. The case was upgraded to serious as it was considered to be medically significant per reporter. The case is closed. This is one of several reports received from the same source. Other business partner numbers include E2008-09891. No further information is available.

Other Meds: Unknown

Lab Data: Body temp, 38.0 C

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333102-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Nov-2008	20-Nov-2008	2	24-Nov-2008	26-Nov-2008	FL		14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2732AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0650X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Dehydration, Fatigue, Gait disturbance, Hypoaesthesia, Malaise, Muscular weakness, Myalgia, Myositis, Nausea, Neck pain, Pain, Paraesthesia, Urinary tract infection

Symptom Text: Received vaccines on 11-18-08. Thursday 11-20-08, patient started feeling weak with neck and back pain. Legs numb / tingling, trouble walking. ER visit 11-20-08 12/12/2008 Reviewed ER medical records of 11/29/2008. FINAL DX: weakness, malaise, fatigue, dehydration, myalgia, myositis, UTI Records reveal patient experienced nausea, malaise, generalized aching, numbness, tingling, weakness & aching in legs, difficulty walking x 1 day.

Other Meds: None

Lab Data: Cat scan, 11-2-08; Magnetic resonance imaging, spine, cervical, thoracic, 11-24-08 LABS: CBC WNL. Sodium decreased. UA w/leukocytes & ketones. CT head WNL. Refused LP.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 333109-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Jun-2008	05-Nov-2008	155	24-Nov-2008	04-Dec-2008	NY		05-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Patient and mother feel hair loss and thinning are due to GARDASIL vaccine. Patient uses straightening iron and products and picks hair. Referred to derm.

Other Meds: None

Lab Data: None

History: Fatigue

Prex Illness: None

Prex Vax Illns:

Vaers Id: **333150-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	24-Nov-2008	24-Nov-2008	0	24-Nov-2008	11-Feb-2009	VA		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Hyperhidrosis, Pallor

Symptom Text: patient became pale and swety after receiving shot sat down and had a couple of small jerky movements

Other Meds: albuterol,orthotricyclen

Lab Data:

History: asthma

Prex Illness: none annual exam

Prex Vax Illns:

Vaers Id: 333179-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Jun-2008	25-Jun-2008	14	24-Nov-2008	17-Dec-2008	WI		20-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	2	Left arm	Unknown	FLU HPV4 MEN

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Colonoscopy normal, Computerised tomogram normal, Constipation, Diarrhoea, Headache, Irritable bowel syndrome, Metrorrhagia, Muscle spasms, Nausea, Pain, Pain in jaw, Pelvic pain, Tension headache, Vision blurred, Vomiting

Symptom Text: 08/20/2007-hpv and meningococcal conjugate shot-11/08/2007-hpv and influenza vaccine 06/11/2008-hpv shot after 3rd shot started with diarehha, vomiting,headaches,spotting, aching joints, blurred vision, severe abdominal pain. Had a colonopsity,upper gi-and ct scan ,blood work, urine test all came back negative. Been on 7 different meds. Now only on celexa thinking its IBS. Not helping. 1/12/2009 MR received from PCP. Seen 7/21/2008 with c/o persistant diarrhea, abdominal pain and nausea. Sx began apprx 2 months ago with acute onset of nausea and then diarrhea. ? medication side effect or IBS. F/u 8/19/08 for ? IBS and tension type H/As. No alternating loose stool with constipation, cramping and nausea. H/A on R side of head/jaw, worse with stress. DX: IBS. Tension type H/As. Additional records received. Seen by OBGYN consult re: pelvic pain and spotting between periods. Exam WNL. Changed OCs and referred to GI. Seen 9/19/09 for 3 mon hx of abdominal pain, and loose stools. Exam WNL. Improvement with 1 dose of prilosec. ? IBS. Seen 10/22/08 for continued hx of vomiting, diarrhea and achiness. Recent onset of joint aches. GI F/U 10/27/09 -no dx made.

Other Meds: birth control

Lab Data: see above. Labs and diagnostics: H. pylori (-). Gastric and colon bx all (-). CRP 4.0. CBC WNL. Endomysial Ab (-). UA with trace WBCs, many epis, (+) bacteria. ESR 18.

History: na. PMH: Anxiety, Depression.

Prex Illness: na

Prex Vax Illns:

Vaers Id: 333213-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	17-Oct-2007	01-Dec-2007	45	25-Nov-2008	26-Nov-2008	--	WAES0811USA02618	09-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Alopecia, Aphthous stomatitis, Dermatologic examination, Erythema, Exfoliative rash, Herpes simplex, Immune system disorder, Mouth ulceration, Psoriasis, Seborrhoeic dermatitis, Tinea versicolour, Vaccination complication

Symptom Text: Information has been received from a physician concerning a 23 year old female who on 17-OCT-2007, was vaccinated with the first 0.5 ml dose of GARDASIL (lot # 659435/1265U) in the left deltoid, on 19-DEC-2007, was vaccinated with the second 0.5 ml dose of GARDASIL (lot # 659439/1267U) in the left deltoid and on 15-APR-2008, was vaccinated with the third 0.5 ml dose of GARDASIL (lot # 659182/1757U) in the left deltoid. Concomitant therapy included LO OVRAL. In December 2007, the patient experienced severe psoriasis over face, neck, hands, feet and entire scalp causing hair loss. On an unspecified date, the patient was seen by a Dermatologist who performed a "work up". AT the time of reporting, the patient did not recover. Follow-up information on 19-NOV-2008 was received from a physician who reported that she was not able to add much more to her initial report. She stated that the patient's chart did not reflect when the adverse event occurred in December 2007. It was unknown if the onset was before or after the second GARDASIL dose on 19-DEC-2007. The doctor did report that there was no pertinent medical history and no concurrent conditions. She confirmed that the events were disabling and important medical events. The patient was currently taking HUMIRA and using a special shampoo. Dermatology reported that the events were an immune response to the vaccine. Current outcome was not recovered. The physician would not be seeing this patient again until October 2009. The physician considered severe psoriasis and hair loss to be disabling and other important medical event. Additional information has been requested. 12/3/08 Dermatology consults received beginning 6/5/08 with DX: Sebopsoriasis. Pt presented with 6-8 month hx of facial, scalp and hand scaly patches. F/u 7/7/08 with Dx: Seborrheic dermatitis. Psoriasis. Tinea versicolor. PE (+) for erythematous scaly patches on face, extremities and scalp. Started on Humira. Reported severe sores in mouth. Dx: aphthous ulcers. Herpes simplex virus. Humira d/c.

Other Meds: LO/OVRAL

Lab Data: Unknown. Labs: CBC & chem WNL

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **333215-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Oct-2008	20-Oct-2008	0	25-Nov-2008	26-Nov-2008	FR	WAES0811USA02037	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0467U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: This case is linked E2008-09891, E2008-09892, E2008-10185 and E2008-10191 (same reporter, vaccine and date of vaccination). Up to now this case is poorly documented but more information from Health Authority is expected. Information has been initially received from a physician on 21-OCT-2008 via health authority. A female adolescent patient (6th level of education) was vaccinated with a dose of GARDASIL (lot number, site and route of vaccination not reported) on 20-OCT-2008. The patient collapsed 2 hours post vaccination. No medical history reported. Follow up information received from a Health Authority (docu#29182) on 13-NOV-2008. The female was an 11 year old child. GARDASIL lot #0467U, #NG14300. The female recovered on an unspecified date. The case was upgraded to serious as it was considered to be medically significant per reporter. Other business partner numbers include E2008-09893. The case is closed.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333216-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	23-Oct-2008	23-Oct-2008	0	25-Nov-2008	26-Nov-2008	FR	WAES0811USA01985	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0467U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Headache, Nausea, Vertigo

Symptom Text: Information has been received from a physician on 03-NOV-2008 concerning an adolescent female patient who on 22-OCT-2008 was vaccinated with the first dose of GARDASIL (lot# 0467U) (site and route not reported). On 22-OCT-2008 10 to 20 minutes after she developed nausea. She recovered on an unspecified date. No medical history reported. Follow up information received on 13-NOV-2008 from Health Authority, documentation #29179: A 13-year old female patient with no medical history was vaccinated with 1st dose of GARDASIL (lot# NG14300, INTRAMUSCULAR) on 23-OCT-2008. Ten to fifteen minutes after vaccination she developed vertigo, headache and feeling hot. RR 111/60, heart rate 103. She recovered one hour later. Other business partner agreements include E2008-10191. This case is linked to E2008-09891, E2008-9892, E2008-09893, and E200810185 (same reporter, same vaccine, same vaccination action at school). This case was upgraded to serious as considered to be medically important per reporter. This case is closed. No further information is available.

Other Meds: Unknown

Lab Data: blood pressure measurement, 23Oct08, 100/60; total heartbeat count, 23Oct08, 103

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333217-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Oct-2008	21-Oct-2008	0	25-Nov-2008	26-Nov-2008	FR	WAES0811USA01983	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0467U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Fatigue, Headache, Nausea, Vertigo

Symptom Text: Information has been received from a physician on 03-NOV-2008 concerning an adolescent female patient who on 21-OCT-2008 was vaccinated with the first dose of GARDASIL (lot #0467U) (site and route not reported). On 21-OCt-2008 the same day she developed heavy nausea and fatigue, after 3 days she recovered. No medical history reported. Follow up information received on 13-NOV-2008 from health authority, documentation#29181: The female patient was 14 years old at time of vaccination. Twenty min after vaccination with GARDASIL (lot #NG14300, intramuscular) she developed nausea, vertigo, and headache. RR 114/52; heart rate 69. The next day, reported through her parents, she suffered from asthenia, fatigue, vertigo and nausea. After three days she recovered. As medical history a disposition for hypotonia was reported, treated with DIHYDERGOT. It was not reported if it was a regular medication or only if needed. Other business partner agreements include E200810185. This case is linked to E2008-09891, E2008-09893, E2008-10191 (same reporter, same vaccine, same vaccination action at school). This case was upgraded to serious as it was considered as medically important by the reporter. The case is closed. No further information is available.

Other Meds: dihydroergotamine tartrate

Lab Data: blood pressure measurement, 21Oct08, 114/52; total heartbeat count, 23Oct08, 69

History: Hypotonia

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333219-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Oct-2007	10-Oct-2007	0	25-Nov-2008	26-Nov-2008	FL	WAES0712USA09111	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1263U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal labour, Caesarean section, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received from a physician concerning a 16 year old female with no medical history, who on 10-OCT-2007 was vaccinated with a first dose of GARDASIL (Lot# 658282/1263U). Concomitant vaccinations included MENACTRA. Concomitant therapies started on 16-OCT-2007 included ceftriaxone sodium 125mg used to treat Gonorrhoea and azithromycin 1gm used to treat a Chlamydial infection. Subsequently, the patient was pregnant. The patient's last menstrual period was 26-SEP-2007 and her estimated delivery date was 02-JUL-2008. It was reported to be unknown if the patient had an ultrasound performed. The patient had no previous pregnancies and no full term deliveries. At the time of the report, the outcome of the patient was unknown. Follow-up information was received from the physician who reported that on 13-APR-2008 the patient had a emergency c-section for failure to progress and repetitive severed deceleration. The patient delivered a male baby, birth weight 6 lb 12 oz. length 481/2 inch, Apgar score 9/9. It was reported that the baby did not have any congenital abnormalities or other complications or abnormalities. Upon internal review, failure to progress and repetitive severed deceleration which resulted in an emergency cesarean section were considered to be other important medical events. Additional information is not expected.

Other Meds: azithromycin, 1 gm; ceftriaxone sodium, 125 mg

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 9/26/2007; Gonorrhoea; Chlamydial infection

Prex Vax Illns:

Vaers Id: 333227-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Sep-2008	09-Sep-2008	0	25-Nov-2008	26-Nov-2008	NY	WAES0809USA04381	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2633AA		Left arm	Unknown	
	PPV	MERCK & CO. INC.	0554U	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0279X		Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Bone marrow oedema, Injected limb mobility decreased, Oedema peripheral, Pain in extremity, Sickle cell anaemia

Symptom Text: Information has been received from a physician concerning a 16 year old female with sickle cell disease who on 09-SEP-2008 was vaccinated in her right arm with PNEUMOVAX 23 (lot #657525/0554U). On 09-SEP-2008 the patient was also vaccinated in her left arm with MENACTRA and GARDASIL (lot # 660555/0279X). Shortly after the vaccinations, the patient developed pain and swelling on the right arm where she received the PNEUMOVAX 23. Unspecified medical attention was sought. The physician also reported that on 23-SEP-2008 the patient was hospitalized and at the time of reporting was still in the hospital. It was unknown if the cause of the hospitalization was the swelling on her arm. No further information was provided. Follow-up information was received from the physician. It was reported that the patient was vaccinated with the first dose of PNEUMOVAX 23 vaccine in her right deltoid at 10:53 am. The patient had no illness at time of vaccination. On 23-SEP-2008 the patient experienced bone marrow edema and pain crisis. Subsequently, the patient was hospitalized for 7 days. Laboratory tests included: X-ray and MRI of humerus. The patient recovered from bone marrow edema and pain crisis on an unspecified date. No further information is available. 12/29/2008 MR including hospital records received from PCP for DOS 9/23-10/1/2008 with DX: Sickle Cell Disease and R arm pain. Pt presented with hx of R arm pain following several vaccinations. Pain area includes R shoulder, upper arm, elbow, forearm, wrist and hand. Pt unable to move hand. MRI c/w sickle cell crisis.

Other Meds:

Lab Data: X-ray, of the humerus; magnetic resonance, of the humerus. Labs and Diagnostics: X-ray arm (-). X-ray humerus (+) for widening of acromioclavicular joint. MRI arm (+) for bone marrow edema c/w sickle cell crisis and acute marrow infarctio

History: PMH: asthma. Sickle Cell disease. Cardiomegaly

Prex Illness: Sickle cell disease

Prex Vax Illns:

Vaers Id: **333232-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	02-Oct-2008	23-Sep-2008	-9	25-Nov-2008	26-Nov-2008	FR	WAES0810CAN00093	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Pregnancy test positive

Symptom Text: Information has been received from a nurse concerning a 23 year old female who on 02-OCT-2008 was vaccinated with the first dose of GARDASIL, lot # not available. The patient's last menstrual period was on 01-SEP-2008. On 23-SEP-2008 the patient had a pregnancy test done which showed a weak positive result. The nurse reported that the medical student who asked her to give the vaccine was not aware of the previous result. The nurse reported that the patient indicated that on 02-OCT-2008 she had not known she was pregnant for sure. On 20-OCT-2008 the nurse reported that another blood test would be done to confirm/re-confirm pregnancy. The estimated date of delivery is 08-JUN-2009. Additional information has been received from the nurse on 12-NOV-2008. It was reported that the patient was 10 weeks pregnant. Additional information has been received from the nurse on 14-NOV-2008. The patient informed her that she had a spontaneous abortion (no further details available). The patient recovered from pregnancy test done which showed a weak positive result and spontaneous abortion. Upon internal review, spontaneous abortion was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 01Sep08)

Prex Vax Illns:

Vaers Id: **333233-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Apr-2008	07-Jul-2008	81	25-Nov-2008	26-Nov-2008	FR	WAES0811USA02483	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1340F	1	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chest pain, Dyspnoea, Palpitations

Symptom Text: Information has been received from a health authority (HA reference # PEI2008015211), concerning a 15 year old female patient with adipositas (body weight: 106.5 kg), who on 07-FEB-2008 was vaccinated with the first dose of GARDASIL (well tolerated) and on 17-APR-2008 was vaccinated with the second dose of GARDASIL (batch #NF32350, lot # 1340F), intramuscularly in the left arm. Subsequently, on 07-JUL-2008, the patient experienced palpitations for two days and on 08-JUL-2008, the patient experienced dyspnoea for approximately 10 days. The patient was hospitalized on an unspecified date. An ECG and echocardiography were performed and showed normal results. The patient recovered on an unknown date. Condition after chest pain at rest was diagnosed. A cardiac cause was ruled out. Other business partner numbers include (E2008-10504). No further information is available.

Other Meds: Unknown

Lab Data: electrocardiogram, Normal; echocardiography, Normal; WBC count, 16Jul08, Leukocyte: 7.1/nl; lymphocyte count, 16Jul08, Lymphocyte: 58.8%

History: Obesity

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333234-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	07-Nov-2008	Unknown		25-Nov-2008	26-Nov-2008	FR	WAES0811USA02552	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adjustment disorder, Asthenia, Bronchospasm, Cyanosis, Mechanical ventilation, Skin discolouration, Syncope vasovagal

Symptom Text: Information has been received from a healthcare professional concerning a female (age unknown) with no relevant history reported who on 07-NOV-2008 was vaccinated with the second dose of GARDASIL (lot and route of administration not reported). She experienced 2 vagal reactions; latency not reported. During recuperation of these vagal reactions, she experienced a third attack and became blue/black and totally weak. According to the healthcare professional it was possible that she had bronchospasm during this attack. She fully recovered after artificial respiration. The bronchospasm, vagal reaction, and adjustment reaction with physical symptoms were reported as Other Important Medical Events. Other business partner numbers included E2008-10407. No further information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333235-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	13-May-2008	14-May-2008	1	25-Nov-2008	26-Nov-2008	FR	WAES0811USA02586	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Platelet count decreased, Purpura

Symptom Text: Information has been received from Health Authority (HA reference # 2008014581) concerning a 21 year old female patient with migraine and WERLHOF'S SYNDROME (diagnosed in April 2006), who on 13-May-2008 was vaccinated intramuscularly with a first dose of GARDASIL. Concomitant therapy included bisoprolol. On 14-MAY-2008 the patient developed symmetrical purpura on legs, thorax and abdomen. On 13-MAY-2008 the thrombocytes were 115,000/nL (normal range 150,000-45,000). A control on 18-MAY-2008 showed decreased thrombocytes 73,000/nL. No further result of laboratory test was available. The patient recovered spontaneously within 4 days. Other business partner numbers include E2008-10338. The case is closed. No further information is available.

Other Meds: bisoprolol

Lab Data: platelet count, 13May08, 115000/nL; platelet count, 18May08, 73000/nL

History:

Prex Illness: Migraine; WERLHOF'S SYNDROME

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333236-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Oct-2008	08-Nov-2008	9	25-Nov-2008	26-Nov-2008	FR	WAES0811USA02589	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Hemiparesis

Symptom Text: Information has been received from a health care professional (reference # CM8239). A 16 year old female patient with no relevant medical history reported received the third dose of GARDASIL (batch number not reported) via intramuscular route on 30-OCT-2008. On 08-NOV-2008 the patient was admitted to hospital for left side paresis. A MRI performed revealed diagnosis of acute disseminated encephalomyelitis (ADEM). At time of reporting the patient had not recovered and remained hospitalized. The patient was treated with cortisone (unspecified dosage). She had no concomitant treatment. The reporter did not associated this adverse effect to vaccination with GARDASIL. Further information was expected. Other business partner numbers include E200810650.

Other Meds: None

Lab Data: Magnetic Resonance Imaging, acute disseminated encephalomyelitis

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **333237-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	04-Dec-2007	01-May-2008	149	25-Nov-2008	26-Nov-2008	FR	WAES0811USA02692	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anal abscess, Anal fissure, Crohns disease

Symptom Text: Information has been received from a general practitioner on 17-NOV-2008. A 19 year old female patient with medical history of glycogenosis type III and who had received the first dose of GARDASIL on 11-OCT-2007 received the second dose of GARDASIL (batch number not reported) via intramuscular route in her deltoid on 04-DEC-2007. In March 2008 the patient presented with anal fissure and abscess of anal margin. She was diagnosed with a Crohn's disease in May 2008 after a colonic biopsy. Treatment with IMUREL was initiated. At time of reporting the patient was stabilized but she had not totally recovered. She had no concomitant treatment. The reporter felt that Crohn's disease was an other important medical event. Other business partner numbers include E2008-10648. Additional information has been requested.

Other Meds: Unknown

Lab Data: colonic biopsy, ??May08, Diagnosed Crohn's disease

History:

Prex Illness: Glycogenosis

Prex Vax Illns:

Vaers Id: **333248-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		25-Nov-2008	26-Nov-2008	--	WAES0811USA02992	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Coma, Paralysis

Symptom Text: Information has been received from a company representative reported that she read about a teen in a High School new article. The article talks about a 23 year old female who went into a coma after receiving GARDASIL (Lot # was not available) and was paralyzed. Upon internal review, paralysis and coma determined to be other important medical events. This is one of several reports from the same source. Attempts are being made to verify the existence of an identifiable patient and reporter.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333249-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		25-Nov-2008	26-Nov-2008	--	WAES0811USA02903	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a company representative she reported that she read about a teen in High School article. The article talks about a 14 year old female who experienced seizures after receiving the first dose of GARDASIL (Lot # was not available). Upon internal review, seizure was determined to be other important medical event. This is one of several reports from the same source. Additional information has been requested. Attempts are being made to verify the existence of an identifiable patient and reporter.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333250-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Nov-2008	Unknown		25-Nov-2008	26-Nov-2008	FR	WAES0811USA02828	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Eye pain, Vaccine positive rechallenge, Visual acuity reduced, Visual field defect

Symptom Text: Information has been received from a female patient (age not reported) that she was vaccinated with a third dose of GARDASIL (lot # not reported) on an unspecified date in November 2008 (some days prior to reporting). Few days p.v. (exact latency not reported), she developed "problems with the eyes" (eye pain, decreased vision, visual field defect). She reported that she had experienced the same symptoms after the first and second dose of GARDASIL (lot #, route, site, and vaccination dates and latencies not reported). She had been hospitalized in an ophthalmologic clinic for some days (date not reported). As a possible etiology, toxoplasmosis was evoked by the treating physicians. The patient had treatment with unspecified tablets and infusions as well as antibiotics and "cortisone". The company was contacted to inquire whether the symptoms could have been caused by the GARDASIL vaccines, as the patient was watching a TV programmed in this regard. The final outcome of the events was not reported. Additional information has been requested. Other business partner numbers include E2008-10656.

Other Meds:

Lab Data: Unknown

History: Scotoma; Eye pain; Eye tenderness; Vision decreased; Hospitalisation.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333253-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	23-Oct-2008	23-Oct-2008	0	25-Nov-2008	26-Nov-2008	FR	WAES0811USA02702	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ04480	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Hyporeflexia, Pain, Somnolence

Symptom Text: Case initially received through medical sales representative on 12-Oct-2008 and then reported by foreign health authority (case n. 91589) and (local case n. IT44208) on 14-NOV-2008. An 11 year old female who was vaccinated on 23-OCT-2008 with the first dose of GARDASIL (batch#NJ04480). On the same day, in the evening, she presented with marked hyposthenia of the lower limbs successively extending to the upper limbs with pain and somnolence. Suspected (but not confirmed) Guillain-Barre Syndrome. The patient was hospitalized and kept under observation from 23-OCT-2008 to 25-OCT-2008. On 12-NOV-2008 the patient underwent a neurological consultation that showed hyposthenia of the limbs, weak ostheo-tendineal reflexes almost absent in the lower limb. Admission was advised in an appropriate facility for further investigation. Other business partner numbers include E200810607. No further information is available.

Other Meds: Unknown

Lab Data: neurological examination, 12Nov08, hyposthenia of limbs, weak osteo tendinal reflexes almost absent in lower limbs

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 333255-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	20-Oct-2008	20-Oct-2008	0	25-Nov-2008	26-Nov-2008	FR	WAES0811USA01714	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Immediate post-injection reaction, Loss of consciousness, Presyncope

Symptom Text: Information has been received from a health authority (reference number ES-AGEMED-120535241) concerning a 20 year old female who on 20-OCT-2008 was vaccinated with a dose of GARDASIL (batch number not reported) by intramuscular route, injection site not reported. On 20-OCT-2008, the patient suffered a presyncope, loss of consciousness with fall, immediately after vaccine administration. The patient recovered immediately. The AE's were considered other important medical event. Other business partner numbers include: E2008-10475. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **333256-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Oct-2008	20-Oct-2008	0	25-Nov-2008	26-Nov-2008	FR	WAES0811USA02059	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0467U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information was received from a Health Authority (documentation # 29183) concerning a female patient (6th level of education) who was vaccinated intramuscularly with a first dose of GARDASIL (lot# 0467U, batch# NG14300) on 20-OCT-2008. The patient collapsed 20 minutes post vaccination. The outcome is not reported. The patient recovered on an unspecified date. The case was upgraded to serious as the reporter considered it to be medically significant. This is one of several reports from the same source. Other business partner numbers included: E2008-09892.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333257-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		25-Nov-2008	26-Nov-2008	FR	WAES0811USA02697	26-Nov-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NH53750	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bronchitis, Eye swelling, Food allergy, Urticaria

Symptom Text: Information has been received from a patient's mother on 13-NOV-2008, concerning a 15 year old female patient with medical history of allergy to acarus during childhood, who received the first dose of GARDASIL (batch# NH53750) on an unspecified date. 15 days later the patient developed urticaria. In spite of a corrective treatment with corticosteroids and antihistamines the patient's condition aggravated with impairment of her face described as swelling eyes. She also received on VENTOLINE and was hospitalized. Then due to important dosage of corticosteroids the patient developed bronchitis. In the following days (unspecified date), the patient was seen by an allergologist who diagnosed an allergy to sulfites. At time of reporting the outcome was not specified. She had no concomitant treatment. Other business partner numbers include E2008-10637.

Other Meds: None

Lab Data: Unknown

History: Allergy to animal

Prex Illness:

Prex Vax Illns:

Vaers Id: **333264-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Nov-2008	18-Nov-2008	0	25-Nov-2008	05-Dec-2008	CA		05-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Orthostatic hypotension, Presyncope

Symptom Text: Orthostatic hypotension with presyncope, close monitoring, and hydration.

Other Meds: None

Lab Data: 11/19 laying down pulse, 70; Blood pressure, 160/64; standing pulse, 106; Blood pressure, 78/40

History: Allergic rhinitis

Prex Illness: None

Prex Vax Illns:

Vaers Id: **333308-1 (S)** **Related reports:** 333308-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	16-Sep-2008	15-Nov-2008	60	25-Nov-2008	01-Dec-2008	--		16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	2	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Anaemia, Atelectasis, Chills, Chronic sinusitis, Conjunctivitis allergic, Cough, Deep vein thrombosis, Dry skin, Dyspnoea, Hypercoagulation, Lymphadenopathy, Ovarian cyst, Pleural effusion, Pneumonia, Pulmonary embolism, Pulmonary infarction, Pyrexia, Respiratory disorder, Sinus tachycardia, Sputum discoloured, Upper respiratory tract infection, Vena cava filter insertion, Venous thrombosis

Symptom Text: 20 y.o. female with no prior past medical history, presents to the Emergency room after 3 weeks of worsening respiratory symptoms. Medical work-up on admission reveals an acute pulmonary embolism patient reports completing GARDASIL vaccine series in August 2008. 2/2/09 Received multiple medical records for 11/4/2008-1/6/2009. 11/4/2008 ER records. FINAL DX: pneumonia Only records were CXR which was WNL. 11/14/2008 Hospital medical records for 11/14-11/22/2008. FINAL DX: hypercoagulable state; venous thrombosis embolic disease w/bilateral LE DVTs & pulmonary embolus w/lung infarct & pleural effusion; s/p IVC filter; sinus tachycardia; anemia; hemorrhagic ovarian cyst for outpatient w/u; possible mood disorder Records reveal patient experienced cough, chills, fever, yellow sputum & worsening difficulty breathing x 3 weeks. Had been on oral antibiotics for pneumonia w/worsening s/s. Heme, Pulmo, GYN & surgery consults. Improved slowly & d/c to home on continued anticoagulants w/outpatient f/u. 12/11/2008 ER records Only records were CXR which revealed bibasilar subsegmental atelectasis; lung VQ scan which revealed large perfusions defects bilateral lung bases, unchanged; and duplex scan of bilateral LEs which revealed resolved thrombus of right common femoral vein. 2/12/09 Received PCP vaccine records & office notes of vaccine visit dates. 2/21/08 #1 was well except for dry hands/feet & allergic conjunctivitis. 4/24/08 pt dx w/chronic sinusitis & recurrent abdominal pain. 9/16/08 #3 pt dx w/URI.

Other Meds: Unknown

Lab Data: Lung perfusion scan; CT chest 11/4/08 CXR WNL. 11/14/08 LABS: CXR & non contrast CT scan of chest c/w RLL pneumonia & pleural effusion. CT scan of chest w/contrast (+) central right pulmonary embolism; RLL consolidation w/effusion; left

History: Unknown

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333308-2 (S)** **Related reports:** 333308-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	16-Sep-2008	04-Nov-2008	49	23-Feb-2009	24-Feb-2009	FL	WAES0902USA02661	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Chest pain, Cough, Deep vein thrombosis, Hypercoagulation

Symptom Text: Information has been received from a physician concerning a 20 year old female with respiratory allergies who on 21-FEB-2008, 24-APR-2008 and 16-SEP-2008 was vaccinated with the first, second and third dose of GARDASIL respectively (first and second dose lot # unspecified, lot # third dose 660612/0229X). Concomitant therapy included MENACTRA (administered on 21-FEB-2008), ZYRTEC and ALLEGRA. On 04-NOV-2008 the patient went to the physician's office with chest pain and coughing. On 07-NOV-2008 and 14-NOV-2008 the patient came back to the physician's office because the symptoms were still persisting. On 14-NOV-2008 the physician suggested to the patient to go to the hospital. The patient was hospitalized on 15-NOV-2008, a lot of different unspecified tests were done, and the patient was diagnosed with hypercoagulable state and deep venous thrombosis. On an unspecified date the patient was released from the hospital, but the physician did not mention how long the patient was in the hospital for. The physician stated he feels that hypercoaguable state and DVT are life threatening, he was unsure if GARDASIL caused the experience. The patient is still recovering. Additional information has been requested.

Other Meds: Zyrtec; Allegra

Lab Data: diagnostic laboratory, 11/15/08, unspecified lab tests

History:

Prex Illness: Allergic respiratory symptom

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333311-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Nov-2008	18-Nov-2008	0	25-Nov-2008	05-Dec-2008	VA		05-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lip swelling, Urticaria

Symptom Text: 11-18-2008 5:30pm lower lip swollen, then both lips swollen, hives on right wrist and fingers. On call Dr advised Benadryl and ER. At the ER patient given Prednisone for six days.

Other Meds: Loratidine 10mg Qd

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 333323-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Sep-2008	05-Nov-2008	42	25-Nov-2008	05-Dec-2008	--		10-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	3922AA		Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2812AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0575X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Asthenia, Chills, Condition aggravated, Decreased appetite, Fatigue, Headache, Immediate post-injection reaction, Lethargy, Loss of consciousness, Nausea, Neurological examination normal, Presyncope, Rhinorrhoea, Upper respiratory tract infection, Vaccination complication, Vomiting

Symptom Text: My 16 year old daughter was given GARDASIL injection #1 on 9/24/08 along with MENACTRA and TdaP. Immediately she was nauseated. One week later she developed a headache that would not go away for seven weeks. We went to a doctor after hours and received a shot of TORADOL which did not stop the pain, they began orders for MRI of the head. Two days later she almost passed out in the shower and was so weak she could not walk up the stairs at home. I took her to the ER where they did blood tests ruling out diabetes, mono, infection, virus etc. 11/5/08. They did a head CT which showed nothing. They gave IMITEX which made the headache worse. We were referred to a neurologist and would need an MRI which we could not get done because of insurance problems, but ultimately the neurologist eluded to problems with the HPV virus and that this should go away and did not need to get MRI. She spent seven weeks straight with a headache and weakness that is unparalleled. She missed a minimum of six days of school due to exhaustion and headache. During those seven weeks she had constant headache, weakness, severe lethargy, nausea and vomiting. She almost missed making her basketball team that she had been working out for every day of the months because she could not even function on the lowest level. 12/2/08 Reviewed ER medical records of 11/05/2008. FINAL DX: chronic HA & fatigue. Records reveal patient experienced HA x 6 weeks & had developed chills, nasal drainage, nausea, decreased appetite. Had completed antibiotic course recently for sinusitis. Had been seen in urgent care & referred to ER for MRI of brain. Phone consult w/neuro who recommended CT scan instead & outpatient f/u. 12/5/08 Reviewed PCP & neuro medical records. FINAL DX: protracted HA related to immunizations or URI. Records reveal patient experienced usual state of good health on day of vaccination. Neuro consult done 11/18/08 for protracted HA. Had HA, fatigue, intermittent weakness & nausea day starting day after vaccination. Also experienced

Other Meds:

Lab Data: Treated over the phone by our doctor for a presumed sinus infection because headache with LEVAQUIN antibiotic. 11/1/08 Mono test - date approximate- 11/3/08 Doctor's visit #2 where she received TORADOL shot for pain and they started orders

History: She has reactive airways disease and an allergy to Sulfa and CEFZIL, that is it. PMH: Migraines since age 6 w/visual aura.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333333-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		26-Nov-2008	01-Dec-2008	FR	WAES0811PHL00009	01-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician concerning a female who in 2008 was vaccinated with GARDASIL In 2008 the patient experienced vaccine exposure during pregnancy. Two months after vaccination, the patient experienced abortion. The physician reported that abortion has also occurred with several of her other patients. Upon internal medical review, abortion was considered an other important medical event. No other information is available. The physician did not respond to requests for additional information.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **333337-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Dec-2007	Unknown		26-Nov-2008	01-Dec-2008	FR	WAES0811USA03065	01-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Headache

Symptom Text: Information has been received from a general practitioner concerning a 17 year old female patient with no relevant medical history reported received the first dose of GARDASIL (batch number not reported) in December 2007 (also reported as December 2008). Less than 1 week later, the patient experienced abdominal pain and cephalgia. Since that first dose symptoms were persisting without any regression. At time of reporting, the patient had not recovered. She received the second dose of GARDASIL in February 2008 and the third dose on 20-JUN-2008. There was hospitalization in order to perform a workup (unspecified date). Abdominal CT scan, cerebral CT scan, blood analysis were normal. Up today she was followed by a pediatrician. She also had been followed by a psychologist and nothing was found. All performed work-ups were negative. Bacteriological, virology and serologies tests were negative. Gynecology and ophthalmology tests were normal. The patient consulted a re-educator of vertebral column and all was normal. endocrinology tests were normal. The patient was treated with antispasmodic, with DOLIPRANE, with codeine, with ADVIL. All corrective treatment were without any amelioration. Other business partner numbers included: E2008-10710. No further information is available.

Other Meds: Unknown

Lab Data: abdominal computed axial tomography, normal; head computed axial tomography, normal; diagnostic laboratory test, blood analysis-normal; diagnostic laboratory test, all performed work-ups-normal; gynecological examination, normal; ophthalmol

History: None

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333338-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	31-Dec-2007	03-Dec-2007	-28	26-Nov-2008	01-Dec-2008	NE	WAES0801USA00316	02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Initial and follow-up information has been received from a certified medical assistant concerning a 15 year old female with no medical history and no drug allergies, who on 31-DEC-2007 was vaccinated intramuscularly with a 0.5mL first dose of GARDASIL (Lot# 658560/1062U). There were no concomitant medications. Subsequently, the patient was pregnant. The patient had an office visit. An ultrasound was performed. The patient's last menstrual period was 30-NOV-2007 and her estimated delivery date was 11-AUG-2008. No product quality complaint was involved. In January 2008 the patient had an elective termination. It was unknown if the fetus was normal and if the products of conception were examined. The patient had no previous pregnancies. Upon internal review the elective termination was considered to be an other important medical event. Additional information is not expected.

Other Meds:

Lab Data: ultrasound

History:

Prex Illness: Pregnancy NOS (LMP = 11/30/2007)

Prex Vax Illns:

Vaers Id: 333339-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Mar-2008	22-Mar-2008	1	26-Nov-2008	01-Dec-2008	FR	WAES0810USA04428	01-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1146U	0	Right arm	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Fibroadenoma of breast, Hyperplasia, Incorrect route of drug administration, Inflammation, Lymphadenopathy, Surgery

Symptom Text: Information has been received from a general practitioner on 10-OCT-2008, concerning a 17 year old female with a history of left breast nodule with no axillary adenopathy at medical examination in Jan-2008, who on 21-MAR-2008 was vaccinated with the first dose of GARDASIL (batch number not reported) via intramuscular route in right deltoid, and on 23-MAY-2008 the second dose of GARDASIL (batch number not reported) via intramuscular route in right deltoid. One to two days, on approximately 22-MAR-2008 after the first dose the patient developed right axillary adenopathy which persisted at the time of administration of the second dose. To be noted that sites of administration of the first and second dose of GARDASIL were the same. A breast ultrasound performed in JUL-2008 revealed a fibroadenoma for her right breast and 2 adenopathies of 11-12mm in concave axillar. A new breast ultrasound performed on 07-OCT-2008 showed several adenopathies, 1of 27mm and others of 13-15mm for the most significant ones. At time of reporting the patient had not recovered and there still were huge eye perceptible tumefactions in concave axillar. To be mentioned that in JAN-2008 there was no axillary adenopathy at medical examination. Follow-up information received through the pharmacovigilance form on 18-NOV-2008: Batch number of first dose was NH00400 and second dose was NG41880. Both doses had been administered via subcutaneous route in her right deltoid. Right axillary adenopathy of moderate intensity persisting at the time of administration of the second dose and worsened to severe were confirmed. The patient had a painful inflammatory reaction after first dose that worsened after second dose. Surgery was necessary. There was anatomopathology analysis of 9 adenopathies. The smallest one sized 0.5cm and the biggest one sized 5cmx3cmx1cm. Conclusion was right axillary adenopathies showing reactional hyperplasia lymph nodes. At time of reporting the patient had not recovered. Other business partner's# includes E200809471. Case of misu

Other Meds: Unknown

Lab Data: ultrasound, ??Jul08, right breast 2 adenopathies of 11-12mm in concave axillar; ultrasound, 07Oct08, several adenopathies, 1 of 27mm and others of 13-15mm for the most significant ones

History: Breast nodule

Prex Illness:

Prex Vax Illns:

Vaers Id: 333341-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Aug-2008	24-Aug-2008	9	26-Nov-2008	01-Dec-2008	CA	WAES0811USA03093	09-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1366U	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1061U	0	Right arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Acute polyneuropathy, Amenorrhoea, Arthralgia, Cerebellar ataxia, Chest wall mass, Guillain-Barre syndrome, Hypoaesthesia, Inflammation, Muscular weakness, Non-cardiac chest pain, Pain, Paraesthesia, Swelling, Tenderness, Vaccination complication

Symptom Text: Information has been received from a office manager concerning a 12 year old female with no known pertinent medical history, and no known drug reactions/allergies, who on 15-AUG-2008 was vaccinated with the first dose of GARDASIL (Lot no 658558/1061U) in her right arm. Concomitant vaccine included VARIVAX. The office manager reported that on 24-AUG-2008 the patient called the office because she was having tingling and numbness in both of her legs. On 28-AUG-2008, the patient went to the doctor's office in which he ordered blood work, a urine test and he did a heavy metal screening and the patient was referred to the neurologist. On 11-SEP-2008, the test all came back normal. On 26-SEP-2008, the patient saw the neurologist whose impression was that the patient had paresthesia to the vaccine injection and he prescribed the patient NEURONTIN (Manufactured unknown) 100 mg twice daily and the patient was scheduled to see the doctor again in a month follow up. On 03-OCT-2008, the patient called the doctor because she was still having the tingling and numbness in both legs and he had diagnosed her with TA paresthesia and added ATAXIA CEREBELAR. On the same day, 03-OCT-2008, the patient had a MRI done of her brain and again was referred to see a neurologist for a second opinion and if it gets worse she may start LYRICA. The office manager stated that the end results of MRI seemed to be normal. The office manager reported that on 24-OCT-2008, the patient left a message which stated that she was now also having pain in her knee. On 27-OCT-2008, the patient saw the doctor again and he was diagnosed her with paresthesia. Then on 03-NOV-2008, the patient received her second opinion with a neurologist and said that she had a mild form of acute polyneuropathy (Guillain Barre) post vaccinating improving. Then on 17-NOV-2008, the patient saw the doctor again because she was stilled having tingling and numbness in both legs but now had worse symptoms in her feet and hand symptoms, and when the patient saw the physician on 17-OCT-2

Other Meds: Unknown

Lab Data: diagnostic laboratory, 08/28/08, normal; magnetic resonance, 10/03/08, normal; hematology, 08/28/08, normal; urinalysis, 08/28/08, normal Labs and Diagnostics: MRI brain WNL. heavy metal testing revealed Arsenic 27 mcg/L. CBC with WBC 3

History: None. PMH: none

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333342-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		26-Nov-2008	01-Dec-2008	CA	WAES0811USA03543	01-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Myoclonic epilepsy

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who on unspecified date was vaccinated with a dose of GARDASIL. After three hours of GARDASIL vaccination, the patient developed myoclonic seizures. The patient sought medical attention at the office and emergency room. Upon internal review, myoclonic seizures were determined to be an other important medical event. At the time of reporting, 20-NOV-2008, the outcome of the patient was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333343-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		26-Nov-2008	01-Dec-2008	--	WAES0811USA03554	01-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse who reported that a patient reported that her "16 or 17 year old" female friend was vaccinated with a second dose of GARDASIL (Lot # not provided). Subsequently, she developed seizures and had to be taken to the hospital. Nurse reported that her patient reported that her friend also claimed that tests were performed in the hospital and the hospital physician felt her seizures were a result of GARDASIL and treated her with unspecified medications. The patient outcome was not provided. Upon internal review seizure was determined to be another important medical event. Attempts are being made to verify the existence of an identifiable patient and reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333344-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	06-Nov-2008	06-Nov-2008	0	26-Nov-2008	01-Dec-2008	CT	WAES0811USA03557	01-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a nurse concerning a female patient who 2 weeks ago, on approximately 06-NOV-2008, was vaccinated with a dose of GARDASIL. The patient experienced syncope and seizure-like symptoms after receiving the vaccine. The patient experienced the symptoms while she was still at the physician's office. The patient sought medical attention through an office visit. Subsequently, the patient recovered. Upon internal review seizure-like symptoms was determined to be another important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333354-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Nov-2008	20-Nov-2008	0	26-Nov-2008	08-Dec-2008	TX		20-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	42730AA		Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Akinesia, Chills, Crying, Dizziness, Hyperaesthesia, Immunisation reaction, Irritability, Malaise, Pain

Symptom Text: Skin sensitivity, crying excessively, could not move. 12/30/2008 MR received for DOS 11/20/08. Pt in for 12 yr WCC and vax. Dx with B OM. Returned to office that pm with c/o irritability, body pain and crying. Referred to ER. 1/5/09 ER records received for 11/20/08 visit with dx: Immunization reaction. Pt presented with lightheadedness, body aches, sensitive skin, malaise and chills. Tx with Solumedrol and Benadryl.

Other Meds:

Lab Data: labs: Glucose 181. Alk Phos 211. CBC WNL. Blood cx (-).

History: None

Prex Illness: BOM

Prex Vax Illns:

Vaers Id: 333364-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	27-Oct-2008	27-Oct-2008	0	26-Nov-2008	08-Dec-2008	AR		16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Pain in extremity, Vaccine positive rechallenge

Symptom Text: Arm pain that radiated to elbow requiring treatment with Ibuprofen and moist heat frequently x 4 mo.- ongoing. Occurred with admin. of GARDASIL #1 (06/19/2008) and #2(10/27/2008). Onset immediately post injection both dates.

Other Meds: "Birth Control Tab"

Lab Data: None

History: None

Prex Illness: HA; vomiting; back pain

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333375-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Feb-2007	20-Feb-2007	0	26-Nov-2008	08-Dec-2008	MD		08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2609AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U1975BA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0087U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Pt received Menactra on 10/12/05. pt given second dose of Menactra on 02/20/07.

Other Meds:

Lab Data:

History: Cephalasporin

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333383-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	19-Nov-2008	21-Nov-2008	2	26-Nov-2008	08-Dec-2008	NJ		08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229 X	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2797DA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Pyrexia

Symptom Text: Child got slight fever on 11/21/08. Then on 11/23/08, got dizzy & fell down on the kitchen floor,no LOC. Is ok now.

Other Meds: none

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **333387-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Nov-2008	19-Nov-2008	0	26-Nov-2008	08-Dec-2008	NM		08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHHAVB289CB	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0650X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2732AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope after injection approx 1 min.

Other Meds: NONE

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: 333390-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	26-Nov-2008	29-Apr-2008	-211	26-Nov-2008	08-Dec-2008	MO		08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Influenza like illness, Pyrexia, Vaccine positive rechallenge

Symptom Text: PATIENT AND HER MOTHER COMPLAINED OF PATIENT EITH LOW GRADE FEVERS AND FLU LIKE SYMPTOMS AFTER GETTING THE FIRST TWO INJECTIONS. ALSO COMPLAINED OF NUMBNESS IN HER ARM

Other Meds: Albuterol, Yaz

Lab Data:

History: Asthma

Prex Illness: None

Prex Vax Illns: SAme as above~HPV (Gardasil)~0~16~In Patient

Vaers Id: **333396-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-Oct-2008	07-Oct-2008	0	27-Nov-2008	08-Dec-2008	AK		22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Convulsion, Dizziness, Fall, Head injury, Muscular weakness, Syncope

Symptom Text: Patient felt dizzy within a minute of the HPV shot. She fainted, fell off the exam table and had a short seizure. She has since fallen from leg weakness which has never before this time ever happen. 12/4/08-records received--clinic visit 10/7/08-brief syncope after shots fell off table and hit head. able to get up within 2 minutes without complaints. Recent C/O abdominal pain mostly with periods. No other office visits.

Other Meds: None

Lab Data:

History: None 12/4/08-records received- PMH: Crohn;s disease.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333398-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	21-Nov-2008	22-Nov-2008	1	27-Nov-2008	08-Dec-2008	WI		08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Chest discomfort, Cough, Diarrhoea, Dyspepsia, Haemoptysis, Headache, Malaise, Nausea, Oropharyngeal pain, Pyrexia, Rhinorrhoea

Symptom Text: Fever 100.4 11/22, cough from 11/24 till present, brown sputum with streaks of blood for four a.m.'s following vaccine, severe sore throat upon a.m. awakening from time of vaccine till present, upper abdominal discomfort on right and left sides on 11/22, diarrhea on 11/22, runny nose from 11/24 till present, severe nausea on 11/22, headache on 11/22, feeling of mailaise on 11/22, chest tightness, heartburn.

Other Meds:

Lab Data:

History: exercise-induced asthma

Prex Illness: none

Prex Vax Illns:

Vaers Id: **333432-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Aug-2008	20-Aug-2008	1	01-Dec-2008	09-Dec-2008	CA		11-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0570X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2605AA	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2899AA	0	Left arm	Intramuscular	
HEPA	MERCK & CO. INC.	1258U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Patient states that night after 8/19/08 she started having joint pain. 2/9/09-records received-11/26/08 presented with C/O joint pain, hands, legs, feet since 8/19/08 per parent. Parent saw TV program about similar problems and wants something done today. PE normal. Per patient 2 weeks of arthralgia after vaccination. No further visits documented.

Other Meds: None

Lab Data: 2/9/09-records received-MCV MCH low, RDW high, ESR westergren high 30. ANA titer <1:40. Rheumatoid factor <15.

History: None 2/9/09-records received- 4/9/08-C/O painful swollen mass on outer external auditory canal of right ear, incision and drainage. DX:acute abscess. office visit 11/17/06 for C/O strep throat and acne vulgarias, headaches behind right eye.

Prex Illness: Fever and sore throat 2/9/09-records received-8/19/08-C/O fever and sore throat since yesterday. Culture positive beta streptoc

Prex Vax Illns:

Vaers Id: 333441-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-May-2007	02-May-2007	0	26-Nov-2008	01-Dec-2008	TN		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0314U	0	Right leg	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Amnesia, Asthenia, Ataxia, Back pain, Confusional state, Dizziness, Dyspepsia, Eye pain, Fatigue, Gastrooesophageal reflux disease, Headache, Migraine, Migraine with aura, Myalgia, Nausea, Neurological examination abnormal, Pain in extremity, Paraesthesia, Photophobia, Speech disorder, Syncope, Tachycardia, Tinnitus, Toothache, Tremor, Vaccination complication, Vertigo, Vision blurred, Visual impairment, Vomiting, Weight decreased

Symptom Text: Frontal headache began day of first dose of GARDASIL vaccine (05-02-2007) - Neurologist consulted 07/2008 after headache continued daily/constantly x over 1 yr - Neurologist states likely migraine cycle triggered by HPV vaccine - Condition now worsened to debilitating status for several days in a row. 1/21/2009 MR received from neurologist. Pt seen for several visits between 11/17/08 and 12/10/08 in f/u for Classic migraine. Seen 11/17/08 for migraine h/a sx which began 6 days prior including nausea and visual disturbance. ROS (+) for fatigue, blurred vision, eye pain, photophobia, dizziness, tachycardia, acid reflux sx of heartburn, nausea and vomiting, back pain, ataxia, confusion, fainting, headaches, memory loss, paresthesias, speech disorder, tremors, vertigo and weakness. PE WNL. DX: Classic migraine. F/u 11/20/08 with no relief of sx-still with global H/A and nausea. Recent syncopal event with ER visit. ROS now includes tinnitus, tooth pain, limb pain, myalgias. Tx with steroid, promethazine and dyphenhydramine. F/U 12/10/08 Migraine now resolved. ROS (+) for unintentional wt loss. On multiple meds.

Other Meds: Birth control pills or Nuva Ring without problems

Lab Data: Neg MRI/CBC/ EKG 2007 and 2008. Labs and Diagnostics: MRI brain WNL

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **333450-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Nov-2008	Unknown		26-Nov-2008	08-Dec-2008	WI		23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Dose 3 was given too soon. It will be repeated per CDC guidelines

Other Meds: AVIANE

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **333455-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Nov-2008	04-Nov-2008	0	26-Nov-2008	08-Dec-2008	NC		08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial pain, Headache, Pyrexia, Sinusitis

Symptom Text: Abrupt onset of headache , low grade fever and fail pain. Patient Evaluated 11/16/2008 and diagnosed with sinusitis.

Other Meds:

Lab Data:

History: Allergic Rhinitin

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333463-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Mar-2008	27-Mar-2008	0	01-Dec-2008	02-Dec-2008	MA	WAES0804USA01140	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1226U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received, for the Pregnancy Registry for GARDASIL, from a physician and a registered nurse (R.N.) concerning a 15 year old female with no previous pregnancies, asthma, dysmenorrhoea, attention deficit/hyperactivity disorder and learning disability who on 25-SEP-2007 was vaccinated IM with a first 0.5 mL dose of GARDASIL (Lot# 657737/0522U). Concomitant therapy included albuterol. On 10-NOV-2007 the patient was vaccinated with a second dose of GARDASIL (Lot# 658563/1063U). On 27-MAR-2008, the patient was vaccinated with a third dose of GARDASIL (Lot# 657145/1226U). It was reported by a registered nurse that the patient had a positive pregnancy test on 23-MAR-2008. At the time of the report, the outcome was unknown. Follow-up information was received on 24-NOV-2008 from the physician and the R.N. indicating that "approximately 3-4 weeks before 17-APR-2008", on approximately 27-MAR-2008, the patient had an elective termination. It was unknown if the products of conception were examined. It was unknown if the fetus was normal. The outcome of the patient was not reported. Upon internal review, elective termination was determined to be an other important medical event. No further information is available.

Other Meds: Albuterol

Lab Data: beta-human chorionic, 03/23/08, posit

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Asthma; Dysmenorrhoea; Attention deficit/hyperactivity disorder; Learning disability

Prex Vax Illns:

Vaers Id: **333464-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jun-2008	01-Jul-2008	30	01-Dec-2008	02-Dec-2008	FR	WAES0811USA03067	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Gait disturbance, Herpes simplex serology positive, Incontinence, Mycoplasma serology positive, Nervous system disorder, Pleocytosis, Visual acuity reduced

Symptom Text: Information has been received from health authorities under reference number ST20080920, concerning a 15-year-old female patient who received an injection of GARDASIL (batch number not reported) in JUN-2008. In JUL-2008 the patient suffered from acute disseminated encephalomyelitis and was hospitalized from 25-JUL-2008 to 05-AUG-2008. On 23-JUL-2008 she had a complete visual acuity decreased of her left eye. On 24-JUL-2008 she had walking troubles associated to sphincter troubles in relation with a medullar syndrome. Analysis of CSF put in relief pleocytosis with 280 leukocytes/mm3 with lymphocytic predominance and cervicospinal fluid proteins at 0.54g/l. Findings for herpes simplex virus with polymerase chain reaction, for enteroviruses, rubella and interferon gamma were negative. Biological work-up: leukocytes at 19300/mm3 with 17700/mm3 of PNN. ESR at 80mm at first hour, fibrinogen at 7.48 g/l, CRP at 64mg/l. Findings for anti nuclear antibodies were positive at 1/320, stained which course had to be followed without any antigenic specificity. Pneumoniae mycoplasma serodiagnosis was positive with IgM at 193U and which course had to be followed. Conclusion was an episode of acute disseminated encephalomyelitis probably post-infectious after infection with mycoplasma pneumoniae or herpes simplex virus type I or type II due to those both serologies were positive with IgM. Evolution was rapidly favourable under corticotherapy and in favour of a dysimmunitary event more than an infectious one. Aetiologic work-up put in relief presence of anti nuclear antibodies at 1/320 to control. At time of reporting the patient was recovering from acute disseminated encephalomyelitis. Other business partner numbers included: E2008-10680. Additional information has been requested.

Other Meds: Unknown

Lab Data: CSF volume, lymphocytic predominance and cervicospinal fluid proteins at 0.54g/l; CSF white cell count, 280 leukocytes/mm3; DNA Ab immunoprecipitation, 1/320; WBC count, 19300/mm3 with 17700/mm3 of PNN; Serum C-reactive protein, 64 mg/l; Er

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333465-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	Unknown	04-Sep-2008		01-Dec-2008	02-Dec-2008	FR	WAES0811USA03688	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cervical conisation, Cervical dysplasia

Symptom Text: Information has been received from a gynaecologist concerning a 24 year old female with a history of PAP smear abnormal with classification type II in 2004 and 2006 who in 2007 was vaccinated with 3 doses of GARDASIL (batch numbers, routes and sites not reported). On 04-SEP-2008 a PAP smear abnormal with classification type IV was detected. On 26-SEP-2008 cervical intraepithelial neoplasia (CIN) 3 and a positive testing for human papillomavirus (HPV) type 16 was detected. On 27-OCT-2008 a conisation for cervical intraepithelial neoplasia (CIN) 3 was performed endocervical and ectocervical at the hospital. The patient was hospitalized for one day. A human papillomavirus (HPV) testing, 3 months after the conisation was outstanding. The patient had not yet recovered. Other business partner number included E2008-10807. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear, 04Sep08, abnormal; serum human papillomavirus 16 antibody, 26Sep08, detected

History: Papanicolaou smear unspecifiable, class II W

Prex Illness:

Prex Vax Illns:

Vaers Id: 333466-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-Oct-2008	22-Oct-2008	1	01-Dec-2008	02-Dec-2008	FR	WAES0811USA03690	02-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Gait disturbance, Headache, Muscular weakness, Myalgia, Mydriasis, Paraesthesia, Vertigo

Symptom Text: Information has been received from 2 health care professionals concerning a 15 year old female received the 3rd dose of was vaccinated with GARDASIL on 21-OCt-2008 intramuscularly injection in deltoid. Batch number unknown. On 22-OCT-2008 she was experienced cephalgia, vertigo and difficulty in walking and due to these events she has been hospitalized for several days (admission date unknown). Neurological examination: normal. Biological examination: WBC increased, CRP normal. Lumbar puncture: normal. She has been discharged from the hospital (date unknown) with persisting difficulty in walking. Clinical examination on 18-NOV-2008: muscular weakness and disturbance of deep sensibility of upper limbs and lower limbs (more severe in lower than in upper limbs), severe myalgia, difficulty in walking (subject is not able to stand on her toes, nor on her heels), bilateral pupil dilatation with good photo-motor reflex. Electromyogram: normal. Guillain-Barre syndrome is excluded (the lumbar puncture did not show a dissociation between increased protein level and cell count in CSF; no abnormalities at peripheral nerves shown by EMG; no pyramidal symptoms). No relevant previous personal medical history, no relevant familial history; allergies not known. She has received GARDASIL D1 injection on 22-MAR-2008 and D2 injection on 24-JUN-2008; no adverse events were associated with these injections. According to 1 of the reporters, all events are related to GARDASIL, "no other explanation for events". Other business partner numbers included: E200810774. No further information is available.

Other Meds: None

Lab Data: electromyography, 18Nov08, normal, no abnormalities at peripheral nerves; neurological examination, normal; spinal tap, normal, dissociation between increased protein level and cell count in CSF; WBC count, increased; serum C-reactive prote

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **333487-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Dec-2008	01-Dec-2008	0	01-Dec-2008	10-Dec-2008	WI		10-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2812AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0575X	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2800EA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Gaze palsy, Hyperventilation, Memory impairment, Posturing, Tremor

Symptom Text: About 1 minute following administration of all three vaccines, client stated that she was going to "pass out." Eyes rolled back into head, exhibited decorticate posturing of right arm and leg, deep raspy breathing, and some tremors of legs. Episode lasted approximately 10-15 sec. Client startled and appeared scared and unable to recognize parents immediatly following episode. Supportive and reassuring measures provided.

Other Meds: lamictal, other psych meds

Lab Data: psychiatric history, on psych meds. for mood disorder

History:

Prex Illness: getting over common cold

Prex Vax Illns:

Vaers Id: **333488-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Nov-2008	26-Nov-2008	0	01-Dec-2008	10-Dec-2008	CA		11-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB213AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0171U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Hyperhidrosis, No reaction on previous exposure to drug, Pallor, Pulse pressure decreased, Syncope

Symptom Text: Client had Hep A vaccine in Left deltoid. I then gave her HPV vaccine in her right deltoid. Her mother, who was sitting in the room, noticed that the client was becoming pale and suggested she needed some "sugar" because she had not eaten in the last few hours. Client then fainted in the chair. With the assistance of another nurse, I was able to lower the client to the floor and elevate her feet without any injury. Her pulse was weak, and she was pale and diaphoretic. Blood Pressure was 118/68. Ammonia inhalant was used and client was responsive within seconds. Client had shown some anxiety over vaccinations but denied any previous reactions. Mother recalled that client had also had a fainting episode after a dental procedure in the past when the dentist was injecting novocaine.

Other Meds:

Lab Data: none

History:

Prex Illness: none reported

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333566-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	28-Nov-2008	29-Nov-2008	1	01-Dec-2008	09-Dec-2008	OH		09-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Urticaria, Vomiting

Symptom Text: Hives, nausea, vomiting 1 day after administration

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333571-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Jul-2008	09-Jul-2008	0	01-Dec-2008	10-Dec-2008	AZ		10-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site urticaria, Throat tightness

Symptom Text: Patient describes hives at site of injection aprorx 2-3" in diameter- onset day of vaccine also describes "tightness in throat" sensation no trouble breathing. No treatment needed or done.

Other Meds: DEPOPROVERA 150mg DVJ. on 6/9/08

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **333582-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	14-Aug-2008	14-Aug-2008	0	01-Dec-2008	10-Dec-2008	WI		10-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0539X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0843X	0	Left leg	Intramuscular	
	TDAP	SANOFI PASTEUR	C2774AA	0	Right leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Skin warm, Tenderness

Symptom Text: Patient was given 8/14/08. Patient developed increased erythema, warmth and tenderness over the next 24hrs. Seen 8/16/08 started on Keflex 200/5 2tsp. bid xiodz.

Other Meds:

Lab Data: Cellutitis Right arm

History: nickel allergy; cystic fibrosis

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333598-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Nov-2008	20-Nov-2008	0	01-Dec-2008	10-Dec-2008	OH		10-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	0299HAA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0381X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Head injury, Headache, Loss of consciousness, Nausea

Symptom Text: Patient received GARDASIL #1, ADACEL, and Depo Provera. She stood up, felt dizzy, started to sit on the floor but passed out, striking her head on the canter. She was out for < 45 sec. She was hanseated, dizzy, and had a headache. She was watched for 20-30 minutes then released home with mom.

Other Meds: Depo Provera 150mg;

Lab Data: none needed

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333625-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-May-2007	28-May-2007	7	02-Dec-2008	03-Dec-2008	FR	WAES0811USA03578	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1340F	1	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Complex regional pain syndrome

Symptom Text: Information has been received from a health authority (HA reference no. PEI2008017247) concerning a 11 year old (also reported as 16 year old) female patient who was vaccinated with a second dose of GARDASIL (lot # 1340F Batch # NF14740), IM into the left arm on 21-MAY-2007. On 28-MAY-2007 the patient developed a "pain syndrome" concerning head and abdomen. CT, spinal MRI, examination of the eyes and teeth and "orthopedic examinations" showed normal results. The patient was hospitalized on an unspecified date. The situation was considered to be life-threatening. The reporter assumed an acute disseminated encephalomyelitis. Despite ongoing SAEs the patient was vaccinated with the third dose of GARDASIL (Batch # NG01520, Lot# 1536F), IM into the left arm on 04-OCT-2007. The patient had not recovered at the time of reporting. The first dose of GARDASIL (lot # not reported) on 23-FEB-2007 was well tolerated. Other business partner numbers include: E2008-10694. Additional information has been requested.

Other Meds: Unknown

Lab Data: Computed axial tomography, normal; Magnetic resonance imaging, normal; Ophthalmological exam, normal; Dental examination, normal; Orthopedic examination, normal

History: The first dose of GARDASIL (lot # not reported) on 23-FEB-2007 was well tolerated.

Prex Illness:

Prex Vax Illns:

Vaers Id: 333627-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Sep-2007	25-Sep-2007	0	02-Dec-2008	03-Dec-2008	FR	WAES0806USA00280	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Fatigue, General physical health deterioration, Headache, Myopathy, Pain in extremity, Paraesthesia, Presyncope, Sinus arrhythmia, Sinus bradycardia, Somnolence, Syncope, Syncope vasovagal

Symptom Text: Information has been received from a health authority (HA reference no. PEI2008006872) through a foreign agency, concerning a 17 year old female patient, who was vaccinated with the second dose of GARDASIL (lot#, route and site of administration not reported) on 25-Sep-07. The patient developed dizziness already during the vaccination and fainted a few minutes later at the elevator. A called physician treated her with a remedy (no name reporter) for improving the circulation and recommended her to take calcium. She recovered from fainting. A few days later, in Sept-07 she complained of headache and pain in limb (arms and legs). She felt exhausted. At the time of reporting symptoms were still ongoing. P1 with GARDASIL in Jul-07 was well tolerated. Follow up information was received on 19-NOV-2008 by the mother of the patient, the case has to be upgraded (hospitalization). Medical letters and hospital report were sent. On 13-NOV-2007 echocardiography and ergometry showed normal findings, vasovagal syncopes were rather suspected. Long term ECG and ECG under rest showed sinus bradycardia and sinus arrhythmia disposition which was interpreted as a normal variant. On 31-MAR-2008 the patient's general condition worsened and she developed paraesthesia of the hands and feet with an increased need to sleep and exhaustion. Detailed diagnosis in terms of an inflammatory rheumatic or cardiological disease was performed. Tarsal tunnel syndrome was suspected. Upon medical letter dated 31-MAR-2008 the reporter assessed a possible relationship to GARDASIL vaccination. On 25-AUG-2008, the patient was admitted to an outpatient department of a hospital. Inflammatory rheumatoid disease was excluded. Significant generalized tendomyopathy was diagnosed. Previous cardiological, neurological and rheumatological examinations showed normal findings. Upon medical letter dated 29-AUG-2008 the clinical picture of generalized tendomyopathy might be caused by a functional genesis of the complaints. The patient was hospitalized from 29-SEP-2008

Other Meds: Unknown

Lab Data: echocardiography, 12-Nov-07, normal findings; cardiac exercise tolerance test, 13-Nov-07, normal findings; electrocardiogram, 13-Nov-07, ECE and ECG under rest showed sinusbradycardia and sinus arrhythmia disposition, normal variant; physic

History: P1 with GARDASIL in Jul-07 was well tolerated.

Prex Illness:

Prex Vax Illns:

Vaers Id: **333628-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Oct-2008	19-Oct-2008	6	02-Dec-2008	03-Dec-2008	FR	WAES0811USA03013	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling abnormal, Muscle contractions involuntary

Symptom Text: Information has been received from a health agency (HA reference # 083884). It was reported that a 14 year old female was vaccinated with the second dose of GARDASIL (route and site of administration not reported) on 13-OCT-2008. She received the first dose of GARDASIL on 12-AUG-2008 (batch # NG31280, lot # 0513U). HA reported muscle contractions involuntary, preceded by dizziness, with onset on 19-OCT-2008. Afterwards, the patient has had 5 more similar episodes with contractions that lasted for 3 hours at the most. She was conscious during the episodes but she did not feel as normal. She had difficulties explain the feeling. The only event reported by the HA was muscle contractions involuntary. EEG inclusive sleep EEG was normal. Concomitant medications were ATARAX and TETRALYSAL capsule (indications not reported). The outcome was at the time of reporting not yet recovered. Case is closed. Other business partner numbers include E200810719.

Other Meds: ATARAX; TETRALYSAL

Lab Data: electroencephalography, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 333629-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Sep-2008	08-Oct-2008	36	02-Dec-2008	03-Dec-2008	FR	WAES0811USA03956	03-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1114U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Medical diet, Pancreatitis acute

Symptom Text: Information has been reported by a gynaecologist that a 15-year-old female patient was vaccinated with a first dose of GARDASIL (Batch # NH10940, Lot 1114U) IM into the left upper arm on 02-SEP-2008. On 08-OCT-2008 acute pancreatitis was diagnosed. The patient was hospitalized from 08-OCT-2008 until 16-OCT-2008. ECG and abdomen sonography showed pancreatitis. No indication for necrotic changes. Serological examination on Coxsackie viruses, enteroviruses, EBV, hepatitis A and B, influenza A/B, leptospires, mycoplasms were negative. The patient was under a special diet and fully recovered. Case is closed. Other business partner numbers included: E2008-10781. No further information is available.

Other Meds: Unknown

Lab Data: Electrocardiogram, pancreatitis; Abdominal ultrasound, pancreatitis; Diagnostic laboratory test, negative Coxsackie virus; Diagnostic laboratory test, negative leptospires; Enterovirus PCR, negative; Plasma Epstein-Barr virus viral load, ne

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **333630-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Nov-2008	21-Nov-2008	16	02-Dec-2008	03-Dec-2008	NY	WAES0811USA04010	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	1	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Gait disturbance, Rash, Urticaria

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who on 05-NOV-2008 was vaccinated with the second dose of GARDASIL (lot# 659655/1486U). Concomitant therapy included VARIVAX and ADACEL. On 21-NOV-2008 the patient developed rash, hives, urticaria and generalized joint pain in her knees, elbows and ankles, but she had no fever. The patient was instructed to take TYLENOL for the pain and she was referred to an urgent care physician who instructed the patient to take BENADRYL. On unspecified date lab tests were performed, but specifics are unspecified. As of 24-NOV-2008 the patient had not recovered. The physician considered the patient's experience to be disabling because "it was hard for the patient to walk". Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **333639-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	05-Nov-2008	05-Nov-2008	0	02-Dec-2008	12-Dec-2008	OR		14-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Disorientation, Gaze palsy, Loss of consciousness, Pallor, Somnolence, Unresponsive to stimuli

Symptom Text: Became very pale within 5 minutes of vaccine. Mom stated pts eyes rolled back and she "Passed out" in waiting room ~10 mins after vaccine. Pt initially unresponsive to voice but slowly recoevered. Mother not concerned initially as pt has hx of fainting after piercings. Pt recovered and taken home. Mother called the following day to say her daughter had been pale and moving slowly for 24 hrs after vaccine. Appeared sleepy and slightly disoriented. Full recovery at time of discussion with mother the following day.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **333659-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	26-Nov-2008	26-Nov-2008	0	02-Dec-2008	12-Dec-2008	OR		14-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperhidrosis, Syncope

Symptom Text: 20 minutes after administration of vaccine client became faint and diaphoretic.

Other Meds:

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **333680-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	10-Sep-2008	24-Sep-2008	14	02-Dec-2008	11-Dec-2008	NY		30-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Anxiety, Arthralgia, Asthenia, Chest pain, Constipation, Diarrhoea, Dizziness, Dyspnoea, Fatigue, Gastritis, Migraine, Myalgia, Nausea, Rash, Rhinorrhoea, Sinus headache, Stress, Vomiting, Weight decreased

Symptom Text: Started 3 weeks ago, improving now. 2 months of joint and muscle aches, weakness, fatigue, migraines, sinus pressure. nausea, vomiting, and diarrhea began 2 weeks after injection and resolved. nausea, vomiting, diarrhea again 3 weeks ago. Intermittent chest pain and shortness of breath 3 weeks ago. Bloody nasal discharge. 1/15/09-records received-6/13/08-did not follow up with referral due to lack of insurance. Pevlic pain now resolved. Changed pills now C/O circumoral rash and increased headaches. 7/8/08-Gardasil given C/O feeling tired. 9/10/08-Gardasil given.12/1/08-C/O fatigue, nausea, vomiting,diarrhea, dizziness, migraines, since last gardasil shot, 2 months of joint and muscle aches, weak, exhaustion.Hair loss improving. PE:normal hair pattern. 1/27/09-records received-on 11/10/08 C/O nausea, vomiting, diarrhea since night prior, increased malaise, joint pain, epigastric pain. Stressed regarding complaints related to Gardasil. Assessment:anxiety, gastritis. 11/19/08-weight loss of 15 pounds. Loose stools and constipation. Tired. Assessment:fatigue, muscle ache, diarrhea/constipation. 11/26/08-diarrhea continues intermittently, mucle aches, joint pain intermittent. Assessment: symptoms related to anxiety and sedentary lifestyle and poor dieting with numerous somatic complaints.

Other Meds: CELEXA, LORATIDINE; FLUTICASONE

Lab Data: 1/15/09-records received-12/9/08-Urine for C&S no growth. 1/9/09-Pap HGS/L. biopsy CIN IL III. 1/27/09-records received-Stool culture negative. Lyme test negative.

History: CODEINE; Hives

Prex Illness: None

Prex Vax Illns:

Vaers Id: **333685-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Sep-2008	30-Sep-2008	0	02-Dec-2008	12-Dec-2008	AZ		14-Dec-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB246AA	0	Left arm	Unknown	
MNQ	SANOFI PASTEUR	U2665AA	0	Right arm	Unknown	
TDAP	SANOFI PASTEUR	C2997AA	0	Right arm	Unknown	
HPV4	MERCK & CO. INC.	0570X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site erythema, Injection site pain, Injection site pruritus, Injection site swelling

Symptom Text: Pt. states she noticed a "brown spot" on arm when she removed the bandaide 4 hours after GARDASIL injection. Area started itching 2-3 days later and has not stopped- (has been scratching). Redness at site started 2 weeks later and then started having pain radiating out 4 inches diameter around site- minor swelling noted. No treatment done. Reported on 12/2/08 to CCHD- Instructed to see PMD immediately.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333703-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	03-Mar-2008	03-Mar-2008	0	03-Dec-2008	04-Dec-2008	MO	WAES0803USA03933	04-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Caesarean section, Cephalo-pelvic disproportion, Drug exposure during pregnancy

Symptom Text: Information has been received from a 24 year old female consumer for the Pregnancy Registry for GARDASIL concerning herself with a history of methicillin-resistant staphylococcal aureus infection in August 2007 who on 24-DEC-2007 was vaccinated with her first dose of GARDASIL (lot# not reported). On 03-MAR-2008 the patient was vaccinated with her second dose of GARDASIL (lot# not reported). There was no concomitant medication. On 10-MAR-2008 the patient found out she was pregnant with 3 positive home pregnancy tests. She also had an examine with the nurse practitioner to confirm she was 9 weeks pregnant. Her estimated LMP was 05-JAN-2008 and her outcome was not reported. Follow-up information was received from a physician concerning the 24 year old female patient with a history of eczema, carpal tunnel and anemia. No previous pregnancies. On 15-APR-2008, ultrasound was performed with result within normal limits. On an unspecified date, the patient developed anemia during pregnancy. On 13-NOV-2008, the patient delivered a liveborn male infant by cesearean section due to cephalo-pelvic disproportion. Infant weighed 9 pounds 11 ounces. The infant's apgar score was 9/9. The infant was normal, with no congenital anomalies. There was no infection or illness during pregnancy. The infant's delivery by cesearean section due to cephalo-pelvic disproportion was considered an other important medical event. Additional information is not expected.

Other Meds: None

Lab Data: ultrasound, 04/15/08, within normal limits; beta-human chorionic, positive

History: Methicillin-resistant staphylococcal aureus infection; Carpal tunnel syndrome; Anaemia; Eczema

Prex Illness:

Prex Vax Illns:

Vaers Id: 333704-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	26-Aug-2008	09-Sep-2008	14	03-Dec-2008	04-Dec-2008	--	WAES0811USA03785	04-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a health professional for the Pregnancy Registry for GARDASIL concerning a 24 year old female who on 26-AUG-2008 was vaccinated with a first dose of GARDASIL (lot # 660620/0571X). There was no concomitant medication. On an unspecified date, she became pregnant. The date of last menstrual period was 09-SEP-2008. On 05-NOV-2008, approximately 7 weeks from the date of last menstrual period, the patient experienced spontaneous abortion. No product of conception was examined. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 9/9/2008)

Prex Vax Illns:

Vaers Id: 333705-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	16-Sep-2008	23-Sep-2008	7	03-Dec-2008	04-Dec-2008	MO	WAES0811USA04121	08-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Chills, Convulsion, Dyspnoea, Grand mal convulsion, Intensive care, Loss of consciousness, Malaise, Postictal state, Pyrexia, Rash generalised, Sinusitis, Syncope, Tongue biting, Vaccine positive rechallenge

Symptom Text: Information has been received from a certified medical assistant concerning a 20 year old female patient with polycystic ovarian syndrome, depression, asthma and insulin resistance, and no known drug reactions or allergies who on 16-SEP-2008 was vaccinated intramuscularly into the left deltoid with the first 0.5 ml dose of GARDASIL (lot# 660618/0572X). Concomitant therapy included ZOVIA, GLUCOPHAGE, spironolactone, XANAX, PROZAC, trazodone HCl and METADATE. The medical assistant reported that the patient experienced rash all over her body a week after getting vaccinated (approximately 23-SEP-2008). On 11-NOV-2008 the patient received the second dose of GARDASIL (lot# 661044/0548X) and reported the rash. On the night of 11-NOV-2008 the patient had trouble breathing and fainted. On 12-NOV-2008 the patient experienced 2 seizures at school and went to the emergency room and was hospitalized. During her hospitalization, the patient had 8 to 10 seizures and was transferred to the intensive care unit. On 18-NOV-2008 the patient was released because she was seizure-free. On the weekend of 22-NOV-2008 the patient was admitted to the hospital because of more seizures. She was still in the care of the hospital. Rash all over her body, trouble breathing, fainted, and seizures were considered to be other important medical events. Additional information has been requested. 12/31/08 Reviewed hospital medical records of 11/12-11/14/2008 FINAL DX: possible pseudoseizures vx seizure disorder Records reveal patient experienced fever, chills, felt unwell after HPV#2, 0548X, received 11/11/2008. Had cold sore on day of vaccination. Had witnessed tonic-clonic seizure activity w/tongue biting, loss of consciousness, & postictal confusion. Neuro consult done & tx w/antiseizure meds. ICU stay. D/C to home w/neuro & psych f/u.

Other Meds: XANAX; ZOVIA; PROZAC; GLUCOPHAGE; METADATE; spironolactone; temazepam; trazodone hydrochloride

Lab Data: Unknown LABS: CBC, chemistry. UA & CXR WNL. Urine drug screen (+)benzodiazepines. CT head c/w sinusitis. MRI brain WNL. EEG WNL.

History: PMH: borderline diabetes; hip displacement in infancy; POS; thyroglossal duct cysts & ITP requiring steroids; anxiety; insomnia. Sinus surgery & ear tube insertion. Allergy: sulfa, ceclor & tylenol. Family hx: seizures, HTN, thyroid disorders. HPV #2 given 11/11/08, RA, lot #0548.

Prex Illness: Polycystic ovarian syndrome; Depression; Asthma; Insulin resistance

Prex Vax Illns:

Vaers Id: 333706-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	25-Mar-2008	03-Nov-2008	223	03-Dec-2008	04-Dec-2008	--	WAES0811USA04215	04-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	2	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a certified nurse midwife (C.N.M.) concerning a 21 year old female who on 18-SEP-2007 (lot # 658558/1061U), 13-NOV-2007 (lot # 659435/1265U) and 25-MAR-2008 (660387/1967U) was vaccinated with the first, second and third dose of GARDASIL in the deltoid respectively. The patient had 3 negative pap smears results since 2006. She was determined to HPV high risk on 03-NOV-2008 with a positive result. The patient underwent a colposcopy procedure related to abnormal paps. The patient had been sexually active prior to GARDASIL and described "occl" condom use. The C.N.M. considered the positive HPV to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: colposcopy, abnormal paps

History: Sexually active

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333722-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	21-Oct-2008	21-Oct-2008	0	03-Dec-2008	14-Dec-2008	IN		14-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope

Symptom Text: Pt. waited in administration room for approximately 5 minutes after administration because of history of dizziness following another vaccine. after she left room and walked down hallway she fainted. She was unconscious very briefly. She was fully recovered after resting for 15 minutes and drinking juice

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **333756-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Nov-2008	01-Nov-2008	0	03-Dec-2008	04-Dec-2008	FR	D0059644A	04-Dec-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPAB	GLAXOSMITHKLINE BIOLOGICALS	NULL	2	Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Convulsion, Fatigue, Hypersomnia, Malaise, Pain in extremity, Syncope

Symptom Text: This case was reported by a physician, via a sales representative and described the occurrence of convulsive seizure in a female subject of unspecified age who was vaccinated with TWINRIX (GlaxoSmithKline). Co-suspect vaccination included GARDASIL (Sanofi Pasteur MSD). In November 2008 the subject received 3rd dose of TWINRIX and GARDASIL (unknown route and application site). In November 2008, less than one month after co-administered vaccination with GARDASIL and TWINRIX, the subject was very tired and slept over a period of 16 hours. Few days after vaccination the subject felt sick, collapsed and experienced convulsive seizure with obstetrician's hand. This case was assessed as medically serious by GSK. At the time of reporting the subject still felt weak and suffered from pain in hands. Follow-up information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **333765-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Sep-2008	22-Oct-2008	22	03-Dec-2008	15-Dec-2008	CA		16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Urine human chorionic gonadotropin positive

Symptom Text: 15 year old female LMP 9/2/08 urine HCG negative 9/28/08. GARDASIL given 9/30/08. Urine HCG positive 10/17/08 with positive exam HCG(126.7) on same day. status post spontaneous abortion 10/22/08.

Other Meds: ZOLOFT; POLYTRIMEYEDROPS; Prenatal vitamins; MOTRIN; SUDAFED

Lab Data:

History: History of LTBI

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333773-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Dec-2008	03-Dec-2008	0	03-Dec-2008	15-Dec-2008	CA		16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Right arm	Unknown	
	UNK	UNKNOWN MANUFACTURER	62878	1	Left arm	Unknown	
	FLU	SANOFI PASTEUR	U2806AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Hot flush, Loss of consciousness

Symptom Text: 3 - 5 min. after vaccines (HPV,flu shot, TST) client felt a warm flush, passed out and slid to the floor from her chair, bumped head RT side - no swelling.

Other Meds: None - denies

Lab Data: None

History: Denies

Prex Illness: Migraine

Prex Vax Illns:

Vaers Id: 333819-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Nov-2008	13-Nov-2008	2	04-Dec-2008	05-Dec-2008	FR	WAES0811USA03959	05-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1864U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Amnesia, Confusional state, Cyanosis, Drooling, Electroencephalogram, Fall, Gaze palsy, Loss of consciousness, Tremor

Symptom Text: Information has been received from a health authority (case #91860), through a foreign agency (local case # IT465/08), concerning a 11 year old female patient who on 11-NOV-2008 was vaccinated with the first dose of GARDASIL (Batch # NJ14750, Lot #1864U). On 13-NOV-2008, about 36 hours post-vaccination, at night she fell out of bed presenting with loss of consciousness, drooling, lip cyanosis, revulsion of eye balls, tremors of the upper limbs that lasted 4-5 minutes. She was taken to the ER in a confusional state and with amnesia regarding what happened. The patient was admitted to the hospital. A CT brain, cardiac exam and blood work were performed and resulted within normal limits. An EEG sleep and wake was also performed (results not reported). The patient was discharged on 17-NOV-2008 with the diagnosis "single critical episode". The child did not present with any further symptoms after 13-NOV-2008. The outcome is recovered. Other business partner numbers include (E2008-10895). No further information is available. Case is closed.

Other Meds: Unknown

Lab Data: head computed axial tomography, Within normal limits; cardiac monitoring, Within normal limits; diagnostic laboratory test, Blood work: within normal limits

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **333820-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Aug-2008	01-Nov-2008	92	04-Dec-2008	05-Dec-2008	FR	WAES0811USA04183	05-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nervous system disorder

Symptom Text: Information has been received from a gynecologist concerning a 17 year old female patient who was vaccinated with a third dose of GARDASIL (lot number, route and injection site not reported) in August 2008. In November 2008 the patient developed neurological failures described as "failures of fingers and hands down to elbows, both sides". Since symptoms were ongoing at reporting time, a neurological check up in a specialized hospital was planned. Concomitant medication included hormonal contraceptives (unspecified). P1 and P2 GARDASIL were given on unknown dates, toleration was not reported. The gynecologist considered the "failures of fingers and hands down to the elbows, both sides" to be an Other Important Medical Event". Other business partner numbers include E2008-10840. No further information is available.

Other Meds: Hormonal contraceptives (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333821-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	01-Aug-2008		04-Dec-2008	05-Dec-2008	FR	WAES0812AUS00001	05-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No reaction on previous exposure to drug, Psychotic disorder

Symptom Text: Information has been received from a physician via CSL as part of a business agreement (manufacturer control # GARD 2008 12 01 001) concerning a 14 year old female with no family or history or personal history of mental illness and no history of substance use who in 2007 was vaccinated with the first dose of GARDASIL. In August 2008, the patient was vaccinated with the second dose of GARDASIL. The patient developed vague symptoms following the second dose of GARDASIL and was admitted to an inpatient centre for treatment. The patient's psychiatrist reported that her symptoms have now developed into a full blown psychotic syndrome requiring treatment with antipsychotic drugs. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333822-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Aug-2008	25-Aug-2008	0	04-Dec-2008	05-Dec-2008	--	WAES0812USA00008	05-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0053X	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Facial bones fracture, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female patient who on 25-AUG-2008 was vaccinated with the first dose of GARDASIL (lot# 0053X). There was no concomitant medication. It was reported that the patient fainted 1 to 2 minutes after receiving the dose. Patient hit her face on the wall and broke her nose which was considered to be disabling. Patient sought medical attention with the nurse practitioner. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333823-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Oct-2008	01-Oct-2008	0	04-Dec-2008	05-Dec-2008	FR	WAES0812USA00198	05-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Impaired work ability, Inflammation, Injection site haematoma, Injection site induration, Muscle atrophy, Muscular weakness, Myositis, Pain in extremity, Vaccine positive rechallenge

Symptom Text: Information has been received from a general practitioner concerning a 19 year old female patient who had hematoma, inflammatory reaction and persisting induration after the first dose of GARDASIL (WAES #0812USA00321), and received the second dose of GARDASIL vaccine in her right deltoid in October 2008. By the following night the patient presented with injection site hematoma and injection site induration of moderate intensity. About 10 days later the patient experienced pain in vaccinated arm with muscular strength decreased and loss of muscular mass (=10cm) of severe intensity. At the time of reporting the patient had not recovered. To be noted, since the first dose of GARDASIL the patient had a persisting induration at the injection site. Blood samples were normal. There was no inflammatory syndrome. Diagnosis of myositis was confirmed by a rheumatologist. Another consultation with a rheumatologist was scheduled in 15 days and complementary investigations will be performed if necessary: electromyogram and auto-antibodies. The patient was on sick leave since 6 weeks. She had just started to recover. She was followed by a kinesitherapist. The events were reported as other important medical events. Other business partner numbers include E200810970. No further information is available.

Other Meds: Unknown

Lab Data: Diagnostic hematology blood test, normal

History: Haematoma; Inflammatory reaction

Prex Illness: Injection site induration

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333824-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-Sep-2008	06-Sep-2008	0	04-Dec-2008	05-Dec-2008	FR	WAES0812USA00200	05-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthma, Incorrect route of drug administration, Urticaria

Symptom Text: Case of misuse from Health Authorities on 24-NOV-2008 under reference number MA20081927. A 20 year-old female patient with no allergic history, with bronchiolitis during childhood and who had no adverse effect after the first dose of GARDASIL received the second dose of GARDASIL (batch number not reported) via subcutaneous route on 06-SEP-2008. She should have received the vaccine via intramuscular route. On 08-SEP-2008 the patient experienced urticaria and 5 days later she had asthma or else respiratory discomfort. At time of reporting the patient had not recovered. All was persisting but with less intensity with corticosteroids and salbutamol. Allergological test were on-going and up to day negative (dietary testing). Other business partner numbers include E2008-10861. No further information is available.

Other Meds: Unknown

Lab Data: allergy test, negative (dietary testing)

History: Bronchiolitis; no adverse effect after the first dose of GARDASIL

Prex Illness:

Prex Vax Illns:

Vaers Id: **333825-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-May-2008	Unknown		04-Dec-2008	05-Dec-2008	FR	WAES0812USA00206	05-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Axonal neuropathy, Blood brain barrier defect, Monoparesis

Symptom Text: Information has been received from a neurologist concerning a 16 year old female who was vaccinated with GARDASIL (route and site not reported). In March 2008, the patient received her first dose of GARDASIL and was well tolerated. On 01-APR-2008, the patient received a booster dose of REPEVAX and MENINGITEC. On 06-MAY-2008, the patient was vaccinated with her second dose of GARDASIL. In May 2008, the patient developed progredient leg paresis (bilateral, right leg more affected). The patient was hospitalized for clarification on an unspecified date. Neurophysiological examinations showed an axonal neuropathy. CSF showed a slight blood brain barrier disorder. Serology of borrelia was negative in serum and CSF. MRI showed normal results. No history of neuropathy in the family. No medication. No illegal drugs. Other business partner numbers included E200811014. Additional information has been requested.

Other Meds: Unknown

Lab Data: CSF B. burgdorferi IgM Ab, negative; Cerebrospinal fluid total protein test, a slight blood brain barrier; Serum Borrelia burgdorferi antibody test, negative

History: In March 2008, the patient received her first dose of GARDASIL and was well tolerated.

Prex Illness:

Prex Vax Illns:

Vaers Id: **333833-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		04-Dec-2008	05-Dec-2008	FR	WAES0811PHL00013	05-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician concerning several females who in 2008 were vaccinated with GARDASIL. In 2008 the patients experienced vaccine exposure during pregnancy. Subsequently, the patients experienced abortion. Upon internal medical review, abortion was considered an other important medical event. This is one of two reports from the same source. No other information is available. The physician did not respond to requests for additional information.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **333834-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	Unknown	Unknown		04-Dec-2008	05-Dec-2008	FR	WAES0812AUS00002	05-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness

Symptom Text: Information was obtained on request by the Company from the agency, via a Case Line Listing, concerning a 24 year old female who was vaccinated with GARDASIL. Subsequently the patient experienced convulsion and loss of consciousness. At the time of reporting to the agency on 16-MAY-2008, the patient had recovered from convulsion and loss of consciousness. The agency considered that convulsion and loss of consciousness were related to therapy with GARDASIL. The original reporting source was not provided by the agency. Upon internal medical review, convulsion was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333835-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		04-Dec-2008	05-Dec-2008	FR	WAES0812AUS00003	05-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Hemiparesis

Symptom Text: Information was obtained on request by the Company from the agency, via a Case Line Listing, concerning a 14 year old female who was vaccinated with GARDASIL as prophylactic vaccination. Subsequently the patient experienced hemiparesis, dizziness and fatigue. At the time of reporting to the agency on 08-MAY-2008, the patient had recovered from hemiparesis, dizziness and fatigue. The agency considered that hemiparesis, dizziness and fatigue were related to therapy with GARDASIL. The original reporting source was not provided by the agency. Upon internal review, hemiparesis was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333836-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		04-Dec-2008	05-Dec-2008	FR	WAES0812AUS00026	05-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pallor, Partial seizures, Syncope

Symptom Text: Information was obtained on request by the Company from the agency, via a Case Line Listing, concerning a 13 year old female who was vaccinated with GARDASIL. Concomitant therapy included VARILRIX. Subsequently the patient experienced pallor, partial seizure and syncope. At the time of reporting to the agency on 09-JUL-2008, the patient had recovered from pallor, partial seizure and syncope. The agency considered that pallor, partial seizure and syncope were related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review, partial seizure was considered to be an other important medical event. Additional information is not expected.

Other Meds: VARILRIX

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 333846-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Sep-2007	21-Jul-2008	296	17-Nov-2008	16-Dec-2008	MO	WAES0710USA00655	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Initial and follow up information has been received from a 14 year old female for the Pregnancy Registry for GARDASIL with an allergy to KEFLEX who on 27-DEC-2006 was vaccinated with a first dose of GARDASIL 0.5 ml IM. Subsequently she received the second dose of vaccine and on 27-SEP-2007 received the third dose of GARDASIL. Concomitant medication included vitamins (PNV). The patient's last menstrual period was 7 weeks ago (approximately 13-AUG-2007). She sought medical attention. On 29-SEP-2007, she found out that she was pregnant. A pregnancy test was performed. At the time of reporting, she had not experienced any adverse reactions. The estimated date of delivery is 19-MAY-2008. Follow-up information was received, concerning a 14 year old female patient with no previous medical history reported. On 18-MAY-2008, the patient delivered a normal, healthy female baby weighing 7-9 lbs, length 21, Apgar score 8/9 and head circumference 14.5. No complication during pregnancy, labor/delivery, infections or illness during pregnancy were reported. On 23-MAY-2008 the baby had a 5 day well child visit and was doing well. Weight was 7.45 pounds. Bilirubin was 10.8 mg/dL. On 02-JUN-2008 a newborn screening for congenital hypothyroidism, congenital adrenal hyperplasia, hemoglobinopathy, galactosemia, fatty acid disorders, organic acid disorders, amino acid disorders and cystic fibrosis were all normal. On 21-JUL-2008 a 2-3 month old well child visit was performed and the baby was doing well. Her parents reported some nasal congestion and constipation. Otherwise she has a bowel movement every 24 hours. The outcome of the congestion and constipation were not reported. No additional information is expected.

Other Meds: Vitamins (unspecified)

Lab Data: Ultrasound, 10/22/07, normal; Ultrasound, 04/23/08, normal; Diagnostic laboratory, 06/02/08, newborn screening: see narrative; Beta-human chorionic, pregnant; Total serum bilirubin, 05/23/08, 10.8 mg/d, 0.0 - 1.0 (normal)

History:

Prex Illness: Pregnancy NOS (LMP = 8/13/2007); Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **333847-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	18-Sep-2007	18-Sep-2007	0	17-Nov-2008	16-Dec-2008	CA	WAES0710USA02833	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Meconium in amniotic fluid

Symptom Text: Information has been received from a physician for the pregnancy registry for GARDASIL concerning a 24 year old female with no known allergies who on 18-SEP-2007 was vaccinated IM with her first dose of GARDASIL (Lot # 658560/1062U). concomitant therapy included (ASTELIN) and Albuterol. Subsequently the patient is pregnant which was confirmed via pregnancy test (LMP = 28-AUG-2007). No further information is available. Follow up information was received from a nurse who reported that on 12-JUN-2008, the patient went into labor spontaneously at 41+ 3/7 weeks with SROM with a moderate amount of meconium in the amniotic fluid. The patient had a vaginally delivered at a healthy female. The baby weight was 8 Lb, 7 oz, and had apgars of 9 and 9. The nurse reported that the patient's EDD was on 03-JUN-2007. The nurse also reported that the baby and the mother were doing well. No further information is expected.

Other Meds: ALBUTEROL, ASTELIN

Lab Data: Apgar Score, 06/13/08, 9

History:

Prex Illness: pregnancy NOS (LMP = 8/28/07)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333848-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.6	F	10-Nov-2006	10-Nov-2006	0	17-Nov-2008	16-Dec-2008	--	WAES0710USA03177	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	6537360868F	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a health professional concerning a 16 year old female with a history of madelung's deformity who, on 01-SEP-2006, was vaccinated with her first dose of GARDASIL, IM. On 10-NOV-2006, the patient was vaccinated with her second dose of GARDASIL, IM. On 28-SEP-2007, the patient was vaccinated with her third dose of GARDASIL, IM, and a urine test in the office was negative. On 11-OCT-2007, a home pregnancy test was positive, and 2 repeated home pregnancy tests on a later date were also positive. The patient sought unspecified medical attention in the office and her outcome is unknown. Follow-up information was received on 29-OCT-2008 via phone call from a nurse indicating that, on 14-JUN-2008, the patient spontaneously delivered a healthy and normal male baby. Weighing 7 pounds, 7 ounces, 52 cm long with a head circumference of 32 cm at 40 and 3/7 weeks estimated gestational age. Apgars were 8/9. The baby was being watched for mild jaundice due to his mother's blood type. The mother was O negative and the baby was RH positive. The baby was discharged home with his adaptive parents on 16-JUN-2008, bottlefeeding and with routine care instructions. The mother did return to the office and saw a certified nurse midwife for her postpartum visit and physiologically was recovering well. Additional information is not expected.

Other Meds: Unknown

Lab Data: beta-human chorionic, 10/11/07

History: Madelung's deformity

Prex Illness:

Prex Vax Illns:

Vaers Id: **333849-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Oct-2007	Unknown		17-Nov-2008	16-Dec-2008	GA	WAES0711USA03477	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received from a mother and 16 year old female patient for the Pregnancy Registry for GARDASIL. On 21-AUG-2007, the patient was vaccinated with her first dose of GARDASIL (Lot # 658222/0927U; site and route not reported). On 23-OCT-2007 (previously reported as approximately 26-OCT-2007), the patient was vaccinated with her second dose of GARDASIL (Lot #657737/0522U; site and route not reported). There was no concomitant medication. Subsequently, the patient found out she was pregnant (LMP approximately 15-SEP-2007).The patient sought unspecified medical attention. On 24-JUN-2008, The patient gave birth to a normal female infant (6 Lb, 2 oz; 18.5 in). There were no congenital anomalies, complications or abnormalities. There were no complications during the pregnancy or labor and delivery. Additional information was provided from the patients physician. Laboratory work from 25-JUN-2008 revealed a CAH (17 Hydroxy Progesterone) level of 75.8 ng/ml. The analysis revealed unsatisfactory specimen. Repeat levels were done on 29-JUL-2008 that were within normal range. At the time of this report mother and baby were reported to be doing well. Additional information is not expected.

Other Meds: None

Lab Data: serum 17- 06/25/08, 75.8 ng/m -, serum 17 - 07/29/08 - normal

History:

Prex Illness: pregnancy NOS (LMP = 9/15/2007

Prex Vax Illns:

Vaers Id: **333850-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	07-Oct-2007	09-Oct-2007	2	17-Nov-2008	16-Dec-2008	--	WAES0711USA03903	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1209U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received through the pregnancy registry from a health care worker concerning a 17 year old female with an allergy to cefaclor (CECLOR) and no concomitant medications (lab diagnostics included a pregnancy test). The patient received three single doses of GARDASIL via injection and became pregnant sometime before she received her third dose. The patient was approximately 8 weeks pregnant at the time she received her third dose. The patient did not have any adverse experience. The first dose of GARDASIL (Lot #0211U) was receiving on 5-APR-2007, the second dose (Lot #0210U) was received on 05-JUN-2007 and the third dose (Lot #65454C/1209U) was received on 9-OCT-2007. Follow up information was received from a health care professional who reported that the patient delivered a full term baby on 04-JUL-2008. The health care professional reported that the baby was normal and healthy with no anomalies. Follow up information was received from a health care professional who reported that the patient delivered a full term baby on 04-JUL-2008. The health care professional reported that the baby was normal and healthy with no anomalies. Follow up information was received from a health care worker who reported that the patient delivered a normal female baby, with no complications during pregnancy, or no known complications during labor/ delivery. The mother's LMP was 40 3/7 weeks. The baby's weight was 6o ponds with 13 oz, and Apgar score was 9/9. There were no concurrent medical conditions reported. Other medications used during the patients pregnancy were reanitidine (ZANTAC) for heartburn, budesonide for allergies, and Zolpidem as needed or PRN for sleep aid. On 23-JAN-2008 a serum alph-fetoprotein test was performed with negative results. On 07-FEB-2008 an ultrasound was performed with normal results. No further information is expected.

Other Meds: None

Lab Data: Ultrasound, 02/07/08, normal; Beta-human chorionic, positive; Serum alph-fetoprotein, 01/23/2008; negative; Apgar score, 07/04/08, 9/9

History:

Prex Illness: Pregnancy NOS (LMP=Unknown) Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **333851-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Oct-2007	11-Oct-2007	0	17-Nov-2008	16-Dec-2008	CA	WAES0801USA00965	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1264U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Urinary tract infection

Symptom Text: Initial and follow-up information has been received from a medical assistant, for the Pregnancy Registry for GARDASIL, concerning a 18 year old female with no previous pregnancy, who on 31-JUL-2007, was vaccinated IM in the left deltoid with the first dose of GARDASIL (658222/0927U). On 11-OCT-2007, the patient was vaccinated IM in the right deltoid with the second dose of GARDASIL (658488/1264U). On 07-JAN-2008, the medical assistant reported that the patient called the office last week stating that she took a home urine pregnancy test, which was positive. The patient sought unspecified medical attention. the medical assistant reported in follow up that on 11-JAN-2008, ultrasound was performed and the result was negative. On approximately 22-APR-2008, the patient developed urinary tract infection. On 22-APR-2008, the patient was treated with nitrofurantoin (MACROBID), 100 mg, twice a day. The outcome of urinary tract infection was unknown. On 02-AUG-2008, the patient delivered a normal, healthy female baby at 39 week gestation. The baby's weight was 7.8 pounds; length was 20.5 inches and Apgar was 8/9. Additional information is not expected.

Other Meds:

Lab Data: Ultrasound 01/11/08, negative; urine beta-human, positive

History: Pregnancy NOS (LMP- 10/11/2007)

Prex Illness:

Prex Vax Illns:

Vaers Id: 333852-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	20-Nov-2007	20-Nov-2007	0	17-Nov-2008	16-Dec-2008	IN	WAES0801USA01800	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour, Premature rupture of membranes, Rash papular, Skin hypopigmentation, Tobacco user

Symptom Text: Initial and follow-up information has been received from the pregnancy registry for GARDASIL via a registered nurse concerning an 23 year old female smoker with "dermatological problems" and a history of cervical cancer with no documented HPV(2007), abnormal pap and loop electrosurgical excision procedure(14-JUN-2006) who on 20-NOV-2007 was vaccinated IM, with a 0.5 ml first dose of GARDASIL (LOT 657872/0515U). Concomitant therapy included DEPO-PROVERA and dermatologic (unspecified). Subsequently the patient became pregnant. On 04-DEC-2007 she had a positive pregnancy test. On 07-DEC-2007, ultrasound revealed gestational age was 7 weeks and 4 days. Last menstrual period was 12-OCT-2007 and estimated date of delivery was 20-JUL-2008. The patient was seen in the physician's office on 09-JAN-2008. Follow up information was received which reported that on 09-JUL-2008 the patient had spontaneous rupture of membranes and delivered a female infant at 38 weeks gestational via spontaneous pitocin augmented delivery. The baby's weight 6lb 12oz. The infant was normal. No congenital anomalies or other complications or abnormalities were noted, head moulding/cone was noted to be resolved. It was also reported that the patient had no complications during the pregnancy and labor. The patient continued to smoke throughout her pregnancy. On 11-JUL-2008 the infant was vaccinated with HEP B virus vaccine (manufacturer unknown), (WAES #0811USA00563). On 11-SEP-2008 it was reported that the patient had a papular rash with mild hypopigmentation to her antecubital crease. Additional information is not expected.

Other Meds: dermatologic (unspecified) DEPO-PROVERA

Lab Data: cervical smear - "current pap test is fine"; ultrasound, 12/07/07 - 7 weeks and 4 days; ultrasound 03/20/07 - normal OB ultrasound; urine beta-human, 12/04/07 - positive

History: Cervical cancer; Loop electrosurgical excision procedure; papanicolaou smear, abnormal

Prex Illness: Pregnancy NOS (LMP = 10/13/2007); Skin disorder; Smoker

Prex Vax Illns:

Vaers Id: **333853-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Apr-2007	26-Dec-2007	243	17-Nov-2008	17-Dec-2008	MD	WAES0801USA02262	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received from a registered nurse concerning a 21 year old female patient with a penicillin allergy who on 27-Apr-2007, was vaccinated IM with first 0.5 ml dose of GARDASIL. On 26-Dec-3007, the patient received her third dose of the vaccine. The patient is pregnant. Unspecified medical attention was sought at the time of this report. Follow up information was received from the registered nurse who reported that in March 2008 , the ultrasound was normal at 29 6/7 weeks from her last menstrual period, the patient had preterm labor. the patient was treated with BETAMETHASONE on 21-May- 2008. The patient also had nifedipine. On 23- May- 2008 the patient took INDOMETHACIN. On 15-Jul-2008 the patient gave birth to a live born male APGAR=9/9. She was 39 1/7 weeks from her last menstrual period. The infant was reported to be normal and there were no congenital anomalies or other complications. Additional information is not expected.

Other Meds:

Lab Data: Ultrasound, 03/08, normal anatomy

History: Pregnancy NOS, (LMP = 12/25/2007); Penicillin allergy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333854-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
35.0	F	09-Jan-2008	09-Jan-2008	0	04-Dec-2008	11-Feb-2009	--	WAES0801USA02515	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, No adverse event, Wrong drug administered

Symptom Text: Information has been received from a health professional concerning a 35 year old female with no known allergies who on 09-JAN-2008 was vaccinated with GARDASIL. Concomitant therapy included unspecified vitamins. On 09-JAN-2008 the patient received the wrong vaccine. Instead of receiving the flu vaccine (manufacturer unknown), the patient received GARDASIL. No adverse experience was reported. The patient sought unspecified medical attention. The outcome of the patient was not reported. On 14-JAN-2008, additional information was received for the Pregnancy Registry for GARDASIL from the patient's brother-in-law. He reported that the patient was pregnant when she received her first accidental dose of GARDASIL. No adverse experience was reported. The patient sought unspecified medical attention. Follow-up information has been received which reported that on an unknown date the patient delivered a normal infant with no congenital anomalies.

Other Meds: Vitamins (unspecified)

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP=Unknown)

Prex Vax Illns:

Vaers Id: 333855-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	27-Sep-2007	11-Dec-2007	75	17-Nov-2008	16-Dec-2008	VA	WAES0802USA00481	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chlamydial infection, Drug exposure during pregnancy, Gonorrhoea, Wheezing

Symptom Text: Information has been received from a consumer and a physician, for pregnancy registry for GARDASIL, concerning a 17 year old female patient with penicillin allergy, sulfonamide allergy, attention deficit/hyperactivity disorder, left side of heart enlarged and asthma and a history of ventricular septal defect and USD, who on 27-SEP-2007, was vaccinated with the first dose of GARDASIL, and was pregnant (LMP- sometime around 11-DEC-2007, ECD- 07-SEP-2008). Concomitant therapy included ADHA medication, heart medication. Other medications used during pregnancy were albuterol on 18-AUG-2008 for wheezing. Subsequently, the patient experienced gonorrhea and chlamydia infection. AFP was performed with the result of negative, and fetal scan was also performed. On 12-DEC-2007, the patient was vaccinated with the second dose of GARDASIL. On 09-SEP-2008, the patient had a normal male infant. The Apgar score was 9/9. No congenital anomalies or complications were noted. Additional information is not expected.

Other Meds:

Lab Data: Ultrasound, 02/18/2008, 11; serum alpha-fetoprotein, negative; Apgar score 9/9

History: Ventricular septal defect; general symptom; Penicillin allergy; Attention deficit/hyperactivity disorder; Asthma; Heart enlarged; Sulfonamide allergy

Prex Illness: Pregnancy NOS (LMP-12/11/2007)

Prex Vax Illns:

Vaers Id: 333856-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Oct-2007	01-Nov-2007	30	04-Dec-2008	11-Feb-2009	WI	WAES0802USA03008	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0181U	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Weight gain poor

Symptom Text: Information has been received through pregnancy registry from a licensed practical nurse concerning a 16 year old female, with an allergy to AMOXICILLIN, AUGMENTIN and no pertinent medical history, who on 02-OCT-2007 was vaccinated with her first dose of GARDASIL (lot # reported as 656371/0181U). On 27-DEC-2007, the patient was vaccinated with her second dose of GARDASIL (lot # reported as 656371/0181U). Concomitant therapy included MENACTRA. Subsequently, the patient became pregnant. The patient's last menstrual period was in November 2007. No symptoms were reported. The patient sought medical attention. A home pregnancy test was performed and the patient had an ultrasound on 12-FEB-2008 which reported that the patient was 12 1/7 weeks of pregnancy and with normal findings. Follow-up information was received from a physician who reported that during the pregnancy, the patient gained low maternal weight (7.4 pound). On 25-AUG-2008 the patient gave birth to a live born female weighing 7 lbs. 15 oz APGAR= 7/8. She was 40 weeks from her last menstrual period. The infant was reported to be normal and there were no congenital anomalies or other complications. Additional information is not expected.

Other Meds:

Lab Data: Ultrasound, 02/12/08, 12 week, normal findings; Beta-human chorionic

History:

Prex Illness: Pregnancy NOS (LMP = 11/1/2007); Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333857-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	26-Nov-2007	26-Nov-2007	0	17-Nov-2008	17-Dec-2008	NY	WAES0802USA03154	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chlamydial infection, Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed practical nurse (L.P.N) for the Pregnancy Registry for GARDASIL concerning an 18 year old female with no known allergies and no reported medical history who received two doses of 0.5ml GARDASIL (unknown lot numbers) intramuscularly at another facility, possible in September and November of 2007. The patient is currently taking prenatal vitamins (unspecified brand) and iron supplements (unspecified brand). At 30 weeks pregnancy was discovered during an ultrasound on 23-JAN-2008. The patients LMP is approximately 25-JUN-2007. The ultrasound was performed since the patient said that she had a tumor which was kicking and biting her. No symptoms have been reported. Estimated date of delivery is 03-APR-2008. Follow up information was received on 17-OCT-2008 from the L.P.N indicating that the patient is a female with no previous pregnancies. On 25-NOV-2007 and 26-DEC-2007 the patient was vaccinated with her first and second 0.5 ml doses, respectively, of GARDASIL (lot # of the two doses was probably 657006/0188U). An ultrasound performed on 23-JAN-2008 confirmed her pregnancy and the results were within normal limits. It was reported that the patient confirmed her pregnancy and the results were within normal limits. It was reported that the patient was late for prenatal care (30 weeks) because she wasn't aware of her pregnancy. Other medication used during pregnancy included prenatal vitamins, once daily from January 2008 to April 2008 and iron supplement, 325 mg daily from February 2008 to April 2008. During pregnancy, the patient developed chlyamdial infection and on 01-FEB-2008, was treated with ZITHROMAX, 1 gram once. The outcome of the chlamdial infection was not reported. On 10-APR-2008 the patient delivered a normal female baby, weighing 7 pounds, 2 ounces. The baby's length was 20, headache circumference was 13.5 and apgar score was 8/9. There were no congenital anomalies. There were no other complications or abnormalities. The patient had no complication during pre

Other Meds:

Lab Data: Ultrasound, 01/23/2008, pregnancy confirmed; within normal limits

History:

Prex Illness: Pregnancy NOS (LMP = 6/25/2007)

Prex Vax Illns:

Vaers Id: **333858-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Mar-2008	25-Mar-2008	0	17-Nov-2008	17-Dec-2008	--	WAES0803USA04191	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1448U	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vaginal examination abnormal, Vulvovaginitis trichomonal

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female with a history of allergic reaction to antibiotics (Ceclor) who on 25-MAR-2008 was vaccinated IM with the first 0.5 mL dose of GARDASIL (lot # 659653/1448U). Concomitant therapy included a dose of HAVRIX (inactive) (GlaxoSmithKline) and a dose of MENACTRA (Sanofi Pasteur). On 25-MAR-2008 the patient intially came in for family planning (to get birth control pills)/ The patient said she had normal periods and no skipped period from 28-FEB-2008 to 06-MAR-2008. The patient denied unprotected sex and was using condoms. During a vaginal exam (part of family planning) by the nurse practioner, it was found the patient had "Trichomonas." The nurse practioner wanted to treat the patient with Metronidazole and did a pregnancy test to make sure it was okay to give this medication. The pregnancy test was positive. Other lad diagnosic studies performed included: hemoglobin (results not provided) and dip stick urine for glucose and protein (results not provided.) The patient's outcome was not reported. There was not product quality control involved. Follow-up information has been received through the pregnancy registry which reported that the pregnancy test was performed on 25-MAR-2008. An ultrasound was performed on 30-APR-2008 and was normal and on 26-JUN-2008 a serum alpha fetoprotein test which was normal. The patient was prescribed promethazine hydrochloride (PHENERGAN) for nausea. Additional information has been requested.

Other Meds: PHENERGAN (PROMETHAZINE) Mg

Lab Data: gynecological, 03/25/08 - patient had Trichomonas; ultrasound 04/30/08 - normal; beta-human chorionic, 03/25/08 - positive; hemoglobin, 03/25/08 - results not provided; serum alpha fetoprotein, 06/25/08 - normal; urine glucose, 03/25/08 - d

History: Allergic reaction to antibiotics

Prex Illness: Vaginitis trichomonal; Pregnancy NOS (LMP = 2/29/2008) vaginitis trichomoinal

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333859-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Nov-2007	15-Nov-2007	0	17-Nov-2008	17-Dec-2008	PA	WAES0804USA02514	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Placental disorder, Urinary tract infection

Symptom Text: Information has been received through the pregnancy registry for GARDASIL from a physician concerning a 18 year old female with a history of smoking (quit when she had a positive pregnancy test) and no known drug allergies, who on 27-JUL-2007, was vaccinated in the right arm with the first dose of GARDASIL (lot#65822/0927U). On 15-Nov-2007, the patient received the second dose in the left arm (lot# 659437/1266U). On 05-Apr-2008, the patient received IM in the right arm a 0.5 ml third dose (lot#659964/1978U). Other medications included prenatal vitamins from 03-APR-2008 to present, once daily. The physician reports that the patient is 15 weeks pregnant. The patient's LMP was 24-DEC-2007, the estimated delivery date is 29-SEP-2008. The patient sought unknown medical attention with her OB/GYN. Follow up information was received which reported that on 08-APR-2008 and 12-MAY-2008, ultrasound indicated low lying placenta. From 16-JUN-2008 to 21-JUN-2008, the patient was treated with ampicillin, 500mg, q8h, for urinary tract infection. From 13-AUG-2008 to 20- AUG-2008, the patient was treated with amoxicillin, 500 mg, q8h, for urinary tract infection. On 03-SEP-2008, the patient delivered a female infant at 36+ weeks from The infant's weight is 6 lb 11 oz with apgar scores of 7/9. The infant was normal, without congenital anomalies and other complications or abnormalities. There was no medical condition after the delivery. Additional information is not expected.

Other Meds: Vitamins (unspecified)

Lab Data: Ultrasound, 04/08/08, low lying placenta; ultrasound, 05/12/08, low lying placenta

History: Ex-smoker

Prex Illness:

Prex Vax Illns:

Vaers Id: 333860-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Apr-2008	08-Apr-2008	0	17-Nov-2008	17-Dec-2008	--	WAES0805USA00832	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Drug exposure during pregnancy, Lice infestation, Pyrexia

Symptom Text: Initial and follow-up information has been received from a 16 year old Hispanic female consumer with head lice and no previous pregnancies, who on 08-APR-2008, was vaccinated with a third dose of GARDASIL vaccine (Lot # 659964/1978U) and later found out that she was pregnant. Concomitant therapy included DOCUSATE SODIUM + minerals (unspecified) (+) OMEGA-3 marine triglycerides (+) succinic acid (+) vitamins (unspecified) (PRIMACARE)). At the time of the report the patient was 6 months gestation. The patient's estimated conception date was approximately 21-NOV-2007, last menstrual period was approximately 30-NOV-2007 and her estimated delivery date was 14-AUG-2008. The patient sought unspecified medical attention. Blood work was taken and the results were not reported. On 24-APR-2008 an ultrasound was performed for an anomaly screening/dating and the results were were within limits. It was reported that it was too late to perform a Maternal Serum Alpha-Fetoprotein Screening (MSAFF). At the time of the report, the outcome of the patient was unknown. Additional information was received from the physician's office stating that the patient delivered a normal infant without congenital anomalies. Additional information was received from a registered nurse concerning the patient who on 14-AUG-2008 (weeks from LMP: 40+) delivered a female normal infant without congenital abnormalities and complications or abnormalities. The infant weight: 7# 7 oz. length: 21". "Apgar scores: 8/10, and 9/10", head circumference : 34cm. It was reported that the patient presented late entrant to care at 25 weeks. In May 2008, the patient was diagnosed with with head lice. In "mid-May" 2008, the patient was treated with RID. The patient experienced maternal fever during labor/delivery. The patient was GBS (+) and was treated with antibiotics in labor. Additional information has been requested.

Other Meds: PRIMACARE; PYRETHRUM EXTRACT

Lab Data: diagnostic laboratory, blood work; ultrasound, 04/24/08, reason-anomaly screen/dating; result-within normal limits

History:

Prex Illness: Pregnancy NOS (LMP = 11/30/2007); Pediculosis capitis

Prex Vax Illns:

Vaers Id: 333861-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Mar-2008	27-Mar-2008	0	17-Nov-2008	17-Dec-2008	OR	WAES0806USA08583	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Unknown	Intramuscular	
	HIBV	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Drug exposure during pregnancy

Symptom Text: Information has been received from a health professional for pregnancy registry for GARDASIL concerning a 16 year old female with no relevant medical history who on 27-JUN-2007 and 24-APR-2008 was vaccinated with a first and second dose of GARDASIL intramuscular injection (lot number and injection site not reported). She also received her first dose of PEDVAXHIB (MSD) on 27-JUN-2007, the second dose on 27-2007, and third dose on 27-MAR-2008. There was no concomitant medication. Then it was discovered that she was pregnant. No adverse effects reported. The patient had her first prenatal care visit this week and an ultrasound was scheduled for 26-JUN-2008. Follow up information was from a registered nurse reported that the patient had no previous pregnancies history. On 26-JUN-2008 ultrasound (checks fetal development late prenatal care) was performed and result was within normal limits. The patient's LMP=14 FEB-2008 and the estimated delivery date = 20-NOV-2008. Follow up information was received from a registered nurse (R.N.) who reported that during this pregnancy, the patient was on placed on ferrous sulfate for the treatment of anemia, globulin, immune (RHOGAM) for treatment of rhesus antibodies negative and prenatal vitamins as supplementation. On 25-JUN-2008 the patient underwent ultrasound. The patient was late in receiving prenatal care (30 weeks). On 23-JUL-2008, 39 weeks from LMP, the patient delivered a normal female baby whose weight was 6 pound and 6 ounce, length 19 inches, head circumference 13.5 inches and Apgar score 9/9. There were no congenital anomalies or other complications or abnormalities. Additional information is not expected.

Other Meds: Unknown

Lab Data: Ultrasound, 06/26/2008, within normal limits

History:

Prex Illness: Pregnancy NOS (LMP = 11/21/2007

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333862-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Jan-2008	14-Jan-2008	0	17-Nov-2008	17-Dec-2008	--	WAES0808USA00161	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received for the pregnancy registry for GARDASIL from a registered nurse concerning a 15 year old female with no pertinent medical history and no drug reactions/allergies, who on 14-JAN-2008 was vaccinated with the first dose of GARDASIL 0.5 mL, IM. On 26-MAR-2008, the patient received the second dose of GARDASIL 0.5 mL, IM. There was no concomitant therapy. The patient is pregnant (positive pregnancy test). At the time of report, the patient was 31 weeks gestation (last menstrual period approximately 20-DEC-2007, estimated delivery date 25-SEP-2008). The patient did not seek medical attention. No other symptoms were noted. Follow-up information was received from the nurse who reported that the patient had a history of asthma and positive PPD. The nurse reported that the patient delivered a normal healthy female baby on 19-SEP-2008 with no congenital anomalies and there were no other complications. The Baby weighed 2810 grams, and APGAR score was 9/9. There were no birth defects and no complications with the infant. There were no infections or illness during the pregnancy. The nurse reported that during the pregnancy on 18-JUL-2008, the patient's ultrasound test resulted normal for fetal anatomy. During the pregnancy, the patient took prenatal vitamins for pregnancy and ferrous sulfate for anemia. The patient had not had any previous pregnancies. Additional information has been requested.

Other Meds: Vitamins (unspecified)

Lab Data: Ultrasound, 07/18/2008, normal for fetal anatomy; Beta-human chorionic, Positive; Apgar score, 9/9

History: PPD skin test positive

Prex Illness: Pregnancy NOS (LMP =12/20/2007), Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333863-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	15-Sep-2008	15-Sep-2008	0	17-Nov-2008	17-Dec-2008	MN	WAES0809USA02176	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Urinary tract infection

Symptom Text: Initial and follow-up information has been received from a physician and a medical assistant for the pregnancy registry for GARDASIL concerning a 19 year old female with no drug reactions or allergies and with a history of papanicolaou smear abnormal and vaginosis bacterial, who on 15-SEP-2008, was seen in the office for symptoms of painful vaginal discharge. During her appointment she was vaccinated with her first dose of GARDASIL (lot#661046/0381x), 0.5 ml, IM. On the same date, she was placed on therapy with amoxicillin 500 mg, three times a day, for urinary tract infection. It was later found prenatal forte. On 22-SEP-2008, ultrasound was performed and results were normal with comments that estimated delivery date was 03-APR-2009 and the patient had been pregnant for 12 weeks and 3 days. The patient sought medical attention in the office. Additional information is not expected.

Other Meds: Amoxicillin; Metronidazole; vitamins (unspecified)

Lab Data: Ultrasound, 09/22/08, normal, EDD 03-APR-2009 12w 3d; urine beta-human, pregnant

History: Papanicolaou smear abnormal; Vaginosis bacterial

Prex Illness: Vaginal discharge; Pregnancy NOS (LMP=unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333864-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	17-Sep-2008	17-Sep-2008	0	17-Nov-2008	17-Dec-2008	NC	WAES0809USA04602	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNK	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from an office manager concerning a female who on approximately 17-SEP-2008 was vaccinated intramuscularly with a first dose of GARDASIL vaccine (yeast). The office manager reported that the patient fainted after receiving vaccination. At the time of reporting, the outcome was unknown. It was not specified if the patient sought medical attention or not. Follow-up information was received from a registered nurse who reported that the patient fainted after receiving the first dose of GARDASIL vaccine (yeast) with immediate recovery. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333866-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	30-Sep-2007	Unknown		17-Nov-2008	17-Dec-2008	--	WAES0810USA00167	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling

Symptom Text: Information has been received from a nurse, mother of the patient, concerning here daughter, who on approximately 30-SEP-2007, was vaccinated with her first dose of GARDASIL. Upon administration the patient experienced pain and swelling at injection site. The swelling lasted approximately 2.5 weeks. No medical intervention was necessary. The patient recovered fully and did receive the second and third dose of GARDASIL with no other adverse experiences. Additional information has bee requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333867-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Jul-2008	Unknown		17-Nov-2008	17-Dec-2008	DE	WAES0810USA00187	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Menstrual disorder

Symptom Text: Information has been received from a nurse concerning a 12 year old female with drug hypersensitivity who on 10-Jul-2008 was vaccinated IM with her first dose of GARDASLI and her second dose of VARIVAX and on 30-Sep- 2008 was her second dose of GARDASIL since receiving the first dose of GARDASIL. She has had a variation of menstrual cycle. Her first menstrual period after the first dose of GARDASIL lasted 8 days. She then had a 2 menstrual periods 20 days apart. She has had a regular cycle for one year prior to receiving her first dose of GARDASIL. At the time of reporting, the patient was not recovered. No additional information at this time. The medical attention was sought in office, Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Drug hypersensitivity

Prex Illness:

Prex Vax Illns:

Vaers Id: **333868-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	30-Sep-2008	Unknown		17-Nov-2008	17-Dec-2008	--	WAES0810USA00196	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Headache, Paraesthesia

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female patient with allergy to penicillin. Who on 30-Sep-2008 received a dose of GARDASIL, (route and injection site not reported). On an unknown date after vaccination, she developed tiredness, headache, and tingling in her ankles. The patient sought medical attention via phone call to office. At the time of reporting she had not recovered from the events. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Penicillin allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: 333869-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	21-Aug-2008	28-Aug-2008	7	17-Nov-2008	17-Dec-2008	--	WAES0810USA00197	02-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Bursitis, Exostosis, Gastrooesophageal reflux disease, Joint effusion, Joint range of motion decreased, Musculoskeletal pain, Myalgia, Osteoarthritis, Ovarian cyst, Pain in extremity, Stomach discomfort, Synovitis

Symptom Text: Information has been received from a consumer concerning her sister, a 16-year-old female, who on 21-AUG-2008 received a first dose of GARDASIL in her left arm. On 28-AUG-2008, a week later, the patient started to have pain in the back of her knee. Then not to long after that she started to have a dull aching pain in her upper right arm, in the triceps area, but was not sure if it was coming from her elbow or shoulder, and at times she would have a sharp pain in triceps as well. The patient has seen her primary care physician about the pain she was having and was treated with naproxen, which gave her stomach problems and so she stopped taking it. The patient's primary care physician did blood work for her on 30-SEP-2008. She will have an ultra sound check on 06-OCT-2008 on her arm and leg. At the time of reporting, the results of her blood test were unknown and the patient's symptoms persisted. Additional information has been requested. 12/15/08 Received PCP medical records. FINAL DX: bursitis/synovitis, gen arthrosis, Records reveal patient expereienced GERD & left knee pain x 3 weeks on 9/16 visit. Tx w/meds. RTC 9/29 w/right arm/shoulder pain & decreased ROM, knee pain had improved. Meds adjusted & labs ordered. RTC 10/8 w/arm & knee pain. Injected knee, changed meds & x-ray/MRI ordered. 2/25/09 Received GYN vaccine records & medical records of 10/19/06-2/12/2009. FINAL DX:none provided. Records reveal patient received only HPV #1 on 8/21/08. RTC for annual exams w/o complaints. On 2/12/09 c/o of muscle aches s/p HPV & no further shots given.

Other Meds: Unknown

Lab Data: Diagnostic laboratory, 09/30/08, Bollo test: results not known LABS: PAP smear WNL. US pelvis done 5/2/07 revealed ovarian cysts. IUD for contraception. CBC, ESR, ANA, RA, Lyme all WNL. MRI & x-ray left knee (+) mild knee joint effus

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **333871-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Oct-2007	Unknown		17-Nov-2008	17-Dec-2008	NC	WAES0810USA00227	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Bronchitis, Gait disturbance, Pain, Pelvic pain

Symptom Text: Information has been received from a nurse reported that her niece, a 17 white female, on 08-OCT-2007 was vaccinated with the first dose of GADASIL (lot # 658556/1060U) into her right deltoid. After vaccination, the patient experienced stomach cramps and extreme pelvic pain as "if her guts were going to fall out". The patient said that it hurt to walk, move and sit down, she had to lie down. Everything she took did not ease the symptoms. Unspecified medical attention was sought. Subsequently, the patient recovered from stomach cramps. The patient said she was not the only one to experience these symptoms, the whole cheerleading squad (total number of girls was not specified) also experienced the symptoms after receiving the first dose of GARDASIL vaccine. In follow up the patient was reported to have taken an unspecified medication to ease the pain, which did not work. She had recovered from all symptoms and will not receive other shots. This is one of the several reports received from the same source. No further information is available. 4/2/09 Received only med record of 10/8/2007 which reveals patient had cough & congestions x few days & dx w/recurrent bronchitis. Tx w/oral antibiotics & received hep A, HPV & flu vaccines. No additional med records available & no additional lot #s available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333872-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	MD	WAES0810USA00234	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a female who on unknown dates was vaccinated with all three doses of GARDASIL. On an unspecified date, the patient on a pap smear tested positive for HPV. The patient's previous pap smears prior to vaccination with GARDASIL were negative for HPV. Unspecified medical attention was south. The outcome of the event was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervical smear, prior to vaccination negative for HPV; cervical smear, after vaccination positive for HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333873-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Oct-2008	01-Oct-2008	0	17-Nov-2008	17-Dec-2008	--	WAES0810USA00247	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Tremor

Symptom Text: Information has been received from a registered pharmacist concerning an 18 year old female with no pertinent medical history and no history of drug reactions or allergies who on 01-OCT-2008 was vaccinated with the first dose of GARDASIL 0.5ml IM. Concomitant therapy included YASMIN and Z-PAK. Within one hour of receiving the vaccine, the patient developed involuntary tremors of upper and lower extremities, as well as an involuntary nervous giggle. The patient's blood pressure elevated to 1160/96. The pharmacist stated that the patient just finished Z-PAK today for an unspecified medical condition. The patient was not recovered. The patient sought medical attention with a physician office visit. Additional information has been requested.

Other Meds: Z-Pak; Yasmin

Lab Data: Blood pressure, 10/01/2008, 160/96

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333874-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	TX	WAES0810USA00249	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning a teenager female who on an unspecified date was vaccinated with the first dose of GARDASIL. There was no concomitant medication. Subsequently the patient experienced dizzy for a week. It was worst in the mornings. The patient decided not to complete the series. Subsequently, the patient recovered from dizzy. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333875-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	--	WAES0810USA00254	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Burning sensation

Symptom Text: Information has been received from a pharmacist concerning several female patients experienced burning sensations while receiving GARDASIL with lot number 660620/0571X. No further information is available. The patients were seen by a nurse.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **333876-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	MD	WAES0810USA00264	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anogenital warts, Condition aggravated

Symptom Text: Information has been received from a physician concerning a female with one genital wart before vaccination who was vaccinated with a dose of GARDASIL. Subsequently the patient developed a whole colony of genital warts. The patient's outcome was unknown. The patient sought medical attention in the physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Genital wart

Prex Vax Illns:

Vaers Id: **333877-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	25-Sep-2008	01-Oct-2008	6	17-Nov-2008	17-Dec-2008	FL	WAES0810USA00397	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling, Pruritus, Urticaria

Symptom Text: Information has been received from a licensed practical nurse concerning a 22 year old female, who 25-SEP-2008, was vaccinated with the second dose of GARDASIL, IM. Concomitant therapy included "birth control". "About a week post vaccination", the patient experienced swelling at the injection site, and two itchy hive like bumps on her opposite-side arm and leg. Physician reported that he recommended diphenhydramine HCL (BENADRYL) to treat the symptoms. No lot number was reported. No further information was provided. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333880-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Dec-2008	03-Dec-2008	1	04-Dec-2008	11-Feb-2009	NC		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Rash

Symptom Text: Pt complains of Dizziness, fatigue, and rash starting 12/3/08.

Other Meds: FemCon 35 mg 1 per day

Lab Data:

History: none

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333892-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Dec-2008	02-Dec-2008	1	04-Dec-2008	17-Dec-2008	WA		01-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	AVB245AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Migraine, Nausea, Vomiting

Symptom Text: Headache, vomiting, chest pain 2/9/09 Received PCP medical records. FINAL DX: none provided Records reveal patient experienced migraine HA, nausea & emesis. Records are difficult to follow but it appears patient had exercise induced asthma on day of HPV #2, otherwise in good health. No further records available. Will attempt to obtain Lot#s

Other Meds:

Lab Data:

History: Asthma PMH: chickenpox, URI, pneumonia, OM, exercise induced asthma, nevi.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **333902-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	05-Nov-2008	05-Nov-2008	0	04-Dec-2008	06-Feb-2009	AR		06-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB297BA	1	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1968U	1	Left arm	Intramuscular	
FLU	SANOFI PASTEUR	U2797AA	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus

Symptom Text: She had recieved the HPV(Gardsil)# 2 vaccine in her left deltoid, when she got home a few hours later her whole left side of her body turned red and was itchy. This lasted for a couple of hours and went away, she did not seek medical attention.

Other Meds:

Lab Data:

History: ASTHMA

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333908-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	19-May-2008	19-May-2008	0	04-Dec-2008	09-Dec-2008	MO		16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Right arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anosmia, Cerebral haemorrhage, Fall, Head injury, Immediate post-injection reaction, Syncope

Symptom Text: Fainted approximately 1 to 2 minutes after the vacinnation. Fell on head due to fainting. Was sent to the emergency room for bleeding within my brain. Was hospitalized for 3 days. Resulted in permanent loss of my sense of smell due to head trauma.

Other Meds: Balziva

Lab Data: Had 3 CT Scans

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **333923-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Oct-2008	27-Oct-2008	0	04-Dec-2008	11-Feb-2009	NY		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Injection site anaesthesia, Menstruation delayed, Rash, Sensation of heaviness

Symptom Text: Delayed menses 3wks. Dizziness x 1wk. Rash on arm and numbness at injection site x 4days (red pin-dot) Arm felt heavy x 1wk Reported to office 12/04/08.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 333955-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-May-2007	Unknown		17-Nov-2008	17-Dec-2008	--	WAES0810usa00409	20-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Headache, Hot flush, Hypoaesthesia, Migraine, Neck pain, Paraesthesia, Phonophobia, Photophobia, Photopsia, Vision blurred

Symptom Text: Information has been received from the physician's assistant concerning a college aged female who an unspecified date who vaccinated with the first dose GARDASIL. After receiving her first dose. The patient developed headaches. The patient sought medical attention, office visit. On an unspecified date,a magnetic resonance imaging(MRI), a computed tomography (CT) scan of head and blood test were performed. All test and studies were within normal limits. At the time of reporting, the patient had not recovered. Additional information has been requested. 1/14/09 Reviewed Neuro medical records of 3/24-8/25/2008. FINAL DX: chronic migraine HA; chronic neck pain. Records reveal patient experienced chronic HA x 1 year w/phonophobia, photophobia, dizziness, fatigue, visual lights flashing/bright spots, blurry vision, neck pain. Had 2 episodes of numbness & tinling of toes/fingers w/hot flashes. Tx w/multiple med trials & PT w/some improvement. Seen in Er 8/08 for intense HA & tx w/flexeril & chiropractor which relieved HA. HA, nausea & blurred vision returned when flexeril d/c.

Other Meds: Unknown

Lab Data: Magnetic resonance, within normal limits; computed axial, of head within normal limits; diagnostic laboratory, unspecified blood test within normal limits LABS: MRI brain & c-spine WNL. ESR, ANA, LE & RA factor WNL

History: Unknown HPV #2, lot # 0525U, given 8/9/07 RA; HPV #3, lot # 1448U, given 12/26/07, LA PMH: Family hx: migraines

Prex Illness:

Prex Vax Illns:

Vaers Id: **333956-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	18-Sep-2008	20-Sep-2008	2	17-Nov-2008	17-Dec-2008	--	WAES0810USA00416	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a nurse practitioner concerning a female who on 18-SEP-2008 was vaccinated with a dose of GARDASIL. Two days after vaccination, on 20-SEP-2008, the patient had a rash. The reporter stated that the patients rash appeared from the upper arm to the shoulder. The rash lasted for two days. The patient sought medical attention and contacted the nurse practitioner. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333957-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	18-Sep-2008	18-Sep-2008	0	17-Nov-2008	17-Dec-2008	--	WAES0810USA00426	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female patient with a family history of migraines and no known allergies, who on 13-AUG-2008 was vaccinated with the first 0.5 ml IM dose of GARDASIL (lot# 658490/0802U). On 18-SEP-2008, the patient received the second 0.5 ml IM dose of GARDASIL (lot# 659964/1978U). There was no concomitant medication. On 18-SEP-2008 the patient experienced intermittent severe headaches after administration of her second dose. No lab diagnostics studies was performed. At the time of this report, the adverse event was ongoing. The patient sought medical attention via telephone. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **333958-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	24-Jun-2008	19-Aug-2008	56	17-Nov-2008	17-Dec-2008	IN	WAES0810USA00431	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Appendicitis, Back pain, Dizziness, Dyskinesia, Headache, Irritable bowel syndrome, Nasopharyngitis, Otitis media, Pharyngitis, Pharyngitis streptococcal, Rash

Symptom Text: Information has been received from a consumer concerning her 10 year old daughter with oesophageal acid reflux who on 24-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine along with varicella virus vaccine live (Oka/Merck) (MSD). Concomitant therapy included (PREVACID). On the week before second dose, the patient experienced cold symptoms and strep throat. On 26-AUG-2008, the patient got a strep throat test, and the outcome of strep throat test was negative. So, on 26-AUG-2008 the patient was vaccinated with the second dose of GARDASIL vaccine. On 08-SEP-2008, the patient was taken to the ER with signs of appendicitis. Since then, she took the CT scans, bloodwork, endoscopy, colonoscopy, and X-rays, and the outcome of those tests turned out normal, but her condition is getting worse. On 09-SEP-2008, the patient developed rash on her belly and left eye. The patient experienced stomach pain, abdominal pain, back pain, headaches, dizziness. It hurts the patient to lift her arms above her head, cross her legs due to pain during sleep. The patient was given DICYCLOMINE (manufacturer unspecified) "in case she had irritable bowel", but this therapy resulted in dizziness. Patient's adverse events persisted. The patient sought medical attention in the ER. Additional information has been requested. 12/11/08 Received PCP medical records. FINAL DX: none provided Records consist of Neuro consult done 10/28/08 for HA, dizziness & abdominal pain which started approx 10 days after HPV#2. Had gone to ER for abd pain on 9/8/08, w/u WNL. 9/19 RTC w/bilateral serous OM. 12/12 RTC w/pharyngitis. GI consult for endoscopy, colonoscopy, CT & US. Had psych eval which was WNL. Ophtho eval. No further records available.

Other Meds: PREVACID

Lab Data: computed axial 09/08/08 - NORMAL diagnostic laboratory 09/08/08 - NORMAL endoscopy 09/08/08 - NORMAL X-ray

History: PMH: GERD. Family hx:migraine HAs.

Prex Illness: Oesophageal acid reflux

Prex Vax Illns:

Vaers Id: **333959-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	18-Sep-2008	Unknown		17-Nov-2008	17-Dec-2008	MI	WAES0810USA00432	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0573X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a physician concerning a 24 year old female with no pertinent medical history and no drug reactions/allergies who no pertinent on 18-SEP-2008, was vaccinated IM with the third dose of GARDASIL 0.5 ml (lot#0573X). There was no concomitant medication. Shortly after her third dose, the patient developed pain at the injection site. The patient's pain at the injection site persisted. No lab or diagnostic studied were performed. It was reported that the patient sought medical attention: office visit. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333960-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	05-Mar-2008	05-Mar-2008	0	17-Nov-2008	17-Dec-2008	KS	WAES0810USA00438	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a nurse concerning a 24 year old female, who on 05-MAR-2008, was administered her first dose of GARDASIL. Subsequently, the patient experienced hair loss "since she was given the first dose of " GARDASIL. The patient was administered second dose of GARDASIL on 06-MAY-2008, and third dose on 08-SEP-2008. The patient's hair loss persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **333961-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	29-Jul-2008	Unknown		17-Nov-2008	17-Dec-2008	--	WAES0810USA00462	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a nurse practitioner concerning a female who on 29-JUL-2008 was vaccinated with the first dose of GARDASIL (lot n. 660389/1668U) 0.5 mL intramuscularly. On 26-SEP-2008. On 26-SEP-2008, the patient was vaccinated with a second dose of GARDASIL (Lot n. unspecified). There was no concomitant medication. Nurse practitioner reported that after dose 1 of GARDASIL, the patient hasn't had any periods. The patient has been diagnosed with amenorrhea. The patient saught unspecified medical attention. The patient's last normal cycle was on 16-JUL-2008. At time of reporting the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333962-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	IL	WAES0810USA00515	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness

Symptom Text: Information has been received from a nurse concerning a 21 year old female, who "several months ago" , was vaccinated with the first dose of GARDASIL, and was fine in the office. When she got home, developed flu-like symptoms. The patient did received a second dose of GARDASIL and was fine. It was unknown if the patient sought medial attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333963-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	NC	WAES0810USA00527	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from an office manager concerning a female who on an unspecified date was vaccinated intramuscularly with a first dose of GARDASIL. The office manager reported that patient fainted after receiving vaccination. At the time time of reporting, the outcome was unknown. It was not specified if the patient sought medical attention or not. Follow-up information was received from a registered nurse who reported that the patient fainted after receiving the first dose of GARDASIL with immediate recovery. This is one of several reports received from the same source. Additional information has been requested

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333964-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	ME	WAES0810USA00533	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash, Pruritus, Rash papular

Symptom Text: Information has been received from a registered nurse concerning her daughter, a 11 year old female with a history of ventricular septal defect (discovered in 2002), who on 31-JUL-2008, was vaccinated with the first dose of GARDASIL, lot # 660553/0070X, 0.5 ml, intramuscularly in her left arm. Concomitant therapy included MENACTRA. It was reported that following the first vaccination with GARDASIL, the patient developed a rash on the injection site, arm. The rash was described as papular, mildly itchy from the elbow to the shoulder. The onset of the rash was unknown at the time of the report. The rash was reported to have "lasted a while", but no time frame was available. On an unspecified date, the patient recovered. The patient did not seek medical attention. Additional information has been requested.

Other Meds:

Lab Data:

History: Ventricular septal defect

Prex Illness:

Prex Vax Illns:

Vaers Id: **333965-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	07-Apr-2008	Unknown		17-Nov-2008	17-Dec-2008	MD	WAES0810USA00535	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a nurse concerning a 20 year old female with drug hypersensitivity to sulfamethoxazole and trimethoprim (BACTRIM), sulfamethoxazole (+) trimethoprim (SEPTRA), and Amoxicillin Clavulanate (AUGMENTIN) with costochondritis (for past year), who on 07-APR-2008, was vaccinated with her first dose of GARDASIL (lot# 659964/1978U), 0.5 ml, intramuscularly. On 09-JUN-2008, the patient received her second dose of GARDASIL (lot#60553/0070X). Concomitant therapy included drospirenone (+) ethinyl estradiol (YAZ). Subsequently, in 2008, days or weeks, after receiving the second dose, the patient experienced intermittent dizziness. There is an orthostatic component to the dizziness, but not always. She was seen by her doctor and a complete blood count, her blood pressure and her ears were all within normal limits. The patient's doctor cleared her for receiving the third dose. The third dose may possibly be given on 03-OCT-2008. The patient's intermittent dizziness persisted. Additional information has been requested.

Other Meds: YAZ

Lab Data: Blood pressure, within normal limits; physical examination, ears within normal limits; complete blood cell, within normal limits

History:

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333966-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	NJ	WAES0810USA00556	09-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date, was vaccinated with a dose of GARDASIL. The physician reported that a month after the patient received GARDASIL, she still had pain at the injection site. No treatment required. At the time of the report, the patient had recovered. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 333967-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Sep-2008	03-Oct-2008	3	17-Nov-2008	17-Dec-2008	--	WAES0810USA00566	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female who on 30-Sep-2008 was vaccinated with the first dose of GARDASIL (Lot # 660618/0572X). Concomitant therapy included ethinyl estradiol/norgestimate (ORTO TRI-CYCLEN LO). On 03-OCT-2008, the patient experienced hives on her chest, arms, back and shoulders after receiving the first dose of GARDASIL. The patient's outcome was not reported. The patient sought medical attention by a phone call. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333968-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	MA	WAES0810USA00568	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle spasms, Pain

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dos of GARDASIL, and subsequently was being treated for generalized body pain and muscle spasms. The patient was not recovered. The patient sought medical attention by an office visit. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333969-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	WA	WAES0810USA00574	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depression

Symptom Text: Information has been received from a nurse concerning a female who was vaccinated with a dose of GARDASIL injection, and subsequently experienced a strong feeling of depression. The patient"s outcome was not reported. The patient outcome was not reported. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333970-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Oct-2008	01-Oct-2008	0	17-Nov-2008	17-Dec-2008	NH	WAES0810USA00594	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	3	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injection site pain

Symptom Text: Information has been received from a physician and a consumer concerning her 19 year old daughter with no previous medical history and allergies reported, who on 01-OCT-2008 a nurse practitioner inadvertently gave another dose of GARDASIL. The patient experienced injection site pain after received the fourth dose of GARDASIL . The patient had completed a series during the summer. Concomitant therapy included meningitis vaccine (manufacturer unspecified) and TB shot (manufacturer unspecified). The patient did not seek medical attention. The patient did not have illness at time of vaccination. Additional information has been requested.

Other Meds: Bog vaccine; Meningococcal vaccine

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **333971-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	15-Aug-2008	01-Aug-2008	-14	17-Nov-2008	17-Dec-2008	--	WAES0810USA00596	02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a nurse practitioner concerning a 25 year old female patient, who on 15-AUG-2008, was vaccinated with a dose of GARDASIL, IM, 0.5 ml. A couple days after vaccination, the patient developed severs arm pain. The patient had seen her family physician and an orthopedist. She had physical therapy for four weeks, but continued to have arm pain. An magnetic resonance imaging will be scheduled. The patient has been taking unspecified oral antiinflammatories for her symptoms. As of 03-OCT-2008, the patient did not recovered. Additional information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333972-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Nov-2007	01-Dec-2007	30	17-Nov-2008	17-Dec-2008	--	WAES0810USA00611	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cryotherapy, Skin papilloma

Symptom Text: Information has been received from a consumer concerning here 17 year old daughter with unspecified allergies and no known drug reactions, who between November and December 2007, was vaccinated with the first dose of GARDASIL. There was no concomitant medication. The patient developed numerous wart-like lesions on the fingers of both hands in December 2007. The patient was treated with cryotherapy as well as an unspecified topical cream by an unspecified dermatologist near her college. The warts improved, but recurred when the topical therapy was discontinued. The patient received the second dose of GARDASIL on an unspecified date and her third dose in August 2008. The patient sought medical attention by an office visit. There were no lab diagnostics studies performed. At time of reporting, the patient had not recovered. Additional information is not expected.

Other Meds: None

Lab Data: None

History: Hypersensitivity

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333973-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Oct-2007	01-Jun-2008	244	17-Nov-2008	17-Dec-2008	KY	WAES0810USA00624	05-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0962F	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Condition aggravated, Headache, Nausea, Phonophobia, Photophobia

Symptom Text: Information has been received from a physician via lawyer concerning a 16 year old female student with no known drug allergies a family history of thyroid disease and a history of headache who on 26-Mar-2007 was vaccinated with the first dose of GARDASIL IM into her left deltoid. On 29-May-2007, the patient received the second GARDASIL. On 01-Oct-2007, the patient received the third dose of GARDASIL IM into her left deltoid. There were no ilness at the time of vaccination. In June 2008. the patient experienced bitemporal headache with phonophobia and phonophibia and photophobia lasting 24 hrs every2-3 days. The patient was treated with TOPAMAX for the headache. In july 2008, the patient experienced sudder hair loss. Lab teste included a serum antinuclear antibodies test (ANA) serum thyroid-stimulating hormone test (TSH) and erythroeyte sedimentation rate (RSR) with normal results. Additional information is not expected. 12/31/08 Reviewed PCP medical records. FINAL DX: alopecia, HA Records reveal that on 11/27/08 office visit patient experienced sudden severe alopecia x 1 week, HA w/nausea, photo/phonophobia intermittently x 1 mo.

Other Meds: Unknown

Lab Data: Serum ANA - Normal, Serum TSH - Normal, Erythrocyte - Normal

History: Concurrent conditions: Headache PMH: family hx: migraines & thyroid dx.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333974-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	--	WAES0810USA00628	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician assistant concerning a female who was vaccinated with GARDASIL 0.5ml. Subsequently the patient experienced rash down her arm. On an unknown date, the patient recovered from rash down her arm. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333975-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Oct-2008	02-Oct-2008	0	17-Nov-2008	17-Dec-2008	KS	WAES0810USA00629	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0572X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 13 year old female with no pertinent medical history, allergies or drug reactions, who on 02-Oct-2008 was vaccinated with the first dose of GARDASIL (lot no. 660618/0572X). The patient was concomitantly vaccinated with a dose of VAQTA (manufacturer unknown). On 02-Oct-2008, the patient experienced syncope/fainting. The office called Emergency Medical Services, and they administered oxygen to her. The physician reported that the patient was fine when EMS arrived. Subsequently, the patient recovered. The physician felt that the patient's syncope was an another important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **333976-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	NY	WAES0810USA00696	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a physician concerning a 20 year old female who was vaccinated with GARDASIL. Subsequently the patient experienced rash. The outcome of the patient was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333977-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	16-Dec-2008	--	WAES0810USA00750	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Pelvic pain

Symptom Text: Information has been received from a nurse who reported that her niece's whole cheerleading squad experienced stomach cramps and/or pelvic pain after receiving the first dose of GARDASIL. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333978-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Sep-2008	05-Sep-2008	0	17-Nov-2008	17-Dec-2008	--	WAES0810USA00806	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pyrexia, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female with no medical history or drug allergies, who on 05-SEP-2008, was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot#:660612/0229X).Concomitant therapy included drospirenone (+) ethinyl estradiol (YAZ). It was reported that the patient experienced fever, nausea and vomiting within a couple of hours of getting home from her appointment. She had no localized reactions. Her symptoms lasted for 48 hours. The patient recovered from fever, nausea and vomiting. Additional information has been requested.

Other Meds: YAZ

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333979-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Oct-2008	01-Oct-2008	0	17-Nov-2008	17-Dec-2008	--	WAES0810USA00803	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pain in extremity

Symptom Text: Information has been received from a nurse for the pregnancy registry for GARDASIL vaccine concerning a female who on 12-May-2008 was vaccinated IM with the first dose of GARDASIL (lot no. unknown). On 01-Oct-2008 she was vaccinated IM with the second dose of GARDASIL (lot no. 359182/1757U). The patient found out on 05-Oct-2008 that she was pregnant. the patient has also experienced soreness of her arm after the second dose of the vaccine. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP=Unknown)

Prex Vax Illns:

Vaers Id: **333980-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	UT	WAES0810USA00810	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed, Nausea, Pyrexia, Vomiting

Symptom Text: Information has been received from a physician concerning a 12 year old female who in approximately August 2008, 2 months ago, was vaccinated with GARDASIL as her first dose. Subsequently the patient experienced a fever for 2 days. She also had not had a menstrual period since she received the dose 2 months ago and in the past week she had been vomiting and nauseous. The patient had not recovered. It was confirmed that the patient was not pregnant. The patient had not sought medical attention. Physician can be contacted. No further information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333981-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	FL	WAES0810USA00814	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a licensed practical nurse concerning an approximately 18 year old female patient with penicillin allergy who was vaccinated on unspecified dates with a first and second dose of GARDASIL. There was no concomitant medication. The patient experienced a rash under her fingernails the day after receiving the second dose. The patient sought medical attention. She was seen at the hospital on 1-Oct-2008 and a complete blood count with differential was normal. But the symptom persisted. The reporter felt that a rash under her fingernails was related to therapy with GARDASIL. No additional information has been requested.

Other Meds: None

Lab Data: complete blood cell, 10/01/08, normal

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333982-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	06-Oct-2008	06-Oct-2008	0	17-Nov-2008	17-Dec-2008	FL	WAES0810USA00819	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site erythema, Injection site swelling

Symptom Text: Information has been received from a nurse concerning a female who on 06-OCT-2008 was vaccinated with the first dose GARDASIL in her arm, and immediately post vaccination she had redness and swelling at the injection site. The patient was treated with ice and medication, unknown name of medication and unspecified if medication was oral or topical. The patient was recovering. The patient sought medical attention at the office. Additional information has been requested.

Other Meds: unknown

Lab Data: unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333984-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	M	01-Jul-2008	19-Sep-2008	80	17-Nov-2008	17-Dec-2008	OH	WAES0810USA01159	23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Gait disturbance, Hyporeflexia, Lumbar puncture, Migraine, Paraesthesia, Paraesthesia oral, Syncope, Visual impairment

Symptom Text: Information has been received from a physician concerning a female patient, who in approximately July 2008, was vaccinated with the third dose of GARDASIL. Recently, the patient experienced GUILLAIN-BARRE SYNDROME and was hospitalized. The patient sought medical attention via ER visit. Additional information has been requested. 2/18/09 Received hospital medical records of 9/22-9/27/2008. FINAL DX: cardiogenic syncope & migraines Records reveal patient experienced tingling of bilateral LEs & 1 arm that progressed to face/throat lasting approx 15 min while in school, with dizziness, lightheadedness when standing from sitting, visual disturbance & difficulty walking x 3 days. Had been seen in ER on 9/22, w/u WNL & released Eval by PCP & sent to hospital as direct admit. Neuro & cardio consults. Exam revealed decreased DTRs. LP done.

Other Meds: Unknown

Lab Data: Unknown LABS: CBC, CMP, CSF all WNL. EKG WNL. Echocardiogram WNL., tilt table exam, MRI brain w/max sinus mucuous retention cyst. EEG WNL.

History: Unknown PMH: migraine HA. Allergy: Keflex, (seizure). Family hx: asthma, migraines, bipolar, lupus.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333985-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	06-Oct-2008	06-Oct-2008	0	17-Nov-2008	17-Dec-2008	FL	WAES0810USA00852	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Immediate post-injection reaction, Injection site oedema, Oedema peripheral

Symptom Text: Information has been received from a medical assistant concerning a 21 year old female, weight 190, high 5'7" with no drug reactions or allergies, a history of migraine, who on 06-Oct-2008 10:30AM was vaccinated with the first dose of GARDASIL (intramuscular, lot # 661044/C548X) at right deltoid at private doctor's hospital. Concomitant therapy included Butisol, YASMIN 28, fexofenadine. On 06-Oct-2008 10:30AM, immediately after withdrawing the syringe, the patient's arm turned red and the redness spread down the arm and became swollen. Ice was applied and the patient was given a prescription for Benadryl and Prednisone. The patient sought medical attention at office. No further information was reported. Follow up information was received: Patient had side effects of erythema and mild edema of the injection site extending to lower right arm. Patient was given Zantac, Prednisone and Benadryl: On 09-Oct-2008, the patient's swelling was better. Additional information has been requested.

Other Meds: BUTISOL SODIUM, YASMIN 28, fexofenadine hydrocholoride

Lab Data: No

History: Migraine

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333986-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	SC	WAES0810USA00854	08-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain

Symptom Text: Information has been received from a physician concerning a 22 year old female who experienced abdominal pain prior to receiving her second dose of GARDASIL vaccine (Lot # was not reported). The date of the abdominal pain began was not specified by the reporter. The patient sought medical attention in physician's office. the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333987-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Oct-2008	03-Oct-2008	0	17-Nov-2008	17-Dec-2008	FL	WAES0810USA00894	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Pain, Rash

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter, who on 03-OCT-2008, was vaccinated with the second dose of GARDASIL, 0.5 ml, intramuscular. The patient was fine and had no pain and no side effect after receiving the first dose of GARDASIL on an unspecified date. By the evening of 03-OCT-2008, the patient experienced pain. The patient complained it hurt a lot. On 05-OCT-2008, the patient developed rash over forehead and spread into hairline to scalp. The mother would alert a physician to examine and assess the patient. This is one of two sibling reports from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: Facial rash; injection site swelling; injection site induration; pain; injection site erythema; injection site warmth~HPV (Garda

Vaers Id: **333988-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Oct-2008	03-Oct-2008	0	17-Nov-2008	17-Dec-2008	FL	WAES0810USA00895	05-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site mass, Injection site swelling, Injection site warmth, No reaction on previous exposure to drug, Pain, Rash

Symptom Text: Information has been received from a physician concerning a 16 year old female who on approximately 03-OCT-2008 was vaccinated with the second dose of GARDASIL. On 03-OCT-2008, about 6 hours after the vaccination, the patient complained pain and experienced rash started on face and then rash all over the face. On 05-OCT-2008 the patient experienced injection site hard swollen, red, warmth to touch and injection site knot. However after the first dose of vaccination, the patient was fine, no pain and adverse event occurred. The mother of the patient informed the doctor about the event and wanted to have her daughters examined, then she called MNSC. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: Pain~HPV (Gardasil)~2~17~In Patient|Rash~HPV (Gardasil)~2~17~In Sibling

Vaers Id: **333989-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	--	WAES0810USA01104	06-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNK		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Smear cervix abnormal

Symptom Text: Information has been received from a registered nurse concerning a 25 or 26 year old female who was vaccinated IM with GARDASIL vaccine. Subsequently that patient experienced abnormal Pap test with high risk human papillomavirus (HPV) "after completing the series" of GARDASIL. The patient sought medical attention: office visit. No further information is available.

Other Meds: Unknown

Lab Data: Pap test, abnormal Pap test

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333990-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Oct-2008	06-Oct-2008	0	17-Nov-2008	17-Dec-2008	OH	WAES0810USA01128	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Nausea

Symptom Text: Information has been received from a registered nurse concerning a 13 year old female who on 06-OCT-2008 was vaccinated with GARDASIL as her first dose. Subsequently the patient experienced nausea, dizziness and sweating 5-10 minutes after receiving the 1st dose of GARDASIL. The patient lay down for 30 minutes at the office and got better. The patient sought medical attention at the office. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333991-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Jun-2008	19-Jun-2008	2	17-Nov-2008	17-Dec-2008	FL	WAES0810USA01134	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Chills, Dizziness, Fatigue, Headache, Malaise, Nausea

Symptom Text: Information has been received form a physician concerning a 16 year old female who on17-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (lot #: 660391/0063X, route not reported). It was reported that the patient experienced extreme nausea, headache, dizziness, tiredness, malaise, low grade temperature and chills starting two days later after her first dose of GARDASIL vaccine. The patient was on school trip when this happen. The patient recovered "several days" after it started. The patient's mother called office for seeking medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333992-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	--	WAES0810USA01149	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Amenorrhoea, Syncope, Type 1 diabetes mellitus, Weight decreased

Symptom Text: Information has been received from patient's grandmother concerning her 15 year old granddaughter who was vaccinated IM with the first dose of GARDASIL (lot number not reported). The patient experienced weight loss, hair loss, cessation of menstrual cycles, and several episodes of fainting after being vaccinated with GARDASIL. The patient was recently diagnosed with type 1 diabetes. The patient's type 1 diabetes persisted. The patient's grandmother did not have physician's information or specified dates. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333993-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	04-Jun-2008	18-Jun-2008	14	17-Nov-2008	17-Dec-2008	FL	WAES0810USA01155	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Pain in extremity, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 21 year old female with a history of anxiety and depression who was vaccinated intramuscularly with a first and second dose of GARDASIL (Lot # 0250X) on 04-JUN-2008 and an unknown date respectively. Subsequently, the patient experienced pain in back and in both arms about 2 weeks after each dose. Unspecified medical attention was sought; no laboratory or diagnostic tests were performed. The patient recovered from pain in back and pain in both arms each time. Additional information has been requested

Other Meds: Unknown

Lab Data: Unknown

History: Anxiety; depression.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333994-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Aug-2008	10-Sep-2008	14	17-Nov-2008	17-Dec-2008	MA	WAES0810USA01164	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Myalgia

Symptom Text: Information has been received from a physician concerning a 14 year old female with no medical history and no known drug allergies who on 27-AUG-2008 was vaccinated with a first 0.5ml dose of GARDASIL intramuscularly. Concomitant therapy included topical clindamycin. The patient experienced myalgia in calves, lower thigh, back and neck after the vaccination in 10-SEP-2008-17-SEP-2008. She also is experiencing fatigue. Medical attention was sought, the patient was seen in the office. Laboratory tests were performed, all of following were negative: lyme panel, CPK level, antinuclear antibody, rheumatoid factor, mononucleosis, sedimentation rate 2, CBC. The patient has not recovered at the time of report. Additional information has been requested.

Other Meds: Clindamycin

Lab Data: Serum B.burgdorferi, negative; Serum creatine kinase, negative; Serum ANA, negative; Serum rheumatoid factor, negative; Serum Epstein-Barr, negative; Erythrocyte, negative; Complete blood cell, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333995-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	30-Sep-2008	01-Oct-2008	1	17-Nov-2008	17-Dec-2008	AR	WAES0810USA01169	02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain

Symptom Text: Information has been received from a licensed practical nurse (L.P.N.) concerning an 18 year old female, who approximately 30-SEP-2008, was vaccinated with a third dose of GARDASIL (lot# was not reported). 24 hours after vaccination, the patient experienced abdominal cramping, which was not recovered at the of reporting. Nurse and physician do not think abdominal cramp is vaccine related. An office visit is scheduled. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333996-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	03-Oct-2008	03-Oct-2008	0	17-Nov-2008	17-Dec-2008	--	WAES0810USA01177	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNK	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a healthcare professional concerning her niece of 10 year old who on 03-OCT-2008, was vaccinated with the first dose of GARDASIL vaccine. The healthcare professional reported that on 03-OCT-2008, her niece had experienced hives after receiving the first dose of GARDASIL vaccine. On unspecified date the patient had recovered.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333997-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	06-Oct-2008	07-Oct-2008	1	17-Nov-2008	17-Dec-2008	--	WAES0810USA01178	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, Pyrexia, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a 21 year old female. On 22-JUL-2008, she was vaccinated with a first dose of GARDASIL vaccine IM into the right deltoid. On 06-OCT-2008, she was vaccinated with a second dose of GARDASIL vaccine IM into the right deltoid. In the morning of 07-OCT-2008, the patient went to urgent care center with complaints of fever, nausea, and vomiting. The patient's temperature was 100.6 F as taken by tympanic thermometer. she was given a strep throat test, with negative result. The patient was released form urgent care center. Treatment was over the counter TYLENOL or Ibuprofen as needed. she had follow up appointment with nurse practitioner. The patient's fever, nausea, an vomiting persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: rapid Streptococcus - negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **333998-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Jul-2007	21-Jul-2007	4	17-Nov-2008	17-Dec-2008	--	WAES0810USA01189	02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Bronchitis, Cough, Erythema, Headache, Oedema peripheral, Peripheral coldness, Pruritus, Urticaria

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with penicillin allergy, asthma and some allergies who on 17-JUL-2008 was vaccinated with the first dose of GARDASIL and with the second dose on 04-Oct-2007. Concomitant therapy included FLOVENT, Albuterol and a prescription drug cough medicine. On 21-JUL-2007 the patient experienced itchiness, redness and swelling of hands and feet. On 05-OCT-2007, after second vaccination the patient experienced hives all around both knees with causes itching and redness. The hives subsequently spread to her feet, and then to her entired body including her face. The patient subsequently developed bronchitis, felt weak all the time and had "never ending headaches". At the time of report, the patient was doing better but she had "no stamina" and she continued to experience coughing spasms and brochitis periodically. Also, whenever her extremities, such as her hand or feet are subjected to coldness or cold temperatures, they turn red and she experienced itchness. The patient was recovering. No additional information is expected.

Other Meds: therapy unspecified; Albuterol, FLOVENT

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy, Asthma, Hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **333999-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	02-Sep-2008	02-Oct-2008	30	17-Nov-2008	17-Dec-2008	IA	WAES0810USA01196	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Diarrhoea, Dizziness, Headache, Malaise, Pain in extremity, Pain in jaw

Symptom Text: Information has been received from a nurse concerning a female patient with no known allergies and no pertinent medical history who on 02-OCT-2008 was vaccinated with the first and only dose of GARDASIL 0.5 ml, IM. There was no concomitant medication. On 02-OCT-2008 after receiving the vaccine, the patient was not feeling well, felt dizzy and experienced headaches. The patient searched on the web site for GARDASIL adverse event symptoms and she realized that she had similar symptoms. The patient complained of diarrhoea, jaw pain, leg aches and anxiety. The patient went to emergency room and was released. No laboratory test were performed. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **334000-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Aug-2008	11-Aug-2008	4	17-Nov-2008	12-Feb-2009	NC	WAES0810USA01202	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Gait disturbance, Vertigo

Symptom Text: Information has been received from a medical assistant concerning a 15 year old female consumer with no allergy or medical history who on 07-AUG-2008 at 13:00 was vaccinated with her first dose of GARDASIL vaccine (LOT# 660557/0072X), 0.5ml, IM on her left arm. There was no concomitant medications. Subsequently on approximately 11-AUG-2008 the patient experienced vertigo, and "it was so bad that she had to hold onto the wall for support". Medical attention was not sought. And three days later, on 14-AUG-2008 the patient recovered without treatment. On 07-OCT-2008 the patient arrived in the doctor's office for her second dose of GARDASIL vaccine. No additional information is expected.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334001-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	29-Sep-2008	29-Sep-2008	0	17-Nov-2008	17-Dec-2008	--	WAES0810USA01636	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a female patient. In February 2008, she was vaccinated with the first dose of GARDASIL. On 29-SEP-2008, she was vaccinated with the second dose of GARDASIL. After getting the second dose of GARDASIL the patient experienced pain at the injection site. No additional information expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334002-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	06-Oct-2008	07-Oct-2008	1	17-Nov-2008	17-Dec-2008	CO	WAES0810USA01654	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Headache, Influenza like illness, Nausea

Symptom Text: Information has been received from a nurse practitioner concerning a 26 year old Caucasian female with reaction to codeine (nausea and vomiting) and had no illness at the time of vaccination who on 06-OCT-2008 was vaccinated with her first dose of GARDASIL vaccine (lot number 661703/0651X) 0.5ml IM into deltoid. Concomitant therapy included MICRONOR. On 07-OCT-2008 the patient woke the day after the vaccination feeling nauseas and had flu-like symptoms. As the day went on, nausea increased. The patient developed mild headache. By 5pm, the patient felt mild to severe nausea, chilly, headache. Symptoms entirely gone by 08-OCT-2008.

Other Meds: MICRONOR

Lab Data: Unknown

History: Nausea, vomiting

Prex Illness: Adverse drug reaction

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334003-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	17-Dec-2008	TX	WAES0810USA01671	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning three female who were vaccinated with a dose of GARDASIL vaccine on an unspecified date. The patient did not have HPV before receiving GARDASIL vaccine. After receiving GARDASIL vaccine, the patient had positive results of HPV. At the time of report, the outcome was unknown. The patient sought medical attention. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available

Other Meds: Unknown

Lab Data: PAP test positive for HPV.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334004-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	24-Jul-2008	Unknown		17-Nov-2008	12-Feb-2009	NJ	WAES0810USA01677	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT General symptom, Rash

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a 23 year old female patient who on 24-JUL-2008 was vaccinated intramuscularly with a first 0.5ml dose of GARDASIL. Subsequently, the patient developed rash and other unspecified complaints. Medical attention was sought, the patient was seen in the physicians office. It was unknown if the patient recovered. Additional information has been requested.

Other Meds: Yasmin

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334005-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	06-Sep-2008	07-Sep-2008	1	17-Nov-2008	12-Feb-2009	NY	WAES0810USA01678	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Headache, Migraine, Nausea

Symptom Text: Information has been received form a register nurse concerning a 19 year old female with a history of migraine who on 28-JUL-2008 and 06-SEP-2008 was vaccinated with a first and second dose of GARDASIL vaccine (Lot # was not reported) intramuscularly in the deltoid. concomitant therapy included YASMIN. Subsequently, the patient experienced dizziness, "weakness all over", nausea, and a headache led to a migraine about 24 hours after the second dose of vaccination. The patient sought medical attention via a telephone call. No laboratory or diagnostic tests were performed. On an unspecified date the patient reported the nausea subsided but weakness and headache persisted. the patient was instructed to call back if symptoms did not resolve. Additional information has been requested.

Other Meds: YASMIN

Lab Data: Unknown

History: Migraine

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334006-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-May-2008	07-May-2008	5	17-Nov-2008	12-Feb-2009	--	WAES0810USA01686	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNK	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acarodermatitis, Blister, Erythema, Pruritus, Weight increased

Symptom Text: Information has been received from a physician concerning a 13 year old female who is daughter of a nurse. The patient was with seasonal allergy and no drug reactions/allergies and a history of anaemia as an infant. On 02-MAY-2008 the patient was vaccinated with her first dose of GARDASIL vaccine and on 23-JUL-2008 her second dose. Concomitant therapy included CLARINEX, VISTARIL and DIPROLENE. The patient experienced itching in the left arm "about 1-2 weeks after the first injection". The family physician treated the patient's symptoms with ZYRTEC; however, the patient's symptoms did not improve. A dermatology specialist diagnosed and treated the patient for scabies (treatment Unspecified). The patient's rash was described as intermitted with red spots on the abdomen and breasts. Raised blister like spots developed on the palms of the patient's hands by the end of August, 2008 (date unspecified.) The family physician prescribed MEDROL DOSEPAK and the symptoms resolved until the dose pack was completed. The patient was currently prescribed an unspecified dose of prednisone. The patient gained 14 pounds since beginning the methylprednisolone on 04-SEP-2008. The patient was scheduled for an evaluation with another dermatologist on 09-OCT-2008. No other symptoms and treatment reported. No other information available. The patient had not recovered from the adverse events at the time of the report. Lab diagnostics studies performed included blood work (complete blood count, liver function studies). Additional information has been requested.

Other Meds: DIPRCLENE CLARINEX VISTARIL prednisone

Lab Data: Unknown

History: Anaemia neonatal

Prex Illness: Seasonal allergy

Prex Vax Illns:

Vaers Id: **334007-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jun-2008	01-Jun-2008	0	17-Nov-2008	12-Feb-2009	--	WAES0810USA01703	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Gluteous maxima	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Anaemia

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter with allergies to amoxicillin and sulfonamide and no pertinent medical history reported, who in June 2008, was vaccinated with her first dose of GARDASIL vaccine. subsequently the patient experienced hair loss. In August 2008, the patient was vaccinated with her second dose of GARDASIL vaccine. The hair loss became worse after the second dose of vaccination and she was "recently" diagnosed with anemia. No further information was given. Concomitant therapy included ALLEGRA. Lab diagnostics studies performed included routine blood work. The patient had not recovered at the time of the report. The patient was seen by a physician. Additional information has been requested

Other Meds: ALLEGRA

Lab Data: None

History:

Prex Illness: Penicillin allergy; Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334008-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	24-Sep-2008	27-Sep-2008	3	17-Nov-2008	12-Feb-2009	CA	WAES0810USA01716	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Rash papular

Symptom Text: Information has been received from a physician concerning a 23 year old female with egg allergy, who on approximately 24-SEP-2008, was vaccinated with her second 0.5 ml dose of GARDASIL, IM. Subsequently, "within days of the second vaccination", the patient experienced small papules on her body which the physician reported was an allergic reaction. The patient sought medial attention by seeing the physician. No further information is available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Egg allergy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334009-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jun-2008	01-Jun-2008	0	17-Nov-2008	12-Feb-2009	--	WAES0810USA01720	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site mass

Symptom Text: Information has been received from a pharmacist concerning a college age female, who on unknown dates, received her first two dose of GARDASIL without adverse symptoms noted, and then in June 2008, was vaccinated with her third dose of GARDASIL, 0.5 ml, therapy route unspecified. Subsequently, the patient developed a 4 cm lump at the injection site, no pain or erythema. The doctor feels it is calcification. Laboratory tests included X-ray, result unspecified. And no treatment has been performed. The patient's lump at the injection site persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334010-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA01726	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a counselor concerning a 21 year old female who was vaccinated with a first dose of GARDASIL. Subsequently, the patient experienced a rash. The patient recovered on unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334011-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	08-Oct-2008	08-Oct-2008	0	17-Nov-2008	12-Feb-2009	--	WAES0810USA01728	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Pain, Syncope

Symptom Text: Information has been received from a nurse concerning a 24 year old female, who on 08-OCT-2008, was vaccinated intramuscularly in deltoid with the first dose of GARDASIL (lot# not reported). The patient was sitting in the chair, complained of pain and fainted within 2 minutes of receiving the vaccine. The patient recovered on 08-OCT-2008. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334012-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Jul-2008	20-Jul-2008	3	17-Nov-2008	12-Feb-2009	WV	WAES0810USA01730	12-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	NULL	1	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	NULL	1	Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a physician concerning an 18 year old female who on unspecified date was vaccinated with a first dose of GARDASIL vaccine. On 17-JUL-2008 the patient was vaccinated intramuscularly in the right shoulder with a second dose of GARDASIL vaccine. Concomitant therapy included MENACTRA which was vaccinated intramuscularly in the left shoulder and ADACEL at the same visit on 17-JUL-2008 at different injection sites. On approximately 20-JUL-2008 the patient experienced generalized rash all over her body. The patient spoke to the physician about the rash. At the time of reporting the patient's generalized rash all over her body persisted. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334015-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Nov-2008	25-Nov-2008	0	05-Dec-2008	08-Dec-2008	IL	WAES0811USA04147	08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cold sweat, Convulsion, Crying, Dizziness, Dyskinesia, Eye movement disorder, Heart rate decreased, Memory impairment, Musculoskeletal stiffness, Pallor, Skin discolouration

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 25-NOV-2008 was vaccinated with her first dose of GARDASIL (lot number 661530/0575X, route and site not reported). On 25-NOV-2008, after vaccination the patient experienced seizure-like episode and within a few minutes the patient was clammy, pale and lightheaded. The patient then was placed in the floor by the nurse who administered the vaccine to lay her down and the nurse noticed the patient's pulse was going down and her color turned from colored pale to shade gray. Patient eyes started fluttering and there was stiffening of her left arm and left leg and at one side of the body. There was a gargling sound coming from patient's throat and later her whole body started jerking. Patient woke up and didn't know where she was and started crying and they observed the patient for 20 more minutes and the patient came back to normal and was sent home. The office is not positive if the patient had a seizure or a severe fainting spell. The patient had previous vaccinations at their office without problems. Seizure-like episode was considered an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334016-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		05-Dec-2008	08-Dec-2008	AL	WAES0812USA00387	08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Systemic lupus erythematosus

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with the first dose of GARDASIL. After the vaccination, the patient was diagnosed with Lupus. The physician felt that lupus was not related to therapy with GARDASIL. The patient's outcome was unknown. It was unspecified if the patient sought medical attention. Upon internal review, lupus was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334021-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Jun-2008	30-Jul-2008	50	05-Dec-2008	08-Dec-2008	FR	WAES0812USA00445	08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Hypersomnia, Incorrect route of drug administration, Myalgia

Symptom Text: Information has been received on 27-NOV-2008 from a Health Authority (reference number ES-AGEMED-430377340) regarding a 15 year old female patient who on 10-JUN-2008 was vaccinated with the first dose of GARDASIL (batch # not reported), by subcutaneous route (site of administration not reported). In September 2008 (exact date not reported) the patient started with hypersomnia, arthralgy and myalgia in arms and legs. On 30-JUL-2008 the patient received another dose of GARDASIL (batch # not reported) by subcutaneous route (site of administration not reported). The reporter did not consider the dose administered on 30-JUL-2008 as a suspected drug for the adverse events. The reporter felt that hypersomnia, myalgia and arthralgia were an other important medical event. Other business partner numbers include E2008-11125. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, 11Oct08, 165; hemoglobin, 11Oct08, 11.6, g/dl; serum C-reactive protein, 11Oct08, <5; serum alanine aminotransferase, 11Oct08, 14; serum aspartate aminotransferase, 11Oct08, 16

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **334024-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Oct-2008	01-Oct-2008	0	17-Nov-2008	12-Feb-2009	MO	WAES0810USA01837	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Aura, Feeling abnormal, Headache, Influenza like illness, Injection site erythema, Injection site pain, Oropharyngeal pain, Syncope

Symptom Text: Information has been received from a nurse concerning a 15 year old female who on 01-Oct-2008 was vaccinated with GARDASIL. There was no concomitant medication. Subsequently, the patient had an injection site reaction "later in the day " following vaccination with GARDASIL that lasted for 24 to 48 hrs The injection site reaction was described as painful, red injection site. Subsequently, the patient developed a severe headache with aura and felt "dazed" with syncope for about 20 minutes on 08-Oct-2008. The patient had a sore throat and flu like symptoms earlier in the day on 08-Oct-2008, outcome of visit was unspecified.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334025-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA01840	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning an 11 year old female patient. The patient fainted during the administration of the first dose of GARDASIL (dose and route not reported). The nurse reported that the patient received her second and third dose of GARDASIL and did not faint. No other information to report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334027-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	VA	WAES0810USA01851	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who couple months ago was vaccinated with the first 0.5ml dose of GARDASIL. Lot number was not provided. Subsequently the patient experienced fainted. the patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334029-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	NJ	WAES0810USA01855	11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a 19 year old female who became sexually active at 16.5 years old and had a normal PAP December 2006. In December 2006 the patient had her first dose of GARDASIL (therapy route, site unknown), second January 2007, and her third March 2007. In August 2008 the patient had an abnormal PAP for high risk HPV. In October 2008 she had a colposcopy (results not provided). At the time of report, the patient was not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: colposcopy, 10/??/08 - ; Pap test, 12/??/06 - normal; pap test, 08/??/08 - abnormal: high risk HPV

History: sexually active

Prex Illness: CONCURRENT CONDITIONS: sexually active

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334031-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA01867	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Gluteous maxima	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cyst, Hypersensitivity, Skin disorder

Symptom Text: Information has been received from a consumer concerning her daughter who was vaccinated with the first dose of GARDASIL (unspecified dose). Subsequently, "shortly after initial dose of GARDASIL", the patient experienced cysts, and marks or her legs, buttocks, and groin areas. The physician felt it may be at allergic reaction to GARDASIL. At the time of the report, the AE did not improved and the patient had not recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334032-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jul-2008	01-Jul-2008	0	17-Nov-2008	12-Feb-2009	--	WAES0810USA01881	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Pyrexia

Symptom Text: Information has been received from a nurse practitioner, concerning a 15 year old female who in "summer 2008", which was in approximately July 2008, was vaccinated with the first dose of GARDASIL (total daily dose and route not reported). An hour after the first dose of GARDASIL, the patient developed a mild fever of 102F (also reported as the patient was "warm" and fever temperature was not determined). An hour after the fever started the patient developed a severe headache and dizziness lasting 24 hours and the patient was unable to go to school. At the time of the report, the patient recovered from mild fever, severe headache and dizziness. It is not known if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334033-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		05-Dec-2008	08-Dec-2008	FR	WAES0812AUS00027	08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning a 13 year old female who was vaccinated with GARDASIL. Subsequently, 1 day after vaccination with GARDASIL, the patient experienced facial palsy. At the time of reporting to the agency on 23-JUL-2008, the patient had recovered from facial palsy. The agency considered that facial palsy was related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review facial palsy was considered on other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334034-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		05-Dec-2008	08-Dec-2008	FR	WAES0812AUS00028	08-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Encephalitis, Headache, Vomiting

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning a 26 year old female who was vaccinated with GARDASIL. Subsequently after vaccination the patient experienced encephalitis, headache and vomiting. At the time of reporting to the agency on 18-JUL-2008, the patient's encephalitis and headache and vomiting persisted. The agency considered that encephalitis and headache and vomiting were related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review encephalitis was considered an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334035-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.4	F	01-Jul-2008	01-Sep-2008	62	17-Nov-2008	12-Feb-2009	--	WAES0810USA01882	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNK		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Information has been received from a registered nurse concerning a female with obesity and no drug reactions/allergies who was vaccinated with GARDASIL vaccine, 0.5 milliliter intramuscular, in May and in July of 2008. In September 2008, the patient experienced bilateral numbness in her arms. The patient sought medical attention in office. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Obesity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334036-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	29-Sep-2008	29-Sep-2008	0	17-Nov-2008	12-Feb-2009	CT	WAES0810USA01883	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope, Vomiting

Symptom Text: Information has been received from a physician concerning a 21 year old female who "sometime last week", which was on approximately 29-Sep-2008, was vaccinated with the second dose of GARDASIL. After receiving GARDASIL, the patient fainted then came shortly after, and after fainting, the patient had vomited. At the time of report, the patient fully recovered from faint and vomiting, but the physician reported it was unsure if the patient was going to finish the rest of the series. The patient sought medical attention in the physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334037-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-Oct-2008	06-Oct-2008	0	17-Nov-2008	12-Feb-2009	--	WAES0810USA01885	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthropod bite, Burning sensation, Erythema, Hyperaesthesia, Oedema peripheral, Pruritus

Symptom Text: Information has been received from a nurse concerning a 20 year old female with no allergy and medical history unspecified who on 06-OCT-2008 was vaccinated the first dose of GARDASIL (Lot# 660612/0229X) injection in her left deltoid. Concomitant therapy included SYNTHROID, ZYRTEC D, YASMIN and hyoscyamine. Eight hours after receiving the vaccine injection, the patient's left hand became swollen, red, and itchy. She also experienced a burning feeling and sensitivity to touch in her index finger. Patient stated "It felt like her finger had a fever". And she saw her primary physician, and the physician said that it was a bug bite. Currently the patient's hand is not swollen. The lab and diagnostic tests were unspecified. At the time of reporting, the patient had recovered. Additional information has been requested.

Other Meds: ZYRTEC-D; YASMIN; Hyoscyamine; SYNTHROID

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334038-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	OH	WAES0810USA01886	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a female with medical history unspecified who on unspecified date was vaccinated a dose with GARDASIL (Lot # was unspecified). Concomitant therapy was unspecified. Subsequently, the patient experienced fainting. The patient sought unspecified medical attention. The outcome of the AE was unspecified. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334039-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA01896	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site urticaria

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with her first dose of GARDASIL (lot# not provided), 0.5 ml, intramuscular. Concomitant therapy included "VIAVAN". The patient had no medical history or drug allergy. Subsequently, the patient developed 3 welts on her arm where the vaccine was administered. The patient sought medical attention and biopsy of welts was performed. Therapy with human papillomavirus vaccine was discontinued. Additional information has been requested.

Other Meds:

Lab Data: Biopsy

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334040-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Mar-2008	01-Mar-2008	0	17-Nov-2008	18-Dec-2008	NJ	WAES0810USA01975	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Blood test, Hypoaesthesia, Muscle spasms, Pain in extremity, Paraesthesia, Raynauds phenomenon

Symptom Text: Information has been received from a consumer concerning her 21 year old daughter with allergy to penicillin and all cillins and a history of Lyme Disease who in Summer 2007 was vaccinated with her first dose of GARDASIL vaccine, IM; second dose in Fall 2007, and third dose in march 2008. concomitant therapy included ALLEGRA, MSD, PANELOR and ESTROPTEP. Subsequently "soon after receiving 3rd shot" the patient experienced occasional tingling in her hands and feet, and numbness in her arms and legs. Laboratory tests included blood work checked for MS, LUPIS and other diseases (results not reported), and will have an MRI in November. At the time of this report the patient's symptoms persisted. The patient sought medical attention with the physician. Additional information has been requested. 12/23/08 Reviewed rheumatology eval of 8/19/2008. FINAL DX: arthralgia, muscle spasm Records reveal patient experienced Raynaud's phenomomen of fingers & toes; paresthesias of hands & feet x 3 mo; joint pain hands. No other medical records available at this time.

Other Meds: ESTROSTEP, ALLEGRA, SINGULAIR, nortriptyline.

Lab Data: Unknown LABS: CBC, CMP, ESR, CRP, ANA & RF all WNL.

History: Lyme disease

Prex Illness: Penicillin allergy; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **334042-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-Oct-2008	09-Oct-2008	0	17-Nov-2008	16-Jan-2009	NY	WAES0810USA01978	16-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	2	Unknown	Intramuscular	
	FLU	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Condition aggravated, Confusional state, Dizziness, Heart rate decreased, Hyperhidrosis, Loss of consciousness, Pallor, Peripheral coldness, Pulse absent

Symptom Text: Information has been received from a physician concerning a 19-year-old female patient, who on 09-OCT-2008 received a third dose of 0.5 ml GARDASIL (lot # 660618/0572X, injection site not reported) via intramuscular route. Concomitant vaccination included a dose of FLUZONE (preservative free). The patient had previously received her first dose of GARDASIL (lot # 658556/1060U), together with a dose of MENACTRA and DTAP on 22-FEB-2008; and her second dose of GARDASIL (lot # 658556/1060U) on 13-APR-2008. On 09-OCT-2008, within 5 or 10 minutes after administration of the third dose of GARDASIL, the patient reported that she felt dizzy and lightheaded and sunk to the floor. Loss of consciousness was suspected. She was very "confused, pale, color poor and limbs cold." The patient was placed on exam table. She did not have a palpable pulse; her heart rate was in 40's via stethoscope and her blood pressure was 80/50. She was diaphoretic. The patient was given some apple juice and condition monitored. According to the patient, she had not eaten breakfast. After given more juice, the patient's heart rate improved and her blood pressure rose to 90/60. After being observed for a while she was sent home. The patient also had a similar episode a few weeks ago after running at a track. On a follow up phone call from the doctor on 10-OCT-2008, the patient was fine. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **334044-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	ND	WAES0810USA02021	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Musculoskeletal pain, Neck pain

Symptom Text: Information has been received from a nurse practitioner concerning a female vaccinated intramuscularly with 3 dose of 0.5 ml GARDASIL. After each dose the patient developed pain from her shoulder to her neck. The patent was seen by a physician in the office. The pain lasted 4 days each time. The outcome is recovered for the first two events of pain and unknown for the last. additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334054-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Sep-2008	23-Sep-2008	0	17-Nov-2008	22-Dec-2008	IN	WAES0810USA02022	23-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Nausea, Night sweats

Symptom Text: Information has been received from a health care worker concerning a 17 year old female patient with penicillin allergy who on 23-SEP-2008 was vaccinated with the first dose of GARDASIL (lot # 660555/0279X), 0.5ml intramuscularly. There was no concomitant medication. The health care worker reported reported that the patient had experienced nausea, epigastric pain and night sweats after receiving the first dose of GARDASIL. It was noted that as 10-OCT-2008, the nausea had not subsided. At the time of the report, the patient had not recovered. The patient sought medical attention, was seen by the physician. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: CONCURRENT CONDITIONS: Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334055-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	08-Oct-2008	09-Oct-2008	1	17-Nov-2008	12-Feb-2009	CA	WAES0810USA02027	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNK		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a registered pharmacist concerning a female patient who on 08-OCT-2008 was vaccinated with a dose of GARDASIL vaccine. The registered pharmacist reported that on 09-OCT-2008, the patient developed a "full body rash" after receiving GARDASIL vaccine. The patient sought medical attention at an office visit. At the time of the report the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334056-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA02070	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Drug administered at inappropriate site, Injected limb mobility decreased, Musculoskeletal pain, Tendon disorder

Symptom Text: Information has been received from a nurse on 30-SEP-2008 concerning a 20 year old female with penicillin and sulfa allergies, and a gynecological history of pap smear in 2005 who was vaccinated with a third dose of GARDASIL vaccine by a pharmacy. Subsequently the patient experienced pain in left shoulder, radiates down to the arm, increases with movement, aggravated by sleeping on the same side, weakness, started after vaccination one month ago and has not gotten any better. The patient's family history included both parents' kidney/blader problems. Assessment of this event was joint pain, shoulder-719.41 (primary). An X-ray in left shoulder was performed. Follow up information has been received on 02-OCT-2008. It was reported that the patient continued to have pain in it shoulder with ROM and is painful at rest. Medications for the event included ibuprofen 600mg 1 tab (s) QID, VICODIN 500mg-5 mg 1 tab(s) Q4H. Assessment were joint pain, shoulder-719.41 (primary), and disorder of tendon of shoulder region NOS-726.10, left intraspinatus partial tear. A MRI in left shoulder was performed. Follow up information has been received on 10-OCT-2008. It was reported that the patient has pain and difficulty in rotating the arm and difficulty in movement. the nurse and the patient felt had an intrasupra splintus tear due to the injection being given in a tendon rather than the deltoid. At the time of the report, the outcome was unknown. The reporter reported that it believed to be mechanical injury on 20-OCT-2008. Additional information has been requested

Other Meds: Unknown

Lab Data: Unknown

History: Pap smear

Prex Illness: Penicillin allergy; Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **334057-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	M	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA02138	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discolouration

Symptom Text: Information has been received from a registered nurse, concerning a 20 year old female who "sometime in June " (was not sure if it given in 2008 or not) was vaccinated with her first dose of GARDASIL, intramusclar. It was reported that the patient developed a "skin discoloration" at the injection site. When the patient returned for her second dose it was given in the other arm and there was no discoloration. It was reported that the adverse event improved after stopping therapy, however at the time of the report the patient status was unspecified by the reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334058-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA02140	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister, Rash

Symptom Text: Information has been received from the relative of a patient concerning the patient was vaccinated with 2 doses of GARDASIL. The patient experienced rash and blisters in vaginal area after first and second doses of GARDASIL. Unspecified medical attention was sought. No outcomes were reported. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334059-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		17-Nov-2008	18-Dec-2008	--	WAES0810USA02159	18-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1660U	1	Unknown	Unknown	
	TDAP	SANOFI PASTEUR	C2889AA	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2545AA	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1448U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Blood test, Bronchial hyperreactivity, Chest pain, Diarrhoea, Dyspnoea, Feeling hot, Gastritis, Nasopharyngitis, Nausea, Nipple disorder, Pain, Ultrasound scan, Vomiting

Symptom Text: Information has been received from a consumer concerning her 13 year old daughter with menstrual problems who in January 2008, was vaccinated with the first dose of GARDASIL (dose and route not reported). Concomitant therapy included albuterol and Zantac. In February 2008, after getting her first dose of GARDASIL, the patient developed vomiting, nausea and stomach cramps and pain lasting about 2 days after the completion of each menstrual period. The patient took blood tests and sonograms (results not reported). She didn't get her 2nd or 3rd doses. She sought medical attention. Her vomiting, nausea, stomach cramps and pain persisted. Additional information has been requested. 12/18/08 Reviewed PCP office records. FINAL DX: epigastric pain, RAD, possible gastritis Records reveal patient experienced cold s/s, felt hot, nauseated, difficulty breathing on 3/08 visit. RTC 7/08 w/nipple discomfort. RTC 9/08 LLQ pain & chest pain s/p vomiting & diarrhea. Tx w/meds. Referred to ER & cardiology. To return if no improvement. No further visits available.

Other Meds: ALBUTEROL, ZANTAC

Lab Data: Unknown LABS: CBC, chemistry, LFTs, abdominal US WNL.

History:

Prex Illness: CONCURRENT CONDITIONS: Menstruation abnormal

Prex Vax Illns:

Vaers Id: **334060-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA02157	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hallucination, Headache

Symptom Text: Information has been received from a physician concerning a 15 year old female who experienced headache and hallucination after the first dose of GARDASIL (lot # not provided). The patient reported the headache and hallucinations when she came in for the second vaccination. The patient did not seek medical attention. Subsequently, the patient recovered from headache and hallucination. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334062-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Dec-2008	03-Dec-2008	0	05-Dec-2008	12-Feb-2009	NY		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	0	Left arm	Intramuscular	FLU

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Patient fainted immediately after injection of Gardasil vaccine. Patient was revived after about 10 seconds and was able to sit up. We had her rest in the office for 5 minutes. She was then able to walk out of the office on her own and is doing fine at home.

Other Meds: n/a

Lab Data: n/a

History: anxiety

Prex Illness: n/a

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334080-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	27-May-2008	27-May-2008	0	07-Dec-2008	12-Feb-2009	VA		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Injected limb mobility decreased, Nausea, Oedema peripheral, Pain in extremity, Vaccine positive rechallenge

Symptom Text: I experienced dizziness, nausea, and headache about an hour after my third Gardasil injection. My left arm was sore and swollen. I had all these symptoms, but much less severe after the first and second injections. I contacted my doctor's office after the third and they instructed me to come in if I felt it were an emergency or take OTC medication for the pain and swelling and see if the symptoms resided. I took 600 mg of ibuprofen which helped mildly with the pain. The dizziness and nausea were gone within 24 hours. My arm continued to be sore to the touch and difficult to move for about 14 days post injection; longer than I have ever experienced after a vaccination.

Other Meds: NuvaRing

Lab Data: N/A

History: Depression.

Prex Illness: None.

Prex Vax Illns:

Vaers Id: **334083-1 (S)** **Related reports:** 334083-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Nov-2007	01-Dec-2007	2	08-Dec-2008	15-Dec-2008	KS		16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Alopecia, Arthralgia, Back injury, Blindness, Blindness transient, Burning sensation, Chest pain, Complex partial seizures, Contusion, Convulsion, Crepitations, Decreased appetite, Disturbance in attention, Dizziness, Drooling, Dysaesthesia, Dyskinesia, Dysmenorrhoea, Dyspnoea, Educational problem, Epilepsy, Facial pain, Facial palsy, Fatigue, Fungal infection, Gait disturbance, Headache, Heart rate irregular, Hemiparesis, Hiccups, Hyperacusis, Hyperaesthesia, Hypoaesthesia, Hypoaesthesia facial, Hypotonia, Inflammation, Joint stiffness, Menorrhagia, Menstruation irregular, Migraine, Mitral valve prolapse, Muscular weakness, Musculoskeletal pain, Myalgia, Nausea, Oedema peripheral, Oropharyngeal pain, Paraesthesia, Paralysis, Pericardial disease, Peripheral coldness, Pruritus, Pyrexia, Rash, Tinnitus, Transient ischaemic attack, Tremor, Unresponsive to stimuli, Vision blurred

Symptom Text: Excessive fatigue, muscle weakness, muscle pain, joint pain, dizziness, severe headaches, severe chest pain, shortness of breath, nausea, rash, tingling and numbness in hands and feet, partial paralysis, partial loss of vision, seizures, and transient ischemic attacks. 12/8/2008 Neurology consult received for DOS 11/12/2008 with DX: Seizure Disorder/ Complex partial Epilepsy Intractable-Status: persistant. Migraine Intractable-persistant. Mitral Valve Prolapse-persistant. Lumbar sprain and strain-improved. Pt presented with multiple worsening sx which began 11/2007 with headaches, muscle fatigue, hair loss, itchy skin rashes, blurred vision, high pitched ear ringing, dizziness, chest pain with shortness of breath (cardiologist found chest wall and pericardial inflammation), rapid heartbeat, easy bruising, cold extremities, nausea with poor appetite, irregular meses with cramps, muscular pain of the calves and upper extremities, muscle weakness all over, joint stiffness and pain, tremors, Bell's Palsy, shuffling gait with difficulty walking, tingling, burning and numbness of the R lower & upper extremities and face. PE (+) for lower extremity swellingfacial hypersensitivity, facial dissymmetry, skin hypersensitivity to touch. Pt recently (10/29/08) had episode of throbbing frontal H/A with R-sided weakness and facial pain, drooping and numbness. Seen in ER. On a seperate occasion the next week pt had a jerking episode which began as a fine tremor with unresponsiveness and hypotonia. Episodes started in ~ 4/2008 occuring several times/week, now increased frequency. Pt drools and mumbles during episodes and hears high pitched sqeals. School performance has droppped due to decreased concentration and no longer able to participate in sports. 01/16/2009 MR received from PCP 11/29/07-10/30/2008. Seen for sick visit 11/29/07for c/o sore throat, exposed to strep(Rapid strep (-)) and yeast infection x 2 months. Dx: Vaginitis. HPV#1 given. Returned 2/29/08 with c/o L shoulder pain and popping, fever, sore

Other Meds: none

Lab Data: Complete blood panels, eye exam, Sonogram, CT Scans, MRI, ECG, EKG, and EEG. Labs and Diagnostics: MRI/MRA brain WNL. EEG abnormal. Head CT WNL. NCS (-). Labs and Diagnostics: NCS WNL. US of GB WNL. Head CT (+) for L maxiallary mucosal

History: none. PMH: MVA age 4.

Prex Illness: none

Prex Vax Illns: none~ ()~~0~In Patient|none~ ()~~0~In Sibling|none~ ()~~0~In Sibling

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334083-2** **Related reports:** 334083-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	01-Sep-2008		19-Dec-2008	22-Dec-2008	KS	WAES0812USA03226	09-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Vasculitis cerebral

Symptom Text: Information has been received from a physician, concerning a patient who was vaccinated with GARDASIL vaccine 0.5ml, intramuscularly. The physician reported that after receiving the GARDASIL vaccine, about 2 months ago, the patient experienced cerebral vasculitis and seizures. The doctor was unsure if it was the first or second 0.5ml dose. The doctor was not sure if the patient would be seeing a specialist about this AE. The outcome is unknown. The patient sought unspecified medical attention. Upon internal review, seizures were determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334087-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Jun-2008	30-Jun-2008	4	05-Dec-2008	10-Dec-2008	IL		30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Burning sensation, Chest pain, Dehydration, Hyperventilation, Oesophagitis, Tremor

Symptom Text: On 6-26-08, pt presented for immunizations as follows: GARDASIL #1, Tdap #1, MENACTRA #1, and Hepatitis A #1. She was seen in the ER on 6-30-08 after experiencing chest pains, shakiness and tremors. At the time her symptoms began, she was lying on a couch, watching TV. Earlier that day, she had been working in the hot sun and symptoms were attributed to dehydration and anxiety accompanied by hyperventilation. The tremors continued in her legs and to a lesser extent in her arms intermittently for several days. She was seen at clinic on 7-01-08 due to the continued tremors. Doctor agreed with the Emergency Room physician's assessment, that the symptoms were due to dehydration, anxiety and hyperventilation. Pt returned for her second GARDASIL on 9-03-08. That evening, she experienced tremors in her legs and to a lesser extent in her arms throughout the following day. These symptoms were not reported at that time since they had not lasted as long and since the family had not connected the two episodes with the GARDASIL vaccine. When the family called to schedule her third GARDASIL vaccine, it was brought to our attention that she had a similar experience following the first two vaccines. With this information being brought to light, the third GARDASIL will not be given. 12/17/2008 ER record received for 7/1/08 with Impression Esophagitis, Tremors. Pt presented with c/o leg shaking and burning in chest. PE WNL. D/C to f/u with PCP.

Other Meds:

Lab Data:

History: PMH: none.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334112-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Dec-2008	04-Dec-2008	0	05-Dec-2008	15-Jan-2009	MO		15-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U		Right arm	Unknown	
	FLU	UNKNOWN MANUFACTURER	U2840AA		Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2666AA		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Tremor

Symptom Text: Patient sat down next to father after vaccines were given in the triage area. Several staff saw patient put head down and shook her head for a few seconds. Vital signs were then obtained of 10 minutes for 30 minutes. Vital signs were stable. Patient was given cold water to drink and crackers.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334119-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	31-Aug-2008	31-Aug-2008	0	17-Nov-2008	12-Feb-2009	FR	WAES0810USA02170	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Keratitis

Symptom Text: Information has been received from a physician concerning her 20 year old daughter who wears eyeglasses and in the "end of August 2008" received her first dose of GARDASIL. The patient had no drug allergy. Soon after receiving the vaccination, the patient experienced a change in vision in one eye. The patient sought medical attention and it was diagnosed as keratitis by an ophthalmologist. The patient's keratitis persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic Laboratory

History: Eyeglasses wearer

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334120-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA02345	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning 3 patients, 13 years old or more who were vaccinated with a dose of GARDASIL. Subsequently, the patients experienced syncope. No additional complications were reported. No outcomes were reported. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334121-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA02413	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pelvic pain

Symptom Text: Information has been received from a nurse concerning a female patient who experienced pelvic pain after receiving the first dose of GARDASIL. The outcome of the event was unknown. The reporter indicated that the patient's whole cheerleading squad also experienced the events after receiving the first dose of dose of GARDASIL. This is one of the several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334122-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA02414	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pelvic pain

Symptom Text: Information has been received from a nurse concerning a female patient who experienced pelvic pain after receiving the first dose of GARDASIL. The outcome of the event was unknown. The reporter indicated that the patient's whole cheerleading squad also experienced the events after receiving the first dose of GARDASIL. This is one of the several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334123-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	NC	WAES0810USA02415	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pelvic pain

Symptom Text: Information has been received from a nurse who reported that her niece experienced pelvic pain after receiving the first dose of GARDASIL. The outcome of the event was unknown. The reporter indicated that the patient's whole cheerleading squad also experienced the events after receiving the first dose of dose of GARDASIL. This is one of the several reports recieved from the same source. Follow-up information was received from a physician who reported that they did not have this patient and they were unaware of any adverse reactions from their practice. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334124-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA02422	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a consumer concerning her 16 year old granddaughter who 1 and 1/2 years ago, was vaccinated with a series of GARDASIL. Last month, the patient's Pap test was abnormal. It was not reported whether the patient sought medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Pap test, 09/??/08, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334125-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	01-Mar-2008		17-Nov-2008	12-Feb-2009	--	WAES0810USA02423	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	WYETH PHARMACEUTICALS, INC	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysplasia, Smear cervix abnormal

Symptom Text: Information has been received form the mother concerning her 21 year old daughter with a history of drug reaction to VERSED who in October 2006 was vaccinated with a first dose of GARDASIL vaccine and on unspecified dates was vaccinated with second and third doses of GARDASIL vaccine. Concomitant therapy included FLUSHIELD. It is reported that the patient received all three dose of GARDASIL vaccine and then two times in March 2008 she had a PAP Test done and they both came back abnormal. In March 2008, the patient was diagnosed with a mild case of dysplasia (HPV). At the time of reporting, the patient's mild case of dysplasia (HPV) persisted. The patient had sought medical attention of the physician. No further information is available

Other Meds:

Lab Data: Pap test 03/??/08 - mild dysplasia; Pap test 03/??/08 - mild dysplasia

History:

Prex Illness: Drug hypersensitivity.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334126-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Oct-2008	13-Oct-2008	0	17-Nov-2008	12-Feb-2009	FR	WAES0810USA02439	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Headache

Symptom Text: Information has been received from a medical assistant concerning a 16 year old female with no history and no known drug allergies, who on 01-Jul-2008 was vaccinated with the first dose of GARDASIL intramusclar. There was no concomitant medication. On 13-Oct-2008, after administration of the patient's second dose. the patient experienced severe fatigue and a headache. The patient did not recover from fatigue and headache. The patient sought medical attention via telephone. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **334127-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	13-Oct-2008	13-Oct-2008	0	17-Nov-2008	12-Feb-2009	IN	WAES0810USA02473	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a nurse concerning a female, who on 13-OCT-2008, was vaccinated with a first 0.5 ml dose of GARDASIL (lot # was not reported). On 13-OCT-2008, the patient experienced headache after the vaccination. The patient sought medical attention. At the time of reporting, it was unknown if the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334128-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	09-Oct-2008	09-Oct-2008	0	17-Nov-2008	12-Feb-2009	AZ	WAES0810USA02477	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ear pain, Paraesthesia

Symptom Text: Information has been received from a nurse concerning a 24 year old female with seasonal allergy who on 09-OCT-2008 was vaccinated IM with the first 0.5ML dose of GARDASIL (lot # 661044/0548X). Concomitant therapy included montelukast sodium (MSD). On 09-OCT-2008, about 6 hours after vaccination the patient experienced tingling of outside of ears and ears became painful to touch which became worse when talking. No treatment required. The patient sought medical attention by phone. Additional information has been requested.

Other Meds: SINGULAIR

Lab Data: None

History:

Prex Illness: Seasonal allergy

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334129-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	PA	WAES0810USA02481	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNK		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL vaccine. Subsequently the patient passed out at the office. At the time of this report, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334130-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	06-Oct-2008	08-Oct-2008	2	17-Nov-2008	12-Feb-2009	FL	WAES0810USA02484	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Decreased appetite, Dysgeusia, Fatigue, Feeling abnormal, Immediate post-injection reaction, Injection site pain, Nausea, Pyrexia

Symptom Text: Information has been received from a medical assistant concerning a 22 year old female who on 06-OCT-2008 was vaccinated with GARDASIL (lot # 660612/0229X). Concomitant therapy included YAZ. It was reported that the patient experienced numerous adverse reactions following vaccination with GARDASIL. The patient experienced pain at injection site immediately following vaccination, but it was described as "not that bad". The next day (07-OCT-2008) the patient felt very tired and by Wednesday (08-OCT-2008) the patient felt tired, had a fever of 100.1, experienced nausea with a "fill feeling", taste disturbance. The rest of the week the tiredness and fever continued with no mention of nausea. The patient would get a fever around 3 or 4 in the afternoon. ALEVE was taken for the fever. On Sunday (12-OCT-2008) the patient felt better, but Monday (13-OCT-2008) the patient called complaining again of tiredness and fever, but no nausea. The tiredness on Monday (13-OCT-2008) was described as not as bad. The patient sought medical attention. At the time of this report, the patient was recovering. Follow-up information has been received from a health professional concerning a 22 year old female with no known drug allergies who on 06-OCT-2008, at 14:00, was vaccinated IM with the first dose of GARDASIL (lot # 660612/0229X) in the left arm. On 08-OCT-2008, at 8:00, the patient started feeling bad, feeling tired, fever of 100.1, nausea, not able to taste food, pain at injection site, and was not able to eat. Additional information has been requested.

Other Meds: YAZ

Lab Data: Body temp, 10/08/08, 100.1

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334131-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Sep-2008	06-Oct-2008	11	17-Nov-2008	12-Feb-2009	--	WAES0810USA02492	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Grip strength decreased, Hypoaesthesia, Pain in extremity, Paraesthesia

Symptom Text: Information has been received from a physician's assistant concerning a 17 year old female with hypersensitivity and anxiety, who on 11-JAN-2008, was vaccinated with the first dose of GARDASIL, and vaccinated IM with the third 0.5 ml dose of GARDASIL (lot # 0947X) on 25-SEP-2008. Concomitant therapy included sertraline HCL (ZOLOFT), hormonal contraceptive (unspecified) and albuterol. On 05-OCT-2008, the patient experienced muscle soreness, numbness and tingling of left arm. The left arm was painful with movement. An exam in the office on 13-OCT-2008 revealed decreased strength of the left hand grip. The patient was prescribed a tapering course of prednisone and rest. The patient was not recovered by the time of this report. The patient visited office for medical attention. Additional information has been requested.

Other Meds: Albuterol; hormonal contraceptive; ZOLOFT

Lab Data: None

History:

Prex Illness: Hypersensitivity; Anxiety

Prex Vax Illns:

Vaers Id: **334132-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	01-Nov-2007		17-Nov-2008	12-Feb-2009	--	WAES0810USA02507	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Biliary dyskinesia, Cholecystectomy, Headache

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female with chronic sinusitis who on 27-JUL-2007 received the first dose of GARDASIL vaccine (yeast) (lot # 658222/0927U), 0.5ml. On 08-Nov-2007, the patient received the second dose of GARDASIL vaccine (yeast) (lot # 659437/12660), and on 17-Mar-2008 received the third dose of GARDASIL (yeast) (lot # 659182/1757U). Concomitant therapy included injected birth control. After the second dose the patient began to have headaches and abdominal pain. The patient had her gall bladder removed at that time because of biliary diskinesia. The patient's headaches and abdominal pain persisted. The patient sought medical attention. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History:

Prex Illness: Chronic sinusitis

Prex Vax Illns:

Vaers Id: **334133-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	15-Aug-2008	15-Aug-2008	0	17-Nov-2008	12-Feb-2009	PA	WAES0810USA02513	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site mass

Symptom Text: Information has been received from a physician concerning a 26 year old female who on 15-AUG-2008 was vaccinated with the first dose of GARDASIL, Lot # 660389/1968U. It was reported that a "couple of weeks later", the patient developed a lump at the injection site. The patient was seen by a surgeon and the lump was removed. The surgeon stated that the lump was due to GARDASIL vaccine. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334134-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	30-Jun-2008	01-Sep-2008	63	17-Nov-2008	12-Feb-2009	NJ	WAES0810USA02521	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received from a nurse concerning her daughter who on 30-JUN-2008 was vaccinated with the first dose of GARDASIL. The nurse reported that the patient had a fever after receiving the first dose. The patient started to have fever just days prior to receiving her second dose of GARDASIL administered on 01-OCT-2008. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334135-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	11-Aug-2008	11-Aug-2008	0	17-Nov-2008	30-Jan-2009	PA	WAES0810USA02696	02-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Headache, Nausea

Symptom Text: Information has been received from a nurse for the pregnancy registry for HPV concerning a 22 female with gastroesophageal reflux and a history of headache, who on 11-AUG-2008, was vaccinated with the first dose of GARDASIL (660620/0571X), I.M. Concomitant therapy included ranitidine. On 11-Aug-2008 and 09-Sep-2008, the beta-human chorionic gonadotropin tests were negative. On 14-OCT-2008, the patient came to the office complaining of headache and nausea since receiving her first dose of GARDASIL. A pregnancy test during her visit revealed that she is pregnant. The patient's LMP was 13-SEP-2008 and EDD 20-JUN-2009.

Other Meds:

Lab Data: Beta-human chorionic, 08/11/08, negative; beta-human chorionic, 09/09/08, negative; beta-human chorionic 10/14/08, positive

History: Headache

Prex Illness: Pregnancy NOS (LMP = 9/13/2008); Gastroesophageal reflux

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334136-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	20-Aug-2008		17-Nov-2008	12-Feb-2009	KS	WAES0810USA02706	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Haemorrhage

Symptom Text: Initial and follow-up information has been received from two registered nurses for the pregnancy registry for GARDASIL and the initial pregnancy questionnaire, concerning a 22 year old female with penicillin allergy who on 21-JUL-2008 was vaccinated with the first dose of GARDASIL, Lot # 660553/0070X. On 18-SEP-2008, the patient was vaccinated with the second dose of GARDASIL, Lot # 660616/0570X. Concomitant therapy included EFEXOR, prenatal vitamins and MACROBID. The patient was pregnant. The patient's LMP was on 20-AUG-2008 and EED on 27-MAY-2009. In follow-up information was reported that the estimated conception date was 26-AUG-2008. Unspecified routine OB labs were normal. On 13-OCT-2008 ultrasound was performed because the patient was bleeding and it showed results within normal limits. It was reported that the patient had no previous pregnancies. Additional information has been requested.

Other Meds: MACROBID; EFEXOR

Lab Data: Ultrasound, 10/13/08, within normal limits; Beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 8/20/2008); Penicillin allergy

Prex Vax Illns:

Vaers Id: **334137-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Apr-2008	01-Apr-2008	0	17-Nov-2008	18-Dec-2008	IN	WAES0810USA02721	18-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Back pain, Blood test, Diarrhoea, Dyspnoea, Gait disturbance, Hypersensitivity, Hypoaesthesia, Injection site erythema, Injection site pain, Pain, Paraesthesia, Rash pruritic, Swelling, Tremor, Vaccine positive rechallenge

Symptom Text: Initial and follow-up information has been received from a mother concerning her 18 year old daughter with no medical history reported, wasp stings allergy and pecans allergy who "about 6 months ago" in approximately April 2008, was vaccinated with a dose of GARDASIL, 0.5 ml. Concomitant therapy included ethinyl estradiol/norgesstimate (ORTHO TRI-CYCLEN). After receiving each of her three GARDASIL shots, the patient experienced pain and redness at the injection site. Also, after the third shot the patient experienced pain throughout her entire body, swelling and numbness that started on her left sided and has also moved to her right side. The patient has difficulty walking. The physician prescribed diphenhydramine hydrochloride (BENADRYL) and ibuprofen (ADVIL). On an unspecified date, a blood work was performed (results not provided). In follow-up information the mother reported that her daughter was experiencing difficulty breathing, pains in her lower back, constant diarrhea, swollen stomach and recently she started to have numbness and tingling on her hands and bottom of the feet and toes. On 16-OCT-2008, patient was given mixed steroids shot for any allergic reaction due to GARDASIL and then she experienced elevated blood pressure. On 18-OCT-2008, patient experienced pain from her heart down to her hand and she was shaky and weak as well. Later, physician did an eletrocardiogram (EKG), but the results were normal. He gave her pain shot. On 20-OCT-2008, she was prescribed ibuprofen (manufacturer unknown) 600 mg, but that did not help her. On 23-OCT-2008, she was given an "ultra monitor" for heart (result not reported) and will be doing another echocardiogram soon. Caller also mentioned that patient will be seeing a rheumatologist on 04-NOV-2008 and neurologist on 31-OCT-2008. On 27-OCT-2008, the patient developed an itchy rash between her left fingers and was using antibiotic ointment to treat it. At the timer of the report, physician prescribed her cyclobenzaprine hydrochloride (FLEXERIL) for muscle relaxati

Other Meds: ORTHO TRI-CYCLEN

Lab Data: Electrocardiogram, 10/08, normal

History:

Prex Illness: Allergy to insect sting; Allergy to nuts

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334138-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA02725	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNK		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Information has been received from a physician who heard from the local news, that a female who was vaccinated with a dose of GARDASIL vaccine (yeast) experienced nausea and vomiting and was hospitalized (length of time unspecified). The patient's outcome was not reported. In follow-up, the office nurse reported she was not familiar with any adverse events being reported from their office. Attempts are being made to verify the existence of an identifiable patient and reporter.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334139-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	09-Sep-2008	09-Sep-2008	0	17-Nov-2008	12-Feb-2009	CT	WAES0810USA02726	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Chills, Nausea

Symptom Text: Information has been received from a nurse concerning a 21 year old female with ovarian cyst and no drug allergies reported who on 09-SEP-2008 was vaccinated with the first and only dose of GARDASIL IM and experienced nausea, chills and stomach pain right after receiving vaccination. There was no concomitant medication. The symptoms disappeared one hour after the vaccination. The patient did not seek medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Ovarian cyst

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334140-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	Unknown	01-Aug-2008		17-Nov-2008	12-Feb-2009	--	WAES0810USA02765	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Haemorrhage, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a certified nurse midwife assistant for the pregnancy registry for GARDASIL, concerning a 27 year old female with a history of papanicolaou smear abnormal (1998), caesarean section (1999), normal deliveries (2002 and 2006) and no known allergies who on 02-MAY-2007 was vaccinated with the first dose of GARDASIL (Lot # 657005/0314U) into the left deltoid. Concomitant therapy included NORDETTE and prenatal vitamins daily. The patient had her last menstrual period on 10-JUL-2008. In August 2008, the patient experienced light bleeding. On 10-SEP-2008, the patient was vaccinated with the second dose of GARDASIL (Lot # 660393/0067X) into the right deltoid and was pregnant. On an unspecified date, a routine blood work was performed (results not provided). The patient sought an initial pregnancy exam as medical attention. The patient had 3 previous pregnancies and 3 full term deliveries (40, 39 and 40 weeks). No birth defects in previous pregnancies and no infant complications were reported. On 10-OCT-2008, an ultrasound was performed but was too early for evaluation dating. A second ultrasound was scheduled for 27-OCT-2008. The estimated date of delivery was 16-APR-2009. Additional information has been requested.

Other Meds: NORDETTE; Vitamins (unspecified)

Lab Data: Ultrasound, 10/20/08, too early for evaluation dating; Pap test, ?/?/98, abnormal

History: Papanicolaou smear abnormal; Caesarean section; Vaginal delivery

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334141-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	AL	WAES0810USA02839	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syphilis test positive

Symptom Text: Information has been received form a physician concerning a female who has tested positive for syphilis test several days after receiving the second dose of GARDASIL vaccine (therapy date, route,site unspecified). At the time of this report the patient was not recovered. The patient sought medical attention, she saw a physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Rapid plasma reagin - positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334148-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		08-Dec-2008	09-Dec-2008	MA	WAES0812USA00344	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Condition aggravated, Crying, Depression, Headache, Impaired work ability, Migraine, Nausea, Pain, Personality change, Quality of life decreased, Vomiting

Symptom Text: Information has been received from a consumer concerning his 26 year old girlfriend with an occasional migraine, who was vaccinated with the complete series of GARDASIL. Concomitant therapy included hormonal contraceptives. Beginning either after the first or second vaccination, she began to experience headaches, depression, nausea, physical pain, crying, migraines, vomiting, and had became "a shell person". The patient was hospitalized overnight for a spinal tap. At one time she was going to the emergency room 3 times a week. She has had a battery of medical tests that included a MRI, an EKG and a spinal tap which all came back normal. The reporter stated that the GARDASIL had ruined her life, her career and his relationship with her. The patient has been treated with many unspecified medications. The patient present status is not recovered. The patient sought medical attention. Ruined her life, her career and relationship were considered to be disabling. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: Magnetic resonance, normal; electrocardiogram, normal; spinal tap, normal

History:

Prex Illness: Migraine

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334149-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	27-Sep-2008	27-Sep-2008	0	08-Dec-2008	09-Dec-2008	FR	WAES0812USA00259	09-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0513U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Oedema peripheral, Pain, Pyrexia

Symptom Text: Information was received from a pharmacist concerning a 21-year-old female patient with no relevant medical history who received the second dose of GARDASIL (lot# 0513U, batch# NG33990) via intramuscular route on 27-SEP-2008. On the same day the patient experienced oedema in the arm, fever and intense pain. She was hospitalized on an unspecified date. She had fully recovered without any sequelae (unspecified timeline). To be mentioned that the case had initially received by a mail letter from a sales representative, upon contacting the reporter, a pharmacist, by telephone, it was understood that the reporter had not seen the adverse event, nor had any proof of the hospitalization. The reporter also mentioned that the report, in her opinion was not trustworthy as the patient's father could not provide any further details beyond what was reported. She only reported the case after the patient's father request. The attending physician's name was also unknown. Other business partner numbers include: E2008-11105. No further information is available. The case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334150-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jan-2006	01-Jan-2008	730	08-Dec-2008	09-Dec-2008	FR	WAES0812CAN00017	09-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Headache, Hypoaesthesia, Loss of consciousness, No reaction on previous exposure to drug, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 16 year old female who in January 2008, was vaccinated with the third dose of GARDASIL, lot # not available. Concomitant therapy included hormonal contraceptives (unspecified). In January 2008, on the way home that day she passed out and 2 hours later suffered from severe headache, since then suffered severe non-remitting headaches. In approximately August 2008, the patient experienced numbness and tingling in legs and hands and fatigue. The physician reported that the patient did not have any reactions post 1st and 2nd doses. Numbness and tingling in legs and hands were determined to be important medical events based on foreign agency requirements. No further information is available.

Other Meds: Hormonal contraceptives (unspecified)

Lab Data: Unknown

History: unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334162-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	03-Dec-2008	04-Dec-2008	1	08-Dec-2008	18-Dec-2008	CA		04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1321X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2829AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site pain, Injection site urticaria

Symptom Text: Raised area of induration and redness, urticaria at site of vaccine administration noted next morning with pain.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334163-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Nov-2008	17-Nov-2008	0	08-Dec-2008	18-Dec-2008	UT		18-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2665AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Unknown	
	DTAP	GLAXOSMITHKLINE BIOLOGICALS	AC14B065AA	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	1285X	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: Administered DTAP instead of Tdap. No side effects.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 334169-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Sep-2008	22-Sep-2008	0	08-Dec-2008	18-Dec-2008	MI		18-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2688AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gait disturbance, Tenderness

Symptom Text: Client received Menactra and HPV4 vaccines during day on 9-22-08. Client states that by 9:00 pm on 9-22-08, her entire body was very sore. Client states it was painful to walk. Client did not seek medical attention but client's mother did call an after hours health access phone line.

Other Meds: Multivitamin with iron daily

Lab Data: None

History: Allergic to Amoxicillin and Penicillin

Prex Illness: None

Prex Vax Illns:

Vaers Id: **334179-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	09-Apr-2008	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA02845	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hot flush, Nausea, Palpitations, Tachycardia, Thyroiditis

Symptom Text: Anemia, Adverse drug reaction; Tachycardia; Nausea; Palpation's; Hot flash, Penicillin allergy Information has been received from a nurse practioner concerning a 25 year old female with a history of anemia (blood transfusion November, 2007) and drug reactions or allergies to penicillin and venlafaxine hydrochloride (EFFEXCR) (not specified) who on 09-APR-2008 was vaccinated with the first dose of GARDASIL intramuscularly in the arm. On 10-June-2008, the patient was vaccinated with the second dose of GARDASIL (lot#659655/14860). On 10- Oct-2008, the patient was vaccinated with the third dose of GARDASIL (lot#661044/0548X). On 10-Oct-2008, the patient developed palpitations, Tachycardia, nausea, and hot flashes within 30 minutes after the third dose of GARDASIL. On 10-Oct-2008 the patient was taken to the emergency room via ambulance and administered diphenhydramine hydrochloride. The patient again experienced hot flashes, nausea, and Tachycardia and went to the emergency room in the hospital where the patient works (date of treatment at the second emergency room is unknown). The patient underwent an electrocardiogram, chest X-ray, and unspecified lab work. The patient continues with symptoms of hot flashes, nausea and Tachycardia that" comes and goes." The patient is out of work and has a follow up appointment with an unspecified primary care provider. The patient reported a similar reaction to venlafaxine hydrochloride in the past (specified symptoms unspecified). No other symptoms or Treatment reported. No other information available. Follow up AE information: The nurse practitioner called back to report that the patient has been diagnosed with thyroiditis. No further information was provided. Additional information has been requested.

Other Meds: Zovia

Lab Data:

History: Anemia, Adverse drug reaction; Tachycardia; Nausea; Palpation's; Hot flash, Penicillin allergy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334180-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Oct-2007	11-Mar-2008	133	17-Nov-2008	12-Feb-2009	--	WAES0810USA02869	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Inappropriate schedule of drug administration, Lymphadenopathy

Symptom Text: Information has been received from a physician concerning a 16 year old female with no allergies and a family history of endometriosis but she tested negative at the beginning of this year, who on 15-DEC-2006 was vaccinated with the first dose of GARDASIL (lot # 655165/1425F) 0.5ml injection. On 20-FEB-2007, the patient was vaccinated with the second dose of GARDASIL (lot # 655165/1425F). On 11-MAR-2008 the patient experienced abdominal pain. On 30-OCT-2008, the patient was vaccinated with the third dose of GARDASIL (lot # 659435/1265U). Concomitant therapy included ORTHO-NOVUM. On 13-OCT-2008 the patient experienced enflamed lymph nodes in the groin. The patient's present status was not recovered. The patient sought unspecified medical attention. No lab diagnostics studies performed. Additional information has been requested.

Other Meds: ORTHO-NOVUM

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334181-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Aug-2008	01-Aug-2008	0	17-Nov-2008	12-Feb-2009	--	WAES0810USA02875	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye swelling, Periorbital oedema

Symptom Text: Information has been received from a physician concerning a 16 year old female who in August 2008, was vaccinated with the first dose of GARDASIL. On 13-OCT-2008 was vaccinated with the second dose of GARDASIL. The patient got a swollen eye (eye unspecified) after receiving GARDASIL. On 15-OCT-2008 the patient was seen in the office today for a swollen eye diagnosed as periorbital edema. In August 2008 the patient had a similar reaction following the first dose of GARDASIL, but the reaction after the first dose was described as "worse". The physician treated the patient with eye drops (unspecified) and BENADRYL. No time frame development information was available other than the mother brought the patient in "right away". The patient's present status was not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334182-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Feb-2008	Unknown		08-Dec-2008	18-Dec-2008	KS	WAES0810USA02882	08-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site atrophy, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a physician concerning a 19 year old female, who in February 2008, was vaccinated with the first dose of (dose and duration not reported). Concomitant therapy included hormonal contraceptives (unspecified). Subsequently, the patient experienced an indentation at the injection site, it appeared that there was soft tissue or subcutaneous fat missing in an area of a centimeter and a half, and there was a little bit of swelling below that area. The patient indicated that the indentation was getting bigger and the indentation was painful at times. At the time of the report, the patient was not recovered. The patient sought medical attention. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **334183-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	04-Sep-2008	02-Oct-2008	28	17-Nov-2008	12-Feb-2009	MD	WAES0810USA03146	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nodule

Symptom Text: Information has been received from a mother concerning her 19 year old daughter with no known pertinent medical history or known drug reaction/allergies, who on 04-Sep-2008 was vaccinated with the first dose of GARDASIL. Concomitant therapy included birth control pills. The mother reported that on 02-Oct-2008, the patient experienced strange lumps on her one leg after getting GARDASIL. On an unknown date an MRI was preformed. The patient sought unspecified medical attention. At the time of the report the patient had not recovered. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334184-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Aug-2008	25-Aug-2008	0	17-Nov-2008	12-Feb-2009	PA	WAES0810USA03175	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope, Syncope vasovagal

Symptom Text: Initial and follow-up information has been received from a physician concerning a 16 year old female patient who on 25-AUG-2008, also reported as about a month ago, was vaccinated intramuscularly with a 0.5 ml dose of GARDASIL (lot number and site not reported). On 25-AUG-2008, the patient fainted and experienced dizzy and vaso vagal at the office after getting GARDASIL. The patient stayed at the office for a little while for monitoring and was released soon after. No lab diagnostic studies were performed. The patient recovered on the same date as injection date. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334185-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	NY	WAES0810USA03188	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Information has been received from a physician concerning a 16 year old female who was vaccinated with the first dose of GARDASIL IM, 0.5 ml. One month after, the patient experienced Bell's Palsy. On an unknown date, the patient completed the three dose series and the symptom disappeared. The patient sought medical attention with the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334186-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	15-Oct-2008	15-Oct-2008	0	17-Nov-2008	12-Feb-2009	--	WAES0810USA03232	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oropharyngeal pain, Pyrexia

Symptom Text: Information has been received from a consumer concerning hr school age daughter with a history of getting a fever about once a month, who on 15-OCT-2008, was vaccinated with GARDASIL (lot # not provided). Concomitant therapy included influenza virus vaccine (unspecified). On 15-OCT-2008, within one hour after the vaccination, the patient experienced fever and sore throat. The fever is continuing at the time of the report on 16-OCT-2008, and was recorded as 102 degrees F. The patient's sore throat persisted. The patient did not seek medical attention. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: Fever

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334187-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	25-Sep-2008	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA03243	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Information has been received from a physician concerning a 13 year old female who "about 2 to 3 weeks ago" on approximately 25-SEP-2008, received the first dose of GARDASIL vaccine (lot# not provided). Subsequently the patient experienced joint pain in one of her knees. The patient sought medical attention and he Orthopedic doctor said it could be from the vaccine. The patient's joint pain in one of knees persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334188-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA03288	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a 20 year old female who was vaccinated with three doses of GARDASIL. There was no concomitant medication. Only after the third dose, the patient broke out in hives on her face, arms and legs. Subsequently, patient recovered. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334189-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA03291	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury

Symptom Text: Information has been received from a nurse practitioner concerning a 19-20 year old female who was vaccinated with the first dose of GARDASIL, and then after receiving the vaccine, the patient had fell off the exam table and hit her head on the counter. The nurse practitioner reported that the patient recovered, and then two months later had received the second dose of the vaccine. Unspecified medical attention was sought. No further AE information provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334190-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		08-Dec-2008	18-Dec-2008	TX	WAES0810USA03309	18-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a physician concerning a female who on an unknown date was vaccinated with the first dose of GARDASIL vaccine. Concomitant therapy included antibiotic (unspecified). The physician reported that about 1 day after the patient received the shot of GARDASIL vaccine, she experienced a rash over most of her body. The patient sought medical attention from the physician. Additional information has been requested

Other Meds: Antimicrobial (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334191-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	16-Oct-2008	16-Oct-2008	0	17-Nov-2008	12-Feb-2009	IL	WAES0810USA03355	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope

Symptom Text: Information has been received from a physician who was told that a female patient of another physician in the same practice, was vaccinated on 16-OCT-2008 with a dose of GARDASIL 0.5 mL IM. Subsequently, the patient fainted while in the office. The patient was unconscious for 20 minutes and was transported by ambulance to the Emergency Room. It was not known yet if the patient was admitted to the hospital or what treatment was given. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334192-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	PA	WAES0810USA03360	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a immunization coordinator concerning 2 or 3 patients who were vaccinated with GARDASIL. Subsequently the patients passed out after getting vaccinated with GARDASIL. All of the patients had recovered on unspecified date. The patients had sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334193-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jan-2007	01-Sep-2008	609	17-Nov-2008	12-Feb-2009	--	WAES0810USA03370	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Gluteous maxima	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received form a nurse practitioner concerning a 16 year old female patient who in 2007 was vaccinated with the three doses of GARDASIL (Lot numbers not available). the last month(September 2008), the patient developed abnormal pap smear after receiving all 3 doses of GARDASIL vaccine. the patient sought unspecified medical attention. Additional information is not expected.

Other Meds: Unknown

Lab Data: Pap test, abnormal.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334220-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-Dec-2008	08-Dec-2008	0	08-Dec-2008	18-Dec-2008	TX		18-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2791CA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0650X	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2658AA	0	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B023AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor

Symptom Text: Pt felt dizzy and got pale, never fainted, MD stated Pt always eating at school but had not eaten today. B/P 90/50, left clinic after 15 min and okay.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **334236-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	PA	WAES0810USA03375	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a adolescent female who was vaccinated intramuscularly with a 0.5ml dose of GARDASIL (lot # not reported). The patient fainted after receiving the vaccine. After she recovered. She stayed at the office for 15 minutes, as she was checking out she fainted again. Outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334237-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	14-Oct-2008	14-Oct-2008	0	17-Nov-2008	12-Feb-2009	--	WAES0810USA03376	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lip swelling, Nasal congestion, Oropharyngeal pain, Pyrexia, Throat irritation, Wheezing

Symptom Text: Information has been received from a nurse practitioner concerning a 25 year old female patient with a bee sting allergy, who on 14-OCT-2008, was vaccinated with the first dose of GARDASIL (lot # 660555/0278X), 0.5 ml, IM. There was no concomitant medication. On 14-OCT-2008, the patient developed a fever of 101 F, stuffy nose, wheezing, itching sore throat, and swollen upper middle lip about 18 hours after receiving the first dose of GARDASIL. The patient took an unspecified amount of diphenhydramine hydrochloride (BENADRYL), and most of the symptoms resolved by the patient phoned the nurse practitioner on 16-Oct-2008. The patient's only remaining symptom was a stuffy nose. The patient sought medical attention by phone. Additional information is expected.

Other Meds: None

Lab Data: None

History:

Prex Illness: Bee sting

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334238-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	15-Nov-2007	15-Nov-2007	0	17-Nov-2008	12-Feb-2009	FR	WAES0810USA03380	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling abnormal, Joint stiffness, Myalgia, Vaccine positive rechallenge

Symptom Text: Information has been received from a health professional concerning a 20 year old female with no known drug allergies and no pertinent medical history reported who on Information has been received from a health professional concerning a 20 year old female with no known drug allergies and no pertinent medical history reported who on 15-Nov-2007 was vaccinated with the first dose of GARDASIL. On 25-Jan-2008, the patient was vaccinated with a second dose of GARDASIL. There was no concomitant medication. After each dose of GARDASIL, the patient developed muscle aches, stiff joints with creaking and a strange feeling. The patient did not seek medical attention. The symptoms developed within hours of vaccinations and resolved within a day or 2. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334239-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA03385	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site cellulitis, Injection site pain

Symptom Text: Information has been received from a health professional concerning a female who on an unknown date was vaccinated with an unspecified dose of GARDASIL, 0.5 mL. Lot # was not provided. Subsequently, the patient developed severe pain and possible cellulitis at the injection site after the GARDASIL injection. The patient sought unspecified medical attention. At the time of reporting the patient had recovered on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334240-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Nov-2007	01-Jan-2008	50	17-Nov-2008	12-Feb-2009	--	WAES0810USA03388	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a health professional concerning and approximately 16 year old female with penicillin allergy who on 12-NOV-2007 was vaccinated with the first dose of GARDASIL vaccine, intramuscularly. On unspecified dates, the patient was vaccinated with the second and third doses of GARDASIL vaccine. Secondary suspect therapy included VARIVAX. Other concomitant therapy included PPD TINE TEST). About two months after completing the GARDASIL Vaccine vaccination series, in approximately 2008, the patient developed arm pain near the injection site and on the opposite of the arm, in the triceps area. The pain is not constant but it does seem to get worse with use. The patient did not see medical attention. At the time of reporting the patient had not recovered. On an unspecified date, was performed to the patient an X-ray and an ultrasound, results for both were normal. Additional information has been requested.

Other Meds:

Lab Data: X-ray, normal; Ultrasound, normal. PPD TINE TEST.

History: Penicillin allergies.

Prex Illness:

Prex Vax Illns:

Vaers Id: **334241-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA03395	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a consumer concerning her daughter who was vaccinated with her third dose of GARDASIL (therapy started date, route, site unknown). Subsequently the patient had been having pain all over her arm. The patient didn't seek medical attention. The patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334242-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Oct-2008	15-Oct-2008	6	17-Nov-2008	12-Feb-2009	--	WAES0810USA03396	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dehydration, Nausea

Symptom Text: Information has been from a physician concerning a 17 year old female who was vaccinated with a first dose of GARDASIL (lot #, route not reported) about "1 week ago", on approximately 09-OCT-2008. Yesterday, on 15-OCT-2008, the patient had office visit and complained of feeling dehydrated and nauseous. It was reported that the patient was sexually active, but on unspecified birth control. Urine pregnancy test was negative. At the time of reporting, 16-OCT-2008, the patient not recovered. Additional information has been requested.

Other Meds: (therapy unspecified)

Lab Data: urine beta-human - negative

History:

Prex Illness: Sexually active

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334243-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	10-Oct-2008	10-Oct-2008	0	17-Nov-2008	12-Feb-2009	--	WAES0810USA03397	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a female who was vaccinated with the first dose of GARDASIL in the "past 1 week". Subsequently, the patient developed a rash over most of her body in the "past 1 week". At the time of the report the was not recovered. The patient did not seek medical attention. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334244-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Sep-2008	Unknown		17-Nov-2008	12-Feb-2009	FR	WAES0810USA03415	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass, Injection site pain

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a 15 year old female who on 22-sep-2008 was vaccinated intramuscularly in the left arm with the first dose of GARDISAL. Subsequently the patient developed a pea sized "knot" or lump under the skin at the injection site. The time frame development of the lump was not specified at the time of the report. The lump was lender or sore to the touch. The patient was seen by a nurse and used warm compresses on the lump. At the time of reporting (17-Oct-2008) the patient was not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334245-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	15-Oct-2008	17-Oct-2008	2	17-Nov-2008	12-Feb-2009	--	WAES0810USA03417	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Paraesthesia oral, Urticaria

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female, who on 15-OCT-2008, was vaccinated with the first dose of GARDASIL, IM, in the deltoid. On 17-OCT-2008, the patient developed hives on the upper body and tingling of the lips. She was seen at the office and given diphenhydramine hydrochloride (BENADRYL). Her symptoms were improving. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334246-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA03481	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received form an advanced registered nurse practitioner concerning a teenage female who was vaccinated with GARDASIL vaccine. Subsequently the patient experienced fever. The fever lasted for 2 days. It was reported the patient sought unspecified medical attention. This was one of 3 reports from the same resource. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334247-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA03672	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ovarian cyst

Symptom Text: Information has been received from a consumer concerning her 19-year-old daughter with no medical history who was vaccinated with a 0.5 mL dose of GARDASIL (lot # not reported). There was no concomitant medication. On an uspecified date, the patient experienced cyst on ovaries after all three doses of GARDASIL. The caller did not have the dates for each dose. Ultrasound was performed. The patient was not recovered by the time of this report. The patient sought medical attention. No further information is available

Other Meds: None

Lab Data: Ultrasound, ovarian cyst

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **334248-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	26-Jun-2008	26-Jun-2008	0	17-Nov-2008	12-Feb-2009	FR	WAES0810USA03685	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female with Penicillin allergy and sulfa allergy and no previous medical history reported who on 24-Apr-2008 was vaccinated with the first dose of GARDISAL, IM. , and on 26-JUN-2008 was vaccinated with the second dose of GARDISAL 0.5ml. Concomitant therapy included ethinyl estradiol/ norethindrone acetate (LOESTRIN). On 26-Jun-2008, after receiving the second vaccination, the patient experienced fever. On an unspecified date, the patient recovered from fever. The patient sought medical attention by spoke to the nurse practitioner. Additional information has been requested.

Other Meds: Loestrin

Lab Data: None

History: Penicillin allergy; Sulfonamide allergy

Prex Illness:

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334249-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Feb-2008	01-Feb-2008	0	17-Nov-2008	12-Feb-2009	NM	WAES0810USA03689	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Pain in extremity, Wrong technique in drug usage process

Symptom Text: Information has been received from a nurse concerning her 13 year old female daughter with no pertinent medical history and no known drug reactions or allergies who in February 2008, was vaccinated with the first dose of GARDASIL vaccine, IM. On an unspecified date, the patient received the second dose of GARDASIL vaccine, IM. There were no concomitant medications. The nurse reported that her daughter experienced soreness of the arm after receiving the first and second dose of GARDASIL vaccine. The daughter recovered about 1-2 days after each vaccination. On 16-OCT-2008, the patient received the third dose of GARDASIL vaccine, IM at the tendon or joint on the arm. She was not able to lift her arm despite using ice and MOTRIM from 16-OCT-2008 for a few days. She is recovering and can move the arm now. But she is still experiencing soreness. the patient sought medical attention and consulted with the nurse's husband who is a physician. There were no lab or diagnostic studies performed. This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns: Pain~HPV (Gardasil)~3~13~In Sibling

Vaers Id: **334250-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Feb-2008	01-Feb-2008	0	17-Nov-2008	13-Feb-2009	NM	WAES0810USA03699	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Information has been received from a nurse concerning her 13 female daughter with no pertinent medical history and no known drug reactions or allergies who in February 2008, was vaccinated with the first dose of GARDASIL vaccine, IM. On an unspecified date, the patient received the second dose of GARDASIL vaccine, IM. On 16-OCT-2008, the patient received the third dose of GARDASIL vaccine, IM. There was no concomitant medication. The nurse reported that the patient experienced soreness after each dose of GARDASIL vaccine. The patient was treated with ice and MOTRIN. The patient recovered the next day after the first and second doses. The patient recovered two days after the third dose on 18-OCT-2008. The patient sought unspecified medical attention. There were no lab or diagnostic studies performed. This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **334251-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Aug-2008	01-Aug-2008	0	17-Nov-2008	13-Feb-2009	--	WAES0810USA03709	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: Information has been received from a consumer concerning her 23 year old daughter who in August 2008, was vaccinated with the first dose of GARDASIL. In August 2008, after vaccination, the patient experienced swollen nodes in her armpit since then. It was reported that the swelling started in her left armpit and then went away, and reappeared in her right armpit. At the time of the report, the swelling was in the left armpit. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334257-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Jun-2008	24-Jun-2008	0	09-Dec-2008	19-Dec-2008	MD		22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	19718U		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2640AA		Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Gaze palsy, Musculoskeletal stiffness

Symptom Text: Soon after receiving GARDASIL and MENACTRA vaccines patient, per mother's report. Felt lightheaded, eyes rolled up in head, went stiff and mom helped her to the floor. Patient was conscious with 1 min of being on ground.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334273-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	04-Nov-2008	04-Nov-2008	0	09-Dec-2008	13-Feb-2009	MA		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oxygen supplementation, Syncope

Symptom Text: Syncope 5 min. Oxygen treatment.

Other Meds: ORTHOTRYCYCLEN - 10

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **334282-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	31-Oct-2008	31-Oct-2008	0	09-Dec-2008	19-Dec-2008	MO		19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Oropharyngeal pain, Pyrexia

Symptom Text: Approximately 4 hours after receiving HPV vaccine developed fever and sore throat and nausea. Did not take temperature-no vomiting. Did not take any OTC medicine (TYLENOL, PEPTO-BISMAL, etc.). Symptoms lasted about 24 hours.

Other Meds: LEXAPRO KLONOPIN DEPAKOTE

Lab Data: N/A

History: Bipolar; allergy to ABISIFY

Prex Illness: Denies

Prex Vax Illns:

Vaers Id: 334285-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-Aug-2008	08-Sep-2008	17	09-Dec-2008	15-Dec-2008	TX		31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2662AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0507X	1	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Balance disorder, Diplopia, Dizziness, Fall, Gait disturbance, Headache, Labyrinthitis, Muscular weakness, Sensory loss, Tinnitus

Symptom Text: 8-22-08 received. Two weeks after receiving HPV #2 and MENACTRA (9-8-08), symptoms consisted of loss of sensation in feet, loss of balance due to no feeling in feet; walks only with assistance. 12/19/2008 MR received for DOS 9/16-19/2008 with D/C DX: Acute labyrinthitis. Headache. Dizziness. Difficulty walking. Pt presented with 1 week hx of difficulty walking, dizziness, frontal h/a after transfer from local facility. Pt reports leg weakness, falling to the left, tinitis and occ double vision. PE (+) for 4/5 motor strength in legs, slow unsteady gait and unable to walk with eyes closed. Pt had some improvement on amitriptyline and d/c.

Other Meds: None

Lab Data: Cat Scans; Spinal Tap; Nerve induction tests. Labs and Diagnostic Studies: X-ray skull WNL. MRI/MRA brain WNL. CT head (-). Audiogram (-). Vestibular nystagmograph WNL except for some evoked double vision and nausea. Later MRI brain (

History: Allergic to tree pollen PMH: none

Prex Illness: None

Prex Vax Illns: Severe hives~Hep B (no brand name)~3~8~In Patient

Vaers Id: **334297-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Nov-2008	10-Nov-2008	0	09-Dec-2008	15-Dec-2008	MN		30-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB260AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0843X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Disorientation, Dizziness, Respiratory rate increased, Syncope, Tonic clonic movements, Tremor, Unresponsive to stimuli

Symptom Text: Approx 2 min after admin of vaccines, mother of pt reported pt was "playing" & acting silly, then started to "shake all over". Initially rhythmic jerking of arms & legs & flexion of neck & rapid respirations were observed for 15 seconds. Approx 2-3 later, again had generalized jerking of arms & legs- lasted -1 min. Pt was given BENADRYL 50mg IM in clinic & transported to hospital. DC from hospital the next day. Diagnosed with Convulsive syncope. Had EEG as out pt on 11/13/08-normal negative CT screen at hospital. Blood sugar in ambulance was 55. 1/26/09-records received for DOS 11/10-11/11/08-DC DX: Likely convulsive syncope can not rule out seizure due to hypoglycemia. Presetned after convulsive syncope following HPV and Hep A vaccine. Prior to event C/O feeling dizzy and flailing arms and legs with tonic/clonic movements with second episode accompanied by rapid respirations and unresponsive for several minutes and not oriented to time and place.

Other Meds:

Lab Data: BP 132/100, 5 min later 128/100; Pulse 102, then 79 upon arrival at hospital; vitals, CBC, BMP, EKG & head CT were WNL with the exception of serum glucose of 54 1/26/09-records received-CBC,BMP, EKG and Head CT normal. Serum glucose 54.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334305-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Oct-2007	17-Oct-2007	0	09-Dec-2008	19-Dec-2008	AZ		19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	10620	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	42330AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2825AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Migraine

Symptom Text: When patient was in for her 12 yr. WCC mom refuse HPV #2 due to "reaction" of severe migraine. 1st HPV was given on 10-17-07 & patient end up with migraine headache that night & ended up in ER- got meds.

Other Meds:

Lab Data: Unsure of what was done in ER

History: ENURESIS

Prex Illness:

Prex Vax Illns:

Vaers Id: **334312-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	07-Nov-2008	08-Nov-2008	1	09-Dec-2008	19-Dec-2008	AZ		19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash

Symptom Text: Pt states rash developed on trunk, arms & head itches since 1 day post receiving GARDASIL #1. Rash is lessening but still has it. Denies HA of fever. Has not taken any rx.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334319-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	29-Nov-2007	29-Nov-2007	0	09-Dec-2008	19-Dec-2008	IN		05-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	2	Unknown	Intramuscular	DTAP MNQ

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope

Symptom Text: Pre-syncopy, tonic

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334323-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	18-Dec-2007	15-Feb-2008	59	09-Dec-2008	15-Dec-2008	PA		06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	0	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Asthenia, Brain neoplasm benign, Convulsion, Headache, Muscular weakness, Urinary incontinence

Symptom Text: 12/18/07 given 1st GARDASIL vaccine. 2/15/08 admitted to hospital with sudden onset lower extremity weakness unable to walk resolved w/in 24 hours. Neurological w/u revealed benign brain cyst & working diagnosis is seizure. Parents told by Neurologist could have been caused by GARDASIL. 2/27/09-records received presented to ED 2/14/08 with C/O 3 days of leg weakness and 1 episode of urinary incontinence at bedtime and mild CP. Occasional infrequent headaches. Impression: Benign brain cyst.

Other Meds: None; Given Rxs for Flexeril/ Mos

Lab Data: EEG-WNL; MRI; CT; EEG; saw Neurology and Neurosurgery. 2/27/09-records received-MRI brain abnormal showed right frontal lobe cystic mass.

History: Mild Scoliosis

Prex Illness: Back Pain

Prex Vax Illns:

Vaers Id: **334330-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Dec-2008	03-Dec-2008	0	09-Dec-2008	19-Dec-2008	CT		19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	3	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gait disturbance, Immediate post-injection reaction, Nausea, Pallor, Vomiting

Symptom Text: Pt received GARDASIL #3 and within a five minutes became pale, limp, nauseous. Pt vomited twice, after lying down for about 20 minutes, recovered fully.

Other Meds: Metformin

Lab Data:

History: Type II Diabetes

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334342-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Jul-2008	18-Jul-2008	0	09-Dec-2008	19-Dec-2008	OR		19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Dizziness, Fatigue, Headache, Pain in extremity, Pyrexia

Symptom Text: Patient had fever, hot, chilled, headache, dizzy and fatigue. Arm pain 3 days after receiving GARDASIL.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334345-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	04-Nov-2008	05-Nov-2008	1	09-Dec-2008	15-Dec-2008	NY		23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Dysarthria, Dysgeusia, Eye irritation, Facial palsy, Guillain-Barre syndrome, Hypoaesthesia facial, Hyporeflexia, Swelling face

Symptom Text: Bilateral facial paralysis. 1/16/2009 MR received for DOS 11/10-13/2008 with D/C DX: Guillain-Barre Syndrome. Pt presented to ER with 7 day hx of L eye burning, numbness of the face, facial palsy. Initially dx with Bell's Palsy by PCP. Pt developed taste alterations and facial swelling. PE (+) for bilateral facial nerve paralysis, slurred speech , decreased muscle strength shoulder area, slightly decreased DTRs. Started on steroids without progression of symptoms. D/C for outpt f/u.

Other Meds:

Lab Data: None. Labs and Diagnstics: MRI brain WNL. CXR WNL. Brain CT WNL. HSV IgM (-). Alk phos 250. Mycoplasma Ab IgG 1.38. IgM (-). TSH 5.13. Free T4 WNL. CSF cx (-). CSF WBCs 8. CSF RBCs(+). CSF glucose 94. CSF protein 26. No oligoclona

History: Mild asthma. PMH: asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334346-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Nov-2008	24-Nov-2008	0	09-Dec-2008	19-Dec-2008	MT		22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest discomfort, Pain, Pharyngeal oedema, Pyrexia

Symptom Text: 2 hrs after vaccination developed body aches, 100 fever. Woke during night with feeling that throat was swelling. Was breathing normally. When woke in the morning, chest felt tight.

Other Meds: None

Lab Data: Strep test negative/ no lymphademapathy or pharyngeal inflammation

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334357-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Oct-2008	21-Oct-2008	1	09-Dec-2008	19-Dec-2008	NE		22-Dec-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0381X	1	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2659AA	1	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B028AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pain, Pain in extremity, Pyrexia

Symptom Text: Patient received shots 10/20/2008 woke up 10/21/2008 with, fever 101, dizzy, achy and sore arms fever lasted all day till approximately 8:30 pm. Treated with Benadryl and Tylenol as told by Hospital.

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334359-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
47.0	M	14-Nov-2008	Unknown		09-Dec-2008	19-Dec-2008	OR		19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: MA gave patient GARDASIL when patient needed Tdap. Will have patient return for Tdap.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334368-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	25-Nov-2008	01-Dec-2008	6	09-Dec-2008	19-Dec-2008	MO		19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dyspepsia, Swelling

Symptom Text: Patient telephoned 12/3/08. Stated she'd had stomach pain, heartburn and swollen uterus.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **334377-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Oct-2006	01-Nov-2006	5	09-Dec-2008	17-Dec-2008	PA		11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0800F	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Antibody test abnormal, Arthralgia, Autoimmune disorder, Condition aggravated, Connective tissue disorder, Immunoglobulins, Joint swelling, Musculoskeletal stiffness, Raynauds phenomenon, Systemic lupus erythematosus, Vaginal ulceration

Symptom Text: Nonspecific autoimmune/connective tissue disorder with joint pain, diagnosed after vaccine given. 3/9/09 Received Lupus consult medical records of 4/10/07-2/16/2009. FINAL DX: SLE; Raynaud phenonmenon; anticardiolipin antibodies; mild alopecia Records reveal patient experienced acute onset polyarthralgias in 10/06 3 days after HPV vaccine & lasted approx 4-6 wks. Had been referred to Rheum. Had scaly rash over elbows & knees. Had recurrence of polyarthralgias, stiffness & ankle swelling 2/2008. Had episode of vaginal ulcer x 1 in 4/2008 which was neg for herpes. No history of oral herpes. 5/2008 found to have polyclonal gammopathy & started on plaquenil w/great improvement. Had developed another vaginal sore thought to be psoriasis. BCP & acne meds d/c 2/09 when found to have pathologic antibody & started on lose dose ASA.

Other Meds: Minocycline; pt was on prior to vaccine

Lab Data: Positive ANA; positive DS DNA LABS: ANA (+) 1:64 0homogeneous pattern. UA w/RBC, WBC, 3+ leukocyte esterase. LFTs WNL. Total protein 8.4(H), ESR 29(H). CRP & RA factor WNL.

History: Psoriasis PMH: ANA neg prior to starting acne meds approx 1 yr prior. BCP started 11/06. Irregular menses. Family hx: psoriasis, ulcerative colitis, RA.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334386-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Oct-2008	18-Oct-2008	2	09-Dec-2008	19-Dec-2008	CA		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised, Rash papular

Symptom Text: 21 Oct 2008 4:46 PM, Pts mom called and states that pts daughter was in on Thursday for the GARDASIL inj and noticed on Saturday a pimple like rash all over her back/stomach/legs/arms...mom would like to know if it is due to the INJ. It was her 2nd dose. Pts mom also states no pain/not itching no fever or other side effects. Mom would like a call back on cell phone. PT's mom also made an appt for derm on 11-6-08. 21 Oct 2008 8:15 PM, Dr inform mom that it is less likely related with the injection site not first time but always possible. Asked her if she would like me to evaluate her before derm appointment...ok to have her come in this week to be seen.

Other Meds: None

Lab Data: None

History: Keratosis Pilaris, dermatitis, sulfa allergy

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334402-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Nov-2008	04-Nov-2008	0	09-Dec-2008	16-Jan-2009	GA		16-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2760AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Oropharyngeal pain, Photosensitivity reaction, Pyrexia, Vomiting

Symptom Text: Headache, described as severe. Photosensitivity, sore throat, fever vomiting- Used Tylenol, Motrin, Lortab 5mg

Other Meds: None

Lab Data: CBC, CRP=2

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334405-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	07-Nov-2008	09-Nov-2008	2	09-Dec-2008	13-Feb-2009	MI		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024AA		Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB320AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0072X		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2728AA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site pain, Injection site warmth

Symptom Text: Upper left arm, lateral aspect, size: 105 mm x 80 mm. Upper right arm, lateral aspect, size: 105 mm x 70 mm. Both sites red, firm, mildly tender, and warm. No fluctuation or fevers.

Other Meds: None

Lab Data:

History: Allergic to Penicillin

Prex Illness: Healthy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334464-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Nov-2008	Unknown		09-Dec-2008	30-Jan-2009	CO		01-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0991X	1	Left arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024AA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2622AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0070X	0	Right arm	Intramuscular	
FLU	SANOFI PASTEUR	U2797AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site inflammation, Pain, Pyrexia

Symptom Text: Fever, body aches, inflammation at site of injection. Patient went to emergency room treatment with Rocephin and Keflex.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334478-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	10-Jul-2008	20-Jul-2008	10	09-Dec-2008	13-Feb-2009	PA		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling

Symptom Text: Large swollen area developed 10 days after GARDASIL shot at the site of shot on her arm. Not red or warm. Mildly painful.

Other Meds: FLUORIDE

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334503-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Apr-2008	24-Apr-2008	0	09-Dec-2008	12-Feb-2009	KY		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0962F	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Dyspnoea, Hypoaesthesia, Hypoaesthesia facial, Hypoaesthesia oral

Symptom Text: Numbness in legs, lips and Rt. side of face, shortness of breath, chest pain, symptoms happened about 2 hours after immunization, numbness on lips and Rt. side of face still happens occassionally, along with chest pain. pt. states ER MD said high risk of blood clots

Other Meds: None

Lab Data: says Follow-up tests done in ER at hospital

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334508-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	M	20-Oct-2008	08-Nov-2008	19	09-Dec-2008	01-Feb-2009	CT		02-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2754AA	5	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0548X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass, Injection site pain

Symptom Text: Painful cystic/lump to area around injections site. No response to KEFLEX. Had sx started 3 wks after injection - ??

Other Meds: None

Lab Data: Sonogram of area, hypoechoic mass

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334515-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Nov-2008	17-Nov-2008	0	09-Dec-2008	12-Feb-2009	CA		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral

Symptom Text: 13 Y/O received 3rd dose of GARDASIL at 10 am in right arm developed swelling of right hand in the evening. On exam she had edema of fingers & palm of the hand with no erythema, there was no tenderness on the hand. No fever good cap refill good radial pulse, sensory intact. Injection site looked good. Patient was examined 28 hrs after the vaccine was given.

Other Meds: N/A

Lab Data: N/A

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334559-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Nov-2008	18-Nov-2008	0	09-Dec-2008	12-Feb-2009	PA		02-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Unknown	FLU
	HIBV	SANOFI PASTEUR	UFF504AA	0	Right arm	Unknown	
	PNC	WYETH PHARMACEUTICALS, INC	D0L074	0	Left arm	Unknown	
	DTAPHE	GLAXOSMITHKLINE BIOLOGICALS	AC21B115CB	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: No adverse reaction after receiving wrong vaccines.

Other Meds: None

Lab Data: None

History: Shellfish

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334582-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	03-Dec-2008	04-Dec-2008	1	09-Dec-2008	12-Feb-2009	MD		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	NULL	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	NULL	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	NULL	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration

Symptom Text: Vaccine administered in left arm and next day area was red and had a 3-4cm induration.

Other Meds: NONE

Lab Data:

History: NO

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334597-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Dec-2008	02-Dec-2008	0	09-Dec-2008	06-Feb-2009	CA		06-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2814AA	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2833AA	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immunisation reaction, Pruritus, Swelling

Symptom Text: REACCTION TO MCV, SWOLLEN,ITCHY

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334609-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	27-Dec-2007	Unknown		09-Dec-2008	12-Feb-2009	NY		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Dermatitis allergic, Fatigue, Heart rate irregular, Hypertension, Menstruation delayed

Symptom Text: I took my HPV shots abroad. The first shot I took was on December 27th 2007. It didn't feel anything special after this first one. I took my first shot before March 1st 2008. Days after my second shot, I start growing out breakouts (which looks like skin allergy) on my face. It has been bothering me until now. I have also experienced increase of hair loss compared to before taking the shot. After taking the 3rd HPV shot, my skin allergic problem has worsen. It also affected my monthly menstruation cycle. It basically shifted my cycle from normally 30 days to now 34 days. After having taken all 3 shots, i feel like i get tired alot easier than before. I went for an annual body check, I was now told that I have high blood pressure. My cardio result showed that I have irregular heart beat according to the nurse.

Other Meds:

Lab Data: I have not done any lab test but I had consulted one doctor regarding my irregular period. He said it was due to irregular hormonal change. However, I had not experienced that before taking the HPV shot.

History:

Prex Illness: none

Prex Vax Illns:

Vaers Id: **334611-1 (D)** **Related reports:** 334611-2; 334611-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	26-Nov-2008	08-Dec-2008	12	10-Dec-2008	10-Dec-2008	IL		04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN	MEDIMMUNE VACCINES, INC.	500569P		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2730AA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0070X	2	Left arm	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Cold sweat, Death, Dizziness, Headache, Malaise, Nausea, Urinary incontinence

Symptom Text: Patient, a previously healthy 19 year-old female college freshman died suddenly yesterday, approximately 10 days after receiving Gardasil & menningococcal vaccines. Vaccines were administered by a medical provider in her hometown while she was home for the Thanksgiving holiday, sometime around 11-28-08. She had a medical appointment pending for 12-8-08 (the day of her death) with the Student Health Service; medical clerk had entered "possible seizure" as the reason for making the appointment. Patient had no history of epilepsy. She complained of a headache and not feeling well in the 24 hours prior to her death. She went to bed at 10:30 PM on 12-7-08, in her dorm room with a roomate. She appeared to still be sleeping the next morning when her roomate left for class. Her body was discovered still in bed around 5 PM that day (12-8-08) with rigor mortis. No history of substance abuse, alcohol intake, or depression or other mental health issues. She was a happy, achieving student. This report is filed by a friend of patient's parents, who is a physician (board certified internal medicine & geriatrics). Report also filed online today with the FDA. Patient's mother can be reached at home for additional details. Memorial service & funeral 12-12-08 and 12-13-08. Only known past medical history requiring physician attention was facial acne. 12/10/2008 Recived records from health center via CDC. Seen 11/3/08 with c/o sore throat, cough, muscle aches and nasal d/c. PE (+) for pharyngeal erythema, purulent nasal drainage, nasal turbinate changes, and lymphadenopathy. Assessment: Probable viral URI with ? sinusitis. Tx: Biaxin. Received from CDC via email: The patient had no previous health problems. She was a freshman and was seen at the college health clinic only once on 11/3/08 for sinusitis. She was on Yaz birth control pills and a topical acne medication. After the death, police questioned her roommate who said that the pt did go out on the evening of 12/6/08 and had a few alcoholic drinks, but not an excessive a

Other Meds: None known. ?? oral contraceptive or an antibiotic for acne.

Lab Data: Autopsy performed 12-9-08 was unrevealing per family verbal report to me; no signs of intracranial bleed, meningitis, cardiomyopathy, trauma. Toxicology report still pending at this time. Post-mortem tox screen (-).

History: Acne. PMH: PCN allergy. Acne. On OCs (Yaz). 12/10/2008 Recived records from health center via CDC. Seen 11/3/08 with c/o sore throat, cough, muscle aches and nasal d/c. PE (+) for pharyngeal erythema, purulent nasal drainage, nasal turbinate changes, and lymphadenopathy. Assessment: Probable viral URI with ? sinusitis. Tx: Biaxin.

Prex Illness: None.

Prex Vax Illns:

Vaers Id: **334611-2 (D)** **Related reports:** 334611-1; 334611-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	20-Nov-2008	08-Dec-2008	18	11-Dec-2008	12-Dec-2008	--		12-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Autopsy, Death, Headache, Malaise

Symptom Text: Previously healthy 19-year old female college freshman found dead in her dorm bed approximately 10 days after receiving GARDASIL and meningitis immunizations over Thanksgiving break while visiting family in her hometown. She had very recently made a doctor appointment for the afternoon of Mon. 12/08/2008- pending at the time of her death. She did not show up for the appointment, was found in her bed in the dorm room dead with rigor mortis. The reason noted by intake clerk at student health for making a medical appointment was "possible seizure", patient had no prior medical history of epilepsy or any other disorder, was physically fit and on the crew team. She was last seen alive the evening of 12/7/08. She had talked on the phone to her out-of-state boyfriend and chatted with her dorm roommate. She had complained of a headache and not feeling well that day. She went to bed at 10:30 PM. In the AM, her roommate arose and thought patient was still asleep. The roommate left for the day of classes. Patient did not return friends text messages that day, leading to the finding of her body in bed in the dorm room about 5 PM 12/08/08. Preliminary autopsy done 12/09/08 shows no obvious cause of death per family's verbal report to me. Toxicology results are pending, due back in 6 weeks. Patient had no history of substance abuse and is not thought to be a suicide risk. She had been thriving in college and happy. No suspicions of foul play. Patient was a non-smoker. Funeral is planned for Sat 12/13/08. Tragic end for a brilliant and beautiful young woman. Please investigate possible role of GARDASIL and/or menigococcal vaccine in this death. This report submitted by patient's family friend MD, Internal Medicine and Geriatrics. Thank you for your prompt attention to public safety.

Other Meds: Patient also reportedly received a meningococcal vaccine at the time of GARDASIL vaccine.

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **334611-3 (D)** **Related reports:** 334611-1; 334611-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	28-Nov-2008	07-Dec-2008	9	24-Dec-2008	26-Dec-2008	--	WAES0812USA02288	29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death, Dizziness, Headache, Malaise, Nausea

Symptom Text: Initial and follow-up information has been received for a direct report from the government(VAERS#334611) concerning a previously healthy 19 year old female happy achieving college freshman with no history of substance abuse, alcohol intake, or depression, or other mental health issues, who was vaccinated on approximately 28-NOV-2008 with a dose of GARDASIL, lot number not reported. Concomitant therapy included: meningococcal vaccine (unspecified). It was reported that on 08-DEC-2008, the student died suddenly, approximately 10 days after receiving GARDASIL and meningococcal vaccine (unspecified). The vaccines were administered by a medical provider in her hometown, while she was home for the Thanksgiving holiday. The student emailed campus health services on Sunday night (07-DEC-2008) complaining of dizziness, headache, and nausea. Student Health Services at her University indicated that it might be a seizure, and arranged an appointment for her to be seen in the health services clinic that Monday (08-DEC-2008) (the day of her death). The medical clerk had entered "possible seizure" as the reason for making the appointment. There was no referral to an Emergency Room (ER). She had no history of epilepsy. She complained of a headache and not feeling well in the 24 hours prior to her death. She went to be at 10:30 PM on 07-DEC-2008, in her dorm room with a roommate. She appeared to still be sleeping the next morning when her roommate left for class. Her body was discovered still in bed around 5:00 PM that day (08-DEC-2008) with rigor mortis. Follow-up information reported that the county medical examiner reported that "examinations performed Dec. 9 were inconclusive, but said there were no signs of foul play and no signs of meningitis or other life threatening infectious diseases. Further tests would be performed and it may take up to six weeks for a final determination." This was originally reported by a physician. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334646-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Nov-2008	Unknown		09-Dec-2008	12-Feb-2009	WA		03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: @ 5 hours post immunization developed 2 hives on (L) shoulder/neck. Symptoms observed by father not health care professional.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **334667-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Dec-2008	05-Dec-2008	2	09-Dec-2008	12-Feb-2009	VA		12-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
IPV	SANOFI PASTEUR	A11092	2	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1448U	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB320AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Pyrexia, Rash

Symptom Text: 12/03/08, Hep A, HPV, IVP administered. 12/05/08, red, non-raised rash bilateral antecubitals. 12/07/08, fever, high 102+/-. 12/08/08, dizziness. 12/09/08, temp 103.9 (T). Denies nausea/vomiting, rash remains. Alert and oriented c/o dizziness, advised TYLENOL prn and referred to PCP to seek medical care immediately if symptoms worsen.

Other Meds:

Lab Data:

History:

Prex Illness: None known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334679-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	20-Nov-2008	20-Nov-2008	0	09-Dec-2008	12-Feb-2009	CA		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	UNK	UNKNOWN MANUFACTURER	C2910AA		Left arm	Unknown	
	TD	MASS. PUB HLTH BIOL LAB	A008B		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0279X		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Dizziness, nausea.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334777-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Dec-2008	03-Dec-2008	1	09-Dec-2008	12-Feb-2009	MA		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0947X	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1183X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site swelling

Symptom Text: About 24 hours after receiving VARIVAX in her left arm, patient noticed a large swollen itchy red area at the injection site on her left arm. She took BENADRYL 25mg, but it did not have much effect on symptoms. On exam 12-4-08, there is an 8cmx7cm red,indurate, swollen area on left upper arm.

Other Meds:

Lab Data: None

History: Penicillin

Prex Illness:

Prex Vax Illns:

Vaers Id: **334779-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	26-Nov-2008	26-Nov-2008	0	10-Dec-2008	22-Jan-2009	CO		23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2751AA	1	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB260AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0650X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Immediate post-injection reaction, Loss of consciousness

Symptom Text: Patient received HAVRIX, FLUZONE, GARDASIL. After receiving shots she was sitting on chair and felt really dizzy --> Fell on to floor (+LOC). She woke up on the floor. Approximately 5 to 10 after event, no pain, vitals normal, A&O X3.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334781-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Oct-2008	08-Oct-2008	2	17-Nov-2008	18-Dec-2008	--	WAES0810USA03726	18-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscular weakness, White blood cell count

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 06-OCT-2008 was vaccinated with the first dose of GARDASIL vaccine (lot #660620/0571X). On 08-OCT-2008 the patient experienced muscle weakness in arms and legs when they called the office. On 09-OCT-2008 the patient called back still complaining of the issue and patient was advised to go to the ER. The patient sought unspecified medical attention. The white blood count test was performed. Office has not heard form patient since. Additional information has been requested

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334782-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Aug-2008	22-Aug-2008	0	17-Nov-2008	12-Feb-2009	TX	WAES0810USA03732	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus generalised

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female with sulfa drugs allergy and no pertinent medical history who on 22-Aug-2008 was vaccinated IM with GARDASIL. Concomitant therapy included meningococcal vaccine (manufacture unknown). The registered nurse reported that on 22-Aug-2008 the patient developed generalized itching after receiving her first dose of GARDASIL. On unspecified date the patient recovered. No lab diagnostics were performed. The patient sought medical attention, "AE was mentioned at the next office visit". Additional information has been requested.

Other Meds:

Lab Data: None

History: Sulfonamide allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **334783-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-May-2007	07-May-2007	0	17-Nov-2008	03-Feb-2009	OR	WAES0810USA03737	20-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bronchitis, Choking, Cough, Dyspnoea, Haemoptysis, Hypoxia, Livedo reticularis, Nodule, Oxygen saturation decreased, Peripheral coldness, Pulmonary vasculitis, Skin discolouration, Sleep disorder, Subclavian artery stenosis

Symptom Text: Information has been received from a physician concerning an 18 year old female who was vaccinated with the third dose of GARDASIL vaccine(dose, route and lot# not reported). The patient might have developed vasculitis after receiving the first dose of GARDASIL vaccine. After the third dose of GARDASIL vaccine, a pulmonologist diagnosed that the patient with vasculitis of the lungs. The patient sought medical attention for her adverse experience and then the patient recovered from the vasculitis of the lungs. The pulmonologist attributed the vasculitis to GARDASIL vaccine. Additional information has been requested. 1/27/2009 MR received from vascular, pulmonary and sleep clinics. Pt seen 3/3/2008 in Vascular clinic for abnormal chest CT which showed an subclavian vein stenosis with collaterals seen to supply R arm. CT done to r/o PE due to SOB. No dx noted. Seen in pulmonary clinic 3/31/2008 for eval of hypoxia. In Jan 2008 pt developed cough with blood tinged sputum. DX with Bronchitis with low O2 sats, now improved, however cough remains with occasional choking episodes. Also recently dx with Livido Reticularis due to lacy mottling and coolness of the distal extremities. Reports subQ nodules after HPV shots. PE (+) for lacy reticular rash in arms and legs. Deep coughing spells noted by parent. No interstitial lung disease and unlikely pulmonary HTN. Referred to sleep clinic. Seen in sleep clinic for choking/coughing episodes at night. On altered school schedule due to sleep disturbances. Purple discoloration of legs noted on PE. 1/23/09 07-JAN-2009, Dr provided to CDC most of the requested information and the following additional details: Concomitant medication: prn Zyrtec; no known drug allergies; concurrent condition? / AE?: livedo reticular rash, all over body, on & off from May 2007, around time of vaccines; OTC cortisone cream ineffective; referred to rheumatologist for rash on 29-JAN-2008 - according to consult note, patient had the same rash on her feet "years before"; on 27-FEB-2008, a CT

Other Meds: Unknown

Lab Data: Unknown. Labs and Diagnsotics: Chest CT w/ evidence of possible R subclavian vein stenosis. CXR WNL. Echo WNL. ANA (-), ESR (-), CRP (-), Normal complement C3, C4, TSH, LFTs Chem and CBC. PFTs with mildly low DLCO, otherwise WNL. Iron

History: Unknown. PMH: Acne. Migraines. NKDA.

Prex Illness:

Prex Vax Illns:

Vaers Id: **334784-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA03841	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: Information has been received from a consumer concerning her daughter who was vaccinated with a first dose of GARDASIL (lot number, injection site and route not reported). Subsequently the patient experienced swollen glands. The patient sought medical attention at a physician's office. The outcome of the patient's experience was unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334785-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	NJ	WAES0810USA03918	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from an office manager concerning a 17 year old female who was vaccinated with the third dose of GARDASIL. The patient then tested positive for HPV. The patient went to her obstetrician and tested positive for HPV. The office was concerned that the vaccine caused the patient to test positive for HPV. No further information is available.

Other Meds: Unknown

Lab Data: diagnostic laboratory - Human papilloma virus test positive.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334786-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	14-Oct-2008	19-Oct-2008	5	17-Nov-2008	12-Feb-2009	--	WAES0810USA03919	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site urticaria, Urticaria

Symptom Text: Information has been received from a pharmacist concerning a 24 year old female with no pertinent medical history or known allergies, who on approximately 14-OCT-2008, was vaccinated with the second dose of GARDASIL (route and site not reported). Concomitant therapy included ethinyl estradiol (+) levonorgestrel (ALESSE). On approximately 19-OCT-2008, (five days after vaccination), the patient experienced localized urticaria in the left arm. As of 21-OCT-2008, the urticaria has extended from the injection site to the forearm. No laboratory test was performed. Additional information has been requested.

Other Meds: ALESSE

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334787-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Apr-2007	Unknown		17-Nov-2008	12-Feb-2009	MT	WAES0810USA03824	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a consumer concerning her 21 year old daughter with no pertinent medical history or known allergies who in approximately April 2007, was vaccinated with the third dose of GARDASIL 0.5 ml, IM. Concomitant therapy included PAXIL and hormonal contraceptives (unspecified). It was reported that after the patient received GARDASIL, had a Papanicolaou test positive for HPV. The patient did not know which strain of the virus it is from. There were no Papanicolaou test done during the series, so she did not know if she would have tested positive before or after it was reintroduced. It was reported that a Papanicolaou test done before the vaccination series was "normal". The reporter did not know where the series begun. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Hormonal contraceptives; PAXIL

Lab Data: Pap test, normal; Pap test, positive for HPV

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334788-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	NJ	WAES0810USA03930	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the first dose of GARDASIL. Subsequently, the patient experienced severe flu-like symptoms after receiving of vaccine. No further information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334789-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	01-Jan-2007	01-Oct-2008	639	17-Nov-2008	12-Feb-2009	--	WAES0810USA03937	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician assistant concerning a 26 year old female with no medical history or allergies who was vaccinated intramuscularly with all three GARDASIL vaccine (lot# not reported) on time last year, in 2007. This month (OCT 2008) the patient was diagnosed with HPV(strain not known). It was reported that a PAP test was performed, outcome was unknown. Concomitant medication included Drospirenone (+) YAZMIN. The patient sought medical attention at physician's office. At the time of report the patient is recovering. Additional information is not expected.

Other Meds: YAZMIN

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334790-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Oct-2008	20-Oct-2008	4	17-Nov-2008	22-Jan-2009	TX	WAES0810USA03951	23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Neck pain, Pharyngeal oedema, Swelling face

Symptom Text: Information has been received from a physician concerning a 11 year old female patient with no pertinent medical history and no drug reactions or allergies, who on 16-OCT-2008, was vaccinated, IM, with the first 0.5 ml dose of GARDASIL. Concomitant therapy included influenza virus vaccine administered on 16-OCT-2008. On 20-OCT-2008, the patient experienced left-side facial swelling, left neck pain and "a feeling like her throat is swollen". The patient was examined in the office on 21-OCT-2008, and a cervical x-ray has been ordered. The patient was scheduled for a consultation with an unspecified ENT specialist on the afternoon of 21-OCT-2008. At the time of reporting, the adverse events were ongoing. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334791-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Oct-2008	01-Oct-2008	0	17-Nov-2008	12-Feb-2009	MI	WAES0810USA03955	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: Information has been received from a physician concerning a 12 year old female with no pertinent medical history, no known allergies or drug reactions, who on 01-OCT-2008 was vaccinated with the first dose of GARDASIL IM. Concomitant therapy included VARIVAX (route and site not reported). On 01-OCT-2008 the patient experienced syncope. The patient was exiting the office and fainted hitting her head. On 20-OCT-2008, the patient recovered. A computed axial tomography was performed (results not reported). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **334792-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	MO	WAES0810USA03956	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician's assistant concerning a female who was vaccinated with the first dose of GARDASIL vaccine (site and route not reported). Concomitant therapy included Drospirenone (+) YAZ, prescribed at the same time as vaccination. On an unknown date the patient experienced hives. the physician's assistant believed that hives were caused by the birth control pills. Additional information has been requested.

Other Meds: YAZ

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334793-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Sep-2008	01-Sep-2008	0	17-Nov-2008	12-Feb-2009	CA	WAES0810USA03960	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Loss of consciousness

Symptom Text: Information has been received from a physician concerning a female who in September 2008, was vaccinated with the first dose of GARDASIL (route and site not reported). It was reported that 2 to 3 minutes after recieveing the vaccine, the patient experienced dizziness and blacked out. The patient was unconscious for approximately 1 minute. The patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334794-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Sep-2008	Unknown		17-Nov-2008	12-Feb-2009	MD	WAES0810USA03962	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: Information has been received from a nurse concerning a 16 year old female who on 01-AUG-2008 was vaccinated with the first dose of GARDASIL vaccine (route and site not reported), on 19-SEP-2008 was vaccinated with the second dose of GARDASIL vaccine (route and site not reported). On an unknown date after receiving second dose of vaccination, the patient developed swollen lymph nodes under both arms. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334795-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	14-Oct-2008	14-Oct-2008	0	17-Nov-2008	12-Feb-2009	AZ	WAES0810USA03986	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise, Oropharyngeal pain, Syncope

Symptom Text: Information has been received from a physician concerning a 8 year old female, who on 14-OCT-2008, was vaccinated with the first dose of GARDASIL, I. M. Concomitant therapy included unspecified flu vaccine manufactured by Sanofi. Subsequently, the patient fainted within two hours. The patient was ill and had a sore throat on the same day that received GARDASIL. Subsequently, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness: Sore throat

Prex Vax Illns:

Vaers Id: **334796-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	04-Sep-2008	11-Sep-2008	7	17-Nov-2008	12-Feb-2009	CT	WAES0810USA03998	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash papular, Rash pruritic

Symptom Text: Information has been received from a physician concerning a 13 year old healthy female with no known drug allergies reported who on 04-SEP-2008 was vaccinated with GARDASIL concomitantly with VARIVAX (Oka/Merck), and on 11-SEP-2008, one week later, the patient experienced a rash on her forearm. The physician characterized the rash as papular and slightly pruritic. The patient was recovering. The patient sought physician's medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334803-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	NJ	WAES0810USA04005	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site warmth

Symptom Text: Information has been received from a physician concerning a number of female patients who were vaccinated with a dose of GARDASIL vaccine and after that felt heat in their arms, at the injection site. The patients sought unspecified medical attention. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information has been requested

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334804-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA04024	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Uterine inflammation

Symptom Text: Information has been received from a nurse who stated a family member of the patient reported a 15 year old female who was vaccinated with GARDASIL (dose, route and lot # were not reported). A family member of the patient told the nurse that after vaccination with GARDASIL the patient had inflammation of the uterus. No additional AE information reported. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334805-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	NY	WAES0810USA04112	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Limb discomfort, Malaise, Pain

Symptom Text: Information has been received from a consumer concerning her daughter who was vaccinated with the first dose of GARDASIL on an unspecified date. Subsequently, the patient "felt achy and not well, and her arm hurt" after vaccination. No problems were reported regarding the second and third doses of GARDASIL. At the time of the report, no additional AE information reported. This is one of several reports of siblings. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334806-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA04114	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling

Symptom Text: Information has been received from an advanced registered nurse practitioner concerning a patient who was vaccinated with GARDASIL. Subsequently, the patient experienced swelling at the injection that lasted for at lest one month after the vaccination with GARDASIL. This was one of 3 reports from the same resource. This is for a multiple patient report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334807-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA04115	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Information has been received from an advanced registered nurse practitioner concerning a patient who was vaccinated with GARDASIL. Subsequently the patient experienced joint pain that lasted for a week after the vaccination with GARDASIL. This was one of 3 reports from the same resource. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334808-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Aug-2008	16-Aug-2008	10	17-Nov-2008	12-Feb-2009	--	WAES0810USA04118	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Vaginal lesion

Symptom Text: Information has been received from a consumer concerning her 13 year old daughter with allergy to sulfa who on 06-AUG-2008 or 08-AUG-2008 received the first dose of GARDASIL vaccine injection, (lot# not provided). There was no concomitant medication. About ten days after receiving the vaccine, the patient started to lose her hair above the to right ear. At first the physician thought it was ring worm and had given her medication, name was unspecified. Since the spot did not get better, the patient saw a dermatologist. the dermatologist did a scraping of the spot and the patient was then diagnosed with alopecia. The consumer also reported that her daughter had a sore in her vaginal are. the patient's sore in vaginal area and alopecia persisted. Additional information has been requested.

Other Meds: None

Lab Data: Skin scraping revealed alopecia.

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **334809-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA04123	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning his daughter, an 11 year old female with no medical history or allergies who was vaccinated with a first 0.5ml and second dose of GARDASIL (lot # not reported) on an unknown date and a month ago, approximately in Sep 2008, respectively. There was no concomitant therapy. Subsequently the patient experienced injection site pain after both doses. The patient sought medical attention. She recovered on an unknown date. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334810-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	16-Apr-2008	Unknown		17-Nov-2008	12-Feb-2009	NJ	WAES0810USA04133	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0755U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site reaction, Injection site swelling

Symptom Text: Information has been received from a healthcare worker concerning a 22 year old female with no medical history and no drug allergies who on 16-APR-2008 was vaccinated with the first dose of GARDASIL 0.5 ml by IM. There was no concomitant medication. The patient has no reactions with her first dose. On 20-JUN-2008, the patient was vaccinated with the second dose of GARDASIL 0.5 ml by IM (lot# 658219/0755U). Subsequently the patient developed injection site reaction, redness, swelling and soreness on her arm. The patient was seen by the physician. The reaction lasted about one week. Then on an unspecified date, the patient recovered from the adverse experience. The patient did not receive the third dose yet. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334811-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	21-Oct-2008	21-Oct-2008	0	17-Nov-2008	12-Feb-2009	IL	WAES0810USA04142	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Feeling abnormal, Hypoaesthesia, Swelling

Symptom Text: Information has been received from a physician assistant concerning a 23 year old female, who on 21-OCT-2008, was vaccinated, IM, with the first dose of GARDASIL, 0.5 ml (Lot # 0152X). Concomitant therapy included drospirenone (+) ethinyl estradiol (YASMIN). On 21-OCT-2008, a few hours after receiving her first dose of GARDASIL, the patient experienced localized area of redness, swelling, numbness and a raw feeling on her chin. The patient's localized are of redness and swelling and numbness and a raw feeling on her chin persisted. It was reported that the patient sought medical attention: contacted the office by phone and an appointment in the office had been scheduled. Additional information was received from a physician assistant stating that the patient received GARDASIL in the morning and later that afternoon/evening, patient experienced swelling tin the jaw and chin. This was patient's first dose of GARDASIL. AE reported back around 22-OCT-2008. The patient had no significant medical history and no concomitant medication. Additional information has been requested.

Other Meds: YASMIN

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334812-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Sep-2008	16-Sep-2008	0	17-Nov-2008	12-Feb-2009	MD	WAES0810USA04152	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Dyskinesia, Loss of consciousness

Symptom Text: Information has been received from the mother of a 13 year old female with a history of mood disorder who on unspecified dates received the first and second doses of GARDASIL. On 16-SEP-2008 was vaccinated with a third dose of GARDASIL. There was no concomitant medication. After she received the 3rd dose on 16-SEP-2008, later that day she felt pain in her back and grabbed her spinal column. The patient lowered herself down to the floor to lie flat on the ground. She became unconscious and rhythmically moved one of her arms back and forth toward her head. This movement then stopped and she re-gained consciousness and opened her eyes. The entire episode lasted only about 1 to 2 minutes. She seemed fine and normal shortly thereafter. As a precaution she was taken to the Emergency Department of a local hospital where she had a number of tests. All of the test results were normal. She did not have to be admitted as an in-patient to the hospital. She has seemed normal ever since this incident occurred. She subsequently went to a cardiologist and a neurologist who specializes in pediatric epilepsy. The patient's mother said that the neurologist would like to do further testing of her daughter. Additional information has been requested.

Other Meds: None

Lab Data: Diagnostic laboratory, normal; Electrocardiogram, normal; Urinalysis, normal.

History: Mood disorder NOS

Prex Illness:

Prex Vax Illns:

Vaers Id: **334813-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Oct-2008	20-Oct-2008	0	17-Nov-2008	12-Feb-2009	--	WAES0810USA04160	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cyst, Influenza like illness

Symptom Text: Information has been received from a consumer concerning her daughter, a 12 year old female, who in April 2008, was vaccinated with the first dose of GARDASIL, 0.5 ml, IM (therapy site unknown). On 20-OCT-2008, the patient received the third dose of GARDASIL, 0.5 ml, IM (therapy site unknown). Concomitant therapy included a tetanus vaccine (manufacturer not specified) given at the same time in the opposite arm. "Within 24 hours of receiving 3rd dose of GARDASIL", she experienced flu-like symptoms and cyst on her toe. The patient sought medical attention. Physician assistant did a physical exam of the patient and evaluated cyst. At the time of reporting, patient had not recovered. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334814-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	01-Jan-2008	01-Jan-2008	0	17-Nov-2008	12-Feb-2009	AR	WAES0810USA04163	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection, Squamous cell carcinoma

Symptom Text: Information has been received from a nurse concerning a 28 year old female who is non-sexually active and still has an intact hyman who in January 2008, finished vaccination whith the complete GARDASIL series, 0.5ml, IM. A recent PAP test for this patient showed her to be positive for high risk HPV and atypical squamous cell of undetermined significance. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pat test, positive for high risk HPV and atypical squamous cells of undetermined significance

History:

Prex Illness: Not sexually active

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334815-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	06-Oct-2008	07-Oct-2008	1	17-Nov-2008	12-Feb-2009	--	WAES0810USA04188	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0930U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Musculoskeletal pain

Symptom Text: Information has been received from a physician assistant concerning an 18 year old female with penicillin allergy who on 06-OCT-2008 was vaccinated with her first dose of GARDASIL into the left deltoid (lot#: 658488/0930U). On 07-OCT-2008 the patient experienced shoulder pain on the same side as the arm where she received GARDASIL. The patient was seen in the office. Her pain was treated with Ibuprofen. The patient's shoulder pain persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334817-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	M	22-Oct-2008	22-Oct-2008	0	17-Nov-2008	12-Feb-2009	TX	WAES0810USA04326	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Pain in extremity, Wrong drug administered

Symptom Text: Information has been received from a registered nurse concerning an 11 year old male who on 22-OCT-2008 was vaccinated with a dose of GARDASIL vaccine, IM. No problems reported. Follow up information was received from a physician who reported that the patient came into the office for Tdap vaccine (unspecified), MENACTRA and VARIVAX (Oka/Merck) and he mistakenly received GARDASIL. The physician reported that the child experienced some soreness in his arm and weakness, but nothing adverse. The physician stated the the child was fine. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334818-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Nov-2007	01-Jan-2008	35	17-Nov-2008	12-Feb-2009	PA	WAES0810USA04334	11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Arthralgia, Dizziness, Feeling abnormal, Headache, Menstruation irregular

Symptom Text: Information has been received from a consumer concerning her 14 year old daughter with no pertinent medical history, allergies or drug reactions, who on 24-MAY-2007 was vaccinated with the first dose of GARDASIL 0.5 ml IM, second dose on 26-JUL-2007 and third dose on 27-NOV-2007. There was no concomitant medication. In January 2008, the patient experienced hair loss, "brain fog", headache, dizziness, joint pain and irregular periods. Blood work was done (results not reported). As of 23-OCT-2008, the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **334819-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Aug-2008	18-Aug-2008	0	17-Nov-2008	12-Feb-2009	CA	WAES0810USA04345	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Unknown	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Influenza like illness, Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning a 12 year old female with no pertinent medical history, known allergies or drug reactions, who on 18-AUG-2008 was vaccinated with a first dose of GARDASIL (lot no. 660553/0070X) 0.5 ml, IM. Concomitant therapy included BOOSTRIX. In August 2008, after vaccination, the patient experienced flu-like symptoms, nausea and vomiting. Subsequently, the patient recovered the symptoms. A urinalysis was performed (no results available). The patient was seen by the physician. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **334820-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	23-Oct-2008	23-Oct-2008	0	17-Nov-2008	12-Feb-2009	PA	WAES0810USA04351	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a healthcare worker concerning a 23 year old female who on 23-OCT-2008 was vaccinated with the first dose of GARDASIL (lot # 661044/0548X) IM into the left deltoid and had a syncopal episode. The patient felt dizzy while sitting down (the room was spinning) immediately after receiving vaccination. It was unclear if the patient lost consciousness, but smelling salts were used and the patient was observed for 15 minutes and then was "fine". There was no concomitant medication. It was unknown if the patient sought medical attention. Follow up information was received who reported that the female subject patient with no known pre-existing allergies, and no illness at time of vaccination, was vaccinated with the first dose of GARDASIL (lot # 661044/0548X) at the physician's office at 11:00 am. On 23-OCT-2008, immediately after receiving vaccination the patient experienced a syncope. The patient did not fall. The patient layed down for 15 minutes, and smelling salts and cold compresses were used. On the same day, the patient recovered 15 minutes later after the vaccination. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334821-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	VA	WAES0810USA04364	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety

Symptom Text: Information has been received from a nurse concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL. It was reported that the patient had anxiety about receiving GARDASIL. No specifics known about the patient. At the time of reporting on an unspecified date the patient had recovered and continued in the series. The patient sought medical attention in office. This is one of several patients received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334822-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
35.0	F	20-Oct-2008	21-Oct-2008	1	17-Nov-2008	12-Feb-2009	IL	WAES0810USA04378	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye pruritus, Lacrimation increased, Pharyngeal oedema, Pruritus

Symptom Text: Information has been received from a nurse practitioner concerning a 35 year old female, who on 20-OCT-2008, was vaccinated with the first dose of GARDASIL. On 21-OCT-2008, the patient's legs were itchy and she also developed tearing, itchy eyes and her throat felt swollen. The patient said it was similar to the reactions she has when she is around cats. The patient was seen in an office visit. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334823-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	FL	WAES0810USA04397	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site, Injection site mass, Injection site pain, Injection site reaction

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the second dose of GARDASIL, 0.5 ml. After receiving the vaccine the patient experienced an injection site reaction, a bump the size of a quarter at the injection site which was tender to the touch. It was also noted that the patient received the vaccine in the buttock. As of 22-OCT-2008 the patient's adverse events persisted. The patient called the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334824-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Dec-2007	01-Aug-2008	244	17-Nov-2008	12-Feb-2009	--	WAES0810USA04498	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea

Symptom Text: Information has been received from a consumer concerning her daughter who in May 2007, July 2007 and December 2007 was vaccinated with her first, second and third doses of GARDASIL respectively. The consumer reported that starting in August 2008, her daughter had been very nauseous and still was very nauseous and in September 2008,her daughter was put on anti-nauseating medication. The consumer reported that her daughter had been working with a GI,, neurologist and primary care physician, but her daughter stated that the anti nauseating medication (name manufacturer is unspecified) only worked in the morning. At the time of this report, 24-OCT-2008, no outcome reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334825-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Sep-2008	01-Sep-2008	0	17-Nov-2008	12-Feb-2009	CT	WAES0810USA04516	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a female patient about 13 to 16 years old, who in approximately September 2008 received a first dose of GARDASIL (lot number, injection route and site not unspecified). Subsequently, "within last month", the patient experienced hives after the vaccination. The patient sought unspecified medical attention. At the time of reporting, the patient's AE improved but the outcome was unspecified. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334826-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	01-Aug-2007		17-Nov-2008	12-Feb-2009	--	WAES0810USA04517	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a female consumer, concerning her 13 year old daughter with no medical history or allergies who on 12-FEB-2007 was vaccinated with the first dose of GARDASIL, the second dose on 30-APR-2007 and the third dose on 07-AUG-2007. There was no concomitant medication. The consumer reported that, in August 2007, "not too long after receiving the third dose of GARDASIL", the patient started to have severe stomach pain on her upper left side. The reporter stated that her daughter's pain level on a scale of 1 to 10 was a 7. The consumer reported that the patient had blood work, ultra sounds and CAT scans done and they all came back normal. The reporter stated that the next time the patient saw the physician they may have to "put a scope in her to check out her stomach area". The patient was not recovered at the time of this report. The patient sought medical attention with a physician. No further information is available.

Other Meds: None

Lab Data: Diagnostic laboratory, normal; Ultrasound, normal; Computed axial, normal.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **334827-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	21-Oct-2008	21-Oct-2008	0	17-Nov-2008	12-Feb-2009	WA	WAES0810USA04531	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Syncope

Symptom Text: Information has been received from a nurse concerning a 23 year old female with no medical history or known drug allergies, who on 21-OCT-2008, was vaccinated, IM, with the first 0.5 ml dose of GARDASIL (lot # 659184/0843X). Concomitant therapy included hormonal contraceptives (unspecified). On 21-OCT-2008, the patient experienced a "fainting episode" after administration of her first dose of GARDASIL. The patient later developed a headache, which lasted 2 days (also reported as the patient had not recovered). At the time of this report, the patient was not recovered from the fainting episode. The patient visited the office for medical attention. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334828-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	12-Sep-2008	15-Sep-2008	3	17-Nov-2008	12-Feb-2009	--	WAES0810USA04539	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Skin exfoliation

Symptom Text: Information has been received from a nurse practitioner concerning a 9 year old female patient who on 12-SEP-2008 was vaccinated with a first dose of GARDASIL (lot # 659184/0843X). Concomitant therapy also given on 12-SEP-2008 included varricella virus vaccine live (MSD). On 15-SEP-2008, the patient's hands and feet began to peel 2-3 days after she was given the first dose of GARDASIL. The patient contacted the office. On an unspecified date, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334829-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	02-May-2008	02-May-2008	0	17-Nov-2008	12-Feb-2009	CA	WAES0810USA04541	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a mother of a patient concerning a 11 year old daughter with headache and seasonal allergy who on 02-MAY-2008 was vaccinated with a first dose of GARDASIL vaccine and on unspecified date was vaccinated with a second dose of GARDASIL vaccine. After each dose of vaccine the patient's headache became more severe. The patient sought unspecified medical attention. On unspecified date the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Headaches; seasonal allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334830-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	24-Oct-2008	24-Oct-2008	0	17-Nov-2008	12-Feb-2009	--	WAES0810USA04713	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site warmth

Symptom Text: Information has been received from a RN concerning a 29 year old female who was intramuscularly vaccinated with the second 0.5 ml dose of GARDASIL on an unspecified date. On 24-OCT-2008 the patient experienced redness, tenderness and warmth at the site of GARDASIL vaccine administration after her second dose. At time of reporting, the outcome of the patient was unknown. The patient called the clinic for medical attention. Additional information has been reported.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334831-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jul-2008	01-Jul-2008	0	17-Nov-2008	12-Feb-2009	IL	WAES0810USA04779	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration

Symptom Text: Information has been received from a nurse concerning a "teenage" female who was vaccinated with GARDASIL 3 months ago. The patient developed a lump on the injection site which she had for 3 months later after vaccine. At the time of the report, the patient was not recovered. The patient sought medical attention by physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334832-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	10-Mar-2007	10-Mar-2007	0	10-Dec-2008	11-Dec-2008	FR	WAES0812USA00208	11-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0902F	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Astigmatism, Erythema, Glaucoma, Inappropriate schedule of drug administration, Iridocyclitis, Iritis, Lymphadenopathy, Myopia, Oedema peripheral, Papillitis, Photopsia, Sarcoidosis, Vasculitis, Vision blurred, Visual impairment

Symptom Text: Information has been received from a 27 year old physician concerning herself who on 11-JAN-2007 was vaccinated with the first dose of GARDASIL (Lot# 654884/0902F, batch # NE24240). On 10-MAR-2007, the patient was vaccinated IM with the second dose of GARDASIL into the deltoid muscle (Lot# 654884/0902F, Batch # NE24240). In MAR-2007, the patient developed erythema, ankle edema and visual disturbance. On 10-JUN-2007, the patient was hospitalized for the first time due to the visual disturbance. Uveitis anterior and increased eye pressure (both eyes) was diagnosed. The patient was hospitalized from 13-JUN-2007 to 15-JUN-2007. Upon hospitalization, the patient presented with visual disturbance with blurred flickering vision. Diagnosis of uveitis anterior, papillitis, iris granuloma and vasculitis was confirmed. After biliary Lymphadenopathy the patient was hospitalized until diagnosis of sarcoidosis was confirmed. Chest x-ray on 11-Jun-2007. In comparison to previous examination on 07-SEP-2007 significant round shadows of lung hilum (bilateral) as an expression of biliary lymphadenopathy were found. X-ray also confirmed picture of sarcoidosis stage I. Echocardiography on 13-JUN-2007 and abdomen sonography on 15-JUN-2007 showed normal results. Opthalmological finding on 12-JUN-2007: diagnosis of papillitis, uveitis anterior, myopia, astigmatism, secondary glaucoma, vasculitis and iris granuloma. Under local antiinflammatory and pressure-lowering therapy the tension normalized and the patient was recovering. The patient additionally developed flat erythema of both lower legs and ankles, but rather untypical for erythema- nodosum. Systemic steroid therapy was initiated. The patient was treated with prednisolone 100 mg for 3 days, from 17-JUN-2007 treatment with prednisolone 50 mg. Additionally the patient was treated with NEXIUM 20, CALCIMAGON D3. The patient was discharged for further outpatient treatment. The final outcome was not reported. GARDASIL (Lot# 654884/0902F, Batch # NE 24240 administered on 11-Jan-2007 was

Other Meds: Unknown

Lab Data: chest X-ray, 11Jun07, biliary lymphadenopathy were found: sarcoidosis stage I; echocardiography, 13Jun07, normal result; abdominal ultrasound, 15Jun07, normal result

History: GARDASIL (Lot# 654884/0902F, Batch # NE 24240 administered on 11-Jan-2007 was well tolerated.

Prex Illness:

Prex Vax Illns:

Vaers Id: **334833-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Nov-2008	18-Nov-2008	0	10-Dec-2008	11-Dec-2008	--	WAES0812USA00549	11-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Dizziness, Gait disturbance, Nausea, Orthostatic hypotension, Sensation of heaviness, Vision blurred

Symptom Text: Information has been received from a Registered Nurse concerning a 15 year old female patient with no known drug reactions or allergies and medical history who on 10-APR-2007 was vaccinated with first dose of GARDASIL (Lot number not provided) 0.5ml, intramuscularly. There was no concomitant medication. On 18-NOV-2008 she received her second dose of GARDASIL (Lot # 661703/0651X) 0.5ml, intramuscularly. On 19-NOV-2008 the patient developed dizziness, nausea, blurred vision, and a feeling of her legs being "heavy and wobbly". It was reported that the patient had difficulty walking due to wobbly legs. The patient was seen in the office that day and was found to have orthostatic hypotension. Urinalysis was performed to rule out dehydration. The patient was advised to increase liquid intake and to rest. An office visit on 20-NOV-2008 revealed the hypotension improved. The patient contacted the office by phone on 21-NOV-2008 and stated the symptom of "wobbly legs" was resolving. Subsequently, she has completely recovered. The patient's difficulty walking due to "wobbly legs" and orthostatic hypotension were considered disabling by the reporter. Additional information has been requested.

Other Meds: None

Lab Data: urinalysis

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **334834-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Oct-2008	Unknown		10-Dec-2008	11-Dec-2008	FR	WAES0812USA00644	11-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Appendicectomy, Appendicitis, Demyelination, Nausea, Neurological examination abnormal, Vomiting

Symptom Text: Information has been received from a physician concerning an 18 year old female patient with medical history of arm hypoesthesia one year and a half ago and with digestive disorder episodes, received the second dose of GARDASIL (batch number not reported) on 11-OCT-2008. On an unspecified date the patient experienced digestive symptoms: abdominal pain, vomiting and nausea. Diagnosis was appendicitis therefore the patient had an appendicectomy. 2 to 3 days later the patient had vomiting and then all came back to normal. After 15 days, she had abdominal pain and vomiting again. There was hospitalization and digestive exploration. As to gastroenterologist there was nothing at digestive level but he suspected a neurological impairment. An MRI was performed which showed demyelinating lesions. Evoqued suspected diagnosis by the radiologist was multiple sclerosis or acute disseminated encephalomyelitis. At time of reporting the patient had not recovered. The patient received the first dose of GARDASIL on 20-JUL-2008. Additional information has been requested. Other business partner numbers include E2008-11235.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, demyelinating lesions

History: Hypoaesthesia; Gastrointestinal disorder

Prex Illness:

Prex Vax Illns:

Vaers Id: **334835-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		10-Dec-2008	11-Dec-2008	--	WAES0812USA00864	11-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Bedridden, Brain oedema, Convulsion, Familial risk factor, Meningism, Migraine

Symptom Text: Information was received from a news broadcast Online (October 29, 2008) reporting that after the first shot of GARDASIL, the patient, an 18 year old female, developed an unknown illness causing migraine-like headaches, coupled with symptoms similar to warning signs of meningitis. Ten days later, while being tested for meningitis in the hospital, she suffered several seizure-like episodes that her neurologist said it was caused by swelling in her brain, which the worst the neurologist said he had ever seen. The neurologist was asked if the patient's reaction could have been caused by GARDASIL and he stated "I can't prove it beyond a shadow of a doubt, but there (was) as much evidence as possible in the medical field to link it." The patient was now bed-ridden and recovering at home. Upon internal review, seizure-like episodes was considered to be an other important medical event. The patient's younger sister also had a similar experience (refer to WAES #0810USA05376). No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334836-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		10-Dec-2008	11-Dec-2008	--	WAES0812USA01244	11-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician who heard from another physician concerning a female who was in high school and was vaccinated with a dose of GARDASIL. Later on during the day ended up, the patient experienced seizure that lasted almost an hour. After the seizure was under control, the patient was taken the clinic for follow-up where it was determined that the seizure was related to therapy with GARDASIL. The patient's outcome was unknown. Upon internal review, seizure was determined to be an other medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334845-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Nov-2007	07-Nov-2007	0	10-Dec-2008	11-Dec-2008	OH	WAES0711USA01935	11-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0187U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse through a Merck pregnancy registry concerning an 18 year old female with no pertinent medical history, drug reactions/allergies or concomitant medication use who on 07-NOV-2007 was vaccinated intramuscularly (site not reported) with the 1st 0.5ml dose of the GARDASIL (lot#656049/0187U). The patient was found to be pregnant post vaccination. Patient sought unspecified medical attention and pregnancy was confirmed with a positive urine pregnancy test. Date of LMP is 30-SEP-2007 and estimate delivery date is 06-JUL-2008. Follow-up information has been received from the nurse, which reported that the patient had a first trimester termination of her pregnancy (date unspecified). The patient was very upset at the unexpected pregnancy and had personal reasons to choose a termination. The reported also stated that it was not chosen because the patient had received the GARDASIL. The patient was fine and did not have any complications. Upon internal review, abortion induced was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: urine beta-human, Positive

History:

Prex Illness: Pregnancy NOS (LMP = 9/30/2007)

Prex Vax Illns:

Vaers Id: 334846-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Sep-2008	09-Oct-2008	14	10-Dec-2008	11-Dec-2008	--	WAES0811BRA00079	21-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abnormal behaviour, Aggression, Agitation, Anorexia, Anxiety, Asthenia, CSF white blood cell count increased, Choking, Delirium, Dizziness, Euphoric mood, Hallucination, Insomnia, Loss of consciousness, Malaise, Nightmare, Poor quality sleep, Pyrexia, Rash erythematous, Salivary hypersecretion, Speech disorder, Suicidal ideation, Syncope, Systemic lupus erythematosus, Thirst, Weight decreased

Symptom Text: Information has been received from an employee concerning a 16 year old female, who on 25-SEP-2008 was vaccinated with GARDASIL (1st dose). The patient never had any psychiatric event, athlete (she plays sand volleyball), does not use to get out at night, studding the 2nd year of high school. Anybody in the family has a history of psychiatric disease or had taken anytime drugs for this condition. Her family begins to notice that the patient was very thirsty (she drunk 31 or more daily), very high anxiety and euphoria approximately 15 days before the outbreak (09-OCT-2008). She used to write happiness notes to her mother, talk about everything with her eyes widened-she gave the impression that "there is no one so happy than me". Her family begins to be surprised, but didn't think that I was something important or severe. On 23-OCT-2008, the patient left school and come back to her home because she had a malaise. On 23 and 24-OCT-2008, she had a very severe insomnia (she slept very little time and woke up thereafter with a peculiar anxiety). Insomnia was higher at the day-break between days 24 and 25-OCT-2008. In the morning of day 25-OCT-2008, from the morning until afternoon the patient was loosing her control, very agitated and anxious- she beat in her relatives, asked for a beer, asked for a knife, she throw out to a window (that had a rail), she told that she was going to materialize with the sofa (hallucinations), much anxiety. The reporter compared the patient's behavior with the character of the movie "exorcist". Starting in the morning, during the afternoon the picture was more intense, the pictures appeared and the patient was uncontrollable. At night, the psychiatrist was called who prescribed EUTONIS, performed a sub-valuation, stating that "it was a very small crisis, with no importance". The patient took a tablet that had no effect, and the physician ordered to take a second one, which she took, but without any effect. The patient nodded (sometimes for 5-10 minutes), when she arouses she didn't disti

Other Meds: Unknown

Lab Data: Electroencephalography, 11/20/08, epileptic focus; spinal tap; magnetic resonance; blood pressure, blood pressure decreased; serum ANA, positive; temperature measurement, 10/30/08, 37/38 C, fever

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334847-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		10-Dec-2008	11-Dec-2008	FR	WAES0812AUS00109	11-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Tonic convulsion

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning a 21 year old female who was vaccinated with GARDASIL. Concomitant therapy included DIANE 35 ED, FERROGRAD C and multivitamins (unspecified). Subsequently after vaccination the patient experienced tonic convulsion. At the time of reporting to the agency on 25-AUG-2008, the patient had recovered from tonic convulsion. The agency considered that tonic convulsion was related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review tonic convulsion was considered an other important medical event. Additional information is not expected.

Other Meds: cyproterone acetate/ethinyl estradiol; ferrous sulfate (+) sodium ascorbate; vitamins (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334848-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-May-2007	15-May-2007	1	10-Dec-2008	11-Dec-2008	FR	WAES0812AUS00111	11-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0138U		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Crying, Pyrexia, Renal pain, Sleep disorder, Swelling face, Vomiting

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 15 year old female who on14-MAY-2007 was vaccinated with GARDASIL (Lot No. 655742/0138U, Batch No. J0799, Expiry date 07-AUG-2009). on 15-MAY-2007 the patient experienced vomiting, crying, pyrexia, renal pain, sleep disorder and swelling face and was hospitalised. It was described that within 24 hours of vaccination, the patient was vomiting, developed a fever, swelling on side of face, cried persistently for 3 hours, had sleep changes and developed kidney pains. The patient was treated with PANADOL, morphine and antibiotics (unspecified). At the time of reporting to the agency on 25-AUG-2008, the outcome of vomiting, crying, pyrexia, renal pain, sleep disorder and swelling face was unknown. The agency considered that vomiting, crying, pyrexia, renal pain, sleep disorder and swelling face were possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334849-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	Unknown	30-Aug-2008		10-Dec-2008	11-Dec-2008	FR	WAES0812AUS00131	11-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Lethargy, Mouth ulceration, Pyrexia

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 24 year old female who was vaccinated with GARDASIL. On 30-AUG-2008 the patient experienced lethargy, pyrexia (fevers) and mouth ulceration. The patient was treated with topical analgesia to mouth ulcers and oral analgesia. At the time of reporting to the agency on 04-SEP-2008 the patient's lethargy, pyrexia (fevers) and mouth ulceration persisted. The agency considered that lethargy, pyrexia (fevers) and mouth ulceration were possibly related to therapy with GARDASIL. The original reporting source was not provided. The adverse events of lethargy, mouth ulceration and pyrexia were considered to be disabling by the reporting agency. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334850-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
35.0	F	02-Aug-2008	09-Aug-2008	7	10-Dec-2008	11-Dec-2008	FR	WAES0812USA01524	11-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNK	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Axillary pain, Back pain, Inappropriate schedule of drug administration, Pain

Symptom Text: Information has been received from a consumer concerning a 35 year old female who was vaccinated on 02-AUG-2008 with the second dose of GARDASIL vaccine (batch # not reported). About 1 week post-vaccination, she presented with underaxillary and back pain and then pain over the entire body. She was alleged admitted to the hospital on 29-SEP-08, no diagnosis was reported. There is no previous medical history reported. The patient received the first dose of GARDASIL vaccine on 09-JUN-2008 with no adverse effect. Other business partner numbers included: E200811121. No further information is available. The case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334853-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Nov-2008	14-Nov-2008	0	10-Dec-2008	05-Feb-2009	LA		05-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TTOX	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoacusis, Hypotension, Immediate post-injection reaction, Monoplegia, Nausea, Syncope

Symptom Text: Immediatly following the vaccine of the Gardisil or HPV she lost partial hearing and had leg paralysis. She fainted and felt nauseated. She was excused to leave less than 10 minutes later. Less than 2 hours later the leg paralysis returned as did the fainting and nausea. The ER doctor stated she had severe low blood pressure that could be causing the inability to use her legs.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **334868-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	08-Dec-2008	10-Dec-2008	2	10-Dec-2008	22-Dec-2008	NY		22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1324X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0072X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site warmth

Symptom Text: RECEIVED CHICKENPOX VACCINE 2 DAYS AGO. NOTICED TODAY REDNESS AROUND THE SITE AND WARM TO THE TOUCH. REDNESS MEASURED 4.5CM X 5CM. ALSO COMPLAINED OF PAIN AT INJECTION SITE. ADVIDED SYMPTOMATIC TREATMENT.

Other Meds: SINGULAIR, ZYRTEC AS NEEDED

Lab Data:

History: ASTHMA

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: 334870-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	25-Nov-2008	25-Nov-2008	0	10-Dec-2008	17-Feb-2009	CA		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Feeling jittery, Injection site induration, Injection site mass, Oedema peripheral, Somnolence

Symptom Text: After 2nd HPV vaccine patient reported feeling fine for 6 hours, then got excessively sleepy for 2 weeks after and had swollen arm with a large hard lump the size of a golf ball at vaccine admin stie. At least 1 week after had episodes of feeling faint, dizzy, and shortness of breath. Felt light-headed and jittery for 2 weeks thereafter. Self-treated with hot compresses on vaccine site and benadryl.

Other Meds: birth control pills, topical antibiotic for acne (cleocin) and occasional Claritin/Nasocort for allergies

Lab Data: none

History: Allergic rhinitis, dishydrotic eczema, acne

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334902-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Dec-2008	10-Dec-2008	0	10-Dec-2008	22-Dec-2008	PA		05-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2742AA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2486AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	05484	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Pt given immunizations getting up to leave felt faint or fainted. Alert and oriented after 15 seconds.

Other Meds: None

Lab Data: Vaso Vagal reaction

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334913-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Oct-2008	24-Oct-2008	1	17-Nov-2008	12-Feb-2009	--	WAES0810USA04764	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthma, Injection site erythema, Injection site pain, Injection site swelling, Injection site warmth, No reaction on previous exposure to drug

Symptom Text: Information has been received from a healthcare worker concerning a 17 year old female with asthma who on 27 Aug 2008 was vaccinated with the first dose of GARDASIL intramuscularly. On 23-Oct-2008, the patient was vaccinated with the second dose of GARDASIL intramuscularly concomitant therapy included unspecified oral contraceptives. It was reported that one day after receiving her second dose, on 24-Oct-2008, the patient experienced an asthma attack. Prior to this, it had been 4 years since this patient had experienced an asthma attack. She was treated with an unspecified asthma inhaler. The patient also developed redness, swelling pain and warmth at the injection site after both of her immunization with GARDASIL. All these symptoms were greater after the second dose than the first dose. The onset date of these symptoms was unspecified. At the time of the report, the patient was recovering. The patient sought medical attention, by phone call.

Other Meds: Contraceptives

Lab Data: None

History: Asthma

Prex Illness:

Prex Vax Illns:

Vaers Id: **334914-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	22-Jan-2009	--	WAES0810USA04787	23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: Information has been received from a medical assistant concerning a female who was vaccinated with a second dose of GARDASIL. Secondary suspected therapy included INFLUENZA (unspecified). The patient experienced vomiting 10 minutes after receiving GARDASIL and "flu" vaccination. Medical attention was received in the office. At the time of reporting, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334917-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Aug-2008	22-Aug-2008	0	17-Nov-2008	12-Feb-2009	IL	WAES0810USA04792	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a nurse concerning a 14 year old female who on 22-Aug-2008 was vaccinated with first dose of GARDASIL intramuscularly. Concomitant therapy included MENACTRA and Atenolol. The patient experienced a headache that lasted for a period of three days after receiving the first dose of GARDASIL. On 25-Aug-2008, the patient recovered from headache. Additional information has been requested.

Other Meds: Atenolol

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334918-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Apr-2008	01-Apr-2008	0	17-Nov-2008	12-Feb-2009	--	WAES0810USA04808	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Presyncope

Symptom Text: Information has been received from a 22 year old female, who on February 2008 and April 2008, was vaccinated with the first and second doses, respectively, of GARDASIL. Concomitant therapy included ethinyl estradiol (+) etonogestrel (NUVARING). in April 2008, after receiving the second dose of GARDASIL, the patient went up to make her neck appointment and started to faint. So the office had her sat down in a chair and gave her some water. The patient reported that she started to lose consciousness, but never fully did, but she sat for 15 minutes and was able to leave the office after the 15 minutes. It was reported that the patient recovered. She was scheduled to get the third dose of GARDASIL in August 2008. Additional information has been requested.

Other Meds: NUVARING

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334919-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	FR	WAES0810USA04811	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Headache

Symptom Text: Information has been received from a nurse practitioner concerning an approximately 21 year old female who in April 2008 was vaccinated with a dose of GARDASIL, (unknown if 1st or 2nd dose). There was no concomitant medication, After receiving her first and second dose the patient experienced breathing difficulty. Shortness of breath and severe headaches. The symptoms resolved by themselves 2 hours after the vaccinations. The patient has not received the third dose. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334920-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Nov-2008	12-Feb-2009	NJ	WAES0810USA04849	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a physician concerning an approximately 14 year old patient who on an unspecified date was vaccinated with the first dose of GARDASIL. It was reported that after received the first dose of GARDASIL, in two instance, the patient experienced more of a general rash after getting vaccine. It was reported that the patient did not continue on with the series. So, the patient only received the first dose. The patient's outcome was not reported. This is one of the two patients concerning the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334921-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Apr-2008	14-Aug-2008	115	17-Nov-2008	18-Dec-2008	FL	WAES0810USA04881	02-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	1	Right arm	Intramuscular	HPV4 MNQ VARCEL

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abnormal behaviour, Adjustment disorder, Chest pain, Depression, Foot deformity, Homeless family, Insomnia, Joint range of motion decreased, Musculoskeletal pain, Neurological examination normal, Neuropathy peripheral, Pain, Paraesthesia, Pharyngitis, Radiculopathy, Suicidal ideation

Symptom Text: Information has been received from a nurse concerning a 13 year old female with no known allergies or drug reactions who on 20-FEB-2008 was vaccinated with the first dose of GARDASIL (lot no. 657736/0389U) IM, into the right arm and the first dose of MENACTRA (lot no 42421AA) IM, into the left arm. On 21-APR-2008, the patient was administered the second dose of GARDASIL (lot no. 657736/0389U) IM, into the right arm. In August 2008, the patient experienced shooting pain, paresthesia in both thighs and legs. The problem went from head, now range of motion in both hips decreased, especially the abdomen. The patient was diagnosed with neuropathy and radiculopathy. The patient also had entire body pain. On 08-OCT-2008, a thoracic and lumbar magnetic resonance imaging were performed (results not reported). On 06-SEP-2008, a complete blood cell count, a complete metabolic panel, serum C-reactive protein test and serum antinuclear antibodies test were performed (results no reported). Additional information has been requested. 2/24/09 Received vaccine records & PCP medical records of 9/4/08-1/30/2009. FINAL DX:adjustment disorder Records reveal patient experienced general body pain, chest pain, right shoulder pain. Neuro exam WNL. Referred for MRI of shoulder & spine & labs. RTC 9/18 & had not been able to get MRI or labs done due to family & homeless developments as well as depression w/suicidal ideation. Psych hospital admit & dx w/adjustment disorder. Developed insomnia, pes plana, pharyngitis as well as continued psych & behavioral issues.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness: Dysmenorrhoea

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334922-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA04886	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gait disturbance, Pain in extremity

Symptom Text: Information has been received from a pharmacist concerning a 11 year old female who was vaccinated with two doses of GARDASIL. There was no concomitant medication. Subsequently, "one day after the second dose", the patient experienced severe leg pain and hurt to walk. It was reported that the patient recovered, but no time to recovery reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334923-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA04888	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a pharmacist concerning a 14 year old female who was vaccinated with two doses of GARDASIL. There was no concomitant medication. Subsequently, "one day after the second dose", the patient's leg became aching, not debilitating. It was reported that the patient recovered, but no time to recovery reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334924-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Jun-2008	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA04899	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	By Mouth	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pharyngitis streptococcal, Rash

Symptom Text: Information has been received from a consumer concerning her daughter a 17 year old female who in June 2008 was vaccinated with the first dose of GARDASIL orally. On an unspecified date, the patient was vaccinated with a second dose of GARDASIL. Lot numbers were not available. The consumer reported that her daughter had strep throat twice during the time period between her first dose and second dose. On an unspecified date, the patient experienced a severe rash all over her face and legs after receiving her second dose of GARDASIL. The patient sought unspecified medical attention. On follow-up information, the patient's mother reported that she took unspecified steroids (manufacturer unknown) and other unspecified psoriasis medications (manufacturer unknown) but they did not help to clear up her rash. An unspecified scrape test was performed but the results were not provided. At the time of reporting the patient had not recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **334925-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Jul-2008	Unknown		11-Dec-2008	13-Feb-2009	PA	WAES0810USA04910	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Menstruation irregular

Symptom Text: Information has been received from a physical therapist concerning her daughter a 16 year old female with no pertinent medical history reported and no known drug allergies who on 06-Nov-2007 was vaccinated with the first dose of GARDASIL (LOT#658490/08020), 05.ml, intramuscularly. On 08-Jan-2008, the patient was vaccinated with a second dose of GARDASIL (lot# 658094/0524U). On 22-Jul-2008, the patient was vaccinated with a third dose of GARDASIL (lot# 660391/0063X). The physical therapist reported that her daughter has had irregular menstrual cycles since administration of her third dose of GARDASIL. Her one and only menstrual period occurred 6 to 7 weeks after receiving her third dose. The patient also experienced injection site soreness on an unspecified date. The patient called to the office. At the same time of reporting the patient had not recovered. This is one of two reports from the same source. Additional information has been requested

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334926-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	03-Sep-2008	28-Sep-2008	25	17-Nov-2008	12-Feb-2009	NJ	WAES0810USA04937	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a consumer concerning her 19 year old daughter with penicillin and amoxicillin allergy and no previous medical history reported, who on 25-FEB-2008, was vaccinated with the first dose of GARDASIL, 0.5 mL, injection. On 28-APR-2008 was vaccinated with the second dose, and on 03-SEP-2008 was vaccinated with the third dose. There was no concomitant medication. " One month ago" on approximately 28-SEP-2008, the patient experienced that falling after the third dose of GARDASIL, the patient was not recovered from hair falling. On an unspecified date a blood test was performed (result not provided). The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **334927-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	VA	WAES0810USA04951	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a nurse practitioner concerning her daughter who on unspecified dates was vaccinated with the first, second and third doses of GARDASIL, 0.5ml intramuscularly. The nurse practitioner stated her daughter was tested positive for HPV on a PAP smear after completing the GARDASIL vaccine series, on an unspecified date. The patient was seen at the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test - positive for HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334928-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	VA	WAES0810USA04952	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pyrexia, Rash

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the first dose of GARDASIL 0.5ml, IM. The physician reported that the patient developed a severe rash on the left side of her body after administration of GARDASIL. She also Developed a fever. At time of reporting, the patient had recovered. The patient sought medical attention via office visit. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334929-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0810USA04964	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pruritus

Symptom Text: Information has been received from a female who in October 2008, was vaccinated with the first dose of GARDASIL 0.5 mL, injection and after that experienced itchiness at the injection site. The patient stated that "she won't be getting rest of doses". The patient was not recovered. The patient did not seek medical attention. No further information.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334932-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	10-Sep-2007		11-Dec-2008	22-Dec-2008	--		22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cardiac disorder, Mitral valve prolapse, Palpitations

Symptom Text: Heart problems related to GARDASIL vaccine. My daughter has experienced severe heart palpation's. She has been diagnosed with Mitro Valve Prolapse and struggles with heart palpitations on an ongoing basis. She never had any of these problems prior to her getting the first shot of the vaccine. She is visiting a cardiologist to see what other problems there maybe with her heart. I feels all these symptoms started after her first dose of GARDASIL vaccine. I never made the connections and she has received all three of the series of shots. Until my daughter brought it up in a conversations about a friend of hers at school experienced a similar reaction to her heart after she received the GARDASIL did I finally realize there might be a connection to this drug.

Other Meds:

Lab Data: Xray-heart no inflamed, Feb2008; EKG-low resting heart rate, Feb 2008; EKG- Mitro Valve Proplapse, April 2008.

History: No allergies to anything. Never experienced heart pain or discomfort prior to this series of shots.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334934-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	19-Nov-2008	21-Nov-2008	2	11-Dec-2008	22-Dec-2008	IA		22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0573X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia, Rash erythematous, Rash papular, Rash pruritic

Symptom Text: GARDASIL # 1 given 11/19/08. On 11/21, pruritus and papular red rash. Low grade fever. Have hx. of allergic reaction to PCN, Sulfa, Bee stings and pertussis vaccine.

Other Meds: NUVARING; BENADRYL

Lab Data:

History: See # 7

Prex Illness: No known

Prex Vax Illns: ~Pertussis (no brand name)~UN~0~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334935-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Nov-2008	25-Nov-2008	0	11-Dec-2008	22-Dec-2008	TX		22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN	MEDIMMUNE VACCINES, INC.	500585P	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Musculoskeletal stiffness, Nausea, Posture abnormal, Tremor, Urinary incontinence

Symptom Text: After nurse gave FLUMIST and GARDIASIL, patients face went blank and patient head deviated to the right, also patients arms went stiff in extension; hands shook a little, legs extended also and loss of urine onto floor, lasted 30-60 seconds, patient was tired and nauseous afterward. 0 vomiting.

Other Meds: None Known

Lab Data: None

History: Syncope 1/19/07

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334939-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Dec-2008	05-Dec-2008	1	11-Dec-2008	22-Dec-2008	NC		22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Joint swelling, Pain in extremity

Symptom Text: Severe bilateral hand pain, swelling, right wrist, elbow, foot pain and swelling. Onset 20 hours after 2nd injection in Right elbow. Treated 2-6 hours with MOTRIN x 48 hours.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **334952-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Sep-2008	20-Oct-2008	47	17-Nov-2008	17-Dec-2008	VA	WAES0810USA05069	16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF452CA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Balance disorder, Blood product transfusion, Diarrhoea, Diplopia, Dysphagia, Gait disturbance, Gastrointestinal tube insertion, Guillain-Barre syndrome, Headache, Hypophagia, Intensive care, Miller Fisher syndrome, Muscular weakness, Paraesthesia, Sensation of foreign body, Speech disorder, Walking aid user

Symptom Text: Information has been received from a physician concerning a 14 year old female who was intramuscularly vaccinated with the first 0.5ml dose of GARDASIL. Concomitantly the patient was given Hepatitis A vaccine injection (manufacturer unknown). A couple weeks later, the patient was admitted to the hospital for guillain-barrce syndrome on an unspecified date. The duration of hospitalization was unknown, as well as the outcome. The patient sought medical attention. Additional information has been requested. 2/27/09 Received PCP medical records which included hospital & rehab hospital d/c summaries. FINAL DX: Guillain Barre syndrome; Miller Fisher variant Hospital admit 10/21-10/27/2008. Records reveal patient experienced progressive ascending bilateral LE tingling & weakness x 5 days, reduced oral intake, lump in throat, difficulty swallowing & walking, balance disturbance, speech alteration, HA & double vision. Had been seen in PCP office & sent to hospital. Had diarrheal illness approx 10/10. Admitted PICU. Neuro consult done. Feeding tube inserted. Tx w/IVIG x 3, neurontin & pain meds. Improved, diet advanced & transferred to inpatient rehab. where she continued to progress & d/c to home 11/15/08 w/Neuro f/u, rolling walker & outpatient PT/OT as well as homebound school. 4/13/09 Received additional hospital medical records of 10/21-27/2008. No new information.

Other Meds:

Lab Data: Unknown LABS: CSF: protein 105, WBC 2, RBC 100, glucose 52. EMG/NCS abnormal & c/w GBS. MRI head & neck. CT of head WNL.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334953-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	29-Aug-2008	Unknown		11-Dec-2008	13-Feb-2009	CA	WAES0810USA05085	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphoedema

Symptom Text: Information has been received from a physician concerning an approximately 27 year old female patient with no known pertinent medical history, or no known drug reactions/allergies, who "2 months ago", on approximately 29-AUG-2008, was vaccinated with the first dose of GARDASIL, 0.5 ml, intramuscularly. Concomitant therapy included birth control pills. The physician reported that after the patient was vaccinated she developed generalized lymphedema. The patient sought medical attention at physician's office. On an unknown date the patient had recovered. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334954-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Jul-2008	Unknown		17-Nov-2008	13-Feb-2009	NY	WAES0810USA05089	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye swelling

Symptom Text: Information has been received from a 22 year old female patient with no known pertinent medical history, or no known drug reaction/allergies, who in July 2008, was vaccinated with first dose of GARDASIL vaccine. The consumer reported that three days after receiving the first dose of GARDASIL vaccine she developed swelling of both of her eyes. The swelling resolved one day later after vaccination. The patient sought medical attention by a phone call. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 334955-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	02-Oct-2008	Unknown		17-Nov-2008	13-Feb-2009	CT	WAES0810USA05100	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site haematoma, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a Registered Nurse concerning a 27 year old female who on 02-Oct-2008 was vaccinated with the first dose of GARDASIL (660393/0067X). Concomitant therapy included TRI-SPRINTEC. Subsequently the patient developed tenderness at the injection site, as well as swelling and soreness. The patient returned to the office on 23-OCT-2008. There was bruising 4 inches below and anterior of the injection site. There was no masses, no redness and no induration. Tenderness was present. The patient was told to use hot compresses three times a day for 1 week and to call the office if her symptoms persisted. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 334956-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	06-Oct-2008		17-Nov-2008	13-Feb-2009	--	WAES0810USA05103	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anger, Condition aggravated, Depression, Dizziness, Headache

Symptom Text: Information has been received from a 21 year old female who received two dose of GARDASIL. She was supposed to get the third dose on 06-OCT-2008, she did not have insurance to pay for it so she did not get it. She started experiencing depression, dizziness and headache "around 19-OCT-2008". The patient mentioned that she had been sad previously after she gave birth to her child (14 months old); however, she was fine for a while and now the depression was back and it was much stronger. She felt angry and sad and wanted to be alone. The patient had the baby before starting the GARDASIL. At the time of reporting the patient was not recovered. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Depressed mood; Depression

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334957-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	29-Sep-2008	Unknown		17-Nov-2008	13-Feb-2009	--	WAES0810USA05114	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Information has been received from a physician's assistant concerning a 21-26 year old female patient, who on unspecified dates, was vaccinated with a first and second dose of GARDASIL, and during the last week of September 2008 or the first week of October 2008, was vaccinated with the third dose of GARDASIL. The physician's assistant reported that the patient was seen about 2 weeks after the last GARDASIL vaccination for a different reason. During the visit, the patient reported that she developed numbness of the right foot from the arch to the ball of foot. At the time of the report, the patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334958-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	M	28-Oct-2008	28-Oct-2008	0	17-Nov-2008	13-Feb-2009	OH	WAES0810USA05117	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from an office manager concerning a 15 year old female, allergic to penicillin, who on 12-AUG-2008, was vaccinated with a first dose of GARDASIL (Lot # 660620/0571X), 0.5 ml. It was reported that the patient did not experience any adverse event on first dose. On 29-OCT-2008, the patient was vaccinated with a second dose of GARDASIL (Lot # 659184/0843X). Concomitant therapy included medroxyprogesterone acetate (DEPO-PROVERA) and vitamins (unspecified). The office manager reported that the patient fainted after getting the second dose of GARDASIL on 28-OCT-2008.The patient recovered the same date. No lab/ diagnostic tests were performed. Unspecified medical attention was sought. There was no product quality complaint. Additional information has been requested.

Other Meds: DEPO-PROVERA; vitamins (unspecified)

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **334959-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		17-Nov-2008	13-Feb-2009	--	WAES0810USA05123	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a registered nurse practitioner concerning a 12 year old female who on an unspecified date was vaccinated with the first dose of GARDASIL (lot # not provided). After getting first dose of GARDASIL, the patient developed rash on her whole body. The patient sought medical attention. At the time of reporting, the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334960-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	13-Feb-2009	--	WAES0810USA05137	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a consumer who reported that she heard some girls experienced hair falling after getting a dose of GARDASIL vaccine. was unknown if the patients sought medical attention. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334961-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	08-Sep-2008	09-Sep-2008	1	17-Nov-2008	13-Feb-2009	AZ	WAES0810USA05139	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthma

Symptom Text: Information has been received from physician concerning a 13 year old female patient with asthma who on 08-SEP-2008 was vaccinated with the first dose of GARDASIL vaccine (site and route not reported). No other vaccines were administered at this time. On 9-SEP-2008, the day after she received the vaccine, the patient went to the physician's office due to was the mother felt was an asthma attack. The patient was treated with levalbuterol and Orapred. The patient was not hospitalized. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **334962-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	29-Oct-2008	29-Oct-2008	0	17-Nov-2008	13-Feb-2009	--	WAES0810USA05140	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Road traffic accident

Symptom Text: Information has been received from a nurse concerning a 17 year old female who on an unknown date was vaccinated with the first dose of GARDASIL. In the morning of 29-OCT-2008, the patient was vaccinated with the second dose of GARDASIL. The nurse reported that the patient was fine after the first vaccine. On 29-OCT-2008, 5 to 10 minutes after vaccination the patient left the office to go to school. The patient passed out while she was driving and got into an accident. The nurse stated that the patient sounded fine on the phone but she went to ER for check up.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334963-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		17-Nov-2008	13-Feb-2009	--	WAES0810USA05170	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 25 year old female who "recently" was vaccinate with the first dose of GARDASIL and fainted. The patient "came to" after she fainted the first time, and then fainted again while she was still in the office. This is one of several reports from same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334964-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	26-Aug-2008	26-Aug-2008	0	17-Nov-2008	13-Feb-2009	NY	WAES0810USA04973	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Joint swelling, Rash generalised

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female with no drug allergies or previous medical history reported, who on 26-AUG-2008, was vaccinated with the first dose of GARDASIL, 0.5 mL, IM, into the right deltoid, and developed random joint swelling and a rash all over her body. The rash was flat and not raised. The patient had also started ethinyl estradiol (+) norethindrone acetate (LOESTRIN) during the same weeks as vaccination and within that same week her symptoms began. The patient discontinued ethinyl estradiol (+) norethindrone acetate (LOESTRIN), and recovered within a week of stopping it. The patient did not notify the office until she went for second dose which had not been administered yet. The physician had not decided whether or not to continue the series. The patient did not seek medical attention. Additional information has been requested.

Other Meds: LOESTRIN

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334965-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	28-May-2008	29-May-2008	1	17-Nov-2008	13-Feb-2009	--	WAES0810USA04976	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depressed level of consciousness, Pain, Somnolence

Symptom Text: Information has been received from a physician concerning her daughter an early 20's year old female who on 28-MAY-2008 was vaccinated with her first dose of GARDASIL injection (lot # 659657/1487U) and on 12-SEP-2008 received her second dose of GARDASIL injection (lot # 660553/0070X). One day after receiving her first dose (on 29-MAY-2008) and her second dose (on 13-SEP-2008) the patient experienced a lot of body aches, sleepiness and decreased of alertness. The symptoms lasted for 3 days. Subsequently, the patient recovered from body aches, sleepiness and decrease of alertness and per physician "patient is fine now". Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334966-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	13-Feb-2009	--	WAES0810USA05044	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Allergy to vaccine, Asthma, Dyspnoea, Hypersensitivity

Symptom Text: Information has been provided from a physician's assistant concerning the daughter of a nurse who was vaccinated with the first doe of GARDASIL vaccine (dose and site not reported). It was reported that the patient developed an allergic reaction to the GARDASIL vaccine. The patient developed shortness of breath and asthmatic type symptoms. The patient did not "come in" for any additional follow-up or any medical treatment. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334967-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	U	Unknown	Unknown		17-Nov-2008	13-Feb-2009	NJ	WAES0810USA05181	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a physician concerning an approximately 14 year old patient who on an unspecified date was vaccinated with the first dose of GARDASIL vaccine. It was reported that after received the first dose of GARDASIL vaccine, in two instances, the patient experienced more of a general rash after getting vaccine. It was reported that the patient did not continued with the series. So, the patient only received the first dose. The patient's outcome was not reported. This is one of two patients concerning the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334968-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Nov-2008	13-Feb-2009	PA	WAES0810USA05240	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a physical therapist concerning an unspecified number of patients, who on unspecified dates, were vaccinated with an unspecified dose of GARDASIL. The physical therapist stated the nurse from the department of health told him that irregular menstrual periods are commonly seen in patients who have received GARDASIL at the clinic.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334969-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		17-Nov-2008	13-Feb-2009	MH	WAES0810USA05251	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a 12 or 13 year old female patient who was intramuscularly vaccinated with the second dose of GARDASIL vaccine on unspecified date. In March or April 2008, the patient experienced with urticaria all over her body within 24 hours of receiving GARDASIL vaccine and returned to the doctor's office for medical attention. There was no wheezing. Subsequently, the patient recovered on an unspecified date and there were no follow up visits. Additional information has been requested

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334970-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Oct-2008	01-Oct-2008	0	17-Nov-2008	13-Feb-2009	IN	WAES0810USA05253	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	UNK	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain

Symptom Text: Information has been received from a Registered Nurse concerning a female who in October 2008 was vaccinated with a first dose of GARDASIL, single dose vial, in physician's office. The patient experienced abdominal pain within 24 hours of receiving her first dose of GARDASIL. Unspecified medical attention was sought. At the time of reporting, the patient's outcome was unspecified. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334971-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	13-Feb-2009	--	WAES0810USA05264	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who received GARDASIL (therapy date, route, site unknown) and fainted. The patient's medical history and concomitant therapy were unspecified. The patient did not seek medical attention. At the time of this report, the patient had recovered. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334972-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	15-Sep-2008	22-Sep-2008	7	17-Nov-2008	13-Feb-2009	NJ	WAES0810USA05320	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site mass

Symptom Text: Information has been received from a 25 year old female with no medical history who on 15-SEP-2008 was vaccinated IM with the first dose of GARDASIL vaccine. Concomitant therapy included YAZ, within a week of getting the vaccine, patient experienced "a hard bump the size of a dime" at the injection site. At the time of this report, the patient was recovered. the reporter did not remember the date of recovery. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: YAZ

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334973-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	13-Feb-2009	NY	WAES0810USA05336	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye swelling

Symptom Text: Information has been received from an Immunization Coordinator, concerning a female patient, who on an unknown date received the first dose of GARDASIL (lot number, route and injection site unknown). It was reported that the patient's eyes "swelled shut" about three days after receiving the vaccine. The patient sought unspecified medical attention. At the time of reporting, the patient "is fine now". Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334974-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	22-Aug-2008	23-Aug-2008	1	17-Nov-2008	13-Feb-2009	IL	WAES0810USA05338	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Pigmentation disorder, Pruritus

Symptom Text: Information has been received from a nurse, concerning a 12-year-old female patient with no known drug allergies, who on 22-AUG-2008, received the first dose of 0.5 ml, GARDASIL (lot# 659437/1266U, injection site unknown) via intramuscular route. On 23-AUG-2008, after the administration, the patient developed several red areas off to the side of the site of injection. According to the mother of the patient, " the areas initially looked like the skin had been burned, almost blister-like. The areas are extremely pruritic". On 30-OCT-2008, the patient was examined by her physician. It was noted that she now had a half-dollar size circle (34 mm by 30 mm) that was without pigmentation (very white). She also had two small red dots an a red area 5 cm by 4 cm to the left of thee white area. The red areas of skin were flattened. The patient stated that the areas never released fluid or became scabbed. At the time of reporting, the patient was not recovered from the events. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **334975-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Sep-2008	30-Sep-2008	0	17-Nov-2008	13-Feb-2009	MA	WAES0810USA05346	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash pruritic, Urticaria

Symptom Text: Information has been received from a physician concerning a 17 year old female with no medical history and no drug allergies who was vaccinated with a first dose of GARDASIL vaccine (lot # not reported) about a month ago, on approximately 30-SEP-2008. Concomitant therapy included CONCERTA. The patient experienced itchy rash/hives that mostly was localized on the legs about a month ago, on approximately 30-SEP-2008. The patient sought medical attention, and lab tests have not performed yet. The patient recovered on an unspecified date. Additional information has been requested.

Other Meds: CONCERTA

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **334976-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	08-Sep-2008	08-Sep-2008	0	17-Nov-2008	13-Feb-2009	CT	WAES0810USA05349	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 08-SEP-2008 was vaccinated with GARDASIL vaccine 0.5ml. Second suspect therapy included VAQTA vaccine (inactive) (manufacture unknown) which was vaccinated at the same time. On 08-SEP-2008 the patient experienced syncope. The patient sought unspecified medical attention. On the same day, the patient recovered. Additional information has been requested

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334977-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Oct-2008	29-Oct-2008	0	17-Nov-2008	13-Feb-2009	--	WAES0810USA05375	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Myalgia

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female patient with no pertinent medical history and no known drug allergies, who on 29-OCT-2008, was vaccinated with the first 0.5 ml dose of GARDASIL, IM, into her left arm (lot # 661764/0650X). Concomitant therapy included cetirizine hydrochloride (ZYRTEC). On 29-OCT-2008, the patient experienced severe joint and muscle pain. No lab diagnostics studies were performed. The patient sought unspecified medical attention, and the physician advised patient to take ibuprofen and to continue taking her cetirizine hydrochloride (ZYRTEC). At the time of reporting, the adverse events were ongoing. Additional information has been requested.

Other Meds: ZYRTEC

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334978-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Nov-2008	13-Feb-2009	VA	WAES0811USA00020	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a nurse practitioner concerning a patient who who on unspecified dates was vaccinated with the first, second and third doses of GARDASIL vaccine. The nurse practitioner stated the patient was tested positive for HPV on a Papanicolaou test (PAP smear) after completing the GARDASIL vaccine series, on an unspecified date. The patient was seen at the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, positive for HPV.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334979-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	08-Jul-2008	01-Sep-2008	55	17-Nov-2008	02-Jan-2009	WI	WAES0811USA00026	19-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	007X		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Blood test, Crepitations, Epistaxis, Joint swelling, Musculoskeletal stiffness, Myalgia, Rheumatoid arthritis, Serology negative, Skin discolouration

Symptom Text: Information has been received from a licensed practical nurse concerning a 19 year old female with medical history unspecified who on an unspecified date was vaccinated with GARDASIL vaccine (Lot#, route was not provided) (where in the series this dose was not known at the time of reporting. There was no concomitant medication. In September 2008, the patient developed muscle and joint pain. The patient had been seen by the physician. And she had blood work on 30-Oct-2008 (results were pending). The physician mentioned to the nurse a possible diagnosis of rheumatoid arthritis. At the time of reporting, the outcome was unknown. Additional information has been requested. 01/13/09 Reviewed Rheumatology medical records of 10/30-11/14/2008. FINAL DX: rheumaoid arthritis, seronegative. Records reveal patient experienced joint pain & swelling of multiple joints beginning 9/08 along with morning stiffness, bluish discoloration of fingers when cold, nose bleeds, . Also had crepitus of TMJs, difficulty opening/closing mouth, spine pain & crepitus x 3-4 years.

Other Meds: None

Lab Data: Unknown

History: None PMH: oligmenorrhea, viral meningitis age 2, iron deficiency anemia.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334980-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jan-2008	01-Jan-2008	0	17-Nov-2008	13-Feb-2009	NY	WAES0811USA00037	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Pain in extremity, Vomiting

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter with no relevant medical history or allergies, who in November 2007, was vaccinated with a first dose of GARDASIL (lot number, injection site and route not reported). In January 2008, the patient was vaccinated with a second dose of GARDASIL in arm (lot number and injection route not reported). There was no concomitant medication. Ten hours after the vaccination, the patient experienced vomiting every 15 minutes and pain in her back and legs. Unspecified medical attention was sought. The day after vaccination, the patient recovered from the events. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334981-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Mar-2007	13-Oct-2008	577	17-Nov-2008	12-Feb-2009	PA	WAES0811USA00054	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vaginal haemorrhage

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for GARDASIL vaccine, concerning a 15 year old female with no relevant medical history or allergies who on 16-MAR-2007 was vaccinated with a first dose of GARDASIL vaccine (lot number, injection site and route not reported). On 13-OCT-2008 the patient was vaccinated intramuscularly with a second dose of GARDASIL vaccine (lot umber and injection site not reported). There was no concomitant medication. On 13-OCT-2008 the patient experienced trace vaginal spotting. On 31-OCT-2008 the patient was determined to be pregnant by urine pregnancy test. The patient's LMP was 27-SEP-2008. Unspecified medical attention was sought. The outcome of the patient's experiences was unknown. Additional information has been requested.

Other Meds: None

Lab Data: Urine beta-human, 10/31/08, pregnant.

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334982-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	TX	WAES0811USA00055	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site irritation, Rash pruritic

Symptom Text: Information has been received from a consumer concerning his 14 year old daughter with latex and a lot of other unspecified allergies who on unknown dates was vaccinated with two doses of GARDASIL vaccine in arm. There was no concomitant medication. "After the first dose" of GARDASIL vaccine, the patient experienced an itchy rash, the injection sites irritated and had pale spots. The caller thought his daughter might have and allergic reaction to GARDASIL vaccine because she had a lot of allergies. At the time of the report the patient received 2 doses already in both arms and arms had itchy rash now that was not going away. The patient sought medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Latex allergy, Hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334983-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	10-May-2008	10-Jun-2008	31	17-Nov-2008	12-Feb-2009	--	WAES0811USA00057	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Headache, Visual acuity reduced

Symptom Text: Information has been received from a physician's nurse concerning a 13 year old female, who on 10-MAY-2008, received the first dose of GARDASIL (lot # 659180/17580), 0.5 ml, intramuscularly. Concomitant therapy included meningitis vaccine (manufacturer unspecified, lot # U2492AA). On 10-JUN-2008, the patient experienced joint pains, headache and decreased visual acuity. The patient returned for the second dose of GARDASIL (lot # 660393/0067X) on 21-JUL-2008. The patient was sent to an ophthalmologist, who diagnosed the decreased in visual acuity. The patient had a complete blood cell count (CBC) and x-ray test (results not provided). The patient would not be getting the third dose. It was not known if the adverse events had improved between the first and second dose of GARDASIL. At the time of the report, on 31-OCT-2008, the outcome of the patient was unknown. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334984-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Mar-2008	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0811USA00062	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Information has been received from a nurse practitioner concerning an 18 year old female who on 10-MAR-2008 was vaccinated with a first dose of GARDASIL vaccine (lot # 659653/1448U) and on 5-MAY-2008 was vaccinated with a second dose of GARDASIL vaccine (lot # 659653/1448U). Concomitant therapy included hormonal contraceptives (unspecified). On unspecified date the patient experienced arm numbness. The patient sought unspecified medical attention. It is unknown if patient experienced the event after the first or second dose. At the time of reporting the patient' arm numbness persisted. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334985-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	29-Oct-2008	30-Oct-2008	1	17-Nov-2008	12-Feb-2009	PA	WAES0811USA00064	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Injection site induration, Injection site movement impairment, Injection site pain, Injection site warmth, Musculoskeletal stiffness

Symptom Text: Information has been received from a physician concerning a 23 year old female with allergies to erythromycin who was vaccinated with first, second, and third dose of GARDASIL on 29-APR-2008. 30-JUN-2008 and 29-OCT-2008 respectively. The third dose of GARDASIL (lot # was 661530/0575X) was IM, 0.5 ml. There was no concomitant medication. On 30-OCT-2008, the patient experienced an injection site reaction after her third dose of GARDASIL. The symptoms included 11 by 7 cm induration with pain and inability to lift her arm. The site was warm to the touch. She also reported stiffness in her fingers. At the time of the report, the patient was recovering. The physician saw the patient. Additional information has been requested.

Other Meds: None

Lab Data:

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **334986-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	Unknown	27-Oct-2008		17-Nov-2008	12-Feb-2009	--	WAES0811USA00074	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Dyspnoea, Influenza, Injection site pain, Myalgia, Pyrexia

Symptom Text: Information has been received from a physician concerning his 24 year old daughter who was vaccinated with the first dose of GARDASIL. Subsequently, the patient experienced general flu symptoms, but the adverse event had gone away. Several weeks ago, the patient received the second dose of GARDASIL. On approximately 27-OCT-2008 ("about 3 or 4 days ago"), the patient experienced arthralgia, myalgia, fever, and severe pain at the injection site. On 30-OCT-2008, the patient experienced having difficulty breathing with her asthma. The physician reported that the patient was not going to receive the third dosed of GARDASIL. At the time of reporting, the adverse events were ongoing. The patient sought medical attention via contacting physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **334987-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Oct-2008	23-Oct-2008	0	17-Nov-2008	22-Jan-2009	MO	WAES0811USA00153	23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Vomiting

Symptom Text: Information has been received from a registered nurse concerning a 16 year old white female who on 23-OCT-2008 in the PM was vaccinated with GARDASIL IM in the right arm. Concomitant therapy included INFLUENZA (unspecified) (manufacturer unspecified). On 23-OCT-2008 the patient experienced vomited immediately after the injections. The patient felt better afterwards. At the time of the report, the patient was recovered. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334988-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	15-Oct-2008	15-Oct-2008	0	17-Nov-2008	12-Feb-2009	NM	WAES0811USA00251	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Nausea

Symptom Text: Information has been received from a physician concerning a 20 year old female who on 15-OCT-2008 was vaccinated with the second dose of GARDASIL vaccine, IM "single dose vial". The patient experienced nausea almost immediately after receiving her second dose of GARDASIL vaccine sometime around 15-OCT-2008. Physician reported that the patient's nausea "got progressively" for a couple of weeks after which it started to diminish. The patient sought medical attention. The pregnancy test was negative. Additional information has been requested.

Other Meds: Unknown

Lab Data: beta-human chorionic - negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **334989-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0811USA00551	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Medical device complication, No adverse event

Symptom Text: Information has been received from a health professional regarding GARDASIL in a prefilled syringe (lot # 0947X). It was reported that the prefilled syringe leaked at the hub. The patient was able to receive the dose. No AE reported. The SR# is 1-3272605316. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334990-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		17-Nov-2008	13-Feb-2009	--	WAES0811USA00598	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 25 year old female who on an unspecified dated was vaccinated with the first dose of GARDASIL vaccine. The physician reported that the patient fainted in the office after receiving vaccine. The outcome was unspecified. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **334991-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		17-Nov-2008	12-Feb-2009	--	WAES0811USA00599	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 23 year old female who on an unspecified date was vaccinated with the first dose of GARDASIL. The patient fainted in the office after receiving the vaccine. The outcome was unspecified. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335048-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Nov-2008	Unknown		11-Dec-2008	12-Feb-2009	SD		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Right arm	Intramuscular	
	DTAP	SANOFI PASTEUR	U2396BA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Patient given DTaP rather than Tdap

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335058-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-Dec-2008	09-Dec-2008	1	11-Dec-2008	12-Feb-2009	FL		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	MSD 0537X	4	Right arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	PMC UF452A	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	PMC U2421AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	MSD 0651X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Discomfort, Injection site erythema, Injection site vesicles, Injection site warmth, Malaise

Symptom Text: Mother state school called her to get child from school 12/10/08 not feeling well slight temperature, blister, red and hot at site of shot "RTR" "area looks like it was burned". Mon called in the reported issues. Cold compress helped with discomfort use of Tylenol for fever.12/11/08 @2:32PM called mother state temp 102.4 last night Tylenol help the large blister broke there are still some small once, will take picture of them, but child in school today

Other Meds:

Lab Data:

History: NONE SPECIFIED

Prex Illness: NONE THAT MOTHER STATE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335100-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-May-2008	28-May-2008	0	11-Dec-2008	22-Dec-2008	MN		22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	19684	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2564AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2937BA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	13664	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypotonia, Loss of consciousness, Pallor, Unresponsive to stimuli

Symptom Text: After patient received vaccine, LOC (loss of consciousness). Medical assistant supported her head to prevent head injury and patient brought to floor to lay down. Feet raised , patient flaccid, skin pale, non responsive. Within 20 seconds patient opened eyes and tried to getup. BP(blood pressure) =116/70; P (pulse) - 68. Patient had not eaten. After resting x 45 minutes, patient left clinic.

Other Meds: ORTHOTRICYELEN LO

Lab Data: None

History: AMOXICILLIN and Penicillin allergy; History of reflux

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335101-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	24-Nov-2008	24-Nov-2008	0	11-Dec-2008	22-Jan-2009	MN		23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	
	MMR	MERCK & CO. INC.	02824	1	Right arm	Subcutaneously	
	FLU	SANOFI PASTEUR	42848AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Immediate post-injection reaction, Loss of consciousness, Pallor

Symptom Text: LOC after vaccine administered. Caught by MA pt did not hit head. Brought to exam table and leveled pt lupine LOC about 30 seconds total. After 30 seconds pt responsive, pale. BP=100/62; P=68 states never fainted with vaccine previously.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 335125-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Aug-2008	28-Aug-2008	5	12-Dec-2008	15-Dec-2008	FR	WAES0810USA00303	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0233U	2	Left arm	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Incorrect route of drug administration, Nausea, Pharyngitis, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a general practitioner concerning a 15 year old female with drug allergy and asthma who on an unspecified date was vaccinated with the first dose of GARDASIL. The patient experienced intermittent nausea and vomiting after receiving the second dose of GARDASIL (batch number not reported) on 03-MAR-2008. On 23-AUG-2008, the patient received the third dose of GARDASIL (batch no. NF3730; Lot no. 0233U) and experienced severe nausea and vomiting. She received corrective treatment with MOTILIUM and VOGALENE which were both ineffective. At the time of reporting, the patient was better, however she had not recovered. Additional information was received from the physician. The lot number of GARDASIL was provided. The patient recovered on 17-SEP-2008. Follow-up information received from a phone call to the physician on 03-OCT-2008: Echography was normal. Hepatic work-up and urinary analysis were normal. Mononucleosis serology was negative. The patient had pharyngitis. At time of reporting the patient had nausea again. Investigations were scheduled. Follow-up information received through the pharmacovigilance form: Case of misuse. Case upgraded by the company due to the patient's hospitalization. The patient received the third dose of GARDASIL via inappropriate route i.e. subcutaneous route instead of intramuscular route in her left arm. Onset date of nausea and vomiting of moderate intensity was on 28-AUG-2008, with relapse on 20-SEP-2008, 30-SEP-2008 and 18-NOV-2008. At time of reporting the patient had recovered (unspecified timeline). Adverse events were reported as non serious by the reporter. The patient was hospitalized on an unspecified date. Hospital report not available. Start therapy date for VOGALENE was on 28-AUG-2008 and she had it via rectal route, start therapy date for NAUSICAIM was on 20-SEP-2008 and she had it via oral route. There was a misuse with the first dose of GARDASIL (Lot number 655635/1019F, Batch number NE56080) received via subcutaneous route in her left arm

Other Meds: Unknown

Lab Data: ultrasound, normal; urinalysis, normal; hepatic function tests, normal; clinical serology test, mononucleosis serology: negative

History: Nausea; Vomiting

Prex Illness: Drug hypersensitivity; Asthma

Prex Vax Illns:

Vaers Id: **335126-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	20-Oct-2008	27-Oct-2008	7	12-Dec-2008	15-Dec-2008	MO	WAES0812USA00589	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthma, Injection site erythema, Pruritus generalised, Rash generalised

Symptom Text: Information has been received from a Licensed practical nurse (LPN) concerning a 26 year old female patient, with concurrent condition of asthma and sulfonamide allergy who on 20-OCT-2008 was vaccinated with the first dose of GARDASIL intramuscularly into the right deltoid (lot# 0947X). Concomitant therapy included rescue inhaler. On approximately 27-OCT-2008, the patient experienced systemic rash, redness at the injection site, systemic itching and asthma attacks. She was prescribed BENADRYL, used her rescue inhaler, and had a steroid injection. After two weeks, the patient recovered (2008). The LPN considered the systemic rash, redness at the injection site, systemic itching and asthma attacks to be Other Important Medical Events. Additional information has been requested.

Other Meds: [therapy unspecified]

Lab Data: None

History:

Prex Illness: Asthma; Sulfonamide allergy

Prex Vax Illns:

Vaers Id: 335127-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Sep-2008	04-Sep-2008	0	12-Dec-2008	15-Dec-2008	FR	WAES0812AUS00136	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Groin pain, Muscle spasms, Nausea, Pain in extremity, Pyrexia

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 12 year old female who on 04-SEP-2008 was vaccinated with GARDASIL. On 04-SEP-2008 following vaccination with GARDASIL, the patient experienced abdominal pain, nausea, groin pain, muscle spasms, pain in extremity and pyrexia and was hospitalized. It was described that the patient was nauseated post vaccine (no vomiting) and attended sick bay at school. The patient developed mild fever and at 8:30 PM of the same day, the patient developed pain in both groins radiating to her kneecaps. The patient also developed abdominal pain and muscle spasms in lower back. The patient was taken to hospital and given IV therapy and PANADOL. Urine and blood testing were done which showed nothing abnormal. At the time of reporting to the agency on 19-SEP-2008 the patient's abdominal pain, nausea, groin pain, muscle spasms, pain in extremity and pyrexia persisted. The agency considered that abdominal pain, nausea, groin pain, muscle spasms, pain in extremity and pyrexia were possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, ??08, nothing abnormal; urinalysis, ??08, nothing abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **335128-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	15-Jun-2008	01-Jul-2008	16	12-Dec-2008	15-Dec-2008	FR	WAES0812AUS00122	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Migraine, Optic neuritis, Visual acuity reduced

Symptom Text: Information was obtained on request by the Company from the agency, via a Case Line Listing and Public Case Details Form, concerning a 26 year old female who on 15-JUN-2008 was vaccinated with GARDASIL, intramuscularly. Concomitant therapy included NORDETTE. In approximately July 2008, "within three weeks of vaccination", the patient developed left optic neuritis and migraine headache and was hospitalised. Results of Magnetic Resonance Imaging (MRI) of the patient's brain and orbits were as follows: "Foci of increased intensities are seen within the periventricular deep white matter bilaterally. Demyelination cannot be excluded at this stage. The orbital contents define normally. Both optic nerves appear unremarkable." The patient was treated with prednisolone. On 21-AUG-2008 the patient had recovered, with sequelae (mild decreased vision), from optic neuritis and migraine. The agency considered that optic neuritis and migraine were possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: ethinyl estradiol (+) levonorgestrel

Lab Data: magnetic resonance imaging, ??08, brain and orbits: Foci of increased intensities seen. Demyelination cannot be excluded at this stage

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335129-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	26-Oct-2007	01-Feb-2008	98	12-Dec-2008	15-Dec-2008	FL	WAES0812USA01616	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a 22 year old female patient, for the pregnancy registry for GARDASIL, with no pertinent medical history and no known drug allergies/drug reactions, who on 26-OCT-2007 was vaccinated with the first dose of GARDASIL (Lot # not provided). It was noted that the patient did not receive her second or third doses. Concomitant therapy included ORTHO TRI-CYCLEN. The patient became pregnant in February 2008 and gave birth on 13-NOV-2008. Her son was born with duodenal atresia and only one kidney. It was noted that the umbilical cord formed correctly but was not nourished "correctly" and therefore it looked "mutilated". There was also a tear in the umbilical cord near the belly button. The patient sought medical attention with the physician. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN

Lab Data: diagnostic laboratory, basic lab work

History:

Prex Illness: Pregnancy NOS (LMP = 2/1/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335130-1** **Related reports:** 335130-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.0	M	30-Jan-2008	22-Oct-2008	266	12-Dec-2008	15-Dec-2008	FR	WAES0812USA01711	06-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Initial information has been received from a health care professional through the patient's mother. The present case concerns a baby who was born with some abnormalities whose mother was administered one dose of GARDASIL (batch # not reported) during early pregnancy mother linked case WAES# 0805USA00774. The patient's mother was vaccinated with the second dose of GARDASIL on 30-JAN-2008 and the last menstrual period was 11-JAN-2008. It is reported that the baby, a male, was born after 40 weeks and 4 days of gestation. The baby was born by a cesarean delivery. Weight at birth was 3.4 kg., height at birth was 52 cm, Apgar 1 min = 9; apgar 5 min = 10. On the 22-OCT-2008 the patient had his first pediatrician revision during which a heart murmur was detected. The pediatrician forwarded the patient to the hospital cardiology ward in order to perform further test. According to the hospital report the patient, a 12 hour-old-male, was sent from the clinic where he was born due to a heart murmur that was clinically asymptomatic. Upon examination the child with normal coloring of mucosa and skin, pulse was symmetric. Transcutaneous oxigention 100% with inspired oxygen fraction of room air. Normal respiratory system. From cardiac auscultation they found first and second sounds to be normal with systolic murmur of grade II-III/VI in the meso, pulmonary and aortic focus. Echocardiogram showed a normal sinus rhythm for the patient's age. An in-depth echocardiogram study was performed. Relevant findings were: situs solitus with concordance A-V and V-A. Normal pulmonary and systemic venous return. Left and right auricles are normal not dilated. Interauricular septum presents a small, 2mm, oval foramen with minimum left to right shunt. Septum interventricular with a 6mm subaortic interventricular communication, there appears to be overriding aorta, being more evident in longitudinal cut, reminding of Fallot's tetrad. Left ventricle is neither dilated nor hypertrophic presenting a correct function. Right ventr

Other Meds: Unknown

Lab Data: Echocardiography, 22?Oct08, normal sinus rhythm for patient's age; Echocardiography, 22?Oct08, see narrative; Ultrasound, 22?Oct08, see narrative; Echocardiography, see narrative; Ultrasound, see narrative

History: Vaccine exposure during pregnancy

Prex Illness:

Prex Vax Illns:

Vaers Id: **335130-2** **Related reports:** 335130-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	30-Jan-2008	30-Jan-2008	0	03-Feb-2009	04-Feb-2009	FR	WAES0805USA00774	04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Foetal disorder, Inappropriate schedule of drug administration

Symptom Text: Initial information has been received from a health care professional through a 28 year old female with a history of 1 pregnancy and 1 live birth who on 30-NOV-2008 was vaccinated with a first dose of GARDASIL. The patient was vaccinated during pregnancy LMP date was 11-JAN-2008 and on 30-JAN-2008 the patient was vaccinated with a second dose of GARDASIL (batch number not reported). No adverse events were reported. The expected delivery date is 10-OCT-2008. The patient had a previous pregnancy. It was reported that the patient gave birth by cesarean to a healthy child. Follow up information was received on 23-JUL-2008. The evolution of the pregnancy was normal. Test results and morphologic echography results are also normal. Follow up information was received that the patient gave birth to a baby with some anomalies by cesarean on the 21-OCT-2008 after a 40 week gestational period. It is reported that the baby has been born with Fallot's tetrad, a congenital heart anomaly. It was reported that the baby, a male, was born on the 21-OCT-2008 after 40 weeks and 4 days of gestation. The baby was born by a cesarean delivery. Weight at birth was 3.4 kg, height at birth was 52 cm, Apgar 1min-9, Apgar 5 min-10. On the 22-OCT-2008, the patient had his first paediatrician revision during which a heart murmur was detected. The paediatrician forwarded the patient to the hospital cardiology ward in order to perform further test. According to the hospital report the patient, a 12 hour-old male, was sent from the clinic where he was born due to a heart murmur that was clinically asymptomatic. Upon examination the child presented with normal coloring of mucosa and skin, pulse was symmetric. Transcutaneous oxygenation 100%, with inspired oxygen fraction of room air. Normal respiratory system. From cardiac auscultation they found first and second sounds to be normal with a systolic murmur of grade II-III/VI in the meso, pulmonary and aortic focus. Echocardiogram showed a normal sinus rhythm for the patient's age. An in-depth echoca

Other Meds: Unknown

Lab Data: diagnostic laboratory test, normal; ultrasound, normal; echocardiography, normal sinus rhythm for the patient's age; diagnostic laboratory test, a small, 2 mm, oval foramen with a minimum left to right shunt; ultrasound, a minimum permeable

History:

Prex Illness: Pregnancy NOS (LMP = 11Jan08)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335135-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	30-Jan-2007	30-Jan-2007	0	12-Dec-2008	15-Dec-2008	GA	WAES0812USA00535	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a registered nurse through the pregnancy registry for GARDASIL concerning a 20 year old female patient with zithromycin allergy who on 29-NOV-2006 was vaccinated with the first dose of GARDASIL 0.5 mL IM and on 30-JAN-2007 with the second dose of GARDASIL 0.5 mL IM. Concomitant therapy included NUVARING. The patient became pregnant during the GARDASIL series. Approximately around December 2007, the patient delivered a male child early at 35-36 weeks gestation with a congenital anomaly that was diagnosed with cardiomyopathy (also reported as cardiac defect). The patient received all her prenatal care with an OB-GYN physician. It was unknown if the patient received the third dose of GARDASIL. The patient sought medical attention at office visit. Cardiomyopathy (cardiac defect) was considered a congenital anomaly by the nurse. Additional information has been requested.

Other Meds: NUVARING

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 3/31/2007); Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: 335137-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Sep-2008	01-Nov-2008	35	12-Dec-2008	15-Dec-2008	FR	WAES0812USA01529	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute lymphocytic leukaemia, Chemotherapy, Fatigue, Pallor

Symptom Text: Information has been received from a general practitioner as part of business agreement, concerning a 14-year-old female patient with back pain since the beginning of SEP-2008 received the first dose of GARDASIL (lot number not reported) on 27-NOV-2008. Post vaccination on an unspecified date the patient presented with intense fatigue and pallor. A complete blood count revealed 5 g/l of hemoglobin, diagnosis of acute lymphoid leukemia was established by the beginning of NOV 2008. The patient was hospitalized (unspecified dates). She was under cancer chemotherapy during 5 weeks. At time of reporting, the patient had not recovered. Other business partner number included E2008-11277. No further information is available.

Other Meds: Unknown

Lab Data: complete blood cell count, 01?Nov08, hemoglobin 5 g/l

History:

Prex Illness: Back Pain

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335138-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	23-Apr-2008	23-Apr-2008	0	12-Dec-2008	15-Dec-2008	--	WAES0805USA03622	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Initial and follow-up information has been received from a certified nurse midwife, for the Pregnancy Registry for GARDASIL, concerning a 22 year old female with inherited bilateral sensoneural hearing loss and a history of vaginal bacterial infections, alcohol abuse and urinary tract infections, and no known drug allergies, who on 23-APR-2008 was vaccinated intramuscularly in the right arm with a 0.5 ml first dose of GARDASIL (Lot# 659964/1978U) while pregnant. There was no adverse event post vaccination. Other medications included prenatal vitamins (unspecified). Prior to the vaccination, the patient was administered a urine and blood test to test for pregnancy. The urine test result was unclear. The blood test result came back with a positive result the next day (LMP = 17-Mar-2008). Results are pending for an ultrasound and CF screen performed on an unspecified date. Unspecified medical attention was sought in the office. The patient's outcome is unknown. Follow-up information was received. Other medications included prenatal vitamins, started on 05-MAY-2008, 1 tablet daily for pregnancy. Complication during pregnancy included fetal vascular thrombosis. On 25-NOV-2008, more than 35 weeks from LMP, the patient experienced fetal death/still birth. The products of conception were examined. The fetus was normal. Upon internal review, fetal death/still birth was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: urine beta-human, 04/23/08, unclear; serum beta-human, 04/23/08, positive

History: Vaginal infection; Alcohol abuse; Urinary tract infection

Prex Illness: Pregnancy NOS (LMP = 3/17/2008); Hearing loss bilateral

Prex Vax Illns:

Vaers Id: 335139-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Mar-2008	10-Mar-2008	6	12-Dec-2008	15-Dec-2008	FR	WAES0812AUS00112	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0583U		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Headache, Lethargy, Malaise

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 14 year old female who on 04-MAR-2008 was vaccinated with GARDASIL (Lot No 657872/0583U, Batch No J2896, Expiry Date 12-FEB-2010). On 10-MAR-2008 the patient experienced headache, dizziness, lethargy and malaise and was hospitalised. It was described that the patient developed bad headache, dizziness and lethargy for 3 days. On 17-MAR-2008 the same symptoms returned but more severe than the initial reaction. The patient was unwell until 19-MAR-2008. On 23-MAR-2008, the same symptoms re-occurred and the patient is still experiencing the same symptoms. The patient was treated with NUROFEN, PANADEINE and ENDONE. At the time of reporting to the agency on 25-AUG-2008, the patient's headache and dizziness and lethargy and malaise persisted. The agency considered that headache, dizziness, lethargy and malaise were possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335140-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Jul-2008	01-Aug-2008	31	12-Dec-2008	15-Dec-2008	FR	WAES0812AUS00125	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Lymphocytic hypophysitis

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 19 year old female who on 01-JUL-2008 was vaccinated with GARDASIL. On 01-AUG-2008, 31 days after vaccination with GARDASIL, the patient developed hypophysitis which was described as lymphocytic hypophysitis. The patient was treated with corticosteroids. At the time of reporting to the agency on 20-SEP-2008 it was not known if the patient had recovered from the hypophysitis. The agency considered that hypophysitis was possibly related to therapy with GARDASIL. The original reporting source was not provided. The adverse event of hypophysitis was considered to be disabling by the reporting agency. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335141-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Dec-2007	Unknown		12-Dec-2008	15-Dec-2008	PR	WAES0812USA00356	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for GARDASIL concerning a female who in December 2007, was vaccinated with the second dose of GARDASIL (dose, route, lot# not reported). The patient learned that she was pregnant in April 2008 and delivered the baby in October 2008. She had a "C-section", but she delivered a healthy baby. The patient had not yet received the third dose of GARDASIL. No further information was available. Obstetrical complication was considered as an other important medical events. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 335142-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	02-Jul-2008	04-Jul-2008	2	12-Dec-2008	15-Dec-2008	NV	WAES0812USA01598	21-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Alcohol use, Contraception, Diarrhoea, Pancreatitis, Pyrexia, Vaccination complication, Vomiting

Symptom Text: Information has been received from a physician concerning a 23 year old female with no allergy or medical history who on 02-JUL-2008 was vaccinated with the first dose of GARDASIL, 0.5ml, IM. Concomitant therapy included YASMIN. 2 days after the vaccination (on 04-JUL-2008) the patient developed pancreatitis. The patient was admitted to an unknown hospital on 04-JUL-2008 and was diagnosed with pancreatitis. The physician is unable to provide details of the hospitalization except that the patient was discharged fully recovered on 09-JUL-2008. The patient underwent abdominal ultrasound during hospitalization. The physician considered the pancreatitis to be immediately life threatening and disabling. Additional information has been requested. 1/20/09 Reviewed hospital medical records of 7/5-7/9/2008 FINAL DX: acute pancreatitis; recent Gardasil shot; use of BCP for contraception. Records reveal patient experienced abdominal cramping pain, diarrhea, vomiting, fever after light ETOH consumption day prior to admit. GI consult done. Tx w/IVF & kept NPO. Improved & d/c to home w/PCP f/u.

Other Meds: YASMIN

Lab Data: Unknown LABS: CT abdomen abnormal w/peripancreatic edema & free intraperitoneal fluid. US of abdomen WNL. Lipaase 209 (H). Amylase 304 (+). WBC 13,700(H). LFTs WNL. Blood c/s neg. Urinalysis WNL.

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335143-1** **Related reports:** 335143-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Apr-2008	02-Apr-2008	1	12-Dec-2008	12-Feb-2009	VA		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site reaction, Skin reaction

Symptom Text: Skin reaction around site of injection within weeks of vaccine. Then generalizing over entire skin surface over next 3-4 months.

Other Meds: None

Lab Data: See enclosed skin biopsy

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **335143-2** **Related reports:** 335143-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		15-Dec-2008	13-Jan-2009	VA	WAES0811USA02326	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dry skin, Injection site reaction, Pigmentation disorder

Symptom Text: Information has been received from a consumer concerning his 16 year old daughter with allergic to AMOXILILLIN who was vaccinated with 3 doses of GARDASIL (route and site not reported). The patient had no reaction to the first 2 doses. Right after the 3rd dose of GARDASIL the patient experienced a reaction at the injection site, that later spread to most of her body. The patient lost tremendous amount of pigmentation in her skin, and the skin is dry and itchy and a lot of times cracks from the dryness. The pediatrician referred her to a dermatologist where she had biopsy done. The office said it was not an allergic reaction. The loss of pigmentation and dryness was mostly all over her face, both arms and legs. The patient's experiences persisted. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **335144-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	15-Jan-2008	30-Jul-2008	197	12-Dec-2008	15-Dec-2008	FR	WAES0812AUS00117	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing and Public Case Detail form concerning a 24 year old female patient who on 20-NOV-2007 and 15-JAN-2008 was vaccinated with her first and second dose of GARDASIL. The patient's last menstrual period (LMP) was on 14-JAN-2008. On 30-JUL-2008 the patient went into premature labour and was hospitalized. The baby was born at 28 weeks gestation. The agency stated that there were no other causes found for premature labour. The agency considered that premature labour was possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 14JAN08)

Prex Vax Illns:

Vaers Id: **335153-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		12-Dec-2008	15-Dec-2008	FR	WAES0812AUS00124	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Anxiety, Immediate post-injection reaction

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form and a Case Line Listing concerning a 25 year old female, who has never had a history of anxiety problems before who was vaccinated with 3 doses of GARDASIL. Subsequently after vaccination with the first dose of GARDASIL, the patient developed anxiety. It was described as severe anxiety symptoms immediately after the first dose of GARDASIL, which continued until approximately 4 months after the last (third) dose. The patient was treated with psychological therapy. At the time of reporting to the agency on 29-SEP-2008, the patient had recovered from the anxiety. The agency considered that anxiety was possibly related to therapy with GARDASIL. The original reporting source was not provided. The adverse event of anxiety was considered to be disabling by the reporting agency. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 335154-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	28-Nov-2008	30-Nov-2008	2	12-Dec-2008	15-Dec-2008	FR	WAES0812HUN00003	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal tenderness, Dilatation intrahepatic duct acquired, Hepatitis, Lip dry, Mental status changes, Pallor, Pyrexia, Somnolence, Vomiting

Symptom Text: Information was received from a physician concerning a 10 year old female patient with no medical history mentioned who on 28-NOV-2008 received on arm (not specified if left or right arm) the first dosage (shot) of GARDASIL, 0.5 ml, prefilled syringes, intramuscular, out of 3 for immunization against HPV types 6, 11, 16, 18. No concomitant medications were reported. In about two days after vaccination, the patient presented fever (38 C, axillar), sleepiness, biliary vomiting, abdominal pain (periumbilical/periophalic and epigastric). The patient was referred to the hospital where the acute hepatitis diagnosis was suspected. On clinical examination were reported: altered general status, somnolence, dry lips, pale teguments, subcutaneous cellular tissue weak represented, balanced cardio-vascular and respiratory, slight sensitive abdomen on palpitation on periumbilical area. On laboratory test were found elevated serum levels of AST (GOT), ALT (GPT), Gamma-GT, alkaline phosphatase. Total and direct bilirubinemia were found in normal values. On abdominal ultrasonography examination were found signs of hepatitis with enlargement of an all intra-and extra-hepatic ducts. Also, there were found right polycystic kidney and left kidney with modified structure on ultrasonography. During one day of hospitalization in the pediatric department treatment with an antibiotic (not mentioned which one and dosages) and perfusion with glucose and natrium chloride solutions (not mentioned the volume and concentrations) were administered. The patient was referred to the infectious disease department with a diagnosis of acute hepatitis and the outcome was reported as not recovered. In the opinion of the reporting physician, the reported adverse events could be in relation with administration of GARDASIL. Additional information is expected.

Other Meds: None

Lab Data: Abdominal ultrasound, 01Dec08, dilation of important hepatic ducts, R. polycystic kidney; Abdominal ultrasound, 01Dec08, L. kidney w/modified structure on ultrasonography; Serum alanine aminotransferase, 01Dec08, 503 u/l, abnormal high: hep

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 335155-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Nov-2007	01-Dec-2007	22	12-Dec-2008	15-Dec-2008	FR	WAES0812USA01706	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1340F	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Granulocytosis, Leukocytosis, Lymphadenopathy

Symptom Text: Information has been received from a health authority concerning a 17 year old female patient who was vaccinated with GARDASIL (BATCH # NF14740 LOT # 1340F) on 09-NOV-2007. In December 2007, the patient developed swelling of the lymph nodes (cervical, nuchal, supraclavicular, mediastinal, axillary). Lymphadenopathy of unclear cause was diagnosed. Histological clarification was not performed at the time of reporting. Laboratory findings please see lab comments. Despite ongoing events the patient was vaccinated with a second dose of GARDASIL (BATCH # NF32810 LOT # 1537F) on 21-JAN-2008. Marked leukocytosis was seen by significant granulocytosis. Granulocytosis could indicate a bacterial infection or a systemic inflammatory event. A marked cellular immunodeficiency was not present. The patient was hospitalized from 09-APR-2008 to 16-APR-2008. Virological examination showed no indication for HIV, Hepatitis A, B or C infection, no indication for CMV or EBV infection, HHV-6 IgG positive, Parvo B19 negative, antibodies to VZV and rubella positive. Toxoplasma infection negative. On 16-APR-2008 the suspicion of Hodgkin's disease was diagnosed. The patient and the patient's parents refused further treatment or follow-up examination recommended by the reporter. Therefore the outcome was unknown. Case is Closed. Other business partner numbers include E200811173 and PEI2008018367. No further information is available.

Other Meds: Unknown

Lab Data: Epstein-Barr virus antibodies, ??Apr08, negative; parvovirus B19 PCR, ??Apr08, negative; serum Herpes simplex virus IgG antibody, ??Apr08, positive; serum hepatitis B Ab, ??Apr08, negative; virology test, ??Apr08, HIV negative; serum hepati

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335156-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		12-Dec-2008	15-Dec-2008	FR	WAES0812USA01708	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Wheelchair user

Symptom Text: Case received from an employee (no pharmacist) of pharmacy on 2-DEC-2008. This case is not medically confirmed, it is a hearsay case, with poorly information. The female employee of a pharmacy (no pharmacist) told that it was reported to her from male (no health care professional) that an about 17 year old female was sitting in wheel chair after being vaccinated with GARDASIL (lot, route and site not reported) on an unknown date. After vaccination she was sitting in a wheel chair. The male also reported that causality to vaccination was proofed. Neither the reason why the female was sitting in a wheel chair was reported nor if she still needs a wheel chair or not. As the female employee does not know the male reporter very well, and also in fear that with reporting this case she could get some trouble, it will not be possible to get further information. The outcome was not reported. Other business partner numbers include E200811252. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335157-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Nov-2008	11-Nov-2008	0	12-Dec-2008	15-Dec-2008	FR	WAES0812USA01948	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Loss of consciousness, Muscle spasms

Symptom Text: Information has been received initially by a foreign health authority concerning a 14 year old female patient who was administered on 11-NOV-2008 the first dose of GARDASIL (Batch # not reported) by intramuscular route (site of administration not reported). It was reported that immediately after vaccine administration, 11-NOV-2008, the patient suffered dizziness, muscular spasm and loss of consciousness. The patient recovered quickly that same day. Patient's blood pressure was 90/50. Dextro 85. Case reported as serious by the Health Authority with other medical important condition as criteria. Other business partner numbers include E2008-11316. No further information is available.

Other Meds: None

Lab Data: blood pressure measurement, 90/50; blood glucose, 85

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335158-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-May-2008	01-Sep-2008	111	12-Dec-2008	15-Dec-2008	FR	WAES0812USA01932	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hypoaesthesia, Nervous system disorder

Symptom Text: Initial case was reported from a physician on 04-Dec-2008: A 14 year-old female patient was vaccinated with the third dose of GARDASIL (lot number, site and route not reported) on 13-May-2008. In September/October 2008 the female developed a feeling of numbness in the upper arms and neurologic disorders (not specified per reporter). The female patient was taken into hospital in Department Neurology, for about one week, where a suspicion of multiple sclerosis was diagnosed. Up to time of report the physician did not know what kind of examinations in the hospital were performed, but he will try to get more information. The physician commented that he didn't see a relation between vaccination and the symptoms. The female patient has not yet recovered. Other business partner numbers include E2008-11359. This is one of several reports from the same source. This case is link to case E2008-13371 (same vaccine, same reporter, same date of reporter).

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 335170-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Oct-2008	23-Oct-2008	0	12-Dec-2008	15-Dec-2008	FR	WAES0812USA02075	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427U		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Nausea, Paraesthesia, Vision blurred

Symptom Text: Information has been received from a health authority (HA ref no. PEI2008017607). It was reported that a 16 year old female patient was vaccinated with a dose of GARDASIL (Lot #1427U and Batch #NH15200, injection site not reported) IM on 23-OCT-2008. On the same day, the patient experienced blurred vision, paraesthesia in both thighs, dizziness and nausea. The patient was hospitalized and received an infusion (not further specified). Seven hours later her general health condition was good. Discharge was not reported. The patient recovered. Previous vaccinations with GARDASIL (not further specified) were well tolerated. CASE CLOSED. Other business partner numbers included: E2008-11329.

Other Meds: Unknown

Lab Data: Unknown

History: Previous vaccinations with GARDASIL (not further specified) were well tolerated.

Prex Illness:

Prex Vax Illns:

Vaers Id: **335171-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Mar-2008	01-Mar-2008	0	12-Dec-2008	15-Dec-2008	FR	WAES0812USA02077	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Dermatitis atopic, Pruritus

Symptom Text: Information has been received from a Health authority concerning a 17 year old female patient with a history of atopic eczema and various allergies (penicillin, house dust mite) who on an unknown date, was vaccinated with the first dose of GARDASIL lot number, route and injection site not reported. Concomitant therapy included MINISISTON. In March 2008, the evening post vaccination, the patient developed pruritus of the entire body surface. Within the following days the patient experienced an acute exacerbation of a known atopic eczema. Before the vaccination, the patient had rarely experienced any skin disorders and never before had the entire surface been affected. The patient was hospitalized and received systemic steroid therapy which led to temporary improvement. When the therapy was stopped, exacerbation reoccurred. At the time of reporting, the patient was still in the hospital and had not yet recovered. Other business partner numbers include E2008-11328. No further information is available.

Other Meds: MINISISTON

Lab Data: Unknown

History:

Prex Illness: Atopic eczema; House dust mite allergy; Penicillin allergy

Prex Vax Illns:

Vaers Id: **335172-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		12-Dec-2008	15-Dec-2008	FR	WAES0812CAN00018	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthritis

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with GARDASIL (Lot # not provided). Subsequently the patient experienced severe arthritis (within 8 hours) in the same arm as the injection. The reporter felt that severe arthritis (within 8 hours) in the same arm as the injection was related to therapy with GARDASIL. Upon internal review severe arthritis (within 8 hours) in the same arm as the injection was considered other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335173-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Oct-2008	28-Oct-2008	12	12-Dec-2008	15-Dec-2008	FR	WAES0812USA02074	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Menorrhagia, Thrombosis

Symptom Text: This case was initially reported to an agency by the health authority and it concerns a 12 year old female patient. The patient had 28 day menstrual cycles with five days bleeding. The patient received GARDASIL. Batch number not reported, on 16-OCT-2008. On 28-OCT-2008, 12 days post vaccination, the patient experienced heavy bleeding with clots which was described as very abnormal and the patient was unable to attend school. At the time of the reporting the patient had not yet recovered. The reporter considered the event to be disabling and medically significant. Other business partner numbers include E200811402. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335174-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		12-Dec-2008	15-Dec-2008	FR	WAES0812AUS00120	15-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Conversion disorder, Paralysis

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning an 18 year old female who was vaccinated with GARDASIL. Subsequently after vaccination, the patient experienced paralysis and conversion disorder. At the time of reporting to the agency on 29-SEP-2008, the patient had recovered from paralysis and conversion disorder. The agency considered that paralysis and conversion disorder were related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review paralysis was considered an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335214-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
4.0	F	09-Dec-2008	Unknown		12-Dec-2008	12-Feb-2009	TX		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	UNKNOWN MANUFACTURER	UNKNOWN		Unknown	Unknown	
	MMR	UNKNOWN MANUFACTURER	UNNKNOWN		Unknown	Subcutaneously	
	DTAP	UNKNOWN MANUFACTURER	UNKNOWN		Unknown	Subcutaneously	
	HPV4	MERCK & CO. INC.	0650X		Unknown	Subcutaneously	
	IPV	UNKNOWN MANUFACTURER	UNKNOWN		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: N/A

Other Meds: N/A

Lab Data: N/A

History: N/A

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: **335216-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Dec-2008	10-Dec-2008	5	12-Dec-2008	06-Feb-2009	TX		06-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2683AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0381X	0	Right arm	Intramuscular	
FLUN	MEDIMMUNE VACCINES, INC.	550552P	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Drug exposure during pregnancy, Pyrexia

Symptom Text: PT RECEIVED FLU MIST, MENINGITIS, TDAP, AND HPV VACCINES ON 12/05/08. ON 12/10/08 DEVELOPED FEVER, STOMACHACHE AND WENT TO EMER RM. PREGNANCY DIAGNOSED @ 8-12 WKS GESTATION. LMP WAS 30 DAYS PRIOR TO VACCINATIONS.

Other Meds: NONE KNOWN

Lab Data:

History: NONE STATED

Prex Illness: NONE NOTED

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335218-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	08-Dec-2008	08-Dec-2008	0	12-Dec-2008	17-Dec-2008	MN		24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Amenorrhoea, Arthralgia, Chills, Cough, Dehydration, Delirium, Dizziness, Ear pain, Flank pain, Haematuria, Headache, Myalgia, Nausea, Neck pain, Oropharyngeal pain, Photophobia, Presyncope, Pyelonephritis, Pyrexia, Syncope, Tremor, Urinary tract infection, Vomiting

Symptom Text: high fever, delerious, syncope, dizziness, headache, hematuria, abdominal pain, neck pain, light sensitivity, shaky, nausea 2/12/09 Received ER medical records of 12/11/2008. FINAL DX: abdominal pain, nonspecific; UTI, like pyelonephritis; mod dehyrdation Records reveal patient experienced fever, chills, arthralgias, myalgias, vomiting, abdominal pain, sore throat, cough, HA, lightheaded. Tx w/IVF, antiemetics, antihistamin & IV antibiotics for probably pyelonephritis. Improved & d/c to home on continued oral antibiotics & f/u w/PCP in am. 2/20/09 Received PCP medical records of 12/8-12/12/08 FINAL DX: UTI Records reveal patient experienced likely hormonal amenorrhea w/neg preg urine when seen 12/8/08. RTC 12/12 w/N/V, right flank/RLQ abdominal pain, eye sensitivity, fever, bone/joint pain, shaking chills, ear pain, neck pain, HA, dizziness, near fainting, delerious w/fever. Had been seen in ER for UTI on 12/11. To continue oral antibiotics & return if no improvement. No further records available.

Other Meds: none

Lab Data: LABS: WBC 10.8(H), neutros 77.5%, lymps 13.2%(L). Sodium 132(L). UA abnormal. Throat c/s neg. Urine preg neg.

History: pcn, vicodin, benadryl,droperidol PMH: iron def anemia, irregular menstruation;off BCP x several months.

Prex Illness: slight fever 99.0

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335270-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	21-Apr-2008	16-Jul-2008	86	15-Dec-2008	16-Dec-2008	FR	WAES0812USA02421	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Autopsy, Death, Headache, No reaction on previous exposure to drug, Pain, Ruptured cerebral aneurysm

Symptom Text: Information has been received from a general practitioner concerning an 18 year old female with pollen allergy, allergic asthma and who was overweight, with a family history of the mother having multiple sclerosis, who on 12-MAR-2008 was vaccinated with the first dose of GARDASIL, lot # not reported, which was well tolerated. It was reported that the second dose of GARDASIL, lot # not reported, was given intramuscularly (IM) to the right deltoid on 21-APR-2008. Concomitant therapy included SERETIDE, albuterol, NASACORT and KESTINE. There was no contraceptive use. On 16-JUL-2008 the patient experienced sudden brutal cephalgia and then she suffered from a pain evocating an aneurysm during rupture. The patient suddenly died in spite of resuscitation technique performed by the agency which evoked a ruptured aneurysm. An autopsy was on-going and the results would be provided. As to the reporter there may not be any link between adverse effect and vaccination. The reported cause of death by the ageny was ruptured cerebral aneurysm, but it had not been confirmed yet by the results of the autopsy which were still pending. Additional information has been requested. Other business partner numbers include E2008-11575.

Other Meds: KESTINE; NASACORT; SERETIDE; albuterol

Lab Data: Unknown

History:

Prex Illness: Pollen allergy; Allergic asthma; Overweight

Prex Vax Illns:

Vaers Id: 335274-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Oct-2008	28-Nov-2008	36	15-Dec-2008	16-Dec-2008	FR	WAES0812USA01710	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1285U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Biopsy liver abnormal, Hepatic necrosis, Jaundice

Symptom Text: Information was received from a health professional concerning a 18 year old female who was vaccinated intramuscularly with a second dose of GARDASIL (lot# 1285U, batch# NH35150) into the deltoid muscle on 23-Oct-2008. On 18-Nov-2008, the patient developed a progressive increase of transaminases AST and ALT up to 1100 and high total bilirubin value. The patient was hospitalized. On 02-DEC-2008 laboratory testings revealed the following values (units and normal values not reported): Bilirubin total 17, bilirubin direct/indirect 10, LDH normal, AST and ALT decreasing. Serological infectiological examination was without any pathological findings. There was no history of alcohol or drug abuse. On 28-NOV-2008 the result of the liver biopsy showed a distinctive liver necrosis (toxic). The patient was treated with Legalon. At the time of reporting the patient had jaundice but was clinically in a good general condition. The first dose of GARDASIL was given on unknown date, toleration not reported. Other business partner numbers included: E2008-11225. No further information is available.

Other Meds: Unknown

Lab Data: total serum bilirubin, 02Dec08, 17; laboratory test, 02Dec08, bilirubin direct/indirect 10; serum LDH, normal; serum alanine aminotransferase, up to 1000; serum aspartate aminotransferase, up to 1000

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 335275-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jul-2008	02-Jul-2008	0	15-Dec-2008	16-Dec-2008	CA	WAES0812USA01810	27-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Chest pain, Convulsion, Dilatation atrial, Dilatation ventricular, Dyspnoea, Hypoxia, Mitral valve incompetence, Obesity, Pulmonary hypertension, Syncope, Tachycardia, Tricuspid valve incompetence

Symptom Text: Information has been received from a physician assistant concerning an 18 year old female who on 12-OCT-2007 was vaccinated with the first dose of GARDASIL, the second dose of GARDASIL on 08-FEB-2008, and the third dose of GARDASIL on 02-JUL-2008 (lot numbers and routes were not specified). Concomitant therapy included YASMIN. It was reported that on 02-JUL-2008 after the administration of her third dose the patient experienced shortness of breath and tachycardia upon exertion. The patient has experienced two seizures, the first one was two weeks ago and the second one 3 days ago. An echocardiogram performed on 26-NOV-2008 showed right dilated atrium and ventricle with mitral valve and tricuspid regurgitation. The patient's heart rate increased from 80 to 150 after a short walk in the physician's office on 05-DEC-2008. Patient was admitted into the hospital on 05-DEC-2008. Shortness of breath, tachycardia, seizures, resulted in hospitalization and were considered to be disabling and immediately life-threatening. Additional information has been requested. 12/23/08 Reviewed hospital medical records of 12/5-12/12/2008. FINAL DX: severe pulmonary hypertension, etiology unknown; seizure vs pseudoseizure secondary to hypoxia & tachycardia; mild obesity. Records reveal patient experienced SOB, chest pain x approx 6 wks, syncope & seizures x 2. Cardiac consult done.Tx w/meds & improved.

Other Meds: YASMIN

Lab Data: Echocardiography, 11/26/08, right dilated atrium and ventricle with mitral valve and tricuspid regurgitation LABS: Cardiac cath abnormal.

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335277-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	09-Dec-2008	09-Dec-2008	0	15-Dec-2008	16-Dec-2008	--	WAES0812USA02172	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Convulsion, Dyskinesia, Loss of consciousness

Symptom Text: Information has been received from a registered nurse concerning a 26 year old female patient who on 09-DEC-2008 was vaccinated with the first dose of GARDASIL, lot # was not specified. After being vaccinated, the patient passed out completely for 60-90 seconds. The nurse stated that 4-5 minutes after the patient came to, she did not make sense and her arms were moving about as if she was having a seizure. The patient reported to her nurse that she had bad luck when it comes to vaccinations (unspecified products and reactions). The patient was referred to primary care physician. Patient recovered. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Vaccination adverse reaction

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 335278-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Sep-2008	29-Oct-2008	29	15-Dec-2008	16-Dec-2008	FR	WAES0812USA02214	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Asthenia, Hypertension, Hypertrophic cardiomyopathy, Intensive care, Loss of consciousness, Pulmonary embolism, Tachycardia, Thrombosis

Symptom Text: Case initially received on 04-DEC-2008. Information has been received from a patient's grandmother concerning her 17 year old granddaughter with no pertinent medical history, who was vaccinated with a first dose of GARDASIL (Lot #, route, injection site not reported) in the end of Sep-2008. 14 days post vaccination, the patient developed adynamia ("could not climb any stairs") and experienced loss of consciousness twice. She presented to a physician, but examination revealed no findings. Then the patient developed thacycardia (pulse rate 160) and hypertension of 150/100. On 29-OCT-2008, the patient lost consciousness again and was admitted to hospital. Due to suspected myocarditis or pulmonary embolism and the life-threatening condition the patient was transferred to a university hospital for further examination. The patient was diagnosed with bilateral pulmonary embolism, thrombosis of right leg and hypertrophic cardiomyopathy ("triplication of myocardium"). The patient was in the intensive care unit for a long time (no further specified). Duration and outcome were not reported. Other business partner numbers include E2008-11327. No further information is available.

Other Meds: Unknown

Lab Data: Blood pressure measurement, 150/100; Total heartbeat count, 160

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335280-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	06-Dec-2008	07-Dec-2008	1	15-Dec-2008	16-Dec-2008	FR	WAES0812USA02273	16-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1693U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dyskinesia, Fatigue, Headache

Symptom Text: Information has been received from a physician concerning an 18 year old female patient who received the first dose of GARDASIL on 06-DEC-2008 (lot # 1693U batch # NJ02770). On 07-DEC-2008 the patient presented with dyskinesia of the four limbs. She was hospitalized on 07-DEC-2008. The patient had neither concomitant treatment nor corrective treatment. The patient had spontaneously recovered in a few hours. At the hospital the psychologic investigations were negative. The reporter did not know if infectious and neurologic work-up had been performed. At time of reporting the patient presented with cephalgia and fatigue (onset date not reported). Additional information has been requested. Other business partner numbers included E2008-11534.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 335298-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	27-Oct-2008	27-Oct-2008	0	15-Dec-2008	24-Dec-2008	MA		05-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Confusional state, Coordination abnormal, Disturbance in attention, Eye swelling, Fatigue, Feeling hot, Heart rate decreased, Hyperhidrosis, Malaise, Muscle twitching, Muscular weakness, Nausea, Pain in extremity, Pallor, Presyncope, Staring, Tremor

Symptom Text: Near syncope at time of injection. Then noted nausea and muscle twitches in (R) arm and chest the following day. 5 days later, still weak and tremulous. Also, c/o decreased concentration/attention in class. Exam WNL. CK 66. Lyme titer, negative. Negative CBC, Chem seven, normal, except low CO2; TSA, normal. 1/5/09 Reviewed PCP medical records. FINAL DX: none provided. Records reveal patient experienced with HPV#1 on 10/27/2008: pale, diaphoretic, BP 70/30, P56 post injection. Within 10 min, color improved, BP98/70, P64. Malaise, feverish, muscle twitches & had sore arm next day. By 11/3/08 felt uncoordinated, confused, staring, fatigue, weak legs, muscle tremors, pale, puffy eyes.

Other Meds:

Lab Data: See above LABS: Chemistry WNL. Lyme's test neg.

History: Hx. near syncope with phlebotomy; Lyme disease 2005

Prex Illness: None

Prex Vax Illns:

Vaers Id: **335337-1** **Related reports:** 335337-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	26-Nov-2008	27-Nov-2008	1	15-Dec-2008	06-Feb-2009	CA		06-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	UNKNOWN MANUFACTURER	NULL	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Anorexia, Arthralgia, Asthenia, Chest pain, Pyrexia

Symptom Text: fever, weakness, joint pain, chest and stomach pain, loss of appetite

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **335337-2** **Related reports:** 335337-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	23-Nov-2008		17-Apr-2009	08-May-2009	CA	WAES0903USA03967	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Arthralgia, Muscular weakness, Pain, Pain in extremity, Pyrexia

Symptom Text: Information has been received from a patient's mother concerning her daughter with no pertinent medical history and no know drug allergies/drug reactions who on an unspecified date was vaccinated with the first dose of GARDASIL. On 22-NOV-2008 the patient was vaccinated with the second dose of GARDASIL. Concomitant therapy on the same visit of the second dose included influenza virus vaccine (unspecified). It was reported that the patient had an adverse experience after both doses of GARDASIL. After the first dose she had arm pain for 2 days. It was reported that after the second dose the patient had arm pain, joint pain, aches, fever of 101F, stomach pain, weak muscles and could not get out of bed. It was reported that these symptoms began about 18 hours after vaccination. It was reported that it took her about a week to recover. Additional information has been requested.

Other Meds: Influenza virus vaccine

Lab Data: temperature measurement, 101 F

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **335340-1 (S)** **Related reports:** 335340-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	15-Sep-2008	10-Nov-2008	56	15-Dec-2008	16-Dec-2008	NJ		09-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947XX	1	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Chemotherapy, Diarrhoea, Lumbar puncture, Lymphadenopathy, Mediastinal mass, Primary mediastinal large B-cell lymphoma, Surgery

Symptom Text: Patient recieved 2 doses of gardasil, july 15th 2008 and sept 15th 2008. She was diagnosed with non-hodgkins lymphoma on 11-20-08. She had lymphadenopathy in the neck and anterior mediastinum. She is currently undergoing chemotherapy. I read articles about recepients of HPV vaccine developing lymphadenopathy. 1/23/09 Reviewed hospital medical records of 11/17-11/20/2008; 12/4-12/5; and 12/12-12/15/2008; same day stays on 12/10 & 12/17. FINAL DX: primary mediastinal large B-cell lymphoma, Murphy stage III. Records reveal patient experienced left supraclavicular lymphadenopathy x 10 days beginning 11/7 along w/intermittent diarrhea & abdominal pain x 1 mo. Surgery & cardio consult done. Returned to hospital 12/4 to have port placed for chemotherapy & diagnostic LP & also intrathecal methotrexate & steroids. Returned to hospital for chemo & f/u CT scan 12/10. Returned to hospital 12/12-15 for chemo. Returned to hospital 12/17 for LP w/intrathecal chemotherapy.

Other Meds: NONE

Lab Data: Lynphnode biopsy consistent with primary mediastinal large b-cell lymphoma. Pet scan, Ct scans also done localising the disease to neck and chest LABS: WBC 12.7(H), neutros 79.8%(H). ESR 39(H). Alk phos 105(H). Blood c/s neg. CXR abn

History: NONE PMH: family hx: lung cancer, brain tumor.

Prex Illness: NONE

Prex Vax Illns: NONE~ ()~~0~In Sibling|NONE~ ()~~0~In Patient

Vaers Id: **335340-2 (S)** **Related reports:** 335340-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	15-Sep-2008	10-Nov-2008	56	17-Feb-2009	18-Feb-2009	--	WAES0901USA03876	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Biopsy lymph gland, Chemotherapy, Lymphadenopathy, Non-Hodgkins lymphoma, Primary mediastinal large B-cell lymphoma

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 23 year old female patient was vaccinated with the second dose of GARDASIL (Lot # 0947X), intramuscularly in the left arm on 15-JUL-2008. On 15-SEP-2008, the patient was vaccinated with the third dose of GARDASIL. There was no concomitant therapy. The patient was diagnosed with Non-Hodgkins on 20-NOV-2008. She had lymphadenopathy in the neck and anterior mediastinum. She is currently undergoing chemotherapy. A lymph node biopsy was performed with primary mediastinal large b-cell lymphoma. A Pet scan, and Ct scans also done localizing the disease to neck and chest. Chemotherapy, lymphadenopathy and Non-Hodgkins lymphoma were considered to be life-threatening by the reporter. The original reporting source was not provided. The vaers ID# is: 335340. A standard lot check investigation was performed. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center and was released. No further information is available.

Other Meds:

Lab Data: lymphatic structure, primary mediastinal large b-cell lymphoma; positron emission, localising the disease to neck and chest; computed axial, localising the disease to neck and chest

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 335342-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Dec-2008	11-Dec-2008	1	15-Dec-2008	18-Dec-2008	NY		06-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2841BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1311X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Disorientation, Dizziness, Gaze palsy, Grand mal convulsion

Symptom Text: On 12/10/08, pt was given gardasil dose #3 and menactra. on 12/11/08, while sitting in school, pt had a tonic-clonic seizure and was taken to hospital, admitted, observed 24 hours. CT scan and blood tests were normal. EEG abnormal. MRI and repeat EEG to be done. Patient has no history of seizure or syncope. 1/29/09-records received for DOS 12/11/08-presented to ED with questionable seizure, tonic-clonic seizure witnessed along with eyes rolling back. Unable to recall event and was disoriented to place and time. PE: slight dizziness.

Other Meds: none

Lab Data: CT scan head normal, EEG abnormal. 1/29/09-records received-CT head negative. EKG NSR. Labs WNL. EEG diffusely abnormal with irritative features compatible with a seizure disorder.

History: allergy to penicillin and cephalosporin antibiotics 1/29/09-records received-PMH:asthma, allergies to Amoxicillin and Cefzil.

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335344-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	15-Dec-2008	15-Dec-2008	0	15-Dec-2008	17-Dec-2008	TX		12-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	1	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope

Symptom Text: Pt experienced syncope. Upon recovering Pt's blood pressure was 92/62 pulse 64. Pt was out approxiamately 1-2 seconds.

Other Meds: Metoprolol 200mg bid, Lisinopril/HCTZ 20mg-2 inmorning, Ortho Tri-cyclen Lo

Lab Data:

History: Hypertension

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335362-1 (S)** **Related reports:** 335362-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Aug-2008	07-Dec-2008	110	15-Dec-2008	18-Dec-2008	WA		23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X CTC	0	Left arm	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Oligohydramnios, Premature rupture of membranes, Vaginal haemorrhage

Symptom Text: Patient likely conceived with pregnancy day of vaccine administration. Her pregnancy has been complicated by oligohydramnios at early as 16 weeks, and eminent concern for loss of pregnancy. 1/16/2009 ER record received for 12/7/08 with DX: Vaginal bleeding at 18 wks pregnant, anhydramnios, mid trimester ROM, 2 vessel umbilical cord, possible TGA in fetus. Prognosis poor. Pt presented with large amount of vaginal bleeding.

Other Meds: None

Lab Data: Labs and Diagnostics: Pelvic sono-no amniotic fluid. WBCs 10.4. UA with 4+ blood, 2+ leuk est, 10-20 WBC, >100 RBC, few bacteria. UC (+).

History: Amoxicillin allergy. PMH: allergy to amoxil

Prex Illness: None

Prex Vax Illns:

Vaers Id: **335362-2 (S)** **Related reports:** 335362-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Aug-2008	Unknown		11-Feb-2009	12-Feb-2009	--	WAES0901USA03873	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Left arm	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Drug exposure during pregnancy, Oligohydramnios

Symptom Text: This report was identified from a line listing obtained on request by the Company from FDA under the Freedom of Information Act.. A 16 year old female with AMOXICILLIN allergy and no previous illnesses who on 19-AUG-2008 was vaccinated with the first dose of GARDASIL (lot # 660616/0570X) in her left arm, route unknown. The patient likely conceived with pregnancy the day of the vaccine administration. Her pregnancy had been complicated by oligohydraminos as early as 16 weeks, and eminent concern for loss of pregnancy. The listing indicated that one or more of the events required hospitalization and were considered to be immediately life-threatening. The original reporting source was not provided. The VAERS ID # is: 335362-1. A lot check has been requested. Follow up information was received on 03-FEB-2009. A standard lot check investigation was performed for GARDASIL (lot # 660616/0570X). All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center and was released. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 8/19/2008); Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335376-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		16-Dec-2008	17-Dec-2008	FR	WAES0812AUS00119	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning a 13 year old female who was vaccinated with GARDASIL. Subsequently after vaccination, the patient experienced convulsion. At the time of reporting to the agency on 30-SEP-2008, the outcome of convulsion was unknown. The agency considered that convulsion was related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review convulsion was considered an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335377-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Jul-2008	20-Jul-2008	19	16-Dec-2008	17-Dec-2008	FR	WAES0812AUS00123	17-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abscess drainage, Injection site abscess, Injection site pain, Injection site swelling, No reaction on previous exposure to drug, Scar

Symptom Text: Information was obtained on request by the Company from the agency, via a case Line Listing and Public Case Details form, concerning a 22 year old female who in July 2008 was vaccinated with her second dose of GARDASIL as prophylactic vaccination. The patient had nil adverse events with her first injection of GARDASIL. On 20-JUL-2008, following vaccination with her second dose of GARDASIL, the patient experienced swelling and pain and was hospitalised. It was described that the patient "developed pain and swelling at injection site. She was in hospital for six days. 90 mls of pus was drained, and the patient now has an unsightly scar". Subsequently, on 08-AUG-2008 the patient recovered from swelling and pain. The agency considered that swelling and pain were probably related to therapy with GARDASIL. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335403-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Dec-2008	Unknown		16-Dec-2008	12-Feb-2009	MO		12-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1186X	1	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2670AA	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2998BA	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB257AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Client received vaccines on 12-1-08 and found out on 12-11-08 she is pregnant.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335410-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Jan-2008	24-Nov-2008	301	16-Dec-2008	18-Dec-2008	GA		30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Right arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Asthenia, Axillary mass, Cyst, Hodgkins disease, Menstruation irregular, Pruritus generalised

Symptom Text: Patient received last of 3 Gardasil vaccinations. Approximately 2 months later was diagnosed with Hodgkins Lymphoma. Symptoms became evident just after the third vaccination. 3/9/09-records received-office visit 1/22/09-C/O tired SOB, Irregular menses which is secondary to chemo. Monitor labs if not better 3-6 mos. 4/29/09-records received-office visit 1/23/08 for C/O possible brachial cleft cyst or neck mass. Past 2 weeks swelling in left axilla. Decreased energy and generalized pruritus.

Other Meds: None

Lab Data: Ultrasounds, chest xrays, ct and pet scans showed tumor growth. CBC out of normal range for months. 4/29/09-records received. WBC 30.1, lymph % 12.6, neut % 77. Biopsy of lymph node partial involvement Hodgkin lymphoma nodular sclerosis t

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335442-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	09-Dec-2008	10-Dec-2008	1	16-Dec-2008	26-Dec-2008	TX		27-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2742AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1758U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Eye pruritus, Fatigue, Malaise, Nausea, Somnolence

Symptom Text: Patient complain of dizziness, eye itchy, nauseated, doesn't feel well, fatigue and sleeping more.

Other Meds:

Lab Data:

History: ADD

Prex Illness: dealt step

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335461-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	24-Sep-2008	24-Sep-2008	0	16-Dec-2008	26-Dec-2008	AZ		27-Dec-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0570X	0	Left arm	Unknown	
MNQ	SANOFI PASTEUR	U2683AA	0	Right arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	C2998BA		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction

Symptom Text: Within 1 minute of administering 3 immunizations listed above, pt began having seizure. o2 was administered and vitals monitored. Seizure was approx. 5-10 secs. She was observed for more than 30 mins until she was able to leave office safely.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **335484-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	10-Sep-2008	10-Sep-2008	0	17-Dec-2008	18-Dec-2008	MA	WAES0809USA01813	06-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0573X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Initial and follow-up information has been received for the pregnancy registry for GARDASIL from a nurse, a physician and a 29 year old female with a history of anemia, asthma and seasonal allergies, who on 10-SEP-2008 was vaccinated with the first dose of GARDASIL (lot # 0573X) 0.5 mL, IM into her deltoid, when she was six and a half months pregnant. Concomitant medication included REPLIVA and FLONASE. The nurse and the physician reported that the patient has an estimated delivery date of 01-DEC-2008. The patient's condition was not determined to be life threatening, or resulting in significant disability/incapacity, not related to a congenital anomaly, not related to an overdose, not related to cancer, and there was no need for intervention to prevent serious criteria. The patient sought unspecified medical attention. On an unspecified date, there was a pregnancy test performed resulting positive. On 14-JUL-2008, a routine ultrasound test was performed resulting in a normal survey. Follow-up information was received from a physician who reported that the patient delivered a normal baby on 26-NOV-2008. The baby was male and weighed 9 pounds 5.9 ounces, and the APGAR score was 9/9. The infant was born with a congenital small ear tag in his left ear. There were no other complications or abnormalities. The physician reported that during the pregnancy the patient had a normal level II ultrasound/fetal survey at 20 weeks. The patient had no complications during the pregnancy and labor/delivery. There were no infections or illnesses during pregnancy. The patient's medications used during this pregnancy included REPLIVA 1 tablet daily since 11-SEP-2008 for anaemia, and FLONASE daily since preconception. Additional information has been requested.

Other Meds: REPLIVA 21/7, tab; FLONASE

Lab Data: Ultrasound, 07/14/08, normal survey; Beta-human chorionic, positive; Apgar score, 9/9

History:

Prex Illness: Pregnancy NOS (LMP = 2/24/2008); Anaemia; Seasonal allergy; Asthma; Antiallergic therapy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335485-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	12-Nov-2008	16-Nov-2008	4	17-Dec-2008	18-Dec-2008	FR	WAES0812AUS00218	18-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Chills, Feeling hot, Pain, Rash, Rash generalised, Serum sickness

Symptom Text: Information has been received from a physician as part of a business agreement (manufacturer control # GARD 2008 12 12 001) concerning a 25 year old female who on 12-NOV-2008 was vaccinated with GARDASIL. Concomitant therapy included MICROGYNON. On 16-NOV-2008, 84 hours after vaccination with GARDASIL, the patient developed serum sickness. It was described that the patient developed a rash on the lower trunk which spread over several hours. The patient the developed chills and felt worse when she was hot. Two days later, on approximately 18-NOV-2008 the rash became generalised and the patient was admitted to the hospital with a possible diagnosis of scarlet fever. The patient was aching all over and her temperature was 38-39 degree C. A biopsy was done which revealed serum sickness. Subsequently, the patient recovered from the serum sickness. Additional information is not expected.

Other Meds: Ethinyl estradiol (+) levonorgestrel

Lab Data: biopsy, ??Nov08, serum sickness; body temp, ??Nov08, 38-39 degree C

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **335486-1 (S)** **Related reports:** 335486-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	Unknown	Unknown		17-Dec-2008	18-Dec-2008	FR	WAES0812CAN00055	18-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NG09710	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Constipation, Influenza like illness, Malaise, Pain, Pyrexia, Sleep disorder, Vomiting

Symptom Text: Information has been received from a nurse concerning a 10 year old female who was vaccinated with the first dose of GARDASIL, batch # NG09710. There was no concomitant medication. Subsequently the patient experienced vomiting, mild fever, generally ill and achy, altered sleeping pattern and flu like symptoms. Subsequently the patient experienced serious constipation and was hospitalized. It was reported that there was no initial reaction local or otherwise to vaccination. Subsequently, the patient recovered from vomiting, mild fever, generally ill and achy, altered sleeping pattern, flu like symptoms. Subsequently the patient recovered from serious constipation and on 09-DEC-2008 was released from hospital. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **335486-2 (S)** **Related reports:** 335486-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	Unknown	Unknown		23-Dec-2008	23-Dec-2008	FR	WAES0812CAN00065	30-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0735U		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Constipation, Influenza like illness, Malaise, Pain, Pyrexia, Sleep disorder, Vomiting

Symptom Text: Information has been received from a nurse concerning a 10 year old female who was vaccinated with the first dose of GARDASIL, batch # NG09710/ lot # 658216/0735U. There was no concomitant medication. Subsequently the patient experienced vomiting, mild fever, generally ill and achy, altered sleeping pattern and flu like symptoms. Subsequently the patient experienced serious constipation and was hospitalized on 08-DEC-2008 (no other details provided). It was reported that there was no initial reaction local or otherwise to vaccination. Subsequently, the patient recovered from vomiting, mild fever, generally ill and achy, altered sleeping pattern and flu like symptoms. On 09-DEC-2008 the patient recovered from serious constipation and was discharged from hospital. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335487-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Dec-2008	01-Dec-2008	0	17-Dec-2008	18-Dec-2008	FR	WAES0812CAN00056	18-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope, Urinary incontinence

Symptom Text: Information has been received from a physician concerning a 11 year old female with no history of fainting or seizure who on 01-DEC-2008 was vaccinated with second dose of GARDASIL (Lot # not provided). On 01-DEC-2008 the patient experienced seizure (urinated) and syncope "as she walked out the vaccination (given at school)". On 02-DEC-2008 the patient experienced another seizure "at breakfast". The patient had an electroencephalography done and follow up with neurologist (no details provided). Subsequently, the patient recovered from the seizure and syncope. Upon internal review seizure (urinated) and syncope were considered other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Electroencephalography, ??Dec08, pending results

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 335488-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		17-Dec-2008	18-Dec-2008	--	WAES0812USA01813	18-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Endometriosis, Foetal disorder, Ovarian cyst, Surgery

Symptom Text: Information has been received from a 25 year old female patient with polytrim eye drops allergy and a history of a tumor taken out of her chest and blood transfusion at age 4, and nose surgery because of a sinus problem in 2005, who received all 3 doses of GARDASIL. In 2007 (last year) was vaccinated with the first dose of GARDASIL (Lot # not reported). On approximately 15-MAY-2008 (mid May 2008), was vaccinated with the third dose of GARDASIL (Lot # not reported). Concomitant therapy included ADVAIR and "birth control". Around July 2008, the patient got pregnant. The patient is feeling fine, however the ultrasound discovered that the baby has a club foot. The patient also mentioned that before receiving the third dose she had a surgery because endometriosis, and had an ovarian cyst drained. The patient sought unspecified medical attention. Normal laboratory tests and first trimester screen were performed (results not provided). Last menstrual period was approximately on 25-JUL-2008 and estimated delivery date is on 01-May-2009. Upon internal review club foot was determined to a congenital anomaly. Additional information has been requested.

Other Meds: ADVAIR; hormonal contraceptives

Lab Data: ultrasound, baby has club foot

History: Neoplasm; Blood transfusion; Rhinoplasty; Sinus disorder; Tumour excision

Prex Illness: Pregnancy NOS (LMP = 7/25/2008); Drug hypersensitivity

Prex Vax Illns:

Vaers Id: 335489-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Jun-2008	25-Jul-2008	54	17-Dec-2008	18-Dec-2008	--	WAES0812USA02338	18-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed practical nurse concerning a 20 year old female patient who in June 2008, was vaccinated with the first dose of GARDASI, lot # was not reported. It was reported that the patient became pregnant with twins and had a miscarriage about one week ago. Patient was hospitalized. LMP was 25-JUL-2008. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 7/25/2008)

Prex Vax Illns:

Vaers Id: 335490-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Sep-2008	10-Nov-2008	70	17-Dec-2008	18-Dec-2008	FR	WAES0812USA02403	18-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Meningitis, Optic neuritis, Pyrexia, Visual acuity reduced

Symptom Text: Information has been received from Health authorities concerning a 20 year old female patient who in July 2008, was vaccinated with the first dose of GARDASIL. On September 2008, the patient received the second dose of GARDASIL(batch number not reported). On 10-NOV-2008 the patient developed fever at 38.5 degrees C and decrease bilateral visual activity. She was hospitalized in neurology unit for lymphocytic meningitis and optic neuritis. MRI showed an hypersignal in cerebellar area. At the time of report the patient had not recovered. Other business partner include E2008-11597. No further information is available.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 10Nov08, showed an hypersignal in cerebellar area; temperature measurement, 10Nov08, 38.5 degrees C

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335511-1** **Related reports:** 335511-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Dec-2008	14-Dec-2008	2	17-Dec-2008	29-Dec-2008	OR		29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: 48 hours after administration of Vaccine the injection site became very red and swollen. With in a few minutes the redness radiated down her arm near her wrist.

Other Meds: Citalopram 40 mg Trazadone 100 mg,Necon 0.5/35, Albuterol inhaler

Lab Data: None

History: Concerta, milk Mushrooms

Prex Illness: None

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335511-2** **Related reports:** 335511-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Dec-2008	14-Dec-2008	2	29-Dec-2008	07-Jan-2009	OR		13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Injection site erythema, Injection site swelling

Symptom Text: 48 hrs after administration of Vaccine the injection site became very red and swollen. Within a few minutes the redness radiated down her arm near her wrist.

Other Meds: CITALOPRAM 40 mg; TRAZADONE 100mg; NECON 0.5mg; ALBUTEROL inhaler

Lab Data: None

History: Concerta; Milk Mushrooms

Prex Illness: None

Prex Vax Illns:

Vaers Id: **335520-1 (S)** **Related reports:** 335520-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Dec-2007	05-Feb-2008	62	17-Dec-2008	18-Dec-2008	MO		18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0012U	0	Left arm	Intramuscular	DTAP

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Allodynia, Diarrhoea, Disability, Dizziness, Drug interaction, Epistaxis, Eructation, Fatigue, Flank pain, Galactorrhoea, Gastrointestinal disorder, Headache, Hyperlipasaemia, Hyperprolactinaemia, Hypersensitivity, Ileus, Laparoscopy, Nausea, Ovarian cyst, Pain, Pancreatitis, Parenteral nutrition, Pneumonia, Retching, Vaccine positive rechallenge, Vomiting

Symptom Text: nose bleeds, headaches sudden onset after first shot continued after second and third shot third shot 6/9/08 fatigue, end of July received meningits vaccine sept started pain, cyst on ovaries,then nausea,vomiting,pancreatitis,gastrointestinal disorders,dizziness,pnenmonia,lactating,hypersensitivity,8 weeks in hospital still sick 1/27/09 Link with 338052. 2/2/09 Received hospital & clinic medical records for 9/18-12/10/2008. FINAL DX: Pancreatitis Records reveal patient seen in ER 9/18 for RLQ flank/abdominal pain with nausea, fever & cough x 2 days. Improved w/meds & d/c to home. Returned w/severe pain. Hospital admit 9/20-9/22/2008. FINAL DX: right flank pain, resolving; pneumonia, resolving. Records reveal RLQ flank/abdominal pain improved. d/c to home on continued oral antibiotics for pneumonia & w/GYN f/u. OB/GYN records of 10/7 & 10/8 & Operative report of 9/24/2008. FINAL DX: RLQ pain w/bilateral ovarian cysts Patient had laparoscopic aspiration of ovarian cysts as same day surgery. Had continued post op RLQ abdominal pain. US was WNL. referred to PCP for additional GI w/u. Returned to ER 10/23/2008 W/persistent RLQ pain. Labs all WNL & d/c to home. Returned to ER 12/10/2008 w/nausea, vomiting, dry heaves x 1 day, diarrhea x 2 weeks. Had recently been d/c from higher level of care w/dx pancreatitis & was on TPN. Found to have ileus. Tx w/meds & d/c to home. 2/17/09 Received hospital medical records of 11/21-12/3/2008. FINAL DX:allodynia w/abdominal wall pain improving; hyperlipasemia, etiology uncertain; galactorrhea & hyperprolactinemia secondary to Lexapro; marked disability in association w/chronic pain; intermittent, frequent belching/retching related to disability & chronic pain. Records reveal patient experienced RLQ pain. Had been transferred from outlying hospital where she had been admitted 10/15/08 & extensive medical record review of that hospitalization included. Endocrine, pain mgt, psych consult done & meds adjusted. Tx w/TPN. Improved & d/c to home w/c

Other Meds:

Lab Data: pancreatitis,labs - pnemonia, x-ray- cyst,ultrasound- upper and lower scope,gastrointestinal- central line for TPN and Lipids LABS: CT scan suggested RLL pneumonia & bilateral ovarian cysts. CBC, chemistry & UA WNL. KUB revealed ileus.

History: none PMH: constipation HPV#2 Lot # 1267U, given 3/21/08 IM/LA HPV#3 Lot # 1740U, given 6/9/08 IM/LA

Prex Illness: was not ill at time of gardasil started having nose bleeds,headaches,and fatigue by the meningitis vaccine in July

Prex Vax Illns: none~ ()~~0~In Patient|none~ ()~~0~In Sibling|none~ ()~~0~In Sibling

Vaers Id: **335520-2 (S)** **Related reports:** 335520-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	09-Jun-2008	09-Jun-2008	0	23-Jan-2009	26-Jan-2009	MO	WAES0901USA02577	27-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Pancreatitis, Parenteral nutrition, Pelvic pain

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who on 15-DEC-2007 was vaccinated with the first dose of GARDASIL (lot# 655503/0012U). On 21-MAR-2008 she received her second dose of GARDASIL (lot# xxxxx) and on 09-JUN-2008 she received her third dose of GARDASIL (lot# 659962/1740U). On September 2008 the patient started to develop pelvic pain and was diagnosed of pancreatitis. Patient was hospitalized and received total parenteral nutrition and lipids and had an IV port. Pancreatitis was considered to be an other important medical event by the physician. Pancreatitis was considered to be disabling. At the time of this report the patient had not yet recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **335521-1 (S)** **Related reports:** 335521-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	13-Nov-2008	29-Nov-2008	16	17-Dec-2008	18-Dec-2008	OH		06-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Cellulitis, Chills, Fatigue, Hypophagia, Injected limb mobility decreased, Injection site erythema, Injection site pain, Injection site warmth, Lethargy, Pyrexia

Symptom Text: Patient received vaccine and initially had soreness at the injection site for about 2 weeks. On 11/29 she noticed redness and warmth in addition to pain in the area. This initally improved without any treatment. Symptoms began to worsen again (redness, pain, warmth in the deltoid area of the arm) and she was seen at an urgent care facility on 12/9 and was given Keflex 250mg TID. Symptoms continued to worsen. She presented to the Emergency Department on 12/13/08 and was given a 1 gram dose of Vancomycin IV and was ultimately discharged home on Keflex 500mg QID and Bactrim DS - 1 tab BID. Patient reports initial improvement after the antibiotic change but then symptoms again worsened and she returned to the ED on 12/16/08 and was admitted to the hospital for IV antibiotics with worsening erythema and pain. She is currently on vancomycin IV and Clindamycin IV was added today because symptoms are not significantly improving. There is no abcess associated with the cellululitis. Patient is still in the hospital- anticipated discharge date unknown. 2/2/09-records received for DOS 12/16-12/19/08 DC DX:Myositis/fascitis.Presented to ER with 6 week history of LUE cellulitis at which time received 3rd gardasil injection in left arm. After injection noticed army sore 1 week later with red ring around injeciton site and treated with oral antibiotics. LUE pain worsing and redness spreading, decreased ROM, fever feeeling lethergic/fatigued. Presented with chills decreased oral intake.

Other Meds: Sprintec

Lab Data: WBC on 12/13 was 12.5 but on 12/16 (day of admission) was 7.0. All other labs are within normal limits. CT of arm on 12/13 was within normal limits but MRI with and without contrast of arm on 12/16 indicated: 1. EVIDENCE OF A FAIRLY DIFFUS

History: Codeine- reaction is rash

Prex Illness: None

Prex Vax Illns:

Vaers Id: **335521-2 (S)** **Related reports:** 335521-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	13-Nov-2008	13-Nov-2008	0	27-Apr-2009	28-Apr-2009	OH	WAES0904USA03413	28-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Cellulitis, Hypokinesia, Injection site inflammation

Symptom Text: Information has been received from a registered nurse, an office manager and a medical assistant, concerning a 23 year old female with no known drug reaction/allergies and a history of a staphylococcal skin infection in abdomen (3 years ago), who on 13-NOV-2008 was vaccinated with the third dose of GARDASIL in the left arm. Subsequently, the patient experienced cellulitis in her arm. The office manager (based on patient's account and medical records) reported that the patient's first visit to ER was on 13-NOV-2008. The patient was admitted to the hospital from 16 to 19-DEC-2008. As inpatient, she received treatment with VANCOMYCIN IV and Clindamycin. The patient had a CT scan of the upper left extremity in December 2008, followed by MRIs of the left upper arm on 16-DEC-2008 (abnormal with increased inflammation), February 2009 (showed improvement) and 17-APR-2009 (increased inflammation). There was no additional information in their records regarding dates, sites and lot numbers for GARDASIL doses or any concomitant vaccines. The medical assistant reported that by the moment the patient was admitted to the hospital, her movements were "very restricted". The registered nurse reported that the patient had been a dietary intern at a hospital. The patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance, 12/16/08, In shoulder: abnormal with increased inflammation; magnetic resonance, 02/??/09, showed improvement

History: Staphylococcal skin infection

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335546-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-Dec-2008	13-Dec-2008	0	17-Dec-2008	29-Dec-2008	CA		29-Dec-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0790X		Unknown	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AL52B029AA		Right arm	Unknown	
HPV4	MERCK & CO. INC.	0575X		Left arm	Unknown	
FLU	SANOFI PASTEUR	U2833AA		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Nausea, Pallor

Symptom Text: Pt. had dizziness and nausea after vaccination. Had pallor and diaphoresis. Vital stable. CNS exam. WNL. Referred to ER for eval.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **335556-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		18-Dec-2008	19-Dec-2008	FR	WAES0812AUS00222	19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial palsy, Hypoaesthesia oral, Migraine

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning a 12 year old female who was vaccinated with GARDASIL. Other suspect therapy included VARIVAX (manufacturer unknown). Subsequently 1 day after vaccination with GARDASIL and VARIVAX (manufacturer unknown), the patient developed facial palsy, hypoaesthesia oral and migraine. At the time of reporting to the agency on 23-OCT-2008, the patient had recovered from the facial palsy, hypoaesthesia oral and migraine. The agency considered that facial palsy, hypoaesthesia oral and migraine were related to therapy with GARDASIL and VARIVAX (manufacturer unknown). The original reporting source was not provided. Upon internal medical review the adverse event of facial palsy was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 335557-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-May-2007	04-May-2007	0	18-Dec-2008	19-Dec-2008	MD	WAES0812USA02328	19-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	HEPA	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Amnesia, Back pain, Blindness unilateral, Blood test, Fall, Fatigue, Headache, Hypoaesthesia, Lumbar puncture, Mood altered, Nuclear magnetic resonance imaging, Nuclear magnetic resonance imaging brain, Optic neuritis, Paraesthesia, Urinary incontinence

Symptom Text: Information has been received from a patient's mother concerning her 17 year old daughter with penicillin allergy and a history of erythematous multiforme (about 10 years ago) who was vaccinated with the first dose of GARDASIL on 04-MAY-2007, she received the second dose of GARDASIL on 06-JUL-2007 and then received the third dose of GARDASIL on 06-NOV-2008. Vaccinations also received on 04-MAY-2007 included a first dose of Hep A (manufacturer unknown) and a second dose of Hep A (manufacturer unknown) on 06-NOV-2007. Concomitant therapy included YASMIN and vitamins (unspecified). It was reported that the patient started complaining of extreme back pain that went from the head down to the spine in May-2008 and then on 22-SEP-2008 the patient started to have vision loss in her one eye, which eye was unspecified. The patient was then admitted to the hospital on 06-OCT-2008 because of the vision problem, she could not control her bladder, very moody, tired, extreme head and back pain. At the hospital she had spinal test done. MRI of her brain and spine, and numerous blood work was done. The patient was diagnosed with optic neuritis and is totally blind in the one eye, and was then sent home from the hospital on 11-OCT-2008. It was reported that the patient still was having problems with the back pain, she also had short term memory loss, she falls a lot, and had tingling and numbing of the hands and feet. It was noted that the patient still had most of the symptoms and they were trying to rule out multiple sclerosis. The patient's mother reported that lot # that she had was 655165/1425F, but she was unsure what dose that lot # was for. At the time of the report the patient had not recovered. Additional information has been requested.

Other Meds: YASMIN; Vitamins (unspecified)

Lab Data: Unknown

History: Erythema multiforme

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **335558-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Jul-2008	10-Oct-2008	95	18-Dec-2008	19-Dec-2008	MD	WAES0812USA02806	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Epilepsy, Grand mal convulsion, Headache, Hypothyroidism, Loss of consciousness, Migraine, Postictal state, Sinusitis, Tongue biting, Vomiting

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female patient with a history of motor vehicle accident in 2003 (CT scan at that time was normal) and minor head injuries due to sports that required stitches who on 03-MAR-2008 was vaccinated with the first dose of GARDASIL (0.5 ml, intramuscularly, lot # 660387/1967U), and on 07-JUL-2008 the second dose of GARDASIL (0.5 ml, intramuscularly, lot # 660553/0070X). On 10-OCT-2008 the patient experienced a petit mal seizure and on 18-OCT-2008 had a second seizure. The nurse stated that each seizure lasted 2 to 3 minutes and it took 30 minutes post seizure for the patient to fully recover. Patient was seen in Emergency Room after the 2nd seizure because she bit her tongue which required treatment. The 3rd GARDASIL dose was delayed pending neurologist's decision. EEG showed bilateral seizure activity. Patient is now taking TOPAMAX. Upon internal review, petit mal seizure, and seizure were determined to be other important medical events. Additional information has been requested. 12/29/08 Received ER medical records for 10/11/2008. FINAL DX: new onset seizures & hypothyroidism. Records reveal patient experienced HA followed by LOC & parent witnessed generalized seizure lasting approx 2-3 min followed by postictal period of approx 15-20 min. Had 1 prior seizure on 10/10/08 & seen by PCP. Referred to neuro. No further seizure activity while in ER & d/c to home. 2/26/09 Received Neuro consut of 10/16/2008. FINAL DX: solitary seizure & migraines Records reveal patient experienced witnessed seizure activity w/tongue biting & postictal period & preceeded by emesis. Tx w/meds & referred for EEG. No further records available. 3/3/09 Received Neuro consult of 10/22/2008. FINAL DX: Epilepsy Records reveal patient had 2 generalized tonic-clonic events c/w epilepsy but unable to determine if partial onset or primary generlized. Was to continue meds & obtain copy of MRI & EEG done at outlying hospital for review. No further r

Other Meds: Unknown

Lab Data: computed axial, ?/?/03, normal; electroencephalography, 10/??/08, bilateral seizure activity LABS: CBC,chemistry & UA WNL. TSH 6.93(H). Urine drug screen neg. CT head revealed chronic sinusitis. EEG abnormal.

History: Motor vehicle accident; Head injury PMH: headaches, food allergies(carrots, anaphylaxis), bronchitis, pneumonia, tonsillitis. Using contraception. Prior head injuries: 2003, MVA; 2005 sports injury; 2007 struck beam. RAD, migraines, ear tube insertion, adenoidectomy.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335576-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	M	11-Aug-2008	11-Aug-2008	0	18-Dec-2008	29-Dec-2008	FL		29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Nausea, Syncope

Symptom Text: Reported 4 month after #2 GARDASIL. Temp. 101. Nausea and fainting episode.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **335577-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Dec-2008	10-Dec-2008	0	18-Dec-2008	29-Dec-2008	HI	HI0809	29-Dec-2008

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHA4B246AA	0	Right arm	Intramuscular	
FLU	SANOFI PASTEUR	U2806AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1208F	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2538AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B020AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia

Symptom Text: Client closed eyes, looked like she was going to faint and then she had two jerky movements. She then opened her eyes and asked what happened. Jerky movements lasted three seconds. Involved head and upper body.

Other Meds:

Lab Data:

History:

Prex Illness: Mild cold symptoms, cough, runny nose

Prex Vax Illns:

Vaers Id: 335632-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	07-Oct-2008	08-Oct-2008	1	18-Dec-2008	29-Dec-2008	NY		29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Diarrhoea, Headache, Influenza like illness, Pain in extremity

Symptom Text: Mild Headache, Pain in entire left arm (not at injection site), general weakness, mild diarrhea, mild flu like symptoms. Symptoms began the day after the injection and lasted for 4-7 days.

Other Meds: Lexapro 10 mg

Lab Data: Negative/N/A

History: None

Prex Illness: None

Prex Vax Illns: Flu like symptoms~HPV (Gardasil)~1~23~In Patient

Vaers Id: **335696-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	15-Apr-2008	08-Oct-2008	176	19-Dec-2008	22-Dec-2008	FR	WAES0811USA00193	22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dysphagia, Ear pain, Infectious mononucleosis, Malaise, Pyrexia

Symptom Text: Initial and follow-up information has been received from a healthcare professional via local authority (reference # RA-042-2008) concerning a 20-year-old female who on 15-JUN-2008 was vaccinated with the second dose of GARDASIL (lot number and injection site unknown) via intramuscular route. Concomitant therapy included oral contraceptive. The patient had received the first dose of GARDASIL via intramuscular route on 15-APR-2008. In August 2008 ("2 months before reporting"), the patient experienced infectious mononucleosis, fever, asthenia and deglutition disorder ("odinophagy"). Deflazacort was given the week before time of reporting to reduce symptoms without success. On 09-OCT-2008, epstein-Barr virus positive on blood smear. The patient also experienced ear pain and general malaise. She was treated with cefaclor and deflazacort. After therapy, she presented with white cell lineage alterations, namely young lymphocyte count decreased with hyper basophilic nuclei. The transaminase levels were increased. There were no palpable or echography visible adenopathies. The patient's outcome was not reported. Follow-up information received from the local authority (reference # RA-042-2008) reported that adverse events occurred on 08-OCT-2008, i.e. 3 months and a half after vaccination with the second dose and the patient had recovered on 16-OCT-2008 without any therapy. Results of lab tests performed on 08-OCT-2008 and on 14-NOV-2008 were provided: leukocytes numbers have normalized with the lymphocytosis and hyperbasophily disappearance on 14-NOV-2008. In spite of a semiological recovery the anti-EBV IgIM was above the maximum cut-off value. The physician considered the case to be serious event though she stated there was no causal relation between the symptoms and vaccination, only a temporal association. The patient will be submitted to new lab tests in March and re-challenge to vaccine in April. The adverse events were considered to be other important medical event. Other business partner numbers included: E20081012

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Diagnostic laboratory test, 09Oct08, Epstein-Barr virus was positive on blood smear; Diagnostic laboratory test, Transaminase levels were increased; Diagnostic laboratory test, anti-EBV IgIM was above the maximum cut-off value; WBC count, 1

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 335697-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Nov-2008	01-Nov-2008	0	19-Dec-2008	22-Dec-2008	WI	WAES0812USA03210	08-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion

Symptom Text: Information has been received from a physician concerning a 16 year old female patient with a history of seizure disorders who in approximately 15-NOV-2008 "about a month ago", was vaccinated with a second 0.5ml dose of GARDASIL. The physician reported that the patient experienced a seizure after receiving the vaccine. The patient sought unspecific medical attention. The patient recovered within a few minutes. Upon internal review seizure disorders were considered as an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Convulsion disorder

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335698-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	01-Sep-2008		19-Dec-2008	22-Dec-2008	KS	WAES0812USA03226	22-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Vasculitis cerebral

Symptom Text: Information has been received from a physician, concerning a patient who was vaccinated with GARDASIL vaccine 0.5ml, intramuscularly. The physician reported that after receiving the GARDASIL vaccine, about 2 months ago, the patient experienced cerebral vasculitis and seizures. The doctor was unsure if it was the first or second 0.5ml dose. The doctor was not sure if the patient would be seeing a specialist about this AE. The outcome is unknown. The patient sought unspecified medical attention. Upon internal review, seizures were determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335769-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
41.0	F	15-Dec-2008	16-Dec-2008	1	19-Dec-2008	29-Dec-2008	TX		21-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthma, Nausea

Symptom Text: Asthma, Nausea. 1/20/09 Reviewed GYN medical records of 12/15/08. FINAL DX:none provided. Normal GYN exam. Records reveal patient experienced asthma like symptoms reported by phone.

Other Meds:

Lab Data: LABS: CBC, chemistry, PAP smear all WNL. HPV test neg.

History: PMH: uterine fibroids, DDD, insomnia, painful intercourse, anxiety/depression, migraine HA, irritability, elective abortion, . Allergy: pollen.

Prex Illness: No

Prex Vax Illns:

Vaers Id: 335777-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	21-Nov-2008	21-Nov-2008	0	19-Dec-2008	29-Dec-2008	FL		29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3027AA	0	Right arm	Intramuscular	MMR
	HPV4	MERCK & CO. INC.	1522U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Cold sweat, Dizziness, Injection site erythema, Injection site pruritus, Pallor

Symptom Text: Gardasil administered to left deltoid IM. Client complained of feeling dizzy approx. 15 - 25 seconds later. Slight paleness to skin and hands clammy. 2nd nurse called to assist. Feet were propped up, cold compresses applied, client stated approx 5 - 7 minutes later that she was feeling better. Client left office on own accord, with mother, after approx. 10 minutes of observation. When client presented to another clinic in health department she refused 2nd Gardasil shot with complaints of feeling weak for 2 days post vaccine. Further stated that injection site was itching and red.

Other Meds: None

Lab Data: N/A

History: Aspirin allergy.

Prex Illness: None

Prex Vax Illns:

Vaers Id: 335795-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-Nov-2008	12-Nov-2008	1	19-Dec-2008	22-Dec-2008	OH	MEDI0007625	02-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN	MEDIMMUNE VACCINES, INC.	500553P		Unknown	Unknown	HPV4
	HPV4	MERCK & CO. INC.	0523U	2	Unknown	Unknown	MNQ
							TDAP

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Asthenia, Chest pain, Conversion disorder, Facial paresis, Gait disturbance, Headache, Hypoaesthesia, Mood altered, Oropharyngeal pain, Pain in extremity, Pharyngitis, Viral infection, Weight decreased

Symptom Text: A serious, spontaneous report of conversion disorder reaction, facial muscles have not moved and numbness in toes and fingers was received from a consumer concerning a 12 year old female subsequent to FLUMIST. The patient has a history of psychosocial issues. The patient received GARDASIL the same day as FLUMIST. The patient received FLUMIST intranasal for Flu vaccination on 11-Nov-2008. On 11-Nov-2008 the patient was seen in the pediatricians office for chest pains and during the visit received FLUMIST and GARDASIL. Since 24 hours after administration the patients facial muscles have not moved and she has numbness in her toes and fingers. The patient subsequently was seen by a neurologist, cardiologist and the pediatrician for the events and an MRI was taken. Results are not available. The events are on going and the patient is scheduled to begin physical therapy. The responsible physician assessed the events as not related to vaccine administration and instead considered the event a conversion disorder reaction. The event is considered a serious important medical event. 1/2/09 Received PCP, ER & Neuro medical records of 11/24-12/3/08 FINAL DX: none provided; possible conversion reaction Records reveal patient experienced HA, weakness, difficulty walking, pain in all extremities x approx 3 wks. Missed several days of school. Had been seen in Urgent care 11/24 & 11/27 for sore throat, HA & body aches. W/u WNL. Dx w/viral illness & pharyngitis. Flat affect, weight loss.

Other Meds: Concomitant Drug(s) Not Reported

Lab Data: LABS: CBC, CRP, CK, CMP all WNL.

History: Psychosocial issues in school PMH: eczema, constipation, head trauma 1 yr ago, fall, umbilical hernia repair. Family hx: SLE & mental health issues.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335798-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	05-Dec-2008	16-Dec-2008	11	19-Dec-2008	29-Dec-2008	PA		05-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myalgia

Symptom Text: Left arm muscle soreness for 1 week duration

Other Meds: OCP Folic acid V.TC

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **335799-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	17-Jul-2008	18-Jul-2008	1	19-Dec-2008	29-Dec-2008	FL		12-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal distension, Body temperature increased, Cervical dysplasia, Colposcopy, Headache, Inappropriate schedule of drug administration, Papilloma viral infection, Vaginal discharge, Vaginitis gardnerella, Viral infection

Symptom Text: Headache about 24hrs later no pain killers helped. Temperature about 48hrs later. Both got worse went to Dr 6 days later , said viral must fight off. Continued a full 2 weeks after vaccination. Then a week of severe stomach bloating. 3/9/09 Received PCP medical recods of 07/17/08-1/26/2009. FINAL DX: Low grade squamous intraepithelial lesion, HPV infection Records reveal patient experienced good health on 7/17/08. RTC 11/10/08 & 11/26/08 w/vaginal discharge. Colposcopy done 1/12/09. RTC 1/26/09 & tx w/meds.

Other Meds: Loestrin birth control, Multivitamin

Lab Data: Blood work run. Very high enzymes (3 of 4) LABS: PAP smear of 7/17/08 HPV(+). Repeat PAP 11/26/08 LSIL. Vaginal c/s 1/26/09 (+) Gardnerella vaginalis & HPV.

History: Splenectomy from ITP

Prex Illness:

Prex Vax Illns:

Vaers Id: 335801-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	19-Dec-2008	19-Dec-2008	0	19-Dec-2008	29-Dec-2008	MD		12-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Excoriation, Fall, Syncope

Symptom Text: 2nd dose of GARDASIL administered on 12/19/08. Pt experienced syncope, fell to the floor, experienced abrasion on (L) side of face. After 30 mins. pt "felt better",given water for hydration. Driven home by mother

Other Meds:

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 335807-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	21-Nov-2008	15-Dec-2008	24	19-Dec-2008	29-Dec-2008	IL		02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0737U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Her whole arm hurts. Hurts most on her deltoid and travels down her arm. Has seen MD to get labs done and neurology exam.

Other Meds: LIPITOR, 40mg; CLOBETASOL, 0.05

Lab Data: Neurology exam, negative per patient

History: KNA or medical conditions

Prex Illness:

Prex Vax Illns:

Vaers Id: **335844-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Nov-2008	01-Nov-2008	0	22-Dec-2008	02-Jan-2009	--	WAES0812USA03375	02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Coma, Endotracheal intubation, Guillain-Barre syndrome, Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from Company representative who was told by a friend of the patient's family. The patient was a 24 year old female patient who was vaccinated in approximately November-2008 with the third dose of GARDASIL. Concomitant therapy included influenza virus vaccine (unspecified). In approximately November-2008, the patient reported tingling in her fingers and toes shortly after the vaccinations. It got worse over night and she went to the Hospital the next day. The hospital did test for persistent numbness and the patient was sent home. The patient's mother found her crawling on the floor a few days later and she was taken by ambulance to the hospital where she was admitted, intubated and in coma. The patient was diagnosed with Guillain-Barre. As of 16-DEC-2008, the patient was still in coma. Guillain-Barre syndrome and coma were considered to be immediately life-threatening and disabling and other important medical event. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335852-1** **Related reports:** 335852-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Nov-2008	26-Nov-2008	0	22-Dec-2008	29-Dec-2008	NM		29-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	1	Left arm	Unknown	
	FLUN	MEDIMMUNE VACCINES, INC.	500552P	0	Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB222AA	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Hypoaesthesia, Paraesthesia, Vision blurred

Symptom Text: Headache, occasional blurring vision, tingling numbness, dizziness

Other Meds: Allergra, Advair, Singular

Lab Data: CT head, CBC, CMP, T4, TSH

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **335852-2 (S)** **Related reports:** 335852-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-Feb-2009	20-Feb-2009	--	WAES0902USA02454	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Chelation therapy, Drug toxicity, Neurological symptom, Surgery

Symptom Text: Information has been received from a physician via e-mail concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL. "After receiving GARDASIL", the patient experienced neurological symptoms, possible seizures and toxic poisoning and was hospitalized. It was reported that the patient "had to undergo chelation and a surgery". The outcome of the patient was not reported. The reporter considered the patient's events to be other important medical events due to the surgery. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335864-1** **Related reports:** 335864-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Sep-2008	22-Sep-2008	4	22-Dec-2008	31-Dec-2008	NC	NC09004	21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2582AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Asthenia, Diarrhoea, Fatigue, Flushing, Gait disturbance, Headache, Hyperhidrosis, Hypersensitivity, Nausea, Neurological examination normal, Vomiting

Symptom Text: Four days after vaccine administration, Pt became unable to walk. Was evaluated by neurologist who advised pt to never again take the GARDASIL vaccine. 3/13/09 Received Neuro medical records of 9/24/08. FINAL DX:generalized weakness, fatigue, N/V s/p HPV vaccine Records reveal patient experienced weakness. States patient developed weakness, N/V/D, fatigue, HA, abdominal pain, flushing, diaphoresis within 2 days of HPV #1. Seen in ER & referred to Neuro. Examination WNL & referred back to PCP. 3/16/09 Received ER medical records of 9/24/2008. FINAL DX: medication reaction; r/o GBS Records reveal patient experienced weakness, N/V/D, difficulty walking.

Other Meds:

Lab Data:

History: PMH: asthma. Family hx: stroke, PD, migraines, HTN.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335869-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	29-Sep-2008	30-Sep-2008	1	22-Dec-2008	31-Dec-2008	CT		31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	00114	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Client returned to office for #2 GARDASIL states 'after last shot broke out in Hives'.

Other Meds: Oral contractive; Benadryl PRN

Lab Data:

History: "Soy"

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335916-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Jul-2008	30-Sep-2008	85	22-Dec-2008	31-Dec-2008	OH		31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Hair loss/thining at 2 mos after administration of 2nd GARDASIL shot on 7/7/08

Other Meds: ADVAIR

Lab Data: None

History: asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335919-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-Dec-2008	22-Dec-2008	0	22-Dec-2008	31-Dec-2008	UT		31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Migraine

Symptom Text: Migraine immediately after GARDASIL injection

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **335935-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		23-Dec-2008	23-Dec-2008	FR	WAES0812AUS00221	23-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HEP	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness, Somnolence

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning a 13 year old female who was vaccinated with GARDASIL. Other suspect therapy included RECOMBIVAX HB. Subsequently, 1 day after vaccination with GARDASIL and RECOMBIVAX HB, the patient experienced convulsion, loss of consciousness and somnolence. At the time of reporting to the agency on 22-OCT-2008, the patient had recovered from convulsion, loss of consciousness and somnolence were related to therapy with GARDASIL and RECOMBIVAX HB. The original reporting source was not provided. Upon internal medical review, convulsion was considered an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **335946-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Dec-2008	Unknown		23-Dec-2008	31-Dec-2008	ID		02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypersensitivity, Vomiting

Symptom Text: Had episode of emesis and hypersensitivity after vaccine. Resolved with breathing in paper bag.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **335951-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Dec-2008	16-Dec-2008	0	23-Dec-2008	31-Dec-2008	PA		02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2823AA	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB320AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0570X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: After 10 minutes - stood up in hallway - collapsed - to floor - got up with help - assisted back to room - gave O2 2 - took vitals every 5 minutes - gave water - after 20 minutes - could walk without help - referred to ER. Was taken by mother.

Other Meds: DIFFERIN GEL; BENZODIAZEPINE

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 335960-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	10-Dec-2008	10-Dec-2008	0	23-Dec-2008	31-Dec-2008	VA		31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Pallor, Rash erythematous, Rash macular

Symptom Text: Approximately ten minutes following administration of GARDASIL #2, patient experienced erythematous blanchable macules on both arms. Denied SOB, nausea, itching and/or pain. No reaction following GARDASIL #1. Rash began to resolve with no treatment except BENADRYL, 25 mg.

Other Meds: LESSINA

Lab Data: O2 Sat 97

History: Reports allergy to Sulfanamides

Prex Illness: None

Prex Vax Illns:

Vaers Id: **336031-1** **Related reports:** 336031-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Dec-2008	22-Dec-2008	0	23-Dec-2008	02-Jan-2009	CA		15-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1143X	1	Left arm	Subcutaneously	
HEP	MERCK & CO. INC.	1884U	2	Right arm	Intramuscular	
FLU	NOVARTIS VACCINES AND DIAGNOSTICS	89985	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2617AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0279X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Pallor

Symptom Text: Client received vaccines listed below-Advised to remain seated while paper work was being filled in and signed. I noticed patient sliding down in her chair she became very pale I assisted her to sit up in the chair advised her to lower her head and she did-I applied ice pack advising her to take slow deep breaths which she did client agreed to lie down. Take to clinic area per co-worker where checked by physician.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **336031-2** **Related reports:** 336031-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		15-Apr-2009	16-Apr-2009	CA	WAES0904USA01022	16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning an 11 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL. After receiving the vaccine (date unspecified) the patient experienced a seizure. On an unspecified date, the patient recovered from seizure. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336047-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	10-Dec-2008	10-Dec-2008	0	24-Dec-2008	05-Jan-2009	NY		06-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2803AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	0650X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted after receiving vaccines

Other Meds: None

Lab Data:

History: NKDA

Prex Illness: None

Prex Vax Illns:

Vaers Id: **336049-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	31-Jan-2008	03-Feb-2008	3	24-Dec-2008	05-Jan-2009	TN		03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB215AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	14466	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Cellulitis, Chills, Decreased appetite, Ear pain, Erythema multiforme, Malaise, Nausea, Otitis externa, Pseudomonas infection, Rash erythematous, Rash generalised, Rash papular, Rash pruritic, Weight decreased

Symptom Text: On 10-02-2008 the patients mother was in the health department for services and reported that patient became very ill 3 days after getting vaccine here 1/2008. She began with rash and itching on 1 leg that spread in patches all over her body. She did not have a fever. She chilled, had nausea , and was unable to eat. she had no energy. Over the course of her illness (3mo) she lost 20lbs. Shortly after onset of illness, she saw a doctor and was sent to a Dermatologist. According to the patients mother diagnosis was pseudomonas. After 3 months the patient began to have relief from symptoms and is now feeling recovered. Any treatment/ Medications is unknown to me. 12/31/08 Reviewed PCP medical records of 4/08. FINAL DX: erythema multiforme Records reveal patient experienced papular red itchy rash all over x 1 week, decreased appetite, fever & chills x 2 days. Seen in ER on 4/12 & dx w/cellulitis. Tx w/antibiotics. PCP dx w/EM & tx w/steroids. RTC 4/29 w/o improvement, now w/left ear pain & 9# wt loss. Dx w/otitis externa, treated w/ear drops & referred to Derm. No other records available.

Other Meds: Oral Contraception

Lab Data: Per non blood work was done - reports are not available

History: Allergic Antihistamines septra PMH: BCP. allergic: sulfa. 37 wk preemie w/NICU x 1 week.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336057-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Oct-2008	01-Oct-2008	0	24-Dec-2008	26-Dec-2008	FR	WAES0810USA04411	27-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Incorrect route of drug administration, Pain in jaw

Symptom Text: Case reported by a physician (the patient's father) on 02-OCT-2008: A 16 year old female patient received the third dose of GARDASIL (batch number not reported) on 01-OCT-2008. DOLIPRANE 1 gram was given in the evening after vaccination and the patient slept well. The following day morning i.e on 02-OCT-2008 at 11.30 am, the patient experienced important headache, jaw bone pain rather at the side of injection and temperature up to 37.4 centigrade. There was no adenopathy, induration nor pain at injection site. At the time of the report, the patient had not yet recovered. To be noted that the patient had received first and second doses of GARDASIL which had been well tolerated. Follow-up information received through the pharmacovigilance form on 17-DEC-2008: Case of misuse. Case upgraded to serious due to hospitalization. The patient was born in 1992 and had medical history of colopathy. She received the vaccine via subcutaneous route instead of intramuscular route. Cephalgia of severe intensity and master pain of moderate intensity (previously reported as jaw bone pain) appeared 15 hours after vaccination (previously reported on the following day morning i.e. on 02-DEC-2008 at 11:30). The patient had recovered on the next day. Fever was no longer reported. There was hospitalization (unspecified date). Complete blood count was normal. The case was closed. Other business partner numbers included E2008-09141.

Other Meds: Doliprane

Lab Data: Unknown

History: Colopathy

Prex Illness:

Prex Vax Illns:

Vaers Id: **336059-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Oct-2008	06-Nov-2008	7	24-Dec-2008	26-Dec-2008	FR	WAES0812USA04032	27-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NH17630		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diarrhoea, Lactose intolerance, Nausea, Stomach discomfort, Vomiting, Weight decreased

Symptom Text: Information has been received from a health professional concerning a 14 or 15 year old female patient, the patient had a medical history of cat allergy but otherwise was fit and well. The patient's family had a concurrent stomach upsets from which they recovered (including the patient's sister who also received HPV vaccine (WAES#0812USA03684).The patient received GARDASIL vaccine (yeast) (batch #NH17630, lot#662860/1617X) on 30-Oct-2008. On an unreported date, one week post vaccination the patient developed nausea and vomiting and had one bout of diarrhea. The symptoms lasted for four weeks and the patient was hospitalized for investigations and was found to have lactose intolerance. The patient lost 2lbs in weight during this time , the patient outcome was not reported. Other business partner numbers include E200812599. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Allergic to cats

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336077-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Sep-2008	03-Sep-2008	1	26-Dec-2008	05-Jan-2009	MA		20-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	17524	2	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	0537X	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pruritus, Injection site swelling

Symptom Text: Pt pruented in office 2 days post VARIVAX vaccine with swelling and itching around injection site, starting 1 day prior.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336089-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Dec-2008	23-Dec-2008	1	27-Dec-2008	06-Jan-2009	AL		16-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Burning sensation, Candidiasis, Chlamydial infection, Dizziness, Fatigue, Headache, Injection site pain, Muscle spasms, Trichomoniasis, Urinary tract infection, Vaginal infection

Symptom Text: Severe dizziness and unable to function. Severe headache. Fatigue and pain in arm at injection site. Burning on the front of the forehead. This is her second injection. 1/14/09 Reviewed GYN medical records of 12/22/2008. FINAL DX: candida vaginitis; uti; (+) Chlamydia & trichomonas 10/08, resolved. Records reveal patient tx for UTI on day of vaccination. Parent stated previously via voicemail message that patient not seen by PCP or ER for treatment & has fully recovered from HA following HPV vaccination of 12/22/08. Has back spasms couple of times/wk only & treats w/OTC meds.

Other Meds:

Lab Data:

History:

Prex Illness: bladder infection and yeast infection

Prex Vax Illns: headache, pain in arm~HPV (Gardasil)~2~16~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336102-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Dec-2008	02-Dec-2008	1	26-Dec-2008	05-Jan-2009	MI		06-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB436AA		Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2568AA		Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1154X		Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0575X		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Local reaction

Symptom Text: Local injection reaction - treatment ice, NSAIDS

Other Meds: Concerta, Benzaclin

Lab Data: None

History: Acne, ADHD

Prex Illness: None

Prex Vax Illns:

Vaers Id: 336121-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	11-Sep-2008	11-Sep-2008	0	10-Dec-2008	12-Feb-2009	MA	200802949	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X		Right arm	Intramuscular	TDAP
	MNQ	SANOFI PASTEUR	U2636A	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling of body temperature change, Flushing, Headache, Hypoaesthesia facial, Paraesthesia, Paraesthesia oral, Skin warm

Symptom Text: Initial report was received 18 September 2008 from a health care professional. A 12-year-old female patient had received a left deltoid intramuscular injection of MENACTRA, lot number U2636AA and a first dose right deltoid intramuscular injection of GARDASIL, lot number 0843X (Merck) on 11 September 2008, and on the evening of vaccination, she developed numbness in her face. By the following morning, the numbness had worsened and she complained of a prickly feeling in her cheeks and around her lips, and her face felt hot and cold. According to the mother of the patient, when the mother touched the patient's face, her hand felt cold. The patient's face also appeared pink and puffy. By the afternoon, her lips became tingly. The patient's mother called their health care provider to report the symptoms and stated the patient complained that her head was hurting (onset time and date not reported). The patient had not experienced any fever and no other symptoms occurred. The patient received corrective treatment with BENADRYL. By the following morning (date not reported), all symptoms had resolved. The patient had also received an injection of ADACEL (lot number not reported) within four weeks prior to receipt of MENACTRA and GARDASIL. No further information was provided.

Other Meds: FLONASE

Lab Data: None

History: Chronic rhinitis; allergies to AMOXIL, AUGMENTIN, CEFZIL, Dust mites and cats.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 336130-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	11-Dec-2008	11-Dec-2008	0	29-Dec-2008	05-Jan-2009	OR	OR200849	23-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0381X	1	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	UB259AA	1	Right arm	Intramuscular	
MMR	MERCK & CO. INC.	0890X	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Chest pain, Condition aggravated, Dehydration, Headache, Immunisation reaction, Immunosuppression, Malaise, Myalgia, Oropharyngeal pain, Pyrexia, Respiratory tract infection viral

Symptom Text: Admit ER 12/11/08 with fever, chest pain transfer to hospital, infectious disease consent, tested for viruses. Discharge diagnosis likely acute viral respiratory tract disease. 12/29/08 VAERS report submitted with medical records attached. Pt received 3 vax on 12/11/08. Had been feeling poorly at time of vax, but felt progressively worse afterward with headache, myalgias, fever and sore throat. Dehydrated on admission. Tx with IVF. Sx likely due to vaccine side effect and/or virus. DX: Fever. Immunosupression.

Other Meds: Tacrolimus; Mycophenolate; Prednisone

Lab Data: Respiratory viral panel; CBC; Vacts; Blood culture; CXR. Labs and Diagnostics: Creatinine 1.13. UC (+) for 10K mixed flora. CMV PCR, EBV PCR (-).

History: Kidney transplant 2004. PMH: Renal translants x 2, on immunosupressives. Chronic h/a.

Prex Illness: Nasal/Sinus congestion; general ache; sore throat; fever; chronic HA

Prex Vax Illns:

Vaers Id: **336145-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	28-Mar-2008	09-Jun-2008	73	29-Dec-2008	07-Jan-2009	--		08-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	3446U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hyperaesthesia, Oedema peripheral, Tenderness

Symptom Text: Pt received her second GARDASIL vaccine in June on her left arm. Patient states that her arm is stills swollen and feel very tender. She is sensitive to touch.

Other Meds:

Lab Data:

History: No known drug allergy.

Prex Illness:

Prex Vax Illns:

Vaers Id: **336146-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Dec-2008	13-Dec-2008	0	29-Dec-2008	07-Jan-2009	--		08-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Disorientation, Fatigue, Headache, Immediate post-injection reaction, Sensation of heaviness, Syncope

Symptom Text: Patient was given the GARDASIL shot at county health dept. She had two other shots done in her right arm, before the GARDASIL shot was given on the left side. Patient immediately fainted. When the nurse and I got her back up onto the table, she seized for about 30-60 seconds. It scared the nurse and I both. When she finally "came to" she was extremely disoriented. She said that her legs felt really "heavy" and that her head hurt. It took her about 30 minutes to be able to just stand up. She was then really tired and exhausted all day the rest of that day. This really scared both of us. She really doesn't want to take the next 2 series of the shots because she is scared to death the same thing will happen again. Frankly, so am I. Is this going to be a possibility? Or do we not take the shots now? Please let us know as we are both really concerned.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336152-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	19-Dec-2008	20-Dec-2008	1	29-Dec-2008	07-Jan-2009	NH		08-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	2	Right arm	Intramuscular	
	FLUN	MEDIMMUNE VACCINES, INC.	500584P	3	Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	1012X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Pruritus

Symptom Text: Within 24 hrs arm itchy and red-swollen-size of tennis ball. 2nd day redness and swelling doubled in size. 3rd day still red and swollen size - 15X16 cm at office.

Other Meds: None

Lab Data: None

History: None

Prex Illness: Healthy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336153-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Dec-2008	23-Dec-2008	0	29-Dec-2008	07-Jan-2009	NY		08-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF456CA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Vision blurred

Symptom Text: Pt reported dizziness, blurry vision 15 min after injection. Pt laying down X 15 min. Pt stated "feeling better".

Other Meds: SERTRALINE 150mg po

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 336154-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	07-Nov-2008	07-Nov-2008	0	29-Dec-2008	07-Jan-2009	NJ		08-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Right arm	Intramuscular	FLU

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Lip swelling, Pruritus, Swollen tongue, Urticaria

Symptom Text: Approx. 20 minutes following the vaccination, pt began experiencing hives across both shoulders and neck. Hives were red and "itchy." Pt began experiencing swelling of the tongue and eventually of the lips as well. Treatment was administered by ER.

Other Meds: ORTHOTRICYCLINE

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **336161-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Sep-2008	18-Sep-2008	7	29-Dec-2008	07-Jan-2009	CT		08-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Condition aggravated, Dizziness, Rhinitis allergic

Symptom Text: Intermittent dizziness and elevated temps (98.9-99.9) starting one week after injection and lasting one week. Simultaneously experienced exacerbation of allergic rhinitis.

Other Meds: None

Lab Data: None

History: Allergic Rhinitis, LKDA

Prex Illness: None

Prex Vax Illns:

Vaers Id: **336164-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Dec-2008	Unknown		29-Dec-2008	19-Jan-2009	MD		03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2818AA		Unknown	Unknown	
	FLUN	MEDIMMUNE VACCINES, INC.	500558P		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Patient given FLUMIST and GARDASIL and subsequently noted urine HCG was positive.

Other Meds:

Lab Data: Urine HCG

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336198-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Dec-2008	22-Dec-2008	0	29-Dec-2008	12-Feb-2009	TX		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2816AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1978U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Client fainted immediately post vaccine administration and regained consciousness within moments. Her last meal was breakfast & vaccine administration occured in the mid PM. Mother called me today (12/29/08)reporting the client ate upon returning home the day of vaccine administration, slept the rest of the day, and had no further problems. Mother verbalizes the client had never experienced this problem post vaccine administration in the past.

Other Meds:

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336205-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Dec-2008	29-Dec-2008	0	29-Dec-2008	12-Feb-2009	OH		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Syncope

Symptom Text: Patient received an injection while in the supine position. Following 12 minutes lying down, patient sat up for about 5 minutes on the exam table. Public Health Nurses then went on to assist her to a chair and allowed her to sit for an additional 5 minutes. The patient then fainted and fell off the chair. The entire time the patient never complained of feeling faint, she had little warning it was going to happen. After the patient fainted, nurses assisted her to a supine position and kept her that way for about a half hour when she felt much better. Patient was only out for about 30 seconds. She came back to and an ice pack was placed behind the patients neck. She was pale throughout the course until she started felling better at which time she began to get her pink color back. She was assisted to the car by wheelchair and transported home per parent.

Other Meds: N/A

Lab Data: N/A

History: N/A

Prex Illness: N/A

Prex Vax Illns: Fainting~HPV (Gardasil)~1~14~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336226-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	28-Nov-2007	12-Aug-2008	258	29-Dec-2008	05-Jan-2009	TX		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	2	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Autoimmune disorder, Myasthenia gravis

Symptom Text: Diagnosed with Myasthenia Gravis (autoimmune disease)

Other Meds: YAZ

Lab Data: ANA Panel results were higher then normal. I had a blood test for acetylcholine receptor antibodies. Normal is .05 and below. My results were 64.o.

History: Allergy to Penicillin

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **336237-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Jan-2008	02-Feb-2008	25	30-Dec-2008	31-Dec-2008	FR	WAES0804USA00199	31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NG30020	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cervical incompetence, Cervix cerclage procedure, Drug exposure during pregnancy

Symptom Text: Information has been received from a gynaecologist concerning a 17 year old female patient with no medical history reported, who on 08-JAN-2008 was vaccinated intramuscularly in the left deltoid with the first dose of GARDASIL (Batch # reported as "NG30020"). It was reported that the patient's last menstrual period was on 02-FEB-2008. Subsequently the patient became pregnant. Her estimated due date is 08-NOV-2008. At the time of reporting the patient was 4+2 gestation week. Upon receipt of new information on 18-DEC-2008, this case was upgraded because of hospitalization. The patient experienced cervical incompetence in 25th week of gestation. She was hospitalized from 10-JUL-2008 to 21-JUL-2008 and a cerclage was performed. Spontaneous birth of a healthy girl (height = 50cm; weight = 2.960 kg) was on 29-OCT-2008. The postnatal examination of mother and child showed no pathologies. Apgar score was 07-09-10. Other business partners numbers: E-2008-01938. No further information is available.

Other Meds: Unknown

Lab Data: Apgar score, 07-09-10

History:

Prex Illness: Pregnancy NOS (LMP = 02Feb08)

Prex Vax Illns:

Vaers Id: **336238-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	08-Apr-2008	Unknown		30-Dec-2008	31-Dec-2008	--	WAES0812USA04566	19-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Breast cancer, Chemotherapy, Lymphadenectomy, Mastectomy, Radiotherapy

Symptom Text: Information has been received from a Nurse practitioner concerning a 25 year old female patient who on 18-APR-2008 was vaccinated with the first dose of GARDASIL. After receiving the first dose of GARDASIL the patient was diagnosed with right breast cancer (2008). In November 2008, the patient had a right segmental mastectomy and lymph node dissection. As per the oncologist the breast cancer is not related to the GARDASIL. The patient was continuing on HERCEPTIN chemotherapy treatments until May 2009. She was also currently receiving radiation therapy. Upon internal review, breast cancer was considered to be an Other Important Medical Event. Additional information has been requested. 1/19/09 Reviewed PCP medical records of 11/14/2008. FINAL DX: right breast cancer, clinical stage T1C N0 M0; ER-positive, HER-2-positive; neoadjuvant chemotherapy; BRCA1 & 2 gene negative; right segmental mastectomy & sentinel lymph node biopsy 11/5/08.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336239-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Dec-2008	04-Dec-2008	3	30-Dec-2008	31-Dec-2008	FR	WAES0812USA04589	31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Adenoidal disorder, Convulsion, Gaze palsy, Hypertonia, Muscle rigidity, Nuchal rigidity, Postictal state, Thinking abnormal, Trismus

Symptom Text: Initial information received on 18-DEC-2008 through the patient's mother regarding an 11 year old female who was administered on DEC-2008 the first dose of GARDASIL (batch number not reported), site and route not reported. Exact date of vaccination has not been reported. According to the hospital discharge report dated 06-DEC-2008, the patient was brought to the emergency room after having an afebrile convulsion during 10 minutes. The patient presented with rigidity in neck and limbs, jaw spasm, eyes rolling into the head, loss of reality and relaxation of sphincters. The patient had a 10 minute postcritical period and afterwards recovered. Patient referred no toxic ingestion, fever, symptoms of infectious disease or any other symptoms. According to the medical history included in the hospital report, the patient had obstetrical brachial palsy. No known drug allerigies. The patient had a family history of pulmonary hypertension, and she's examined in the hospital once a year in the pediatric cardiac ward. Patient's mother had medical history of migraine. A patient's cousin was hospital admitted due to a only one tonic-clonic crisis. Patient's mother's aunt had pulmonary hypertension. Physical exploration: Weight: 52.6 Kg, temperature: 36.5 degrees C, blood pressure: 128/85, cardiac frequency: 91 per minute. Respiratory frequency: 22 rpm. Oxygen saturation: 100%. Upon examination the patient was conscious and oriented, with good general appearance, well nourished and hydrated. The patient presented a mild asymmetry of upper limbs. Right arm hypotrophy. Neurology: PEARL (pupils equal and reacting to light); conserved and symmetric cerebellar penducles. No nystagmus or dysmetria. No meningeal signs. Labial herpes. No petechiae or exanthemas. Abdomen was soft and depressible, no painful upon palpation. No masses or megalies. Normal persitaltism. Heart auscultation presenting clear sounds and rhythm. No cardiac murmurs. Respiratory auscultation: normal vascular murmur. Nasal voice. Pharynx: normal. No lesions in the t

Other Meds: Unknown

Lab Data: blood pressure measurement, 128/85; head computed axial tomography, adenoid hypertrophy, without significant pathologies; ophthalmological exam, normal eye bottom; neurological examination, PEARL; electrocardiogram, normal; WBC count, 5/01

History: Palsy

Prex Illness:

Prex Vax Illns:

Vaers Id: 336240-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
41.0	F	28-Nov-2008	28-Nov-2008	0	30-Dec-2008	31-Dec-2008	FR	WAES0812USA04590	31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0902F	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blepharitis, Dry eye, Eyelid oedema, Eyelids pruritus, Facial palsy, Hypersensitivity, Inappropriate schedule of drug administration, No reaction on previous exposure to drug, Ophthalmological examination abnormal

Symptom Text: Information has been received from a health authority. This is a case of misuse as the patient was treated outside the terms of the product license as she was 41 years old. This case was initially reported by a health care professional and by the agency on 18-DEC-2008 (IMB 041253). This case concerns a 41 year old female patient. The patient received the first two doses of GARDASIL on 01-APR-2008 and 30-APR-2008 with no adverse effect. The patient was taking concomitant therapy ZYPREXA and PROTHIADEN for unknown indications. The patient received the third dose of GARDASIL (batch# NE 24240, lot # 654884/0902F) on 28-NOV-2008. On 28-NOV-2008, half an hour post vaccination, the patient rang the clinic to say there was a lump on her left eyelid and she was worried it was a wart. The patient was seen in the clinic on 15-DEC-2008 and reported that her eyelid was drooping. On examination both eyelids were inflamed and the patient was referred to an ophthalmologist who treated the patient for dermatitis of the eyelids (treatment unspecified). The health care professional stated that she considered the event to be non-serious. The agency reported that on 28-NOV-2008 the patient experienced hypersensitivity, eyelid oedema, dry eyes and pruritus of the eyelids and considered the events to be medically significant. At the time of reporting, the patient had not yet recovered from any of the events. Other business partner numbers include E200811882.

Other Meds: Prothiaden; Zyprexa

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 336241-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jul-2008	01-Oct-2008	92	30-Dec-2008	31-Dec-2008	FR	WAES0812USA04596	31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Epilepsy, Loss of consciousness, Muscle spasms

Symptom Text: Information has been received from a health care professional concerning a 14 year old female who in May-2008, was vaccinated with the first dose of GARDASIL (Batch number and LOT# not reported), in JUL-2008, was vaccinated IM with the second dose of GARDASIL (Batch number and LOT# not reported). No concomitant drugs were administered. Following the second vaccination i.e in October 2008, the patient experienced clonic spasms and loss of consciousness. On an unspecified date, the patient was hospitalized. MRI scan and encephalography were performed. The finding were indicative of epilepsy. Corrective treatment with KEPPRA dose unknown, was initially given and TEGRETOL dose unknown, was currently given. At the time of the report, the outcome was not reported. According to the reporting physician, events were not related to GARDASIL. To be noted that the patient had no individual or family history of seizure or epilepsy. Additional information has been requested.

Other Meds: None

Lab Data: magnetic resonance imaging, finding: indicative of epilepsy; electroencephalography, finding: indicative of epilepsy

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 336242-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	27-Nov-2008	08-Dec-2008	11	30-Dec-2008	31-Dec-2008	FR	WAES0812USA04598	31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0510U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Facial paresis

Symptom Text: Case initially received from a health care professional on 18-DEC-2008. It was reported by a paediatrician that a 12 year old female patient was vaccinated with a first dose of GARDASIL (batch # NG20180, Lot # 0510U) IM into the left upper arm on 27-NOV-2008. on 08-DEC-2008 the patient experienced a peripheral facial paresis and was hospitalized on an unspecified date for about 6 days. At the time of reporting the patient has not yet recovered. Further information is requested. Other business partner numbers include E2008-11828.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336244-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	13-Dec-2008	13-Dec-2008	0	30-Dec-2008	31-Dec-2008	FR	WAES0812KOR00020	31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	J3165		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest discomfort, Dizziness, Ocular discomfort, Shock, Urticaria

Symptom Text: Information has been received from a physician via a company representative (business partner) concerning a 22 year old female who on 13-DEC-2008 was vaccinated with GARDASIL. At that time, the patient suffered from cold (without fever). Concomitant therapy included amoxicillin/clavulanate potassium, MUCOLASE, NAXEN F and (composition unspecified) from 13-DEC-2008 to 16-DEC-2008 for the treatment of cold. On 13-DEC-2008, 2 hours after the patient was vaccinated with GARDASIL (lot number J3165), the patient experienced shock. The patient experienced blood pressure decreased, chest discomfort, urticaria, ocular congestion and dizziness (symptoms of shock). The patient's blood pressure was 70 mmHg on 13-DEC-2008. The patient was treated for shock in a local clinic (specific contents of treatment was not reported). Subsequently, the patient recovered from shock on 13-DEC-2008. The reporter felt that shock was related to therapy with GARDASIL. The reporter considered the patient's shock as an other important medical event. Additional information has been requested.

Other Meds: [composition unspecified]; Amoxicillin/clavulanate potassium; Carbocysteine; Naproxen

Lab Data: Blood pressure measurement, 13Dec08, 70 mmHg

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336245-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	13-Aug-2008	13-Aug-2008	0	30-Dec-2008	31-Dec-2008	FR	WAES0810USA04453	31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1147U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Hyperhidrosis, Paraesthesia

Symptom Text: Information has been received from a health professional concerning a 17 year old patient who had no relevant medical history and was not taking any concomitant medications. The patient was vaccinated with dose 1 of GARDASIL (lot #1147U, batch #NH17630) on 13-AUG-2008. One hour post vaccination the patient experienced a prickling sensation in the lower back radiating to the lower abdomen and felt hot and sweaty. The feeling then went down both the patient's legs to calf level. The patient only experienced the event on upon movement and the feeling would abate when she stood still. The patient recovered after 3 days. Follow-up information received from the Nurse Practitioner on 17-DEC-2008. The case had been upgraded from non serious to serious. This case concerns a 21 year old female patient (not 17 as previously reported). The patient received the GARDASIL intramuscularly in the arm. The patient was not to receive any further vaccination with GARDASIL. The reporter considered that the events were serious for other medically important condition and were probably related to the vaccine. Other business partner numbers include E2008-09669. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336246-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	27-Feb-2008	27-Feb-2008	0	30-Dec-2008	31-Dec-2008	PA	WAES0807USA00806	31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Drug exposure during pregnancy, Foetal disorder, Gestational diabetes

Symptom Text: Information has been received from a licensed practical nurse (L.P.N) through the Merck pregnancy registry concerning a 22 year old female with cardiac murmur with a history of 2 pregnancies and 2 live births and a history of hypothyroidism who on 27-FEB-2008 was vaccinated with the first dose of GARDASIL (lot # 659653/1448U). Concomitant therapy included FLINTSTONES Multivitamin. The patient was pregnant. The reporter stated that the patient's last menstrual period was 16-FEB-2008. The estimated conception date was 02-MAR-2008. The patient was in for first obstetrics (OB) visit on 10-JUN-2008 and urine pregnancy test was positive and ultrasound due date was 24-NOV-2008. On 02-JUL-2008 ultrasound was performed for size and dating. The result was within normal limits (MNL) and the estimated delivery date was 23-NOV-2008. No product quality complaint was involved. Follow-up information on 19-DEC-2008 was received from a licensed practical nurse (L.P.N) concerning a 23 year old patient who was a smoker, on 27-FEB-2008 at 1535 was vaccinated intramuscularly into left deltoid with the first dose of GARDASIL (lot # 659653/1448U). Ferrous sulfate, FLINTSTONES Multivitamin and omeprazole were used during pregnancy. On 12-NOV-2008, the patient delivered a female baby with congenital anomaly weighing 3103gm (weeks from LMP: 38). Length: 20 inch. Apgar score: 8/9. The baby had a cleft palate. There were no other complications or abnormalities. The complications during pregnancy included gestational diabetes and anemia. Ferrous sulfate was taken for the treatment of anemia. At the time of reporting, the outcomes for cleft palate, gestational diabetes and anemia were unknown. Additional information has been requested.

Other Meds:

Lab Data: Ultrasound, 06/10/08, due date is 24-NOV-2008; ultrasound, 07/02/08, within normal limits; urine beta-human, 06/10/08, positive; Apgar score, 11/12/08, 8/9

History: Hypothyroidism

Prex Illness: Pregnancy NOS (LMP = 2/16/2008); Cardiac murmur; Smoker

Prex Vax Illns:

Vaers Id: **336247-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	12-Dec-2007	16-Jan-2008	35	30-Dec-2008	31-Dec-2008	NJ	WAES0802USA06370	31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse, for the Pregnancy Registry for GARDASIL, concerning a 25 year old female with environmental allergies to pollen and mold who on 12-DEC-2007 was vaccinated 0.5mL, IM with a 1st dose of GARDASIL (lot# 659439/1267U). Concomitant therapy included PREVACID. It was reported that the patient had a positive urine pregnancy test (LMP 16-JAN-2008). The patient sought unspecified medical attention in her doctor's office. Follow-up information was received from the registered nurse to report that the patient went to another facility and had elective termination on 19-APR-2008. The patient's outcome was unknown. Upon internal review, elective termination was determined to be an other important medical event. Additional information is not expected.

Other Meds: PREVACID

Lab Data: Urine beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/16/2008); Pollen allergy; Mycotic allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336248-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	23-Oct-2008	30-Oct-2008	7	30-Dec-2008	31-Dec-2008	FR	WAES0812USA04313	31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injected limb mobility decreased, Sensory disturbance

Symptom Text: Information has been received from a gynecologist concerning a 27-year-old female with no known relevant medical history, who 23-OCT-2008 was vaccinated with the first dose of GARDASIL (lot #, route and injection site unknown). Approximately 1 week post vaccination, she developed decreased mobility of the injected limb and a sensory disorder of this limb beginning in the hand and later the whole arm was concerned. The patient was hospitalized on an unspecified date. The outcome was not reported. Other business partner numbers included: E200811762. No further information is available. The file is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 336249-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-May-2007	28-May-2007	7	30-Dec-2008	31-Dec-2008	FR	WAES0812USA04312	31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1340F	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Chronic sinusitis, Disability, Dizziness, Ear pain, Febrile infection, Headache, Hypersensitivity, Hypothyroidism, Lymphadenopathy, Oropharyngeal pain, Pain, Sinusitis, Spondylolisthesis

Symptom Text: Information has been received from Health Authority on 18-NOV-08. Health authority reported that 11 year old female patient was vaccinated with a second dose of GARDASIL (Lot # 1340F and batch NF14740) IM into the left arm on 21-MAY-07. On 28-MAY-07 the patient developed a "pain syndrome" concerning head and abdomen. CT, spinal MRI , examination of the eyes and teeth and "orthopedic examinations" showed normal results. The patient was hospitalized on an unspecified date. The situation was considered to be life-threatening. The reported assumed an acute disseminated encephalomyelitis. Despite ongoing events the patient was vaccinated with third dose of GARDASIL (Lot # 1536F batch NG01520) IM into the left arm on 04-OCT-07. The patient had not recovered at the time of reporting. The first dose of GARDASIL, lot # not reported administered on 23-FEB-07 was well tolerated. Follow up information received from Health Authority on 17-DEC-2008. Case is linked with E2008-10694 (WAES 0811USA03578) (different AEs and hospitalization after first dose). The patient has a history of migraine (without aura, but with vomiting, dizziness and nausea) since she was 7 years old and cramp-like abdominal pain in the course of menstrual bleeding (menarche at the age of 10). The patient was vaccinated with a second dose of GARDASIL (Lot # 1340F and batch NF14740) IM into the left arm on 21-MAY-2007. Five days after the second dose she developed a febrile infection with earache and sore throat. She was treated with antibiotics. Despite ongoing events she was vaccinated with D3 of GARDASIL (Lot # 1536F and batch NG01520) IM into the left arm on 04-OCT-07. Approximately 3 weeks after the third dose she developed intolerable headache and attacks of dizziness which led to disability. Hospital letter (13-MAY to 15-MAY-08): Latent hypothyroid metabolism was diagnosed, but sonography showed normal results. An autoimmune thyroid disorder was ruled out. The patient was treated with thyroid hormones. Schellong test on 13-MAR-2008 and EEG on 14-MAR-

Other Meds: AUGMENTIN; OTRIVEN; thyroid

Lab Data: diagnostic laboratory test, 29Feb08, 10.4 IU/ml, mAK; orthostatic hypotension measurement, 13Mar08, Normal; electroencephalography, 14Mar08, Normal; magnetic resonance imaging, 26Mar08, Normal, spinal MRI; magnetic resonance imaging, 26Mar0

History: Migraine; Lymph nodes enlarged; Hypersensitivity reaction

Prex Illness:

Prex Vax Illns:

Vaers Id: 336250-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Oct-2008	06-Nov-2008	31	30-Dec-2008	31-Dec-2008	FR	WAES0812USA04476	31-Dec-2008

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Convulsion, Respiratory distress, Suicide attempt

Symptom Text: Case received from the Health Authorities (reference number LL20080476) on 19-DEC-2008, concerning a 17-year-old female patient who had received the third dose of GARDASIL (batch# not reported) on 06-OCT-2008 and from 06-NOV-2008 to 14-NOV-2008, she was hospitalized for acute respiratory distress and convulsions, events considered life-threatening. She had received the first two doses of GARDASIL in March and May 2008 without problems. The patient finally confessed an attempted autolysis with tramadol and atenolol (dosage unknown) on 06-NOV-2008. The patient received anticonvulsants. At the time of reporting she had recovered. Additional information received by e-mail from Health Authority on 23-DEC-2008: treatment with anticonvulsants started on 07-NOV-2008. Other business partner numbers include E200811869. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 336283-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	30-Dec-2008	Unknown		30-Dec-2008	12-Feb-2009	PA		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bradycardia, Dizziness, Fall, Pallor

Symptom Text: ALERT INITIALLY. SOON C/O FEELING LIKE SHE WAS GOING TO PASS OUT (PHYSICIAN CAUGHT PATIENT AS SHE WAS FALLING FACE FIRST OFF EXAM TABLE). WAS PALE X 1 MIN, BRADYCARDIC X 2 MIN. PT WAS LAID ON EXAM TABLE WITH KNEES ELEVATED. COMPLETE SET OF VITALS OBTAINED BY PHYSICIAN AND THOROUGH EXAM PERFORMED WITH NEGATIVE OUTCOME. PT GIVEN POPSICLE AND WAS ABLE TO LEAVE IN 15 MINUTES.

Other Meds: NONE

Lab Data: SYNCOPAL EPISODE

History: NKDA,H/O HEART MURMUR AS INFANT

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **336294-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Dec-2008	20-Dec-2008	8	30-Dec-2008	06-Feb-2009	CA		06-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	NULL	0	Right arm	Subcutaneously	
	MEN	SANOFI PASTEUR	NULL	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Intramuscular	
	HEPA	UNKNOWN MANUFACTURER	NULL	1	Left arm	Intramuscular	
	FLU	UNKNOWN MANUFACTURER	NULL		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister, Erythema, Rash papular, Rash pruritic, Skin lesion

Symptom Text: 10 days after Varivax pt developed generalized pruritic rash of clear vesicles and erythematous papules which progressed to open lesions. Treatment was symptomatic only w/ topical Calamine lotion, Aveeno baths, and oral Benadryl.

Other Meds: Zovia, ranitidine, Trazodone

Lab Data: varicella IgG neg. IgM pending.

History:

Prex Illness: abdominal pain

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336303-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Oct-2008	30-Oct-2008	0	30-Dec-2008	09-Jan-2009	CA		09-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	0495U	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0525U	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C2888AA	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1782U	1	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: None Stated

Other Meds:

Lab Data:

History: Asthma, mild

Prex Illness: None

Prex Vax Illns:

Vaers Id: 336318-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Jun-2007	25-Aug-2008	434	31-Dec-2008	02-Jan-2009	FR	WAES0809USA04911	02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Back pain, Dysaesthesia, Headache, Hypoaesthesia, Musculoskeletal chest pain, Pain in extremity, Paraesthesia, Post lumbar puncture syndrome, Sensory disturbance

Symptom Text: Information has been received from a gynecologist that a 15 year-old female patient was vaccinated with a third dose of GARDASIL (Lot # 1427U, Batch # NH15200) into the deltoid muscle on 25-AUG-2008. On 26-AUG-2008 the patient experienced pain in the left arm and left leg and musculoskeletal chest pain (upon pressure, left sided). An outpatient examination in a pediatric clinic was inconspicuous. On 27-AUG-2008 the patient developed headache. Outcome was not reported. The first dose of GARDASIL (Lot # 1339F, Batch # NF23310) given on 18-JUN-2007, and the second dose of GARDASIL (Lot # 654884/0902F, Batch # N24240) given on 23-AUG-2007, were well tolerated. Follow-up information was reported by a health authority (reference no. PEI2008016336) with reported that the patient has a history of asthma bronchial, house dust mite allergy and birch pollen allergy. Concomitant medication included SULTANOL and a combination of AARANE. The patient was vaccinated into the left deltoid. Pain started 30 minutes post-vaccination. Additionally, she developed approximately 30 minutes post-vaccination progressive sensory disturbance first of the vaccinated arm, the of the left leg, left half of the face and finally of the left half to the body. At the time of the reporting to HA , the patient was recovering from sensory disturbance. MRI of cervical spine and CSF date showed normal results. Final outcome was reported as not recovered. File is closed. Upon receipt of new information on 18-DEC-2008 this case was upgraded because of hospitalization. The patient was hospitalized due to persisting symptoms from 27-AUG-2008 until 29-AUG-2008. Hemihypaesthesia and dysaesthesia of the left body half and a marked post puncture syndrome was diagnosed. Neurological finding on admission showed sensory disturbance of the left half of the body. On 29-AUG-2008 CSF culture was sterile, virological investigations were not performed. On 28-AUG-2008, CSF oligoclonal bands were not detectable. On 28-AUG-2008, cranial MRI and holospinal MRI showed norma

Other Meds: AARANE; SULTANOL

Lab Data: Magnetic resonance imaging, 28Aug08, cranial MRI and holospinal MRI showed normal results; Magnetic resonance imaging, Cervical spine normal; CSF oligoclonal band profile, 28Aug08, not dectable; Cerebrospinal fluid culture, 29-Aug08, steril

History:

Prex Illness: House dust mite allergy; Birch pollen allergy; Asthma bronchial

Prex Vax Illns:

Vaers Id: 336319-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	07-Feb-2008	01-Apr-2008	54	31-Dec-2008	02-Jan-2009	FR	WAES0811USA02045	02-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0352U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anxiety disorder, Ataxia, Cluster headache, Dizziness, Muscular weakness, Neurosis, Oscillopsia, Paraesthesia, Psychosomatic disease, Somatisation disorder

Symptom Text: Information has been received from an internist concerning a 23 year old female who on 07-FEB-2008 was vaccinated IM with her second dose of GARDASIL (lot number 0352U, batch number NG00320, site not reported). The first dose of GARDASIL (lot number 0251U, batch number NF56480) was administered on 04-DEC-2007 and was well tolerated. There was no concomitant medication. In April 2008, the patient developed oscillopsia, weakness in the legs and paraesthesia. In June 2008, the patient additionally experienced ataxia and dizziness. At the time of reporting the symptoms improved significantly but the patient had not completely recovered. Follow-up information was reported by a internist on 18-DEC-2008. This case was upgraded because of hospitalization. The patient was hospitalized from 14-JUN-2008 until 23-JUN-2008. On an unspecified date, the psychosomatic disease with anxiety-neurotic development and vasomotoric headache were diagnosed. The neurological examination on 23-JUN-2008 showed no indication for an early demyelinating disease. Examination by an ENT physician on 16-JUN-2008 showed no otogenous-related dizziness. No organic finding. Somatisation disorder was suspected. The electroencephalography (EEG) showed normal results. Laboratory findings: CSF showed normal results. No oligoclonal bands detectable. No indication to infection of measles virus, rubella virus, varicella-zoster virus, cytomegaly virus and borrelia. The diagnostic results showed no pathologies so that the diagnosis of somatization disorder was established. The final outcome was not reported. No medication was needed. Other business partner control numbers included: E2008-09971. No further information is available. The case was closed.

Other Meds: None

Lab Data: magnetic resonance imaging, 19Jun08, normal result; neurological examination, 23Jun08, no indication for an early demyelinating disease; electroencephalography, normal; cerebrospinal fluid analysis, normal

History: The first dose of GARDASIL (lot number 0251U, batch number NF56480) was administered on 04-DEC-2007 and was well tolerated.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336335-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	20-Aug-2008	21-Aug-2008	1	31-Dec-2008	12-Jan-2009	WI		26-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0834X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Pain in extremity

Symptom Text: Patient had injection on 8/20/08. Patient called on 10/7/08 stating her arm still hurt with certain movements. Felt that her arm was "restricted". Stated ibuprofen was helping. Patient called 12/23/08 and says her arm much improved but not 100% yet.

Other Meds: None

Lab Data: None

History: History of depression

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336339-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	31-Dec-2008	31-Dec-2008	0	31-Dec-2008	12-Feb-2009	NJ		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2735AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	O575X	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C26768BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hypotension, Nausea, Syncope

Symptom Text: Nausea, lightheadedness, hypotension, syncope

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336340-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Sep-2008	11-Sep-2008	9	31-Dec-2008	03-Feb-2009	AZ		24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Right arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Muscular weakness, Pain, Pain in extremity, Radiculitis brachial

Symptom Text: Initial administration of the HPV vaccine on 9/2/08 was in the right deltoid and was administered without incident. On 9/11/08 the patient was seen in the express care clinic by Dr. At this time the patient had compaints of sharp and throbbing arm pain, as well as arm weakness (brachial neuritis). This pain is worse at night. The patient was given Ibuprofen 400mg #30 and Desipramine 25mg #20. Patient was to return to the clinic in 2 weeks for follow up. 2/19/09 Received PCP & ER medical records of FINAL DX: right arm brachial neuritis Records reveal patient experienced constant sharp throbbing pain right arm x 1 week w/decreased ROM when seen in ER on 9/11/08. Tx w/meds & referred to PT.

Other Meds: Bactrim DS, Flonase 50mcg, Loratidine 10mg

Lab Data: physical exam

History: Allergy to Amoxicillin- rash documented 5/01/2000 PMH:allergic conjunctivitis, allergic rhinitis.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **336351-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Dec-2007	23-Aug-2008	261	02-Jan-2009	05-Jan-2009	FR	WAES0806USA01027	05-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0482U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received from a gynaecologist concerning a 17-year-old female patient with a history of missed abortion in October 2007 who on 06-DEC-2007 was vaccinated with a first dose of GARDASIL (lot # not reported) and was well tolerated. On 06-FEB-2008, the patient was vaccinated IM with a second dose of GARDASIL (lot # 0482U, batch # NG09920) into the deltoid muscle. The patient was pregnant during the second dose of GARDASIL vaccine. Her last menstrual period was on 26-JAN-2008. Follow-up information was received on 19-DEC-2008. The reporter was contacted by phone. The patient developed premature labour in the 30th week of gestation and had a premature delivery. The patient was hospitalized. The hospital report is expected. Other business partner numbers include E200802592. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Abortion missed

Prex Illness:

Prex Vax Illns:

Vaers Id: **336352-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Oct-2007	18-Feb-2008	126	02-Jan-2009	05-Jan-2009	IL	WAES0808USA02610	05-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Failed trial of labour, Pre-eclampsia, Threatened labour

Symptom Text: Information has been received from a certified medical assistant (C.M.A.), for the Pregnancy Registry for GARDASIL, concerning a 14 year old female with Ascus positive HR HPV, late care who on 14-AUG-2007 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (Lot #657617/0384U), on 15-OCT-2007 was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL (Lot #657617/0384U) and on 13-MAR-2008 was vaccinated intramuscularly with the third 0.5 ml dose of GARDASIL (Lot #758222/0927U). Concomitant therapy included prenatal vitamins (PVN). There was no concomitant medication. The patient was pregnant, and her last menstrual period was 18-FEB-2008 and the estimated delivery date will be on 17-NOV-2008 (previously reported as 24-NOV-2008). No adverse event was reported. Medical attention was sought via office visit. Follow up information was received which reported that on 02-NOV-2008, the patient delivered a normal and healthy male baby. The patient had complications, she had mild preclampsia and she was scheduled for induction on 31-OCT-2008. The patient underwent CERVIDIL and PITOCIN, the patient failed to dilate past 4 cm. The patient and partner elected for C/section. There was no infections or illness during pregnancy reported. During the pregnancy was used PROCARDIA, 10 mg, every four hours for threatened pre term labor. Upon internal review failed to dilate was considered an other important medical event because the patient required a C-section. Additional information has been requested.

Other Meds: Vitamins (unspecified)

Lab Data: Ultrasound, 07/14/08, with normal limits; Serum alpha-fetoprotein, 06/23/08, negative

History: Atypical squamous cells of undetermined significance

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336353-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Jun-2008	10-Jul-2008	37	02-Jan-2009	05-Jan-2009	FR	WAES0812CAN00097	05-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0195U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 03-JUN-2008 was vaccinated with first dose of GARDASIL (lot # 0195U/NX47870). There was no concomitant medication. On 10-JUL-2008 the patient experienced syncopal episode ? seizure. Subsequently, the patient recovered from syncopal episode ? seizure. On 05-AUG-2008 the patient received second dose of GARDASIL (lot # 0195U/NX47870). On 20-OCT-2008 the patient experienced syncopal episode ? seizure. Subsequently, the patient recovered from syncopal episode ? seizure. Additional information has been requested.

Other Meds: None

Lab Data: medical observation, still under investigation

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336354-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Nov-2008	01-Nov-2008	0	02-Jan-2009	05-Jan-2009	FR	WAES0812USA04467	05-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	N102780	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Discomfort, Hypersensitivity, Injected limb mobility decreased, Injection site oedema, Pain, Vaccine positive rechallenge

Symptom Text: Information has been received from a pharmacist on 12-DEC-2008 concerning a 26 year old female patient with a history of injection site oedema who was vaccinated with the third dose of GARDASIL (batch # not reported) in her arm on an unspecified date. One to two days later she developed an arm oedema of severe intensity with arm movements constraint. She had recovered in two to three days with PARACETAMOL. The patient had no adverse effect after the first dose of GARDASIL (unspecified date) and she had a slight injection site oedema after the second dose of GARDASIL (unspecified date). The case was closed. Follow up information received on 24-DEC-2008: The case was upgraded to serious due to another seriousness criterion, movement discomfort. It was reported that the patient was 25 years at the time of adverse reactions. The GARDASIL (Batch # NJ02780) was administered in November 2008 via the intramuscular route in the right arm. One or two days post-vaccination the patient experienced oedema, discomfort when moving and local pain during 3 or 4 days, and asthenia during a few days. The reactions were considered as moderate and non serious except for movement discomfort which was moderate and serious. The patient was prescribed corrective treatment for pain with PARACETAMOL 1g three times per day and local disinfection. The patient was diagnosed with allergic reaction to vaccination. The patient recovered. The reporter considered the case as non serious but discomfort was highlighted. The case was closed. The reporter considered injection site movement impairment to be an other important medical event. Other business partner numbers include E2008-11702. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Injection site oedema

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336355-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Sep-2008	15-Oct-2008	44	02-Jan-2009	05-Jan-2009	FR	WAES0812USA04711	05-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Asthenia, Central nervous system lesion, Coordination abnormal

Symptom Text: Information has been received from Health Authority concerning a 21 year old female patient who was vaccinated with a dose of GARDASIL (lot# not reported) in the beginning of September 2008. Approximately mid of October 2008, the patient developed "subjective weakness" and coordination disorder of the left leg (the leg "stuck" while getting up from the sofa). She presented at the family physician who referred her to an orthopedist, who carried out chiropractic measures at the spine. Symptoms improved but reoccurred 2 days later. The patient was referred to a neurologist. Electrophysiologic examinations showed normal results. Cranial MRI on 13-NOV-2008 showed a 1 cm-sized lesion at the left cerebellar branch. The patient was hospitalized from 17-NOV-2008 until 19-NOV-2008. Laboratory finding see lab comments. CSF on 18-NOV-2008 showed only slight positive oligoclonal bands. C-reactive protein and leukocytes were increased 1.8 mg/l (normal range: 0.1-5.0), 12.96/nl (normal range: 4.00 - 9.40) respectively. Motor-evoked potentials, medianus SEP (two channels), tibial SEP, acustic evoked potentials and visual evoked potentials on 17-NOV-2008 showed normal results. Chest x-ray and EEG on 18-NOV-2008 normal. According to the findings a Multiple Sclerosis was considered to be unlikely by the hospital physicians, however the cause for the single cerebral focus was unclear at the time of reporting. It was pointed out that the symptoms were possibly overlayed by the patient's considerable anxiety. Follow up examinations including MRI and CSF were recommended in case of ongoing of symptoms. Other business partner numbers include: E2008-11900. No further information is available. File closed.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 13Nov08, approximately 1 cm large T2 lesion in the left peduncle; diagnostic laboratory test, 17Nov08, motor evoked potentials normal; diagnostic laboratory test, 17Nov08, acustic evoked potentials normal; chest

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336356-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	25-Nov-2008	25-Nov-2008	0	02-Jan-2009	05-Jan-2009	FR	WAES0812USA04712	05-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Loss of consciousness, Migraine

Symptom Text: Information has been received from a health authority concerning a 13 year old female who was administered on 25-NOV-2008 the second dose of GARDASIL by intramuscularly route. Site not reported. On the same day 7 hours after being vaccinated, the patient presented with migraine and suffered a loss of consciousness. She recovered fast, but required hospital admission (admission and discharge dates not reported). It was also reported that 15 minutes after the administration of the first dose of GARDASIL (date of vaccination, batch number, route and site of administration not reported), the patient presented with dizziness and pallor, that stopped spontaneously. The patient recovered. Other business partner's numbers include: E2008-11959. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Dizziness; Pallor

Prex Illness:

Prex Vax Illns:

Vaers Id: **336357-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	12-Nov-2008	17-Nov-2008	5	02-Jan-2009	05-Jan-2009	FR	WAES0812USA04713	05-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1693U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Pyrexia

Symptom Text: Information has been received from a health care professional concerning a 14 year old female who on 12-NOV-2008 received the first dose of GARDASIL (batch # NJ02270; Lot # 1693U), route and site of administration not reported. The patient presents mental deficiency and has a medical history of absence seizures. On 17-NOV-2008, five days after being vaccinated, the patient presented with febricula and convulsions. The patient recovered on the same day. A neurologist advised the patient's mother not to administer the second and third dose of the GARDASIL vaccine. Other business partner numbers include E200811925. Case is closed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Absence seizure

Prex Illness: Mental deficiency

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336382-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Jan-2009	02-Jan-2009	0	02-Jan-2009	12-Feb-2009	IL		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dry skin, Dyskinesia, Erythema, Fall, Immediate post-injection reaction, Muscle twitching, Pain, Pallor, Skin warm

Symptom Text: Was in reception area immediately after injection of Gardasil and fell to floor and had full body twitching for 5 to 10 seconds. Was not observed falling. Mother had back to her while paying receptionist. No complete loss of consciousness noted. Has redness on right side of face and c/o of pain in right temple area. PERL. Pale. Skin warm and dry. Not involuntary of bodily functions. Full ROM and good grasp and answers commands appropriately. No prior Hx of medical conditions except anemia when younger. BP130/90. Pulse 88reg. Happened at 9:50am and ambulance arrived to take her to ER at 9:57am. Phone call from mother stating she was discharged to go home at 11:20am.

Other Meds: Taking Birth Contol Pills

Lab Data:

History: NKA; anemia when younger

Prex Illness: None

Prex Vax Illns:

Vaers Id: **336390-1 (S)** **Related reports:** 336390-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-May-2008	24-Jun-2008	54	02-Jan-2009	06-Jan-2009	CA		16-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB28	1	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1758U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Amenorrhoea, Back pain, Chills, Dizziness, Ear pain, Headache, Immobile, Loss of consciousness, Malaise, Menstruation irregular, Migraine, Nausea, Pain in extremity, Paraesthesia, Photophobia, Presyncope, Syncope, Tremor

Symptom Text: syncope or seizure still being determined,events started in june of 08, she has experienced over 100 syncope episodes since that time, a month or so after inoculation, co administered with Hep A, episodes began in june, again in august, september, weekly in november, december, has experienced immobility, nausea, irregular and missed periods, migraine like headaches, left ear pain, leg pain and tingling in hands and feet, lower back pain, to date she has been to the ER 7 times and had two hospital stays for issues of passing out from 3 minutes to over 30 minutes as she passes out repeatedly, no medical treatment other than rest up until this point, she is being admitted for further neurological understanding and a three day hospital evaluation. 2/4/09 Neurology consult received dated 12/22/08 for eval of episodic LOC. Pt initially began having lapses of consciousness in 6/2008 on vacation. Seen in ER and found to be dehydrated, possibly r/t alcohol consumption. Repeat attacks however were with good hydration status. 1 week after 1st episode pt was feeling ill and unable to walk/stand w/o having an episode. W/U (-). Pt may have weeks w/o episodes, but then begin with teeth chattering, then a "head rush", dizziness and the feeling of going to pass out. Holter monitor did not register any abnormalities during episodes. Episode in 8/2008, pt was unable to roused x 30 minutes. W/U (-). In 12/08 episode did not involve complete LOC but had bifrontal H/A with photophobia after. Some events involve hand shaking or whole body shaking. Pt to be admitted for further eval.D/C Summary received for DOS 1/5-8/2009 with D/C DX: Unexplained LOC. PE WNL. One mild event noted during admission with teeth chattering and tremulous movements of the upper extremities, L>R. No LOC. No further events during admission.

Other Meds:

Lab Data: ekg, eeg, cat scan, mri, blood tests. Labs and Diagnostics: EKG WNL. EEG WNL. Normal imaging studies. Brain MRI WNL.

History: none PMH: frontal H/A. Low back pain x 1 yr.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **336390-2 (S)** **Related reports:** 336390-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-May-2008	01-Jun-2008	31	20-Jan-2009	17-Feb-2009	CA	WAES0812USA05120	20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a consumer concerning her 19 year old daughter with no known allergies and no pertinent medical history who on 01-MAY-2008 was vaccinated with 0.5ml of a dose of GARDASIL intramuscularly. Concomitant therapy included hepatitis A virus vaccine (unspecified). Since June 2008, the patient had been experiencing :syncopal episode". She had gone to the ER 6-7 times and was admitted in December. 2008. The reporter also stated that the patient was scheduled to be admitted again in January, 2009. An electrocardiogram, magnetic resonance imaging, computed axial tomography and an Electroencephalography were performed (2008,; no results reported). As of 29-DEC-2008 the patient was not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Electroencephalography, ?/?/08; magnetic resonance,?/?/08; computed axial ?/?/08; electrocardiogram, ?/?/08

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **336393-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Dec-2008	31-Dec-2008	1	02-Jan-2009	12-Feb-2009	WA		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Induration, Skin warm, Swelling, Tenderness

Symptom Text: Marked local swelling, induration, erythema, warmth, and tenderness resulting in a physician office visit.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336436-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	29-Dec-2008	30-Dec-2008	1	02-Jan-2009	12-Feb-2009	AR		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	UNKNOWN MANUFACTURER	U2637AA	0	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	057SX	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	UF455AA	5	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Influenza like illness, Pain, Pain in extremity

Symptom Text: Mom reports child with "severe" hip and joint pain. Complains of severe pain in legs, feels like she has the flu, mom feels this is more than an average reaction, achy all over 12/31/08 feeling a little better, mom did not want daughter to receive anymore HPV vaccines.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336457-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Jan-2008	25-Mar-2008	62	05-Jan-2009	03-Feb-2009	MA		09-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Discomfort, Dyspnoea, Urticaria

Symptom Text: Extreme Hives, trouble breathing / problems have continued since first injection / she breaks out in hives when there is a change of temperature (outside to inside / inside to outside) / has trouble breathing when exerting (cross country runner / basketball player) / has continued with sports but pushes through discomfort / very frustrating 1/23/09 Received PCP medical records of 3/24/08 FINAL DX: hives Records reveal patient w/daily hives since 2/15/08. Referred to specialist & declined further in series. No further records available.

Other Meds:

Lab Data:

History: None HPV #2 given 3/24/08, lot # 1446U, LA.

Prex Illness: None

Prex Vax Illns:

Vaers Id: 336473-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Aug-2007	01-Sep-2007	25	05-Jan-2009	12-Jan-2009	TN		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2207AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2457AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0171U	0	Left arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0804F	0	Left arm	Intramuscular	

Seriousness: LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Ataxia, Blood product transfusion, Budd-Chiari syndrome, Dermatomyositis, Dysphagia, Fatigue, Headache, Muscle atrophy, Muscular weakness, Myalgia, Neuropathy peripheral, Osteomalacia, Paraesthesia, Pernicious anaemia, Polymyositis, Tachycardia, Vaccination complication, Weight decreased

Symptom Text: Onset increased muscle pain, fatigue, weakness, dysphagia, weight loss. Pt requiring Prednisone IVIG every q monthly. Methotrexate headache, muscle atrophy. 2/6/09 Received PCP medical records of 11/11/08-1/20/09. FINAL DX: polymyositis, likely MCV4 vaccine related; osteomalacia; neuropathy; pernicious anemia; tachycardia; ataxia; Budd-Chiari syndrome; dermatomyositis. Records reveal patient experienced muscle weakness, paresthesias, leg pain. Referred to Neuro & Rheum. Tx w/PT & meds including methotrexate, imuran, steroids, enbrel, bicillin, IVGG. Had to drop out of college due to illness.

Other Meds:

Lab Data: muscle biopsy; MRI separate. Dx clinical myositis

History: Iron-deficiency anemia

Prex Illness: None

Prex Vax Illns:

Vaers Id: **336474-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	12-Mar-2008	12-Mar-2008	0	05-Jan-2009	12-Jan-2009	--		24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Anorexia, Arthralgia, Depression, Dizziness, Dry skin, Fatigue, Headache, Irritability, Menstrual disorder, Muscle spasms, Rash, Syncope, Vision blurred, Vomiting

Symptom Text: After my daughter received her 1st shot of 3 (to complete full dose) she started having problems soon after.- light headed, dizziness, fainting, fatigue, loss of appetite, change in menstrual cycle, blurred vision, headaches, joint hip pain, irritability, depression, throwing up and bad cramps. FYI- we opted out of the last two shots. Took patient to regular Dr. appt. We were than told that she should get the HPV shot I was reluctant because I don't have or never had cervical cancer and neither had my mother. They said she would need 3 series of shots all together. After the 1st shot (3/12/08) we started to notice all the symptoms that are describe on page 1. She was a tract runner for her school and very good at that. But after the shot anytime she would run she would throw up and cramp right after. Once she was able to make it half way when she was running 100 yard dash. 1/22/09 Received PCP clinic medical records of 3/12/08 FINAL DX: none provided Records reveal patient experienced rash on abdomen waxing & waning since 12/07. Only dry skin found on exam & tx w/lotion. No other records available.

Other Meds:

Lab Data:

History: Seasonal allergies; Patient was very healthy before this shot and the only conditions that she had or has is seasonal allergies.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336496-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	29-Dec-2008	29-Dec-2008	0	05-Jan-2009	15-Jan-2009	NC		15-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drooling, Loss of consciousness, Posture abnormal

Symptom Text: Immunization was administered in left arm. Patient then passed out & was laid down. Pt was drooling, then her legs & arms extended outward (straight) with contracted flexed fingers. Total episode last approx. 5-10 seconds. Patient was dizzy afterwards & could not recall the incident.

Other Meds: FLUOXITINE

Lab Data:

History: Anxiety Disorder

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336497-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Dec-2008	Unknown		05-Jan-2009	13-Feb-2009	NC		13-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0072X	1	Gluteous maxima	Unknown	
MMR	UNKNOWN MANUFACTURER	1084X	2	Left arm	Subcutaneously	
IPV	UNKNOWN MANUFACTURER	A10602	4	Right arm	Unknown	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHAVB516BA	2	Gluteous maxima	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong technique in drug usage process

Symptom Text: None. Hep B injection in gluteal region.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336525-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Dec-2008	13-Jan-2009	--	WAES0812USA00287	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pigmentation disorder

Symptom Text: Information has been received from a consumer via an office concerning patient who was vaccinated with GARDASIL (route and site not reported). The consumer reported that the office had a "similar but not as serious case" of loss of pigmentation in the skin as his daughter had experienced. The office said it was caused by GARDASIL. The office also said it was not an allergic reaction. Attempts are being made to verify the existence of an identifiable patient and reporter. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336526-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	31-Oct-2008	31-Oct-2008	0	15-Dec-2008	13-Jan-2009	NJ	WAES0812USA00025	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypokinesia, Injection site erythema, Injection site mass, Injection site pain

Symptom Text: Information has been received from a medical assistant concerning a 20 year old female patient with diabetes and hypothyroidism who on 05-AUG-2008 was vaccinated with the first dose of GARDASIL, lot # 660620/0571X, 0.5 mL, intramuscularly; and on 31-OCT-2008 was vaccinated with the second dose of GARDASIL, lot # 661044/054f8X, 0.5 mL, intramuscularly. Concomitant therapy included insulin Novolog and insulin Levemir. It was reported that the patient on 31-OCT-2008 experienced pain and redness at the injection site of the left upper arm after receiving her second dose of HPV vaccine. The pain was increased and the area formed a large, firm lump surrounded by a red ring. The patient had difficulty lifting the left arm. Patient not recovered. She was scheduled for an office evaluation on 28-NOV-2008. Additional information has been requested.

Other Meds: Novolog; Levemir

Lab Data: None

History:

Prex Illness: Diabetes; Hypothyroidism

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336527-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
44.0	F	25-Nov-2008	25-Nov-2008	0	15-Dec-2008	13-Jan-2009	--	WAES0812USA00004	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: Information has been received from a nurse practitioner concerning a 44 year old female who was supposed to receive ADACEL on 25-NOV-2008 was accidentally vaccinated with a dose of GARDASIL (lot # 659184/0843X). The patient was also outside the recommended age for the vaccine. Unspecified medical attention was sought. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336528-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		15-Dec-2008	13-Jan-2009	--	WAES0811USA04235	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Information has been received from a news source concerning a 20 year old female who on an unspecified date was vaccinated with GARDASIL. The reporter indicated that the patient believed that she had an adverse effect after receiving GARDASIL. The patient complained of nausea and dizzy spells after vaccination. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336529-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		15-Dec-2008	13-Jan-2009	--	WAES0811USA04230	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue

Symptom Text: Information has been received from a news source concerning a 14 year old female who on an unspecified date was vaccinated with GARDASIL. The reporter indicated that the patient believed that she had an adverse effect after receiving GARDASIL. The patient now suffers from chronic fatigue. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336530-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Dec-2008	13-Jan-2009	HI	WAES0811USA04149	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site reaction

Symptom Text: Information has been received from a pharmacist concerning an unknown numbers of patients who were vaccinated with GARDASIL. The patients complained of injection site reactions including pain. The reporter did not have any detailed information. The outcome of adverse event was not reported. It was not reported whether the patients sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336531-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	25-Nov-2008	25-Nov-2008	0	15-Dec-2008	13-Jan-2009	AZ	WAES0811USA04129	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a 10 year old female who on 25-NOV-2008 was vaccinated with GARDASIL (lot # not provided) for her first dose. ON 25-NOV-2008, after receiving GARDASIL, the patient fainted. The patient sought medical attention and recovered on 25-NOV-2008. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336532-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	20-Nov-2008	20-Nov-2008	0	15-Dec-2008	13-Jan-2009	TX	WAES0811USA04125	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 9 year old female with penicillin allergy and Rocephin hypersensitivity and a history of gastroesophageal reflux and stomach ache who on 19-JUN-2008 was vaccinated intramuscularly with first dose of GARDASIL (lot # 659655/14486U) 0.5 mL, on 20-AUG-2008 was vaccinated with a second dose of GARDASIL (lot # 660389/1968U) and on 20-NOV-2008 was vaccinated with a third dose of GARDASIL (lot # 659184/0843X). There was no concomitant medication. On 20-NOV-2008 the patient developed a swollen and red area about the size of a golf ball at the site of injection after the third dose of complained of pain when pressure was applied to the area and during movement of her arm. The patient visited the office. Ice was applied to the area and improvement occurred within 20 to 30 minutes. At the time of reporting, the patient was recovering. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Gastroesophageal reflux; Stomach ache

Prex Illness: Penicillin allergy; Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336533-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	20-Nov-2008	20-Nov-2008	0	15-Dec-2008	13-Jan-2009	IN	WAES0811USA04123	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a healthcare worker concerning a 24 year old female with hypersensitivity to AMOXICILLIN (+) AUGMENTIN who on 20-NOV-2008 was vaccinated with the first dose of GARDASIL, lot 660620/0571X, 0.5 ml, intramuscularly. There was no concomitant medication. On 20-NOV-2008 the patient experienced persistent arm pain since she received her first dose of GARDASIL. Patient not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **336534-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	Unknown	Unknown		15-Dec-2008	13-Jan-2009	TN	WAES0811USA04115	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a physician concerning a 10 year old female who was vaccinated with a first dose of GARDASIL. The patient had spotting for two days and then experience resolved. There was no laboratory studies performed. The patient sought medical attention through a call to the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336537-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	15-Oct-2008	15-Oct-2008	0	15-Dec-2008	13-Jan-2009	PA	WAES0811USA03989	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Drug exposure during pregnancy, Ovarian cyst

Symptom Text: Information has been received from a female concerning herself, with no medical history of allergies, who on 15-OCT-2008 was vaccinated with GARDASIL, 0.5ml, intramuscularly. There was no concomitant medication. Caller stated that she was pregnant at the time she received the vaccine. The last menstrual period was approximately on 01-AUG-2008 and the estimated delivery date is 08-MAY-2008. No AE related to the pregnancy reported. Caller stated that she experienced "severe pain" in her abdominal muscle and she no longer had that pain. Caller also stated that she developed a cyst on her right ovary after she got the vaccine. The patient did not indicated if the cyst has improved. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 8/1/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336538-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	21-Jun-2008	21-Jun-2008	0	15-Dec-2008	13-Jan-2009	MD	WAES0811USA03982	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Injection site pain, Injection site rash, Limb discomfort, Rash pruritic

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female patient with AMOXICILLIN allergy who on 21-JUN-2008 was vaccinated intramuscularly with a 0.5 ml first dose GARDASIL and experienced mild tenderness at the injection site for one day. On 01-AUG-2008 she received the second dose of GARDASIL (LOT # 660557/0072X). Following the second dose, the patient experienced an itchy hive-like rash at the injection site that lasted for 4 months, and fatigue and leg symptoms. The reporter stated that the patient was not seen by a physician for the symptoms. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **336539-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Dec-2008	13-Jan-2009	LA	WAES0811USA03947	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site rash

Symptom Text: Information has been received from office manager concerning a patient who on an unspecified date was vaccinated with GARDASIL. On unspecified date the patient experienced a rash at the injection site for 2 weeks. The patient contacted office. On unknown date, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336540-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Dec-2008	13-Jan-2009	--	WAES0811USA03941	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site abscess, Injection site infection

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a first dose of GARDASIL. Subsequently the patient experienced an abscess or an infection at the injection site. The physician reported that this is not a patient of hers and she heard about the experience from a third party. Attempts to verify the existence of an identifiable patient has been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336541-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Jan-2008	08-Oct-2008	265	15-Dec-2008	13-Jan-2009	PA	WAES0811USA03935	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a registered nurse, for the Pregnancy Registry of GARDASIL vaccine, concerning an 18 year old female with migraines who was intramuscularly vaccinated with the first , second and third 0.5 ml doses of GARDASIL vaccine on 27-SEP-2007, 17-JAN-2008 and 10-NOV-2008 respectively (lot number: dose 1: 658563/1063U, dose 2: 658558/1061U, dose 3: 659184/0843X). Concomitant therapy included IMITREX (Sumatriptan). The patient was pregnant and her LMP was 06-OCT-2008. On 23-NOV-2008 the patient performed urine pregnant test but no result provided. No symptoms reported. The patient went to the office for medical attention on 24-NOV-2008. It was reported that the patient began albuterol and augmentin for an unspecified illness. Additional information has been requested.

Other Meds: IMITREX (SUMATRIPTAN)

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 10/6/2008) Migraine

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336542-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Sep-2008	11-Nov-2008	47	15-Dec-2008	13-Jan-2009	CA	WAES0811USA03925	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter without medical history or drug allergies who around 25-SEP-2008 was vaccinated with the first 0.5 ml dose of GARDASIL (lot number not provided). There was no concomitant medication. Around 11-NOV-2008 the patient had PAP and urine analysis done and it was discovered that she had HPV (the patient developed HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68). No further information was provided. The outcome was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Pap test, 11/11/08, HPV types 16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, and 68

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336543-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Oct-2008	01-Oct-2008	0	15-Dec-2008	13-Jan-2009	--	WAES0811USA03822	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed, Menstruation irregular, Metrorrhagia

Symptom Text: Information has been received from a consumer who is the mother of the 18 year old female patient. The patient at the beginning of October 2008, was vaccinated with a first dose of GARDASIL. When the patient received the first dose of GARDASIL, she was supposed to get her menstrual period that next week, but she ended up being two weeks later and when she did get her period it was very light and then it stopped. Then a few days later she had gotten her period again which it was light again and then it stopped. Then a few weeks later the patient got her period again which the bleeding was heavier than it ever has been before. Last week the patient was spotting again. As of 24-NOV-2008, the patient had not started her period again. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336544-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Dec-2008	13-Jan-2009	NY	WAES0811USA03821	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall

Symptom Text: Information has been received from a physician concerning a female adolescent patient who was vaccinated on an unspecified date with a dose of GARDASIL, and stood up right away and got dizzy, light headed and fell down. The patient did not loose consciousness. Subsequently, the patient recovered. The did not seek medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336545-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Dec-2008	13-Jan-2009	--	WAES0811USA03810	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Information has been received from a nurse practitioner concerning an unspecified number of patients who were vaccinated with a dose of GARDASIL (route, site of administration and batch number not reported). The patient have had pain from GARDASIL. The outcome is unknown. This is one of several reports from the same source.

Other Meds: Unknown

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **336546-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Oct-2008	29-Oct-2008	1	15-Dec-2008	13-Jan-2009	--	WAES0811USA03747	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0576X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Menstruation delayed, Pain

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female patient, with no pertinent medical history and no allergies/drug reactions, who on 28-OCT-2008 was vaccinated with GARDASIL (lot # 661530/0575X). There was no concomitant medication. On 29-OCT-2008 the patient experienced fatigue, achiness and menstrual period was late. The patient sought medical attention via telephone. The patient had not recovered as of 21-NOV-2008. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **336547-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		15-Dec-2008	13-Jan-2009	--	WAES0811USA03715	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Feeling cold, Hot flush, Malaise, Menstruation irregular, Migraine, Muscular weakness, Rash erythematous, Swelling, Vomiting

Symptom Text: Information has been received from a consumer concerning her granddaughter, a 14 year old female with a history of migraines who was vaccinated with the first dose of GARDASIL. There was no concomitant medication. Subsequently the patient developed a red rash and swelling. The patient was experiencing dizziness, muscle weakness, malaise, hot and cold flashes, vomiting, irregular menstrual periods and an increase in severity of migraines. The patient was more prone to illness. The patient's red rash and swelling and dizziness and muscle weakness and malaise and hot and cold flashes and vomiting and irregular menstrual periods and increase in severity of migraines and more prone to illness persisted. Medical attention was sought in the physician's office. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Migraine

Prex Illness:

Prex Vax Illns:

Vaers Id: 336548-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Oct-2008	16-Oct-2008	0	15-Dec-2008	13-Jan-2009	IN	WAES0811USA03689	09-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2761AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1487U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Decreased appetite, Dehydration, Diarrhoea, Dizziness, Dyspnoea, Fatigue, Flushing, Insomnia, Nausea, Rash, Renal cyst, Rhinitis allergic, Sinus arrhythmia, Sinusitis, Ventricular extrasystoles, Viral infection, Viral skin infection, Vomiting

Symptom Text: Information has been received from a consumer concerning her 11 year old daughter who on 16-OCT-2008 was vaccinated with her first dose of GARDASIL (route and site not reported). Concomitant therapy included flu vaccine in the same day. On 16-OCT-2008, later that evening the patient experienced vomiting and nausea and was hospitalized for at least 4 days. Patient was vomiting almost every half an hour for those days. When the patient was brought home, she started vomiting again and was hospitalized the second time for 2 days. The patient was recovering. The patient was tested for computed axial tomography (cat scan), magnetic resonance imaging (MRI) and blood test with no result. Follow-up information was received from a registered nurse. The nurse stated that the patient received dose 1 of GARDASIL 0.5 ml IM on 16-OCT-2008. The patient was treated with Phenergan and her symptoms were almost completely resolved. Additional information has been requested. 1/22/09 Received PCP medical records of 10/16-10/25/2008. Records reveal pt in state of usual health on day of vaccination. Later same day, parent had to pick up from school due to SOB, weakness & dizziness. Seen same day by PCP & dx w/allergic rhinitis. Tx w/antihistamines. Developed vomiting. RTC 10/20 for same & sent to hospital. RTC 10/24 s/p hospitalzation. Concerns for PVCs noted in hospital & continued lightheadedness, otherwise feels well. Referred for Holter monitor. Recurrent vomiting 10/25 & was readmitted to hospital. 1/22/09 PCP records included hospital medical records of 10/20-10/23/2008. FINAL DX: vomiting w/dehydration & viral exanthem Records reveal patient experienced bilious vomiting x 5 days, poor appetite, lack of sleep, fatigue. Had been seen in PCP office previous week for viral infection w/SOB & dizziness. In hospital had nausea & diarrhea. On 3rd day in hospital developed facial flushing & rash. 1/30/09 Received additional hospital medical records of 10/25-10/26/2008. FINAL DX: dehydration, bilious vomiting & sin

Other Meds: Influenza virus vaccine

Lab Data: Unknown LABS: rapid strep neg. CXR neg. Segs 82.1%(H), monos 3.3(L). CO2 21(L), creatinine 0.6(L). Calcium 10.7(H). Gastric occult blood neg. UA abnormal w/protein & ketones; c/s neg. Abdominal/KUB x-ray neg. Sinus x-ray WNL. Abdom

History: None PMH: feeding issues in infancy. behavior problems. Cardiac arrhythmia. Allergies & asthma. Family hx: thyroid disorders.

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336556-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Dec-2008	31-Dec-2008	0	06-Jan-2009	16-Jan-2009	MO		16-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	14866	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Patient blacked out after receiving HPV vaccine.

Other Meds:

Lab Data: BPS, 8:10 92/54 P60, 8:15 98/72 P64, 8:18 96/64 sitting P72, 8:20 112/68 P64

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336566-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	20-Nov-2008	20-Nov-2008	0	15-Dec-2008	13-Jan-2009	MI	WAES0811USA03667	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Unknown	Intramuscular	
	VARCEL	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye swelling

Symptom Text: Information has been received from a healthcare worker concerning a 17 year old female who on 19-SEP-2008 was vaccinated with a first dose of GARDASIL vaccine (lot # 661044/0548X) intramuscularly. On 20-NOV-2008, the patient was vaccinated with a second dose of GARDASIL vaccine (lot # 661764/0650X) intramuscularly. Secondary suspected therapy included varicella virus vaccine live on 20-NOV-2008. The patient developed swelling to her eyes after receiving her second dose of GARDASIL vaccine. The patient had office visit to treat the event. The patient may have experienced eye swelling after her first dose of GARDASIL vaccine, but was not certain. At the time of reporting, the patient was recovering from the event. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336567-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	21-Nov-2008	Unknown		15-Dec-2008	13-Jan-2009	--	WAES0811USA03660	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mass

Symptom Text: Information has been received from a physician concerning a female who on 21-NOV-2008 was vaccinated with a second dose of GARDASIL. The patient experienced a lump in right arm after second dose of GARDASIL. The patient sought unspecified medical attention. At the time of reporting, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336568-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	02-Oct-2008	Unknown		15-Dec-2008	13-Jan-2009	--	WAES0811USA03656	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Information has been received from a nurse practitioner concerning a patient who was vaccinated with the second dose of GARDASIL (route, site of administration and batch number not reported) early on 02-OCT-2008. Subsequently the patient experienced pain from GARDASIL. The outcome is unknown. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336569-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	18-Nov-2008	20-Nov-2008	2	15-Dec-2008	13-Jan-2009	--	WAES0811USA03624	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a 19 year old female who on 18-NOV-2008 was vaccinated with a dose of GARDASIL. The patient reported that on 20-NOV-2008, "my arm is hurting me at the injection site". The outcome of the patient was not reported. She did not seek medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 336570-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-Aug-2008	28-Aug-2008	0	15-Dec-2008	13-Jan-2009	OR	WAES0811USA03570	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Pain in extremity

Symptom Text: Information has been received from a registered nurse concerning a 13 year old patient with allergies who on 28-AUG-2008 was vaccinated with a first dose of GARDASIL vaccine into her left arm, in the afternoon approximately at 3:00 pm. Concomitant medication included ZYRTEC, vitamins (unspecified), ZANTAC and NASONEX. The only that she had been taking every evening was apparently mometasone furoate. The patient complained of numbness and pain in the arm that the dose was given the whole night. There was no swelling or redness in the area of injection. It was also reported a little redness. Pain eased up somewhat next day (not a persistent), numbness lasted approximately three days. No medical interventions or treatment for the adverse events. No other signs and symptoms reported besides the above mentioned which lasted approximately three days after injection. The patient came for the second dose of GARDASIL vaccine on 30-OCT-2008 but she did not receive it. Additional information has been requested.

Other Meds: ZYRTEC NASONEX ZANTAC vitamins (unspecified)

Lab Data: Unknown

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336571-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		15-Dec-2008	13-Jan-2009	CA	WAES0811USA03561	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a 17 year old female who on an unspecified date was vaccinated with a first dose of GARDASIL and no reaction was noted. On an unspecified date the patient received a second dose of GARDASIL and developed hives, "4 hours after the second dose was given". The patient did not seek medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336572-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Oct-2008	Unknown		15-Dec-2008	13-Jan-2009	WI	WAES0811USA03542	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Condition aggravated, Cough, Dizziness, Dysmenorrhoea, Erythema infectiosum, Fatigue, Headache, Hypophagia, Injection site pain, Injection site swelling, Lymph node pain, Lymphadenopathy, Malaise, Menorrhagia, Muscular weakness, Nausea, Neurological examination normal, Oropharyngeal pain, Paraesthesia, Rash erythematous, Rash pruritic, Sensation of heaviness, Viral pharyngitis

Symptom Text: Information has been received from a consumer concerning of her daughter, a 17 year old female with no pertinent medical history and without concomitant medication. Who after received the first (MAR-2008) and second dose (date unspecified in 2008) of GARDASIL (site and route unspecified) had injection site reactions (soreness and swelling). Subsequently on early October, the patient was vaccinated with the third dose of GARDASIL (site and route unspecified). About a week after vaccination the patient started experiencing tingling and weakness in her arm and legs, dizziness, tiredness, nausea. The patient has been seen by a neurologist but no cause of the problem could be found. On an unspecified date in 2008, the laboratories studies perform were a blood work, MRI and Lymes test which were negative. At the time of reporting, 20-NOV-2008, the outcome of the patient was not recovered. 1/16/09 Reviewed PCP medical records for 3/27-12/22/08. FINAL DX: Records reveal patient experienced usual state of good health on 3/27/08 when received HPV#1, MCV4 & varivax. On 4/27 seen for erythematous itch rash x 4 days & dx w/probable Fifth's disease. Tx w/topical meds. RTC 6/9/08 w/sore throat & fatigue x 3-5 days, HA resolved, occ cough, oral intake reduced. Rapid strep neg & dx w/viral pharyngitis. RTC 6/12 w/continued sore throat & tiredness & tender cervical lymph node hyperplasia. Dx w/pharyngitis & tx w/oral antibiotics as leaving country next day. RTC 10/13 w/nausea, stomach ache & heavy numb hands & legs. Dx w/dysmenorrhea. RTC 10/26 w/continued fatigue, nausea, stomach ache, lightheaded & extra heavy menstruation x 5-6 days. Dx w/dysmenorrhea, malaise & fatigue & considered BCP. Referred to neuro prior to starting BCP due to hx of migraine HA. Neuro consult 10/24/08 for paresthesias/tingling of hands/feet, balance difficulties, gen. weakness all beginning approx 10/12/08. Neuro exam completely WNL & no dx provided. Returned to neuro 11/11/08 for review of abnormal MRI, no change in physical asse

Other Meds: None

Lab Data: LABS: MRI brain abnormal. CBC, chemistry, ESR, monospot & thyroid studies all WNL. CSF: WBC 1, RBC 1, protein 20, glucose 48 all WNL.

History: None PMH:heart murmur secondary to pulmonic valve insufficiency, migraine HA. Family hx: HTN, migraine, DMII.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336573-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Dec-2008	13-Jan-2009	--	WAES0811USA03529	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Information has been received from a certified nurse midwife concerning a female patient who was vaccinated with the first dose of GARDASIL. The nurse practitioner mentioned that the patient fainted after receiving the vaccine. The patient received her first dose of GARDASIL and waited 15 minutes and was fine. Then when she got up to leave, her knees buckled and she passed out. The practitioner nurse reported that the patient had not eaten that day and was anxious about the shot. The patient recovered without incidence. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Anxiety; Eating disorder

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336574-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	09-Nov-2008	10-Nov-2008	1	15-Dec-2008	13-Jan-2009	WA	WAES0811USA03515	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Burning sensation, Rash generalised, Rash pruritic

Symptom Text: Information has been received from an office manager concerning a 23 year old female with no known drug reactions/allergies and no pertinent medical history, who on 09-NOV-2008 was vaccinated with GARDASIL, 0.5ml, intramuscularly. There was no concomitant medication. The office manager reported that on 10-NOV-2008, the patient developed pruritic and burning rash all over her body after her first dose of GARDASIL. The patient was prescribed an antihistamine. The patient sought medical attention via telephone. At the time of the report, the patient has not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336575-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	03-Sep-2008	03-Sep-2008	0	15-Dec-2008	13-Jan-2009	--	WAES0811USA03495	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Injection site erythema, Injection site induration, Injection site irritation, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a 20 year old female with anatryptaline allergy and a history of eating disorder, acid reflux and pelvic inflammation (physician found " low recessive cells for cervical"; after treatment and another PAP test the physician suggested getting HVP vaccine) who on 03-SEP-2008 was vaccinated in the upper arm with the first dose of GARDASIL. On 13-SEP-2008 she found out she was pregnant. On an unknown date she received a flue shot and prenatal vitamins. On the day of vaccination the patient experienced "burning pain at the time the shot was given, and after the injection she had a little red dot for a couple of days that eventually turned into a swelled up knot that was very painful to the touch". The consumer recovered "2 and a half weeks after getting the vaccine". The consumer sought unspecified medical attention.

Other Meds:

Lab Data: Beta-human chorionic, 09/13/08, positive

History: Eating disorder; Oesophageal acid reflux; Low grade squamous intraepithelial lesion; Pelvic inflammation; Cervical Pap smear

Prex Illness: Pregnancy NOS (LMP= Unknown), Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336576-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	12-Aug-2008	12-Aug-2008	0	15-Dec-2008	14-Jan-2009	TX	WAES0811USA03472	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Headache, Nausea, Oropharyngeal pain, Pyrexia

Symptom Text: Information has been received from a physician concerning an 18 year old female with asthma who on 10-JUN-2008 was vaccinated with the first dose of GARDASIL and the second dose of GARDASIL on 12-AUG-2008, lot # 660557/0072X, intramuscularly in right deltoid. It was reported that the patient experienced nausea, abdominal pain, headache, sore throat and fever "several " hours after receiving her second dose of HPV

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **336578-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	30-Jun-2008	30-Jun-2008	0	06-Jan-2009	07-Jan-2009	NJ	WAES0811USA03496	07-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a Certified Medical Assistant for the Pregnancy Registry for GARDASIL concerning a 19 year old female with penicillin allergy who on 30-JUN-2008 was vaccinated with a 0.5 ml first dose of GARDASIL (LOT # 0250X) and on 29-AUG-2008 received a second dose of GARDASIL (LOT # 0573X). The reporter stated that the patient who had received the GARDASIL vaccine "is pregnant". Her LMP was 19-SEP-2008. Expected date of delivery is 26-JUN-2009. There was no concomitant medication. No adverse effect was reported. The patient was seen in the office for medical attention. Follow up information was received on 30-DEC-2008 from a certified medical assistant who stated that there was a elective termination of the pregnancy. It was unknown if the products of conception were examined or if the fetus was normal. Upon internal review, elective termination was considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 9/19/2008); Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336580-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		06-Jan-2009	07-Jan-2009	FL	WAES0812USA05190	07-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer, for the Pregnancy Registry for GARDASIL vaccine, concerning his 25 year old wife general anesthesia allergy who was vaccinated 3 doses of GARDASIL vaccine (Lot # not reported) prior to becoming pregnant. Concomitant therapy included heart medication. Consumer's wife is the patient in this case. Consumer reported that his wife had completed the GARDASIL vaccine series approximately six months to becoming pregnant with their first child. Consumer reported that they learned at 17 weeks gestation that his wife had lost their baby around 12 weeks of gestation. Laboratory test was performed previous to pregnancy and during pregnancy. Consumer reported that his wife will call back with more specific dates and information. Upon internal review, abortion spontaneous was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown) Drug hypersensitivity

Prex Vax Illns:

Vaers Id: 336581-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-May-2008	30-Aug-2008	95	06-Jan-2009	07-Jan-2009	--	WAES0812USA05011	08-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, for the pregnancy registry for GARDASIL, concerning an 18 year old female with a history of 2 pregnancies, 2 elective terminations, 0 live births and no other medical history who on 27-May-2008 was vaccinated with the second dose of GARDASIL (lot#659964/1978U). There was no concomitant medication. Subsequently, she became pregnant and her LMP was 26-Jul-2008. On 30-Aug-2008, about 5 weeks from her LMP, the patient underwent elective termination. Upon internal review, elective termination was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Termination of pregnancy - elective

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336610-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	19-Mar-2008	20-Mar-2008	1	06-Jan-2009	16-Jan-2009	MA		30-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLU	SANOFI PASTEUR	U2501AA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB171AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1740U	1	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	AC52B016BA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1759U	1	Right arm	Subcutaneously	
TYP	SANOFI PASTEUR	A04462	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Skin warm, Swelling, Tenderness

Symptom Text: Pt presented with approx 5 cm area of redness, sl warmth but minimal swelling. Mildly tender. No streaking. Rx'd Tylenol or Motrin for discomfort.

Other Meds: OMEPRAZOLE 20 MG CAP, DELAYED RELEASE SOLIA 0.15 MG-30 MCG TAB (DESOGESTREL-ETHINYL ESTRADIOL) FLUCONAZOLE 150 MG TAB LORATADINE 10 MG TAB

Lab Data:

History: Allergic to pollen, chronic vomiting.

Prex Illness: Chronic vomiting assoc with history of esophageal dilatation.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336639-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Sep-2008	01-Sep-2008	0	15-Dec-2008	14-Jan-2009	FL	WAES0811USA02823	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site papule, Pain, Skin warm

Symptom Text: Information has been received from a physician concerning an approximately 20 year old female who in approximately September 2008 "a couple months ago" was vaccinated intramuscularly with the first dose of GARDASIL and experienced "small bump" at the injection site that lasted for 3-4 days. On 01-NOV-2008 "17 days ago" the patient was vaccinated with the second dose of GARDASIL and experienced a similar bump for 2 weeks. After 2 weeks, it got larger and painful and it was "hot". At the time of reporting, the patient still has "a little bump" that "hurts a little bit when I touch it". The patient sought unspecified medical attention and had blood work performed. The result was not reported. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **336640-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	--	WAES0811USA02737	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Pyrexia

Symptom Text: Information has been received from a nurse concerning her 18 year old daughter who was vaccinated with the second and third doses of GARDASIL two years ago (in approximately 2006). After receiving her second and third doses of GARDASIL the patient experienced fever and pain at the injection site two years (in approximately 2006). Lot number was not available. The outcome was unknown. The patient sought unspecified medical attention. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336641-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jun-2008	23-Aug-2008	82	15-Dec-2008	14-Jan-2009	IL	WAES0811USA02673	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Smear cervix abnormal

Symptom Text: Information has been received from a registered nurse, for the pregnancy registry for GARDASIL, concerning a 17 year old female with allergy to Amoxicillin and Codeine and no relevant medical history who on 03-Mar-2008 was vaccinated intramuscularly with a first 0.5ml dose of GARDASIL (lot number 659441/1446U) (injection site not reported). On 02-Jun-2008 and 08-Sep-2008, the patient was vaccinated intramuscularly with a second and third 0.5ml dose of GARDASIL (lot number 660387/1967U) (injection site not reported). Concomitant therapy included NUVARING. Subsequently the patient was pregnant. Her LMP was 23-Aug-2008. On 22-Sep-2008 the patient had a low grade PAP smear. The patient went to the physician's office. Laboratory tests included ultrasound and blood work (results unspecified). The outcome of the patient's experience was unknown. Additional information has been requested.

Other Meds: NUVARING

Lab Data: Unknown

History: Pregnancy NOS (LMP=8/23/2008) Penicillin allergy, drug hypersensitivity

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336642-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
31.0	F	28-Sep-2006	28-Sep-2006	0	15-Dec-2008	14-Jan-2009	MI	WAES0811USA02656	03-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a certified medical assistant concerning an approximately 31 year old female, who on 28-SEP-2006 was vaccinated with the first 0.5ml dose of GARDASIL. In October 2006, the patient was vaccinated with the second 0.5 ml dose of GARDASIL. In March 2007, the patient was vaccinated with the third 0.5ml dose of GARDASIL. On an unspecified date, the papanicolaou test was done and the result revealed abnormal. At the time of this report, the outcome was unknown. The patient was see by the physician and sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336643-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	01-May-2008		15-Dec-2008	14-Jan-2009	TN	WAES0811USA02631	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a physician concerning a 26 year old female with no drug reactions or allergies and a history of seborrhoea who on unspecified dates was vaccinated with GARDASIL series. Concomitantly, the patient used medicated shampoo. In May 2008, the patient experienced hair loss. At the time of this reporting, the patient was recovering from hair loss. Biopsy was performed and the results showed alopecia with mild fibroplasia. Unspecified medical attention was sought in the office. Additional information has been requested.

Other Meds:

Lab Data: Biopsy, alopecia with mild fibroplasia

History: Seborrhoea

Prex Illness:

Prex Vax Illns:

Vaers Id: **336644-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Dec-2008	14-Jan-2009	LA	WAES0811USA02545	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse practitioner and a registered nurse concerning a patient who on an unspecified date was vaccinated with a dose of GARDASIL. Shortly after receiving the vaccine the patient experienced syncope. The patient's outcome was not reported. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336645-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	31-Oct-2008		15-Dec-2008	14-Jan-2009	--	WAES0811USA02370	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a pharmacy student concerning a female who was vaccinated with an unknown number doses of GARDASIL. The patient experienced hair loss on the top of her head "about 2 weeks ago", on approximately 31-OCT-20088. The patient's mother called pharmacy. At the time of reporting, the patient recovered. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336646-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jul-2008	01-Jul-2008	0	15-Dec-2008	14-Jan-2009	TX	WAES0811USA02335	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site atrophy, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 15 year old female who was vaccinated with her third dose of GARDASIL (route and site not reported). In July 2008, the patient developed left arm pain and a depression of her skin at the injection after receiving her third dose of GARDASIL. A skin biopsy was consistent with atrophoderma. The patient's left arm pain and a depression of her skin at the injection site persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: skin biopsy, atrophoderma

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **336647-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	05-Aug-2008	05-Aug-2008	0	15-Dec-2008	14-Jan-2009	MO	WAES0811USA02331	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Mobility decreased, Muscular weakness, Pain

Symptom Text: Information has been received from a registered nurse concerning a 25 year old female with no relevant medical history reported who on 03-JUN-2008 and 05-AUG-2008, was vaccinated with the first and second dose of GARDASIL (lot number 0250X) 0.5ml IM into her left arm. Concomitant therapy included allergy medicine as needed. The patient experienced pain, soreness, decreased mobility, decreased strength in her left arm after administration of her second dose of GARDASIL. The patient was examined by a neurologist on 11-NOV-2008. He advised patient not to get the third dose. Additional information has been requested.

Other Meds: Therapy unspecified

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 336648-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	21-Oct-2008	23-Oct-2008	2	15-Dec-2008	14-Jan-2009	VA	WAES0811USA02328	03-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hyperaesthesia, Paraesthesia

Symptom Text: Information has been received from a physician concerning an 18 year old female who was vaccinated with GARDASIL (route and site not reported). On 20-FEB-2008, 22-APR-2008 and 21-OCT-2008, the patient was given the first, second and third dose of GARDASIL separately. There were no adverse effects after the first 2 doses. About 2 days after her last dose of GARDASIL, the patient experienced intermittent episodes of "tingling" in her toes, fingers, and face that last between 30 minutes and 1 hour then resolved. Complete blood panel- complete blood cell count, comprehensive metabolic panel, Sedimentation rate, thyroid stimulating hormone, and Rapid Plasma Reagin done with all results normal. The doctor had characterized this as "a skin disturbance". The patient's tingling in her toes, fingers and face persisted. Follow-up information was received from the physician. She stated that this 18 year old female received her 3rd dose of GARDASIL on 21-OCT-2008 and 2 days later experienced tingling intermittently of fingertips and toes. She stated that the episode last for about 30 minutes and were still occurring intermittently. The patient reported one episode tingling of the face and also reported that the soles of her feet were more sensitive to touch when the tingling was not present and described the sensation as "ticklish". The patient was not reporting any associated pain and did not experience these symptoms following dose 1 or 2. She was concomitantly taking birth control pills since June and was recently treated for Chlamydia. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory, normal; Complete blood cell, normal; Erythrocyte, normal; Serum TSH, normal; Rapid plasma reagin, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336650-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Sep-2008	17-Sep-2008	0	15-Dec-2008	14-Jan-2009	NE	WAES0811USA02313	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Disorientation, Dizziness, Inappropriate schedule of drug administration, Migraine, Paraesthesia, Vomiting

Symptom Text: Information has been received from a physician concerning an 18 year old female with PENICILLIN, BACTRIM and DUAC gel allergy and a history of reactive airways who on 03-JAN-2008, 03-APR-2008, 07-AUG-2008, 17-SEP-2008, was vaccinated with the first, second, third and fourth dose of GARDASIL 0.5ml IM separately. On 17-OCT-2008 the patient experienced the sudden onset of disorientation and dizziness. The patient subsequently experienced parasthesia of the lower extremities which then extended to include both arms and her face, as well as one episode of emesis. The patient was seen in the office within 1 hour of the onset of symptoms. A diagnosis of migraine variant was made and the patient was prescribed PHENERGAN and DARVOCET. The symptoms resolved within 2 hours of onset. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Reactive airways disease

Prex Illness: Penicillin allergy; Sulfonamide allergy; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **336651-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
56.0	F	07-Oct-2008	Unknown		15-Dec-2008	14-Jan-2009	--	WAES0811USA02290	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Pain, Pain in extremity

Symptom Text: Information has been received from a 56 year old female with allergic to Sulfa and no relevant medical history who on 07-Oct-2008 was vaccinated with a first dose of GARDASIL,(lot number, injection site and route not reported). Concomitant therapy included hormone replacement therapy. In October 2008, also reported as a couple of weeks later, the patient experienced pain in her left arm where she received the vaccine. The patient reported that as the weeks went on she had pain in her arm to the point where she could not lift it up, but for now the pain subsided but had a "dull" ache. The patient called the doctor's office. At the time of this report, the patient's events was recovering. No further information is available.

Other Meds: Estrogen (unspecified)

Lab Data: None

History: Sulfonamide Allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **336652-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	26-Aug-2008	01-Oct-2008	36	15-Dec-2008	14-Jan-2009	PA	WAES0811USA02286	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Left arm	Intramuscular	HPV4
							TDAP

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anorexia, Chills, Dizziness, Feeling hot, Headache, Influenza like illness, Joint swelling, Lymph node pain, Neck pain, Pain, Photophobia, Stomach discomfort, Viral infection

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter with no relevant medical history or allergies who on approximately 23-JUN-2008, was vaccinated with a first dose of GARDASIL (lot number, injection site and route not reported). The patient did not have adverse reaction after receiving the first dose. On 25-AUG-2008 the patient was vaccinated with a second dose of GARDASIL (lot number, injection site and route not reported). There was no concomitant medication. In the first week of October 2008, the patient experienced constant headache, loss of appetite, flu like symptoms and joint swelling. Unspecified medical attention was sought. Laboratory test included MRI cat scan, lime test and rheumatoid test (result unspecified). On 14-NOV-2008 the patient complained that her stomach is bothering her. The patient's events persisted. Additional information has been requested. 1/12/2009 Reviewed PCP medical records of 6/25/08-1/8/2009. FINAL DX: pain amplification syndrome Records reveal patient experienced intermittent throbbing frontal HA, photophobia & dizziness x 1 mo when seen 10/31/08. RTC 11/5 w/continued HA, chills, hot feeling & sore neck. Exam revealed tender supraventricular nodule. Dx w/viral illness. Neuro consult done 11/6/08. Tx w/steroid taper. Developed joint swelling Rheumatology consult done 12/1/08 & dx w/pain amplification syndrome.

Other Meds: None

Lab Data: Unknown LABS: CT & MRI/MRV brain WNL. ESR, CBC, ANA & RA factor WNL.

History: None PMH: multiple nevi

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336653-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	29-Sep-2008	29-Sep-2008	0	15-Dec-2008	14-Jan-2009	NJ	WAES0811USA02201	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood creatine phosphokinase, Injection site atrophy, Injection site pain

Symptom Text: Information has been received from an office manager at a physician's office concerning a 13 year old female who on 31-Aug-2006 and 09-Nov-2006, received the first and second doses of GARDASIL (lot# not provided). On 29-Sep-2008 the patient received the third dose of GARDASIL, IM into the left deltoid (lot# 66104/0548X). Concomitant therapy included YASMIN. A couple of days (also reported as "several days" in follow up) post the third dose of vaccination, the patient experienced "pain and dot above the injection site that eventually widened and spread". It was reported that the patient's injection site reaction was presently two inches in diameter and had a concave look (or divet) whereby the muscle seemed to have deteriorated. In follow-up, it was reported the 2 inch by 2 inch area was concave where the muscle seemed to have deteriorated. The patient reported adverse events on 11-NOV-2008. The patient was seeing an orthopedist. A lab work of CPK was performed (result unknown). At the time of the report, on 12-NOV-2008, the outcome of the patient was unknown. Additional information is not expected.

Other Meds: Yasmin

Lab Data: Unknown

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336658-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	06-Aug-2008	Unknown		15-Dec-2008	14-Jan-2009	NJ	WAES0811USA02193	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site atrophy

Symptom Text: Information has been received from a physician's office manager concerning a 24 year old female, caucacic patient who on 06-Aug-2008 was vaccinated with second dose of GARDASIL single dose vial intramuscularly injection, left deltoid. Concomitant therapy included MSD, KLONOPIN and TOPICORT. In Oct-2008 when the patient was accompanying her sibling to an office visit she reported that she experienced a small nickel-sized divet left upper extremity after she received her second dose of GARDASIL on 06-Aug-2008. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Klonopin, Topicort, Singular

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336659-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Aug-2008	Unknown		15-Dec-2008	14-Jan-2009	MD	WAES0811USA02188	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acne, Menstruation irregular, Musculoskeletal discomfort, Musculoskeletal stiffness, Myalgia, Pharyngitis, Vaccination complication

Symptom Text: Information has been received from a 17 year old female who on 18-JUN-2008 was vaccinated "in her buttocks" with a first dose of GARDASIL. In "June 2008", the patient experienced muscle pain and muscle tenderness. On 18-AUG-2008 was vaccinated in her arm with a second dose of GARDASIL. She stated the symptoms never resolved and have become worse since receiving her second dose. At the time of reporting the patient's muscle pain and tenderness persisted. The patient sought medical attention of the physician. Additional information has been requested. 2/4/09 Received PCP medical records of 8/12-11/12/2008. FINAL DX: none provided Records reveal patient in good health 8/12. RTC 11/12 w/pain right gluteal since received HPV #1 in 6/08 at GYN office. Referred to GYN & neuro if sys persist. Also had pharyngitis 11/12. 2/17/09 Received GYN vaccine records & medical records of 6/18-2/3/09. FINAL DX: none provided Records reveal patient experienced irregular periods, acne otherwise in good health for vaccinations. 6/18 vax given right gluteal. 11/6/08 note states had problems w/muscle in buttock since vax. Had stiffness & discomfort in back & hip. Referred to PCP. RTC 2/3 for HPV #3 w/o complaints at that time.

Other Meds: Unknown

Lab Data: None

History: Unknown PMH: irregular periods, contraception. Family hx: cardiovascular dx. HPV#3 given RA on 2/3/09 lot #0650X

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336660-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Oct-2008	Unknown		15-Dec-2008	14-Jan-2009	TX	WAES0811USA02182	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Nausea, Pyrexia

Symptom Text: Information has been received from a physician concerning an 18 year old female who on 28-OCT-2008 was vaccinated intramuscularly with a first dose of GARDASIL (lot number and injection site not reported). Subsequently the patient experienced fever, chills and nausea. On 03-NOV-2008, the patient's mother called the physician's office to report the symptoms. Subsequently, the patient fully recovered from the events without requiring treatment. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336661-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	30-Oct-2008	Unknown		15-Dec-2008	14-Jan-2009	--	WAES0811USA02180	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cardiovascular disorder

Symptom Text: Information has been received from a nurse, concerning her niece who approximately on 30-OCT-2008 ("two weeks ago") was vaccinated a dose of GARDASIL (lot number, route and injection site not reported). The patient believes that she is having cardiovascular problems since she was given GARDASIL. It was unknown if she sought any medical attention. At the time of report, the patient's symptom persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336662-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Aug-2008	27-Aug-2008	0	15-Dec-2008	14-Jan-2009	AL	WAES0811USA02158	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Asthenia, Disorientation, Dizziness, Hypoaesthesia, Loss of consciousness

Symptom Text: Initial and follow-up information has been received from a medical assistant concerning a 14-year-old female patient with type 2 diabetes, anxiety disorder, Disturbance of skin sensation, insomnia hyperlipidemia and no drug allergies, who on 27-Aug-2008 was vaccinated IM with the first dose of 0.5ml GARDASIL (lot number and injection site not reported). Concomitant therapy included PROZAC, CLARATIN, Mirtazapine, Famotidine (reported as "Samotidine" , manufacturer unknown) and gabapentin for type 2 diabetes, anxiety disorder, disturbance of skin sensation, insomnia, and hyperlipidemia. On 27-Aug-2008 after receiving GARDASIL, the patient experienced numbness all over and passed out; she also experienced immediate dizziness, weakness, and disorientation. Since 28-Aug-2008, the patient has experienced daily episodes of temporary numbness of both feet which lasted an unspecified length of time. The episodes have increased to 2-3 times per day and the numbness, during each episode, now extends from the feet to the mid-chest. The patient was referred for neurologic and orthopedic consultation, providers unspecified and 'all testing was normal" The medical assistant also stated that the patient "has missed a lot of school recently because of the symptoms". In October 2008 the patient did receive the second dose of GARDASIL. At the time of reporting, the patient has not recovered. Additional information has been requested.

Other Meds: Famotidine, PROZAC, Gabapentin,CLARATIN,Metformin,Mirtazapine

Lab Data: Diagnostic laboratory all testing was normal

History: Type 2 diabetes mellitus, anxiety disorder, disturbance of skin sensation, insomnia, hyperlipidemia

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336663-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	LA	WAES0811USA02148	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Syncope

Symptom Text: Information has been received from a nurse practitioner and a registered nurse concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL. Shortly after receiving the vaccine the patient experienced syncope and went to the emergency room because she had fallen and hit her head. The patient "did improve". Additional information has been requested. This is one several reports from the same source

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 336676-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	04-Nov-2008	04-Nov-2008	0	15-Dec-2008	14-Jan-2009	--	WAES0811USA02124	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a physician concerning a 27 year old female who on 04-NOV-2008 was vaccinated with the first and only dose of GARDASIL 0.5ml/once IM. One week after the vaccination, the patient developed rash from head to toe. The patient was given ATARAX and BENADRYL for the treatment. The patient's rash from head to toe was not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336677-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-Oct-2008	28-Oct-2008	0	15-Dec-2008	14-Jan-2009	CA	WAES0811USA01921	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN	MEDIMMUNE VACCINES, INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1487U		Unknown	Unknown	
	UNK	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness, Oxygen supplementation, Suture insertion, Syncope, Tooth injury

Symptom Text: Information has been received from a physician and office manager concerning a 13 year old female who was vaccinated with GARDISAL (lot#659657/14870) (date, dose not reported). Concomitant therapy included flu vaccine and "PID" The patient experienced fainting twice after receiving an injection with GARDASIL and required oxygen after the second time. The patient passed out and fell off the table onto her two teeth; on 28-Oct-2008 the patient was taken to a Medical Center. The patient was not admitted but received sutures for her mouth. The patient needed dental work as follow-up and planned to see a dentist. The office manager was unsure of the patient's current status. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336678-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Nov-2008	12-Nov-2008	0	15-Dec-2008	14-Jan-2009	CA	WAES0811USA01860	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	2	Right arm	Intramuscular	
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	89981		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Syncope

Symptom Text: Information has been received from a physician concerning a 17 year old female patient with penicillin allergy and without illness at time of vaccination, who on 12-NOV-2008 at 11:30 was vaccinated with the third dose of 0.5ml GARDASIL (lot # 661766/0652X) IM in the right arm and concomitantly at the same time with FLUVIRIN (lot # 89981) IM in the right arm. On 12-NOV-2008 at 11:55, the patient experienced syncope. The patient was sitting in exam room after injection for 15 minutes, with no problems, after getting up and walked in the hallway, she fell to the ground. Right after hitting the ground she opened her eyes. On the same date, the patient recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: 336679-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	10-Nov-2008	10-Nov-2008	0	15-Dec-2008	14-Jan-2009	--	WAES0811USA01854	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning his 12 year old daughter who on the morning of 10-Nov-2008 was vaccinated with GARDASIL , IM. Subsequently the patient got light headed and "woozy" after getting the vaccine. It was noted that the patient didn't have breakfast that morning. The patient was given some juice and recovered a while later. The patient sought medical attention through the reporting physician. No laboratory diagnostic studies were performed. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336680-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	MA	WAES0811USA01736	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Swelling face, Swollen tongue

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the second dose of GARDASIL. On an unspecified date, eight hours after the administration of the second dose of GARDASIL, the patient's face and tongue got swollen. The physician reported that her entire face was swollen the following day. The patient took BENADRYL and went to bed. She recovered with therapy. The physician noted that the patient was around dogs and had her hair dyed on the same day as the administration. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336681-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	11-Nov-2008	Unknown		15-Dec-2008	14-Jan-2009	NC	WAES0811USA01682	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia

Symptom Text: Information has been received from an emergency room physician concerning a female patient who on an unknown date was vaccinated with GARDASIL. The emergency room physician stated that she received a call from the patient's primary physician who stated that the patient will be sent to the ER because she experienced weakness symptoms. At the time of reporting the patient had not recovered. The patient sought medical attention, contacted the physician. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336682-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	07-Nov-2008	07-Nov-2008	0	15-Dec-2008	09-Jan-2009	FL	WAES0811USA01678	09-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fall, Hypotension

Symptom Text: Information has been received from a nurse concerning a female patient, with no pertinent medical history and no drug allergies/drug reactions, who on 07-NOV-2008 was vaccinated with GARDASIL (Lot # 661764/0650X). Concomitant therapy included Hepatitis A vaccine (inactivated) (manufacturer unknown) and Hepatitis B vaccine (recombinant) (manufacturer unknown). The nurse reported that the patient felt dizzy and fell 10 minutes after receiving GADASIL vaccine. It was noted that her blood pressure was low. There were no laboratory diagnostics studies performed. It was reported that she felt normal 20 to 30 minutes after the fall. The patient was recovered on 07-NOV-2008. The patient was seen by the nurse. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336683-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	06-Nov-2008	06-Nov-2008	0	15-Dec-2008	09-Jan-2009	AL	WAES0811USA01667	09-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	UNK	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral

Symptom Text: Information has been received from a physician concerning a 19 year old female who on 06-NOV-2008 or 07-NOV-2008 was vaccinated with the first dose of GARDASIL. The physician reported that the patient received another vaccine on the same date on the other arm, but the name and manufacturer of that vaccine was unspecified. After receiving the vaccination, the patient's arm was swollen about 6 inches and was very red. The physician reported that the patient has recovered and would not be receiving any more dose of GARDASIL. The patient sought medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336684-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Dec-2008	09-Jan-2009	AL	WAES0811USA01665	09-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with her first dose of GARDASIL (Lot # not reported). After she received the first vaccine her arm was tingling and she had a pins and needles feeling in the arm. The patient sought unspecified medical attention. Subsequently, the patient recovered and she received the second dose of GARDASIL on 10-NOV-2008. At the time of the report, on 11-NOV-2008, the office was unaware if this experience happened again. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 336685-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	20-Oct-2008	20-Oct-2008	0	15-Dec-2008	14-Jan-2009	GA	WAES0811USA01655	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	2	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Autoimmune disorder, Brachial plexopathy, Immediate post-injection reaction, Injected limb mobility decreased, Muscular weakness, Musculoskeletal pain, Myalgia, Pain, Pain in extremity, Tenderness, Tendonitis

Symptom Text: Information has been received from an office manager concerning a 24 year old female with no medical history who in April 2008, was vaccinated IM with a dose of GARDASIL and on 20-OCT-2008 was vaccinated IM with the third dose of GARDASIL (lot # 661530/0575X) in her left arm. There was no concomitant medication. On approximately 20-OCT-2008, the patient experienced myalgia and pain from the injection site all the way down to her arm. The patient said the third dose was given a little bit "higher" in her arm compared to the first and second dose. The patient had no symptoms with the first and second dose. The patient was an athlete and could not raise her arm laterally and could not dress herself. The physician prescribed an anti-inflammatory and an arm sling for one week but the patient had no improvement. The patient said the first week after the third dose her pain was sharp but the second week the pain was a constant ache. The patient saw a neurologist (unspecified name) on 11-NOV-2008 and she thought that the patient had an autoimmune reaction to GARDASIL. The patient was prescribed a steroid (unspecified), LORTAB and physical therapy. At the time of this report, the patient was not recovered. Follow-up information received from the healthcare worker concerning the path forward included an ultrasound of the patient's shoulder. If the patient's ultrasound was clear, the physician would recommend physical therapy. As of the day of this report, the neurologist's report has not been received by the physician's office. Additional information has been requested. 1/23/09 Reviewed GYN & Neuro medical records. Neuro eval 11/11/2008: FINAL DX: left brachial plexopathy. Records reveal patient experienced LUE pain, tenderness & weakness, left hand weakness, inability to raise left arm since vaccination. Had immediate intense pain which worsened & was from under left clavicle to left shoulder. Tx w/steroids, pain med & PT. Referred for EMG/NCS. GYN records: Reveal patient in good health on day of

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336686-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	24-Oct-2008	24-Oct-2008	0	15-Dec-2008	14-Jan-2009	--	WAES0811USA01651	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site pain

Symptom Text: Initial and follow-up information has been received from a nurse practitioner concerning a 23 year old female who on 24-Oct-2008 was vaccinated IM with the first 0.5ml dose of GARDASIL (lot#661764/0650X) in the left deltoid muscle. On 24-Oct-2008 the patient experienced immediate pain at the injection site of the left deltoid muscle after administration of the first dose of GARDASIL. It was noted that the patient initially experienced the pain on the same day that she received the vaccination. The pain "subsided" without treatment in 2 days. The pain at the injection site "returned" on 10-Nov-2008 and was "now" accompanied by firmness" in the area. At the time of this report, the patient's pain and "firmness" at the injection site persisted. The nurse practitioner added that the patient called the practice for medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **336687-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		15-Dec-2008	09-Jan-2009	FL	WAES0811USA01634	09-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Emotional disorder

Symptom Text: Information has been received from a physician concerning a 14 year old female patient who on unspecified date was vaccinated with the first dose of GARDASIL in her pediatrician's office. Concomitant therapy included YAZ. After vaccination, the patient experienced "a feeling of anxiety and being emotional". As of 11-NOV-2008, the patient had not recovered. Additional information has been requested.

Other Meds: YAZ

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336688-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	07-Nov-2008	08-Nov-2008	1	15-Dec-2008	14-Jan-2009	OH	WAES0811USA01628	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea, Nausea, Vomiting

Symptom Text: Information has been received from a health care worker concerning a 20 year old female patient with no pertinent medical history and no drug reactions or allergies reported, who on 02-SEP-2008 was vaccinated with the first dose of GARDASIL (lot # 661044/0548X). It was reported that on 07-NOV-2008 the patient received her second dose of GARDASIL (lot # 660557/0072X) 0.5 ml intramuscularly, and on the next day, 07-NOV-2008, she experienced nausea, vomiting and diarrhea. There were no concomitant medications. The patient sought medical attention at a doctor's office and no lab diagnostic studies were performed. At the time of the report the patient was recovering. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **336689-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	--	WAES0811USA01610	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass

Symptom Text: Information has been received from a female consumer, who was also the patient, who on an unspecified date was vaccinated with a dose of GARDASIL. The patient reported that a huge bump appeared on the injection site after she received the dose. The outcome was unknown. The patient did not seek medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336690-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Dec-2008	14-Jan-2009	--	WAES0811USA01449	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Information has been received from a registered nurse concerning a patient who was vaccinated with GARDASIL. The patient shortly thereafter came down with genital warts. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336691-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	04-Sep-2008	04-Sep-2008	0	15-Dec-2008	14-Jan-2009	NJ	WAES0811USA01403	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Malaise, Vision blurred

Symptom Text: Information has been received from a licensed practical nurse (LPN) concerning a 25 year old female patient who on 04-Sep-2008 was vaccinated with the first dose of GARDASIL in her left deltoid (lot# 659184/0843X). Concomitant therapy included oral hormonal contraceptives (unspecified). Illness at time of vaccination included dizzy lightheaded and blurred vision. On 04-Sep-2008 the patient did not feel well 20 minutes after getting GARDASIL. On 06-Nov-2008 the patient was vaccinated with the second dose of GARDASIL in her left deltoid (lot#661764/0650X). The patient was observed for 20 minutes and had no reaction. Two hours later the patient reported that she experienced the same symptoms as before. The patient recovered from the adverse events. The patient did not seek medical attention. Additional information is not expected.

Other Meds: Hormonal Contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness: Dizziness, Vision Blurred

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336692-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	30-Sep-2007	02-Oct-2007	2	15-Dec-2008	14-Jan-2009	--	WAES0811USA01392	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Arthralgia, Headache, Hypoaesthesia, Menstrual disorder, Myalgia, Paraesthesia, Rash

Symptom Text: Information has been received from a consumer concerning her 13 year old daughter with no previous medical history and no known drug allergies / reactions reported, who near the end of September 2007, was vaccinated with the first dose of GARDASIL (lot number not provided 0.5ml . On 02-Nov-2007, the patient was vaccinated with the second dose of GARDASIL 0.5ml and on 01-Apr-2008 with the third dose of GARDASIL (lot number not provided) 0.5 ml. There was no concomitant medication. Two days after receiving her first dose of GARDASIL , on approximately 02-Oct-2007, the patient got her first menstrual period. After getting the second dose of GARDASIL, on approximately 02-Oct-2007, the the patient got her first menstrual period. After getting the second dose of GARDASIL , on approximately 02-Nov-2008, the patient experienced a headache and stomach issues. Also she experienced a rash on the back of her neck, numbness and tingling in her hands. since the third dose GARDASIL , she experienced joint and muscle pain that had yet to go away, Since she was vaccinated with the first dose of GARDASIL, she not had another menstrual period since until recently. The patient stated that some of her symptoms felt like she was "going through menopause". A blood work was performed (results not provided). The patient sought unspecified medical attention. As of 10-Nov-2008, the patient was not recovered. No further information is available.

Other Meds: None

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **336693-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	PA	WAES0811USA01383	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactic reaction, Rash, Urticaria

Symptom Text: Information has been received from a physician concerning an 11 year old female patient who on an unknown date was vaccinated with the first dose of GARDASIL. Subsequently, the patient experienced an anaphylactic reaction after receiving GARDASIL. The patient recovered from the reaction, but she had recurrent rash and hives. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 336695-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	22-Jul-2008	22-Jul-2008	0	07-Jan-2009	08-Jan-2009	FR	WAES0812USA04632	08-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	UNK	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1114U		Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arachnoid cyst, Burning sensation, Paraesthesia, Paraesthesia mucosal, Paraesthesia oral, Sensation of heaviness

Symptom Text: Information has been received from a gynaecologist concerning a 22 year old female with not reported medical history, who on 22-JUL-20087 was vaccinated with the first dose of GARDASIL (lot # 1114U; batch NH10940) SC into the right upper arm. Therapy also included doxycycline for an unspecified indication, starting on 29-JUL-2008 for 10 days. On 13-AUG-2008, the patient experienced paraesthesia of the lips, the tip of tongue and the buccal mucous membrane. Since 14-AUG-2008 she also developed paraesthesia and feeling of heaviness of the left upper and lower arm. The patient was hospitalized from 15-AUG-2008 to 16-AUG-2008. Neurological examination was normal except for the paresthesia in left upper and lower arm and feeling of heaviness of the left arm. CSF showed normal results for cells and protein. Results of oligoclonal bands were not available at the time of reporting. Cranial magnetic resonance imaging (MRI) showed two small lesions at the anterior and posterior horn. At time of reporting, the patient had not recovered. No final diagnosis was established. Follow-up information was received which reported that final diagnosis was suspicious of CIS (clinically isolated syndrome). The patient has a history of riding accident in February 2008 with compression of the cervical spine and several falls. Concomitant to the sensation of heaviness of the left upper arm and forearm, the patient developed "like an inner burning" of the arm. Physical neurological findings VEP, SEP and ECG on 15-AUG-2008 showed normal results. Laboratory findings (see lab section) were normal except for oligoclonal IgG in CSF with one band. Cranial MRI showed two demyelinating foci in the left hemisphere. Suspicion of disseminated encephalomyelitis could not be ruled out, but no active signs were detected ("old lesions"). As an incidental finding an arachnoidal cyst was detected. The hospital physicians pointed out that as differential diagnosis a reaction after GARDASIL vaccination could not completely be rule out. It was discussed that

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 15Aug08, Two small lesions at the anterior and posterior horn; visual evoked potential, 15Aug08, normal; electrocardiogram, 15Aug08, normal; somatosensory evoked potential, 15Aug08, normal; magnetic resonance ima

History: Riding accident

Prex Illness: Cervical cord compression; Fall

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336705-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-Jan-2009	07-Jan-2009	0	07-Jan-2009	13-Feb-2009	PA		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	UNKNOWN MANUFACTURER	NULL		Left arm	Unknown	
	HEPA	UNKNOWN MANUFACTURER	NULL		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pallor, Tinnitus

Symptom Text: Dizziness, nauseous, ringing in the ears, paleness for about 10 minutes after the vaccine.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336707-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	19-Aug-2008	19-Aug-2008	0	07-Jan-2009	13-Feb-2009	NY		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity, Tenderness

Symptom Text: Patient presented to Immunization clinic on 01/06/09 for the second dose of HPV vaccine, having received the first dose on 08/19/08. During screening, patient stated that she has experienced pain in the upper 3/4 of the upper left arm since the 08/19/08 immunization. She reports that the affected area has been tender to firm touch since then, and that it is painful if she lies on it. She has full use of the arm, with normal strength and ROM. She reports that she experienced no unusual redness, swelling, or excessive pain immediately after the 08/19/08 vaccination. Her account of SX is confirmed by her mother.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 336714-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Nov-2008	02-Jan-2009	48	07-Jan-2009	13-Feb-2009	GA		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Muscle spasms, Pain, Vaginal discharge

Symptom Text: Patient had Gardasil shot and then Depo-Provera about 1 week later. 2 months later, this past Friday she passed a mass of tissue vaginally that was approximately 5" X 2" and was in pain similar to labor. This child is not sexually active, has experience severe cramping. Concerned may have caused permanent damage to her uterus. Ultrasound today, gyn in the next few.

Other Meds:

Lab Data:

History: none

Prex Illness: None

Prex Vax Illns:

Vaers Id: **336726-1** **Related reports:** 336726-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	22-Dec-2008	31-Dec-2008	9	07-Jan-2009	13-Feb-2009	--		01-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Axillary pain, Back pain, Blood urine present, Burning sensation, Chest pain, Erythema, Myalgia, Neck pain, Oral pain, Oropharyngeal pain, Pain, Pain in extremity, Pain in jaw, Photophobia, Pruritus, Pyrexia, Rash pruritic, Swelling, Urticaria, Viral infection, Vision blurred, Visual impairment

Symptom Text: My daughter received her second injection of GARDASIL on December 22, 2008. On December 31, 2008 she had a sudden and severe hives reaction- inner thighs of both legs and feet, blood red, swelled, very painful and itchy. We went to the emergency room where she was treated unsuccessfully with BENADRYL and then was given steroids, which after 12 hours reduced the horrific hives. Then on Friday, January 2, 2009 she started to complain about severe pain in her armpits. By Sunday night the pain spread up her chest, neck, jaw and lips. We have an appointment at our Dr. this afternoon, but felt that since there was NO other reason - sickness, strange meal, etc. I should report this event immediately.4/14/09-records received-presented to ED 12/30/08- C/O rash on legs began morning of visit to ED. Pruritic. Has had similar rash in past. DX: urticaria. Subsequently developed aches in neck and axillae, legs. Assessment: viral syndrome. 1/12/09 C/O body aches and generalized weakness and low back pain and buring of hands. Now severe headache with photophobia and neck stiffness, slight nausea. 4/28/09-office visit 15/09-C/O musculoskeletal symptoms and rash. Previously seen in ED for allergice reaction. Now have aches in neck, axillae, legs. Impression: Viral syndrome. 1/7/09 continues to C/O leg pain and hand and arm pain. Impression: Myalgia. 1/12/09-second opinion for C/O jaw pain, muscle pain and headache. Light sensitive. Spots in eyes. Impression: Parent child concerns. 1/13/09-seen in ED for worst headache of her life. Parent refuses LP. Impression: headache. headache maybe migranoid with photophobia. Myalgia. 1/19/09-C/O blood in urine, fever and sore throat. 3 week history of evolving UTI and strep throat per parent.

Other Meds:

Lab Data: 4/14/09-records received-CT scan brain normal. 4/28/09-records received- Rapid strep negative. Assessment: Acute pharyngitis. WBC 13.0, Antinuclear antibodies direct 95, adenovirus negative. CT head normal.

History: 4/14/09-records received- Allergies:amoxicillin. Obstructive sleep apnea. Tonsillectomy adenoidectomy.

Prex Illness:

Prex Vax Illns:

Vaers Id: **336726-2** **Related reports:** 336726-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	22-Dec-2008	31-Dec-2008	9	16-Jan-2009	20-Jan-2009	CA	WAES0901USA00846	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Kawasakis disease, Pain, Urticaria

Symptom Text: Information has been received from a physician concerning a 9 year old female patient who on 22-DEC-2008 was vaccinated with the second dose of GARDASIL. On 31-DEC-2008 the patient experienced red hives on inner thigh and feet. On 02-JAN-2009 the patient also experienced severe pain in her armpits that moved to the neck and jaw. Pain intensified in her neck, jaw and lips and moved to the back. The physician mentioned that the symptoms resembled Kawasaki disease on a lower scale. At the time of this report, the adverse events persisted. The patient sought unspecified medical attention. Upon internal review, Kawasaki disease was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336730-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	19-Jun-2008	Unknown		07-Jan-2009	13-Feb-2009	MI		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Patient received first dose of GARDASIL and may have been pregnant 7/31/08-LMP-5/15/08 received GARDASIL 16-1608

Other Meds:

Lab Data: + USN ON 7-31-08 with 10W4d on 8-11-08-patient had increased risk downs/on ULTRACET, patient chose termination of pregnancy.

History: AMOXICILLIN

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336731-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Dec-2008	23-Dec-2008	0	07-Jan-2009	13-Feb-2009	VT		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	
	HEPA	UNKNOWN MANUFACTURER	NULL	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope within minutes of administration of vaccines.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **336732-1** **Related reports:** 336732-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Dec-2008	22-Dec-2008	0	07-Jan-2009	03-Feb-2009	IL		10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Left arm	Intramuscular	HPV4

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Tremor

Symptom Text: GARDASIL administered 12/22/08, within hours patient noticed "tremors" (looks like she is having chills). Family and friends noticed episodes too. Episodes are less frequent but still occurring. 1/12/09 Receied PCP medical records of 10/16/08-1/6/2009. FINAL DX: tremors Records reveal patient experienced intermittent bilateral tremors of arms, hands & fingers since 12/22 w/decreasing intensity & duration. No tx rendered & patient was to RTC if worsened.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **336732-2** **Related reports:** 336732-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Dec-2008	23-Dec-2008	1	18-Feb-2009	05-Mar-2009	IL	WAES0901USA00373	27-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Physical examination normal, Tremor

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female patient with no pertinent medical history and no known drug allergies who on 16-OCT-2008 was vaccinated with the first 0.5 ml IM dose of GARDASIL (lot # 661530/0575X). On 22-DEC-2008 the patient was vaccinated with the second 0.5 ml IM dose of GARDASIL (lot # 661764/0650X). There was no concomitant medication. On 23-DEC-2008 ("within a day after administration of her second dose") the patient developed tremors which resemble a shudder from chills. No lab diagnostics studies were performed. On 06-JAN-2009 the patient was examined in the office and she was still experiencing tremors, although less frequent, at least once a day. At the time of reporting, the patient was recovering. Additional information has been requested. 3/4/09 MR received from PCP. Received HPV #2 on 12/22/09. Later that day pt noticed tremors of arms, hands, fingers and knees. Seen by PCP on 1/6/09 for persistant tremors, decreasing somewhat in frequency and intensity. No change in awareness, no associated sensory phenomenon, no post-ictal state. PE WNL. No tx at this time. Will watch.

Other Meds: None

Lab Data: None

History: None. PMH: none

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336734-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	09-Sep-2008	13-Sep-2008	4	15-Dec-2008	14-Jan-2009	VA	WAES0811USA01377	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea

Symptom Text: Information has received from a physician concerning a 15 year old female patient with no known allergies, who on 09-SEP-2008 was vaccinated with the third dose of GARDASIL. Concomitant therapy included ADDERALL. On 13-SEP-2008, the patient experienced shortness of breath. The patient experienced a second period of shortness of breath three weeks later (approximately on 04-OCT-2008). On an unknown date, the patient recovered from shortness of breath. The patient sought medical attention in an office visit. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336735-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	29-Nov-2007	29-Nov-2007	0	15-Dec-2008	14-Jan-2009	VA	WAES0811USA01376	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Urticaria

Symptom Text: Information has been received from a licensed practical nurse concerning a 19 year old female patient with no known pertinent medical history, and no known drug allergies reaction, who on 30-AUG-2007 on an unrelated office visit, was vaccinated with the first dose of GARDASIL. On 29-NOV-2007, the patient was vaccinated with the second dose of GARDASIL (lot No 659055/1522U), 0.5 ml, intramuscularly. The licensed practical nurse reported that patient did not experienced an adverse reaction after her first GARDASIL. On 29-NOV-2007, after the patient received her second dose of GARDASIL, she experienced redness and swelling at the injection site, as well as hives, after she received her second dose of GARDASIL. The licensed practical nurse reported that the patient had elected not to receive her third GARDASIL. On an unknown date the patient recovered without requiring medical treatment. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336736-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	10-May-2008		15-Dec-2008	14-Jan-2009	MD	WAES0811USA01331	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a physician concerning a 14 year old female who on unknown dates was vaccinated with a first, second and third dose of GARDASIL, 0.5 mL. 6 months ago, on approximately 10-MAY-2008, patient experienced stop menstruating between her first through third dose for GARDASIL vaccine (lot # was not provided). At the time of reporting the outcome of the event was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Hematology

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336737-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	27-Oct-2008	27-Oct-2008	0	15-Dec-2008	14-Jan-2009	--	WAES0811USA01328	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a female patient, with no pertinent medical history and no drug allergies/drug rections, who on 26-AUG-2008 was vaccinated with a first 0.5mL dose of GARDASIL vaccine. There was no concomitant medication. The patient reported that on 27-OCT-2008 she experienced injection site pain after getting her second dose of GARDASIL vaccine. No laboratory diagnostics studies were performed. It was noted that she did not have any events after first dose. The patient was not recovered. The patient unspecified sought medical attention. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **336738-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	22-Oct-2008	26-Oct-2008	4	15-Dec-2008	14-Jan-2009	--	WAES0811USA01307	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from a 23 year old female with no drug reaction/allergies, who on 22-OCT-2008 was vaccinated with the first dose of GARDASIL vaccine. There was no concomitant medication. Patient mentioned that she was supposed to have her period on 26-OCT-2008, but until now she had not had her menstrual period yet. Patient noted that she had not done any pregnancy testing. The patient sought medical attention. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **336739-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	--	WAES0811USA01256	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a consumer concerning a her daughter who on unspecified dates was vaccinated wit ha full set of GARDASIL vaccine (reported as HPB). The consumer reported the patient is now positive for HPV and "her family is devastated". The outcome of the patient was not reported.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336740-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-Nov-2008	06-Nov-2008	0	15-Dec-2008	14-Jan-2009	PA	WAES0811USA01143	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness, Nausea, Syncope vasovagal

Symptom Text: Information has been received from a health professional concerning a 20 year old female patient who on 06-NOV-2008 was vaccinated with the first dose of GARDASIL vaccine (lot # 661044/0548X), intramuscularly in her right deltoid at 13:10. The health professional reported that after the vaccine was given, at 13:13, the patient became dizzy, nauseous and her blood pressure decreased to 76/40. At 13:15, the patient was given cold compress. Upon discharge, the patient's blood pressure raised to 92/58. The health professional reported that the patient experienced a vasovagal reaction. On 06-NOV-2008, the patient recovered. The patient sought medical attention. No further information is available.

Other Meds: Unknown

Lab Data: blood pressure 11/06/08 - 76/40 blood pressure 11/06/08 - 92/58 at discharge

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336741-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Nov-2008	03-Nov-2008	0	15-Dec-2008	14-Jan-2009	NJ	WAES0811USA01127	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a physician concerning a 13 year old female who on 03-NOV-2008 was vaccination with a first dose of GARDASIL vaccine (lot # 659180/1758U) intramuscularly in her left arm. The patient had irregular periods after her first dose. The patient had regular periods for almost 1 year. After the first dose of GARDASIL vaccine, the patient had more frequent menstruation and bleed more. The outcome was not reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336742-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Jul-2008	12-Aug-2008	25	15-Dec-2008	14-Jan-2009	--	WAES0811USA01123	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: The information has been received from a mother concerning her 15 year old daughter, with no pertinent medical history, or known drug allergies/drug reactions who on 18-JUL-2008 was vaccinated with her "first dose" of GARDASIL vaccine. There was no concomitant medications. The mother reported that approximately "3 - 4 weeks after vaccination" her daughter experienced alopecia. It was reported that her hair was starting to slowly grow back. "Unspecified tests" were performed (results not provided). The patient did not plan on receiving her second or third dose. At the time of this report, the patient was recovering. The patient sought medical attention. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336743-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Dec-2008	14-Jan-2009	--	WAES0811USA01122	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Migraine

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with a dose of GARDASIL vaccine. The patient experienced migraines after vaccination. Patient went to emergency room but it was not known if the patient was admitted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336744-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	07-Jul-2008	18-Oct-2008	103	15-Dec-2008	14-Jan-2009	KY	WAES0811USA01109	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Skin exfoliation

Symptom Text: Information has been received from a physician concerning a 11 year old female with environmental allergies who on 06-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine (lot # 658282/0929U). The physician reported than on 07-JUL-2008 the patient received her second dose of GARDASIL vaccine (lot # 659441/1446U) and on 18-OCT-2008 the patient experienced peeling on the palms of her hands and between her fingers and the soles of her feet. The patient was seen at an office visit. At the time of the report the patient's peeling on the palms of her hands and between her fingers and the soles of her feet persisted. No lab diagnostic studies were performed. Additional information has been requested.

Other Meds: (therapy unspecified)

Lab Data: None

History:

Prex Illness: Environmental allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336745-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	07-Nov-2008	07-Nov-2008	0	15-Dec-2008	14-Jan-2009	MD	WAES0811USA01106	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, Syncope, Vomiting

Symptom Text: Information has been received from a nurse concerning a 14 year old female patient with a medical history of fainting and no known drug reaction/allergies, who on 18-AUG-2008, was vaccinated with the first dose GARDASIL, 0.5ml, intramuscularly, and on 07-NOV-2008 was vaccinated with the second dose of GARDASIL vaccine (Lot # 660557/0072X), 0.5ml, intramuscularly. Concomitant therapy included ORTHO TRI-CYCLEN. The nurse reported that on 07-NOV-2008, the patient received the second of GARDASIL, and fainted twice while laying in the supine position. Additionally, the patient became nauseous and vomited once. The nurse reported that the patient was observed in the office and then discharged home. The patient recovered from the symptoms on the same day of the vaccination. The nurse reported that the patient did not experience any difficulties with the first dose of the GARDASIL. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN

Lab Data: None

History: Syncope

Prex Illness:

Prex Vax Illns:

Vaers Id: **336746-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Oct-2008	01-Oct-2008	0	15-Dec-2008	14-Jan-2009	--	WAES0811USA01098	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a medical assistant concerning a female patient who in approximately October 2008, was vaccinated with GARDASIL vaccine. The patient experienced rash from waist up after receiving GARDASIL vaccine. On an unknown date in 2008, the patient recovered from the rash. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336747-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	--	WAES0811USA00993	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a 21 year old female who in approximately November 2007, was vaccinated with the first dose of GARDASIL (route and site not reported). Subsequently on an unknown date, the patient was diagnosed with human papilloma virus (HPV). The patient stated she had been unable to get second and third dose of GARDASIL. At the time of report, the patient's outcome was unknown. No further information available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336748-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	CA	WAES0811USA00930	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site erythema, Injection site pain

Symptom Text: Information has been received from a physician concerning a female who "2 months ago" in September 2008 was vaccinated with her first dose of GARDASIL. The physician reported that the patient called the clinic to inform that she developed redness and pigmentation on the injection site after receiving the vaccine. Follow up information from the physician also indicated that the patient had pain at the injection site, and "crescent shaped hypo-pigmented area" at the injection site. The patient sought medical attention from the physician. At the time reporting, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336749-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	WA	WAES0811USA00922	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Feeling hot, Lymph node pain, Lymphadenopathy

Symptom Text: Information has been received from a physician concerning a female patient with no known drug reactions/allergies and medical history, who was vaccinated with the first dose of GARDASIL by an unspecified route in the deltoid area. There was no concomitant medication. The physician reported that the patient developed a swollen lymph node one week after vaccination. The swollen lymph node was warm and tender and about 4 inches from the injections site. The lymph node is still swollen but much less. The patient sought medical attention. At the time of the report it was reported that the patient was not recovered. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336750-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	05-Nov-2008	23-Oct-2008	-13	15-Dec-2008	14-Jan-2009	--	WAES0811USA00917	03-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	HEP HEPA

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Drug exposure during pregnancy, Dyspnoea, Pruritus

Symptom Text: Initial information has been received through the pregnancy registry for GARDASIL from a husband concerning his 19 year old wife who on 05-NOV-2008 was vaccinated with the first dose of GARDASIL. On 23-OCT-2008 the patient was vaccinated with hepatitis A (inactive) (manufacturer unknown), hepatitis B vaccine, recomb (manufacturer unknown), MMR II, DTaP (unspecified), poliovirus vaccine and influenza virus vaccine (unspecified). The husband called to report that his wife, the patient, was already learned that she was pregnant two to three weeks ago through a home urine pregnancy test. On 04-NOV-2008, "since two days ago" the patient experienced stomach ache, itching and difficulty breathing. It was reported that no laboratory diagnostic studies were performed. The patient's stomach ache and itching and difficulty breathing persisted. The LMP was reported as the end of Sep-2008. The patient sought medical attention through a nurse. Additional information has been requested.

Other Meds:

Lab Data: Beta-human chorionic, 10/15?/08, Home pregnancy test

History:

Prex Illness: Pregnancy NOS (LMP = 9/30/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336751-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	02-Jun-2008	Unknown		15-Dec-2008	14-Jan-2009	TX	WAES0811USA00915	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea

Symptom Text: Information has been received from a nurse practitioner concerning a 21 year old female with allergic reaction to CECLOR who on 26-Mar-2008 was vaccinated with the first dose of GARDASIL (lot#659655/1486U). Concomitant therapy included LOESTRIN. On 02-Jun-2008. the patient was vaccinated with a second dose of GARDASIL(lot#660387/1967U. It was reported that after the patient's second dose (date not provided), the patient developed severe and prolonged diarrhea after each meal, with no abdominal pain. Subsequently, the patient recovered on Sep-2008. It was reported that the event was mentioned at the patient's next office visit. The reporter also indicate that the patient "may have experienced diarrhea after her first dose" of GARDASIL . No laboratory diagnostic studies were preformed. Additional information has been requested.

Other Meds: Loestrin

Lab Data: None

History: Allergic reaction to antibiotics

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336752-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Oct-2008	01-Oct-2008	0	15-Dec-2008	14-Jan-2009	WA	WAES0811USA00912	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with the first dose of GARDASIL (lot number was not provided) within the last week (in October 2008). The patient fainted in the waiting room of the physician's office after receiving her first dose of GARDASIL. She was taken to the emergency room for x-rays of her neck, but results were not provided. It was not known if she was admitted to the hospital. The patient recovered on an unspecified date. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336754-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	23-Oct-2008	23-Oct-2008	0	15-Dec-2008	14-Jan-2009	--	WAES0811USA00904	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Swelling

Symptom Text: Information has been received from a nurse concerning a 13 year old female patient female patient who on approximately 23-Oct-2008 was vaccinated with the first dose of GARDASIL. The nurse reported that on approximately 23-Oct-2008 the patient began swelling up and ended up going to the emergency room. It is unknown whether the patient was admitted to the hospital. Additional information has been requested

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **336755-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	26-Aug-2008	02-Sep-2008	7	15-Dec-2008	14-Jan-2009	GA	WAES0811USA00889	14-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pollakiuria

Symptom Text: Information has been received from a 23 year old female medical assistant with sulfonamide allergy, who on 26-AUG-2008 was vaccinated with the first dose of GARDASIL, HAVRIX, and meningococcal vaccine (unspecified). On 02-SEP-2008 she started to have frequent urination. The medical assistant reported that she did see an urologist who did a "cysto test" in which they stretched her urethra, which relieved some of the pressure, but on 03-NOV-2008 the frequent urination started again. The medical assistant stated that she is not sure is the HPV vaccine has caused this, but she is due to receive the second dose on 11-NOV-2008. At the time of the reporting, the patient had not recovered. Additional information has been requested.

Other Meds:

Lab Data: diagnostic laboratory - cysto test

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336756-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	MI	WAES0811USA00878	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information has been received from a physician concerning a female patient, with no pertinent medical history and no known drug allergies/drug reactions, who was vaccinated with the first dose of GARDASIL intramuscularly. There was no concomitant medication. The physician reported that a couple of weeks after vaccination. The patient developed "a couple of warts" on the extremity. None laboratories diagnostics studies performed. The patient was seen by the physician. The patient's outcome was not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336757-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	29-Oct-2008	29-Oct-2008	0	15-Dec-2008	14-Jan-2009	NM	WAES0811USA00872	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Injection site erythema, Injection site nodule, Injection site swelling, Pain, Rash

Symptom Text: Information has been received from a physician concerning a 21 year old female who on 29-OCT-2008 was vaccinated with the first dose of GARDASIL (lot # 661044/0548X), IM, left deltoid. Concomitant therapy included SEASONALE-BARR. On 29-OCT-2008 within 12 hours post vaccination, the patient experienced swelling and redness at the injection site, a rash that was painful to the touch, the area felt hot and felt like a little ball or nodule at the injection site. At time of the reporting, the patient had not recovered. No medical attention was sought. Additional information has been requested.

Other Meds: SEASONALE

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336758-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	--	WAES0811USA00771	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a female who on an unspecified date was vaccinated with a dose GARDASIL. After receiving GARDASIL, the patient "got a pain" in her arm. The outcome of the patient was not reported. The patient did not seek medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336759-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	--	WAES0811USA00758	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Muscle rigidity, Pallor, Syncope

Symptom Text: Information has been received from a physician. The physician who reported this did not administer the dose of GARDASIL vaccine to this patient and therefore does not know if this was reported already by the physician who did administer it. It was reported that a female patient was very nervous about receiving their second dose of GARDASIL and told the physician several times that she was going to faint. After receiving the vaccine she became very pale, fainted and became very rigid. The physician noted that it was not a seizure. The patient was sent to the emergency room but it is not known if she was admitted to the hospital. Subsequently, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 336760-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Oct-2008	29-Oct-2008	0	15-Dec-2008	14-Jan-2009	NH	WAES0811USA00742	14-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Intramuscular	
MNQ	SANOFI PASTEUR	NULL		Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	0652X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Dyspnoea, Ear pain, Erythema, Fatigue, Injection site reaction, Oral dysaesthesia, Pain, Pyrexia, Urticaria

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female with sulfonamide allergy, Penicillin allergy, and asthma who on 29-Oct-2008 was vaccinated at another office with GARDASIL (661766/0652X) intramuscularly in her left arm. Secondary suspected therapy included MENACTRA in her left arm and an unspecified influenza virus in her right arm. All 3 vaccines were received on the same day. The nurse stated that the patient developed a reaction after receiving the 3 vaccines. On 29-Oct-2008 the patient experienced pain bilaterally in her upper and lower back. The patient said her "mouth felt funny" but had no problem swallowing. The patient had ear pain on her right side and ear turned red. The patient also reported mild aches in thighs and knees and a fever of 101f with generalized body aches and fatigue. The patient was seen in the office of the reporter for these symptoms on 30-Oct-2008 and had a transient "hive like" rash on the underside of her left upper arm. The patient also had mild difficulty breathing (her peak flow rate was usually 500 and it dropped to 350). Subsequently, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Peak expiratory flow 10/30/08 350 usual, body temp 10/29/2008 101 degr - fever,

History: Sulfonamide Allergy, Penicillin Allergy; Asthma

Prex Illness:

Prex Vax Illns:

Vaers Id: 336761-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	NC	WAES0811USA00737	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Raynauds phenomenon

Symptom Text: Information has been received from a physician concerning a 15 year old female with no drug reactions or allergies, who in September 2008 was vaccinated with a first and only dose of GARDASIL. Concomitant therapy included hepatitis A virus vaccine (manufacturer unknown) and influenza virus 3v reassortant vaccine live intranasal (cold adapted Ann Arbor master strain) FLUMIST. Within 2 weeks after the vaccination, the patient developed Raynaud's Phenomenon. The physician saw the patient. "Tests for autoimmune disease" were performed. At the time of reporting, the patient's Raynaud's Phenomenon persisted. Additional information has been requested.

Other Meds: FLUMIST

Lab Data: Diagnostic Laboratory, tests for autoimmune disease

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336762-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	--	WAES0811USA00733	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female who in approximately September 2008, was vaccinated with a second dose GARDASIL. After received the second dose of GARDASIL the patient experienced "bumps" right next to the injection site. The patient sought medical attention and was given Benadryl, and the "bumps" went away. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336763-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	05-May-2008	05-Aug-2008	92	15-Dec-2008	14-Jan-2009	PA	WAES0811USA00732	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Information has been received from a registered nurse concerning her 24 year old daughter with allergies to cephalosporins and no pertinent medical history who approximately 05-MAY-208 was vaccinated IM with the third dose of GARDASIL. There was no concomitant medication. On approximately 05-AUG-2008, "three month ago", the patient experienced joint pain three months after receiving the third dose. At the time of this report, the patient's joint pain persisted. No lab tests were performed. The patient did not seek medical attention. Follow-up call was made and the office confirmed that the patient reported was not the patient with the practice. Additional information has been requested.

Other Meds: None

Lab Data:

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336764-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	04-Nov-2008	05-Nov-2008	1	15-Dec-2008	14-Jan-2009	GA	WAES0811USA00712	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: Information has been received from a physician concerning a 19 year old female with no drug reactions or allergies and a history of attention deficit/hyperactivity disorder (ADHD) who on 04-NOV-2008 was vaccinated with the first 0.5 ml dose of GARDASIL. Concomitant therapy included Concerta and Buspar. On 05-NOV-2008 the patient experienced vomiting. At the time of this report, the patient's vomiting persisted. No lab test were performed. The patient was seen by the physician and sought unspecified medical attention. Additional information has been requested.

Other Meds: Buspar; Concerta

Lab Data: None

History: Attention deficit/hyperactivity disorder

Prex Illness:

Prex Vax Illns:

Vaers Id: **336765-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	TN	WAES0811USA00692	14-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	NULL	0	Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a physician concerning a 12-year-old female patient who on an unknown date was vaccinated with the second dose of GARDASIL (lot number, route and injection site unknown). Concomitant vaccinations included the first dose of MENACTRA and HAVRIX. Subsequently, in October 2008 ("sometime last month"), the patient was experiencing hair loss. She didn't sought any medical attention and her outcome was not reported. Additional information has been requested.

Other Meds:

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336768-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	23-Oct-2008	26-Oct-2008	3	15-Dec-2008	14-Jan-2009	NM	WAES0811USA00690	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Local swelling, Lymphadenopathy

Symptom Text: Initial and follow-up information has been received from a nurse and a physician concerning a 23-year-old female patient. According to the physician, on 23-OCT-2008 the patient was vaccinated IM with a first dose of 0.5 ml GARDASIL (lot # 660618/0572X) in the left deltoid. Concomitant medication included YASMIN. About three days post vaccination, the patient experienced "swelling in the neck-top of the shoulder area". The nurse reported that the patient received a dose of GARDASIL on 15-AUG-2008; also reported that she developed hardening of lymph nodes in her arm 3 days after receiving her second dose of GARDASIL. The patient sought unspecified medical attention and recovered on an unspecified date. Additional information has been requested.

Other Meds: YASMIN

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336770-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	PA	WAES0811USA00577	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Mood altered, Personality change

Symptom Text: Information has been received from a physician concerning a female who "about a year ago" in approximately 2007 was vaccinated with a dose of GARDASIL, lot number was not provided. The physician reported that the patient's mother reported that her daughter experienced severe mood/personality changes "about a week post vaccination" after receiving GARDASIL. At the time of the report, the patient's outcome was unknown. This is one of two patients concerning the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336804-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Oct-2008	22-Oct-2008	0	15-Dec-2008	14-Jan-2009	--	WAES0811USA00541	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site nodule, Injection site pain, Injection site reaction

Symptom Text: Information has been received from a medical assistant concerning a 14 year old female patient who on 23-APR-2008 was vaccinated with the first dose of GARDASIL, on 23-JUN-2008 she received the second dose of GARDASIL and on 22-OCT-2008 the patient received the third dose of GARDASIL 0.5 ml, I.M. in right deltoid. The medical assistant reported that after the third dose of HPV vaccine, the patient developed an injection site reaction. The patient experienced pain at the injection site and massaged the area that evening. The patient still had what was described as "BB size hard knot" at the injection site with discomfort. At the time of the report, the patient had no recovered. The patient sought medical attention at the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336805-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	22-Oct-2008	22-Oct-2008	0	15-Dec-2008	14-Jan-2009	--	WAES0811USA00535	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site nodule

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who on 22-OCT-2008, was vaccinated with the third dose of GARDASIL. The nurse practitioner reported that the patient experienced small knot at the injection site after getting the third dose of GARDASIL. The nurse stated that the patient did not experienced any AE on the first and second dose of GARDASIL. At the time of the report the outcome was

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336806-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Oct-2008	23-Oct-2008	0	15-Dec-2008	14-Jan-2009	CA	WAES0811USA00526	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Hemiparesis, Syncope

Symptom Text: Information has been received from a physician and a nurse concerning a 14 year old female patient with no drug reactions/allergies, who on 23-OCT-2008 was vaccinated with the first dose of GARDASIL. The physician reported that the patient fainted after receiving the GARDASIL. The nurse reported that "the patient upon feeling weak on one side of her body, the patient did fall". The patient recovered 15 minutes later after

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336807-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Oct-2008	27-Oct-2008	3	15-Dec-2008	25-Jan-2009	CA	WAES0811USA00512	24-Mar-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B012AA		Unknown	Unknown	
VARCEL	MERCK & CO. INC.	1192X		Unknown	Unknown	
HPV4	MERCK & CO. INC.	0927U	0	Unknown	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB245AA		Unknown	Unknown	
MNQ	SANOFI PASTEUR	U2378BA	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site swelling, Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 24-OCT-2008 was vaccinated with the first dose of GARDASIL. The same day she received additional vaccines VARIVAX (Oka/Merck), (duration and dose not reported), DTAP (manufacturer unknown), MENACTRA and HEP A (manufacturer unknown). The physician reported that the patient experienced throwing up for a week, after receiving GARDASIL and VARIVAX (Oka/Merck). The patient outcome was not reported. The patient sought unspecified medical attention. Additional information has been requested. 1/22/08 MR received from PCP. WCC with multiple vax 10/24/08. TC from parent 10/29/08 with report of injection site swelling and 2 days of nausea. Not seen in the office for c/o.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336808-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	30-Sep-2008	Unknown		15-Dec-2008	14-Jan-2009	--	WAES0811USA00509	17-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass

Symptom Text: Information has been received from a nurse practitioner concerning a 25 year old female with irritable bowel syndrome as concurrent condition and no known drug allergies who on 30-SEP-2008 was vaccinated intramuscularly in her left arm with 0.5 mL of the first dose of GARDASIL (Lot # 660387-1967U). Concomitant therapy included hormonal contraceptives (unspecified) and CLARITIN. On an unspecified date the patient developed a lump at the site of injection. The patient sought medical attention via telephone. At the time of the report the patient had not recovered. Additional information has been requested.

Other Meds: hormonal contraceptives; CLARITIN

Lab Data: None

History:

Prex Illness: Irritable bowel syndrome

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336809-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	04-Sep-2008	04-Sep-2008	0	15-Dec-2008	14-Jan-2009	AZ	WAES0811USA00500	17-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hypoaesthesia, Nausea, Vomiting

Symptom Text: Information has been received from a physician and a health care worker concerning a 13 year old female patient who on 04-SEP-2008, was vaccinated with her first dose of GARDASIL (lot # 660555/0279X). The physician reported that after receiving GARDASIL, the patient waited for 15 minutes and then went home. When the patient got home, she felt numbness in her legs, severe nausea, dizziness and vomiting (also reported by the office manager as occurring 15 minutes after being vaccinated). The physician and office manager reported that the numbness in her legs resolved in 30 minutes and the physician stated that the the severe nausea, vomiting and dizziness resolved sometime in September, 2008. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336810-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		08-Jan-2009	13-Feb-2009	TX	WAES0811USA00270	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning an 18 year old female with no relevant medical history or allergies who in approximately 2007, also reported as last year was vaccinated intramuscularly with a first, second and third 0.5 ml dose of GARDASIL (lot number and injection site not reported). There was no concomitant medication. The physician reported that the patient tested positive for GARDASIL. The patient called the physician's office and unspecified medical attention was sought. At time of this report, the patient's event persisted. Additional information has been requested.

Other Meds: None

Lab Data: cervix HPV DNA assay - positive

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336811-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Oct-2008	24-Oct-2008	7	15-Dec-2008	14-Jan-2009	--	WAES0811USA00257	17-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Local swelling, Skin nodule

Symptom Text: Information has been received from a consumer concerning her daughter with no medical with no medical medical history and no known allergies who on approximately 17-Oct-2008 was vaccinated with the third dose of GARDASIL given on the right a cause but believe that it could be the HPV vaccine" The consumer did not want to provide any or demographics or further information until she speaks with her daughter's physician. At the time of the report the patient had not recovered. Follow-up information was received which reported that the patient received the shot on 17-Oct-2008. The "bumps" started on " the weekend of October 24th" and she saw the doctor on 31-October-2008 and again on 07-Nov-2008. The bumps "stopped getting lager" on 05-Nov-2008 and now "they are getting smaller again". When the AE started, "you could not see them but you could feel them because they were under her skin. At their largest , "her neck looked swollen on that side and you could see them. "Presently, they are not visible but they can be felt". She did not have the lot# and the doctor did not do any tests when he saw the patient about this AE. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **336812-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	21-Aug-2008	21-Aug-2008	0	15-Dec-2008	14-Jan-2009	--	WAES0811USA00233	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pain, Vomiting

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female patient who on 21-AUG-2008 was vaccinated intramuscularly with the first 0.5 dose of GARDASIL (Lot # 660555/0279X) and on 27-OCT-2008 was vaccinated intramuscularly with the second 0.5 dose of GARDASIL (Lot # 660555/0279X). Concomitant therapy included birth control pills (unspecified). The nurse reported that after the first and second dose of GARDASIL, the patient experienced headache, vomiting and general body aches. The patient recovered 24 hours after the symptoms started. At the time of the report the nurse was thinking of premedicating her before her third dose of GARDASIL, with ibuprofen and PHENERGAN suppositories. The patient did not seek medical attention. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336813-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		15-Dec-2008	14-Jan-2009	NJ	WAES0811USA00222	17-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has been received from a physician concerning a patient who on an unspecified date was vaccinated with GARDASIL. The physician reported that the patient experienced an adverse event. The physician is not sure whether or not the adverse event is related to the vaccine. No further information was provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336814-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	PA	WAES0811USA00218	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Mood altered, Personality change

Symptom Text: Information has been received from a physician concerning a female who "about a year ago" in approximately 2007 was vaccinated with a dose of GARDASIL, Lot number was not provided. The physician reported that the patient's mother reported that her daughter experienced severe mood/personality changes "about a week post vaccination" after receiving GARDASIL. At the time of the report, the patient's outcome was unknown. This is one of two patients concerning the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336815-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-Feb-2008	27-Feb-2008	0	15-Dec-2008	14-Jan-2009	NY	WAES0808USA05335	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Nausea, Vomiting

Symptom Text: Initial and follow-up information has been received from a registered nurse for the pregnancy registry of GARDASIL, concerning an 18 year old female who on 27-FEB-2008 was vaccinated with the first dose of GARDASIL vaccine (Lot # 658556/1060U) (Expiration date 13-APR-2010), 0.5 mL, I.M. It was noted that on 27-FEB-2008, the patient received MENACTRA. After vaccination the patient discovered that she was pregnant. On an unknown date was performed a prenatal blood work with no abnormal results and an ultrasound with negative results. In follow-up, on 21-NOV-2008, a registered nurse was reporting that the patient experienced nausea and vomiting shortly after receiving the first vaccination on 27-FEB-2008. At the time of the initial report, the time of gestation was 32 weeks. Estimated date of delivery was 23-OCT-2008. In follow-up was also noted that the patient had competed her pregnancy. The date of delivery was not available. The patient sought medical attention at the office. Additional information has been requested.

Other Meds:

Lab Data: ultrasound - negative results.; hematology - (prenatal) no abnormal results.

History:

Prex Illness: Pregnancy NOS (LMP = 1/15/2008)

Prex Vax Illns:

Vaers Id: 336816-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Dec-2007	22-Dec-2007	17	15-Dec-2008	14-Jan-2009	NY	WAES0808USA04895	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Anaemia, Drug exposure during pregnancy, Small for dates baby

Symptom Text: Information has been received from a licensed practical nurse for the pregnancy registry for GARDASIL concerning an 18 year old female with asthma, peanut allergy and 1 previous pregnancies and 1 full term delivery (no birth defects or infant complications noted) who on 05-DEC-2007 was vaccinated with the first dose of GARDASIL IM 0.5 ml. On 05-FEB-2008 the patient was vaccinated with the second dose of GARDASIL IM 0.5 ml. Concomitant therapy included albuterol inhaler as needed. Other medications used during pregnancy included ferrousSO4 and biotin (+) carbonyl iron (+) docusate sodium (+) folic acid (+) minerals (unspecified) (+) vitamins (unspecified) (PRENATE ELITE) and iron supplement for anemia (begin on 12-JUN-2008 until delivery). The patient was pregnant with an estimated date of confinement of 30-SEP-2008. Fetal ultrasounds and positive pregnancy test were performed. On 09-SEP-2008 the ultrasound was performed with the result of "small gestational age". On 23-APR-2008 serum alpha fetoprotein was performed with negative results. The complete blood cell count was performed with the result of anemia. On 22-SEP-2008 the patient delivered a normal male baby weighing 6 pounds 2 ounces at 38 weeks with apgar scores 9/9. There were no congenital anomalies and no other complications or abnormalities. There was no complication during labor/delivery. The patient sought medical attention in the office visit. Additional information is not expected.

Other Meds: Albuterol; Vitamins (unspecified)

Lab Data: Ultrasound, 09/09/08, small gest age; Beta-human chorionic, positive; Serum alpha-fetoprotein, 04/23/08, negative; Complete blood cell, anemia; Apgar score, 09/22?/08, 9/9

History:

Prex Illness: Pregnancy NOS (LMP = 12/22/2007); Asthma; Peanut allergy

Prex Vax Illns:

Vaers Id: 336817-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	08-Oct-2006	28-May-2007	232	15-Dec-2008	14-Jan-2009	NJ	WAES0807USA03876	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0962F	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, for Pregnancy Registry for GARDASIL, concerning a 15 year old female with a history of 0 pregnancies and 0 live births and no other medical history or drug allergies who on 08-OCT-2006 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL in the deltoid and on 10-AUG-2007, was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL in the deltoid (lot # 654510/0962F). Concomitant therapy included minocycline. The patient delivered a healthy baby on 27-FEB-2008. Weight: 6 pounds 14 ounces, Length: 50.0cm, Apgar score: 9/9, Head circumference: 20 inches. No adverse symptoms. Medical attention was sought via office visit. No product quality complaint was involved. There were no congenital anomalies or other complication or abnormalities. Pediatric medical records were received and reviewed and the following experiences were identified: A 06-MAR-2008 office visit noted that the male child had eye discharge and required special formula due to lactose intolerance. The healthy male, was born on 27-FEB-2008 via normal spontaneous vaginal delivery. On 27-FEB-2008, poly vitamin with fluoride with Iron multiple vitamins with Iron and Fluoride 0.25 50, 1 dropperful, PO, once a day and erythromycin ophthalmic ointment 0.5%, QID, were prescribed. On 15-MAY-2008 the male child was vaccinated with PEDIARIX, PNEUMOVAX, ROTATEQ (manufacturer unknown) and HIB (manufacturer unknown). On 25-AUG-2008 the child was vaccinated with PEDIARIX, PNEUMOVAX (manufacturer unknown) and HIB (manufacturer unknown). Additional information is not expected.

Other Meds: Minocycline

Lab Data: Apgar score, 9/9

History:

Prex Illness: Pregnancy NOS (LMP = 5/28/2007)

Prex Vax Illns:

Vaers Id: **336818-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
57.0	U	10-Jul-2008	10-Jul-2008	0	15-Dec-2008	14-Jan-2009	MD	WAES0807USA01871	03-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Information has been received from an office manager concerning a 57 year old patient who inadvertently was vaccinated with a dose of GARDASIL by human error. No adverse effect reported. Follow-up information was received from a physician who reported that on 10-JUL-2008 the patient was given GARDASIL, IM, in the left arm instead of ADACEL inadvertently. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **336823-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	31-May-2007	31-May-2007	0	08-Jan-2009	13-Feb-2009	MO		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Left arm	Unknown	MEN

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Immediate post-injection reaction, Tremor, Vomiting

Symptom Text: Within about one minute of receiving Gardasil I immediately started throwing up, became dizzy, covered in sweat, shaking, and felt faint. I was required to lay down for about 45 minutes and then was allowed to leave when these symptoms went away. I did not continue with the other two shots in the series.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336825-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Jan-2009	07-Jan-2009	0	08-Jan-2009	06-Feb-2009	NY		06-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	2	Right arm	Intramuscular	
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	89623		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Dizziness, Heart rate decreased, Hyperhidrosis, Pallor

Symptom Text: after the vacc,pt c/o dizzyness,when seen pt looked pale and sweaty,pulse 55,bp 88/54,pt put on table at trendlenberg position felt better ,bp 99/69,pulse 82

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **336834-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
44.0	F	25-Jul-2008	26-Jul-2008	1	08-Jan-2009	03-Feb-2009	CA		10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0530U	1	Right arm	Intramuscular	HEPAB

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Balance disorder, Cervicobrachial syndrome, Facet joint syndrome, Grip strength decreased, Headache, Hypoaesthesia, Inappropriate schedule of drug administration, Injected limb mobility decreased, Intervertebral disc protrusion, Muscular weakness, Musculoskeletal pain, Myalgia, Neck pain, Neuropathy peripheral, Osteoarthritis, Paraesthesia, Spinal column stenosis, Tremor, Vision blurred

Symptom Text: Pt reports tingling and numbness/neuropathy-type symptoms in arm vaccine was administered (right). She also states some motor symptoms, mainly difficulty at times with gripping in the arm vaccine was given. There are some symptoms on the left as well, but less pronounced. 1/23/09 Received PCP medical records which consisted of Neuro consult. FINAL DX: cervical radiculopathy Neuro Records of 10/21/08 reveal patient experienced numbness & weakness of right arm x 3 mos, right hand trmor, neck & shoulder pain, difficulty lifting arm, disequilibrium, muscle aches, blurry vision & HA.

Other Meds: Wellbutrin XL

Lab Data: LABS: MRI c-spine c/w disc protrusion, spinal stenosis, neural foraminal narrowing, facet arthrosis.

History: Penicillin allergy PMH: head trauma, hypercholesterolemia, chronic migraines, constipation, depression. Allergies: codeine. Family hx: Parkinson's & Alzheimers.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336848-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Jan-2009	06-Jan-2009	0	08-Jan-2009	13-Feb-2009	PA		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Loss of consciousness approximately ten minutes after GARDASIL, episode lasting less than 30 seconds.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **336852-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	23-Jan-2008	08-Mar-2008	45	08-Jan-2009	09-Jan-2009	MN	WAES0805USA00247	09-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Failed induction of labour, Gestational diabetes, Nausea

Symptom Text: Initial and follow up information has been received from a licensed practical nurse (L.P.N.) for the Pregnancy Registry for GARDASIL concerning a 26 year old female with a history of drug hypersensitivity to TYLENOL #3, DEMEROL, and CODEINE, who on 23-JAN-2008 was IM vaccinated with her first dose of GARDASIL (lot number 659439/1267U). On 24-MAR-2008 the patient was IM vaccinated with her second dose of GARDASIL (lot number 659964/1978U). The patient became pregnant after receiving two doses. She has not received her third dose yet. The patient's LMP is 08-Mar-2008. The patient sought unspecified medical treatment with an office visit. The patient has had one previous pregnancy and one previous live birth, with no birth defects and no infant complications reported. Patient outcome was not reported. Follow-up information was received 05-JAN-2009 from the L.P.N. indicating that the patient's estimated conception date was approximately 22-MAR-2008. Ultrasounds were performed on 07-JUL-2008, 19-AUG-2008, 15-SEP-2008, 22-OCT-2008 and 04-NOV-2008, respectively (results not provided). Other medication used during this pregnancy included HUMALOG daily for the treatment of gestational diabetes, LANTUS daily for the treatment of gestational diabetes, "gummi vitamin/folic acid" daily and ZOFRAN), as needed for the treatment of nausea. On 03-DEC-2008, the patient had a C-section due to failure to progress and delivered a normal female baby, weighing 6 pounds, 12 ounces. The baby's length was 18 inches, head circumference was 13 inches and apgar score was 9/9. There were no congenital anomalies or other complications. The patient had no concurrent medical conditions. The outcome of the patient was not reported. Upon internal review, "C-section due to failure to progress" was determined to be an other important medical event. Additional information has been requested.

Other Meds: folic acid; vitamins (unspecified)

Lab Data: Beta-human chorionic, positive

History: Drug hypersensitivity

Prex Illness:

Prex Vax Illns:

Vaers Id: 336853-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Aug-2007	18-Aug-2007	0	08-Jan-2009	09-Jan-2009	CO	WAES0812USA02633	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Acne, Aphthous stomatitis, Behcets syndrome, Blindness transient, Catheter placement, Cellulitis, Depression, Dysuria, Flushing, Hirsutism, Hypoaesthesia, Inflammation, Influenza like illness, Lymphadenopathy, Oropharyngeal pain, Pain, Paraesthesia, Pyrexia, Rash erythematous, Rash pruritic, Suicidal ideation, Vulval ulceration, West Nile viral infection

Symptom Text: Information has been received from a physician concerning a female patient with a history of mouth ulcers who on an unknown date was vaccinated with a dose of GARDASIL, lot # unspecified. The patient came back to the physician's office 4 hours after getting GARDASIL with "vulvar ulcers" diagnosed as "bipolar aphthosis". The physician stated that the patient had gotten the shot when she was experiencing symptoms of West Nile virus; however it was not diagnosed after she had been given GARDASIL. The patient became sexually active "shortly before" she got GARDASIL. At the time of reporting, the outcome of the event was unknown. Follow-up information was received from the physician who reported that the patient had a history of canker sores. The physician also reported that the patient had a viral illness (not specified) prior to receiving the third dose of GARDASIL. The physician stated that the patient had experienced bipolar aphthosis every month for over one year. Follow-up information was received from the physician, who reported that the patient was vaccinated with the third dose of GARDASIL IM, on 18-AUG-2007. The physician reported that within 4 hours of vaccination, the patient had the first outcome of nonherpetic vulvar ulcers. Major work up negative. Presumed to be bipolar aphthosis. At the time of reporting, the patient had not recovered. The patient had numerous cultures and laboratories (unspecified) and a presumptive positive West Nile virus test. The physician considered the event to be disabling. This is one of two reports from the same source. No further information is available. 2/17/09 Received Immunology Clinic records of 7/15-9/26/2008. FINAL DX: Bechet's disease Records reveal patient did not have symptoms when initially evaluated. Valtrex d/c. Had bout of depression w/suicidal ideation. Being seen by counselor & tx w/meds. Developed oral canker sores that waxed & waned & by 9/18 had over 40+ vulvar ulcers w/exudate & bilateral lymph node adenopathy. Depression aggravated by eruption,

Other Meds: Unknown

Lab Data: Diagnostic laboratory, STD testing LABS: pathergy test neg. ESR 32(H), CRP 10.5(H). CBC, chemistry, LFTs WNL. HSV/PCR neg. HSV I (+), HSV II(-). Biopsy vulvar lesion.

History: Mouth ulceration; Canker sores oral; Viral infection PMH: PCOS, ? DMII on oral meds. Allergy: sulfa.

Prex Illness: Vulval ulceration; West Nile viral infection

Prex Vax Illns:

Vaers Id: **336854-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Dec-2008	07-Dec-2008	1	08-Jan-2009	09-Jan-2009	NY	WAES0901USA00056	22-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Unknown	Intramuscular	
	FLU	SANOFI PASTEUR	U2853AB		Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Abdominal rigidity, Activities of daily living impaired, Cough, Diarrhoea, Gait disturbance, Gastrointestinal sounds abnormal, Muscle strain, Nasopharyngitis, Nausea, Pallor, Pancreatic calcification, Pancreatic disorder, Pancreatic duct dilatation, Pancreatitis acute, Pancreatitis chronic, Pancreatolithiasis, Sick relative, Stent placement, Upper respiratory tract infection, Vomiting

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with no medical history or drug allergies who on 06-DEC-2008 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. Within 24 hours after vaccination the patient started experiencing pain and within 2 days she started vomiting. She was admitted to a hospital on 12-DEC-2008 (enzyme levels were over 800) and released on the 16th. The hospital determined it was pancreatitis. Multiple tests were performed in the hospital including CAT scan and ultrasound but the results were not provided. The patient was not fully recovered yet, however her mother stated that she was better and her enzyme levels were coming back to normal. Additional information has been requested. 3/16/09 Received PCP medical records of 7/31/08-2/13/2009. FINAL DX: acute on chronic pancreatitis w/strictures & pancreatic stones s/p stent placement; pancreas divisum; asymptomatic until 12/10/08. Records reveal patient experienced good health on 12/6/08 when received HPV #1 & flu shot. RTC 12/10/08 w/cough, cold s/s & chest/upper abdomen pain near diaphragm. Dx w/muscle strain & URI. RTC 12/12 w/continued upper abdominal pain w/vomiting, watery diarrhea, pale w/decreased bowel sounds, guarding & rebound. Sent to hospital for acute abdomen. RTC 12/17 s/p hospitalization w/resolving pancreatitis. 4/16/09 Received hospital medical records of 12/12-12/15/2008. FINAL DX: pancreatitis, etiology unknown Records reveal patient experienced progressively worsening epigastric pain x 5 days, N/V x 1 day. Seen by PCP & dx w/musculoskeletal pain. Continued to worsen &unable to walk or attend school. ALso had cold s/s during the week & multiple sick contacts. Surgery & GI consult done. Labs & PE improved & able to tolerate diet. D/C to home W/PCP & GI f/u.

Other Meds: None

Lab Data: Diagnostic laboratory, 12/12/08, enzyme levels over 800 LABS: CT scan & US abdomen abnormal w/pancreatic & common bile duct dilation & calcification of pancreatic head. MRI/MRCP abnormal w/dorsal duct syndrome, pancreatic stones & stric

History: None PMH: Foreign travel 7/08. Family hx: IBS.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336858-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	21-Jan-2008	21-Jan-2008	0	15-Dec-2008	14-Jan-2009	IN	WAES0806USA03426	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour, Urinary tract infection

Symptom Text: Information has been received from a physician for the pregnancy registry for GARDASIL, concerning a 16 year old female with allergic reaction to cephlosporins and a history of 1 pre-term delivery at 36 weeks with complication of apnea of prematurity and no birth defects who on 21-JAN-2008, was vaccinated with the first dose of GARDASIL (lot#657872/0515U). Concomitant medication included ALESSE for birth control. The physician reported that on 24-MAR-2008, the patient was vaccinated with the second dose of GARDASIL (lot # 657872/0515U) at her primary care office. On 09-JUN-2008, the patient had a blood test and urine test for pregnancy, and an ultrasound that confirmed the pregnancy and showed the patient was 23 weeks and 6 days pregnant and the fetus had a normal anatomy. The patient's LMP was 25-DEC-2007 and EDD 30-SEP-2008 and her date of conception was approximately 05 to 10-JAN-2008. The patient sought medical attention at the physician's office. In further follow up, the physician reported that the baby delivered on 31-AUG-2008 was male and weighed 5 pounds, 2 ounces, was 18 1/2 inches, and the APGAR score was 6/9. The infant was normal, with no congenital anomalies and there were no other complications. The patient had complications during the pregnancy and labor/delivery because was a precipitous delivery. She was on bed rest at 31 weeks. On 26-AUG-2008, the patient had an ultrasound which was normal size/fluid. Other medications were used during this pregnancy, was terbutaline 5 mg every 4 hours for pre term labor from 06-AUG-2008 to 07-AUG-2008 and MACROBID, bid, for treatment of a urinary tract infection from 06-AUG-2008 to 13-AUG-2008. No further information is available.

Other Meds: ALESSE, dose

Lab Data: Ultrasound, 06/09/08, confirmed the pregnancy: 23 + 6 weeks, normal anatomy; Ultrasound, 08/26/08, normal size/fluid; Serum beta-human, 06/09/08, confirmed the pregnancy; Apgar score, 6/9; Urine beta-human, 06/09/08, confirmed the pregnancy

History: Early onset of delivery

Prex Illness: Pregnancy NOS (LMP = 12/25/2007); Allergic reactions to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336859-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Aug-2007	10-Oct-2007	57	15-Dec-2008	14-Jan-2009	AR	WAES0806USA00085	03-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Inappropriate schedule of drug administration, Infection, Medication error

Symptom Text: Information has been received from a registered nurse (R.N.) for the Pregnancy Registry for GARDASIL regarding a 15 year old female who on 14-AUG-2007 was vaccinated intramuscularly with her first dose of GARDASIL (Lot #, and site not reported). Concomitant therapy included a first dose of MENACTRA. On 27-SEP-2007, the patient was vaccinated with a second dose of MENACTRA was received in error. On 16-OCT-2007, the patient was vaccinated intramuscularly with her second dose of GARDASIL (Lot #, and site not reported). On 22-FEB-2008, the patient was vaccinated with her third dose of GARDASIL (Lot # 655165/1425F, site not reported). ON 10-APR-2008, the patient was vaccinated intramuscularly with her fourth dose of GARDASIL (Lot #655165/1425F, site not reported). The patient received the fourth dose of GARDASIL in error. Concomitant therapy included Tylenol. On an unspecified date the patient took a urine pregnancy test which was positive. The patient "thinks she became pregnant in the first week of November 2007" (LMP approximately 10-OCT-2007). On an unspecified date, the patient had an ultrasound (not further specified). The patient had no symptoms. The patient sough unspecified medical attention by seeing the nurse. No further information is available. Follow-up information was received on 03-NOV-2008 from the R.N. and a physician indicating that the patient is with) previous pregnancies. The patient had no significant past medical history or concurrent medical conditions. It was reported that the third dose of GARDASIL (Lot #655165/1425F) was under bad storage and the dose was therefore repeated on 10-APR-2008. Other medication used during this pregnancy included occasional prenatal vitamins for nutrition and Zithromax (initialized on 05-MAY-2008), 250 mg, daily for an unknown infection (it was also reported that the patient had no infections or illness during pregnancy). The outcome of the infection was not reported. An ultrasound performed on 05-MAY-2008 was normal. On 11-AUG-2008, 40 weeks from her LMP, the

Other Meds: Tylenol

Lab Data: Ultrasound, 05/05/08, normal; Urine beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = 10/10/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336860-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Feb-2008	27-Feb-2008	0	15-Dec-2008	14-Jan-2009	--	WAES0805USA00373	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Gastrooesophageal reflux disease, Perineal laceration, Placental disorder

Symptom Text: Information has been received from a nurse practitioner, for the Pregnancy Registry for GARDASIL, concerning a 20 year old white female with allergies to PROZAC, attention deficit /hyperactivity disorder, bipolar disorder and depression with a history of 1 pregnancy and 1 live birth who on 28-Aug-2007 was vaccinated intramuscularly with the 0.5ml first dose of GARDASIL (lot#658282/0929U). On 27-Feb-2008, the patient was vaccinated with the second dose of GARDASIL (lot#659437/1266U). Concomitant therapy included LAMICTAL and RITALIN. Subsequently, she became pregnant. The estimated delivery date was 02-Aug-2008. The patient sought medical attention at the office. On 17-Apr-2008, an ultrasound was performed for dating and that result showed 24.5 weeks. During the pregnancy, other medications included PREVACID 15mg daily for Gastroesophageal reflux disease. On 02-Aug-2008 the patient delivered a normal, healthy female baby weighing 5 pounds 14 ounces. The apgar scores were 8/9. There were no congential anomalies and no other complications/abnormalities. Additional information has been received from a physician concerning a 20 year old female smoker who had a precipitous spontaneous delivery of a healthy female infant on 02-Aug-2008. On 02-Aug-2008, it was reported that the mother had a calcified placenta and 2nd degree lacerations on her left labial and peri clitoral. On approximately 19-Sep-2008, the patient reported having upper respiratory symptoms. On 02-Aug-2008, the patient's infant had cord around her neck x2. The patient's infant was born without abnormalities. The infant's length was 19 3/4 inches. On 02-Aug-2008, the newborn had a hearing screening test and passed. On 12-Aug-2008, the mother took her infant to a well child visit. She had concerns for some bleeding from the umbilicus. The mother also reported that her infant was spitting up and requested to switch formula to Isomil. Overall, newborn screen and PKU status were normal. On 27-Aug-2008, the mother brought her infant to the physician's office in

Other Meds: LAMICTAL, RITALIN

Lab Data: Ultrasound 04/17/08 - normal 24.5 weeks, due to dating, erythrocyte Rhesus - A positive , Rapid plasma reagin - NR, serum hepatitis B - Negative, Apgar score 08/02/08 - After one minute: 8 (infant), Apgar score 08/02/08 - After five minutes

History: Pregnancy NOS (LMP=Unknown) Drug hypersensitivity; Attention deficit/hyperactivity disorder; Bipolar disorder; Depression; Smoker; Bipolar disorder; Depression

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336861-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	25-Feb-2008		09-Jan-2009	13-Feb-2009	WY	WAES0804USA02244	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pre-eclampsia

Symptom Text: Information has been received from a consumer, who is the mother of the patient, for the pregnancy registry for GARDASIL concerning an 18 year old female who sometime last year (2007) was vaccinated with the first dose of GARDASIL (lot# not reported). Per the reporter, the patient received the second dose of GARDASIL (lot # not reported) either in November or December 2007. About a week ago, the patient found out that she was pregnant (gestation = "patient is 3 months pregnant") and her due date is on 27-OCT-2008 (LMP is approximately 19-JAN-2008). The patient sought unspecified medical attention. About a week ago the patient had a positive urine pregnancy test. No further AE information was provided. Follow-up information was received from a physician concerning the patient with no known allergies and a history of epilepsy, loop electrosurgical excision procedure in Aug 2007 and gastroesophageal reflux disease who at 06:06 on 05-NOV-2008, delivered a normal male infant with no congenital anomalies. It was reported that patient's prenatal testing included ultrasound which was performed on 30-MAY_2008, 05-AUG-2008 and 25-SEP-2008, and her estimated delivery date was 01-DEC-2008. The patient's medication used during pregnancy included prenatal vitamins, prilosec, 20 mg for gastroesophageal reflux disease and Zetran 4 mg for nausea. It was reported that the patient experienced mild pre-eclampsia since 14:23 28-OCT-2008, and severe pre-eclampsia since 13:46 30-OCT-2008. Vacuum assisted delivery was done for problematic fetal heart rate pattern (deep recurrent variables to 100 returning to baseline with overshoots. Minimal progress with pushing from +2 station). Apgar scores included: apgar 1 min: 6; apgar 5 min: 7. The outcome of birth infant included: weight: 2845 gm (6lbs + 4.354 oz) length: 49.50 cm (19.5 inches), head circumference: 34.50 cm (13.6 inches), chest circumference: 32.50 cm (12.8 inches). Additional information has been requested.

Other Meds: Unknown

Lab Data: Urine beta-human, 04/02?/08, positive; Erythrocyte ABO antigen, AB positive; Serum hepatitis B, Negative; Rapid plasma reagin, Non-reactive; Serum HIV-1 and/or 2, non-reactive.

History: Loop electrosurgical excision procedure; Gastroesophageal reflux disease

Prex Illness: Pregnancy NOS (LMP = 2/25/2008); Epilepsy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336862-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	27-Mar-2008	Unknown		15-Dec-2008	14-Jan-2009	--	WAES0804USA01350	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Hepatic enzyme increased, Pregnancy induced hypertension, Premature baby, Proteinuria

Symptom Text: Information has been received from a 22 year old female consumer with no pertinent medical history or drug allergies, for the Pregnancy Registry for GARDASIL, concerning the consumer who on 27-MAR-2008 was vaccinated with the first 0.5 ml dose of GARDASIL. Concomitant therapy included "petrocyclin." On 02-APR-2008 the consumer took a pregnancy test, and discovered that she was pregnant. The date of LMP was 03-MAR-2008, the estimated date of delivery was 08-DEC-2008. The patient would discontinue the rest of the series until the pregnancy was over. No further information was provided. The patient sought unspecified medical attention. Follow-up information was received from the patient who reported that she saw certified nurse midwife and she was well, not having any problems and her EDD was 08-DEC-2008. Follow-up information on 24-NOV-2008 from a Certified Nurse Midwife who reported that on 27-MAR-2008, the patient who was a positive Group B streptococcus carrier and with no previous pregnancies was vaccinated with the first dose of GARDASIL. Concomitant therapy included unspecified therapy. On 18-APR-2008, the patient underwent serum alpha-fetoprotein test and result was within normal limit (negative). On 21-JUL-2008, the patient underwent ultrasound for tetracycline exposure and family history of Meckel and result was normal. On 03-NOV-2008, the patient delivered a normal infant (Weeks from LMP: 35). There were no congenital anomalies. The patient experienced pre term dilation, pregnancy induced hypertension, elevated liver enzymes, and positive proteinuria during the pregnancy. Tetracycline was used for dermatologic reason during the pregnancy prior to knowledge. At the time of reporting, the outcomes were unknown. Additional information was requested.

Other Meds: (Therapy unspecified)

Lab Data: Ultrasound, 07/21/08, normal survey; Beta-human chorionic, 04/02/08, pregnant; Serum alpha-fetoprotein, 04/18/08, within normal limit (negative)

History:

Prex Illness: Pregnancy NOS (LMP = 3/3/2008); Group B betahaemolytic streptococcal positive; Drug exposure before pregnancy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336863-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Aug-2007	09-Aug-2007	0	15-Dec-2008	14-Jan-2009	IA	WAES0804USA01117	17-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Infection

Symptom Text: Information has been received through the pregnancy registry and a nurse concerning a 17 year old female who on 09-AUG-2007 and 11-OCT-2007 was vaccinated with a first and second dose of GARDASIL, respectively. Subsequently, she became pregnant. Her last menstrual period (LMP) was reported as July 2007. She received late prenatal care. On 30-MAR-2008, the patient was hospitalized "for delivery" and delivered a healthy baby. Her pregnancy was reported as normal. At the time of this report, the patient had recovered. No product quality complaint was involved. In follow up medical record it was reported that patient developed an infection two days after delivery. The outcome was not reported. Pediatric medical records were received and reviewed. The following experience with the baby were identified. On 08-APR-2008 the baby was brought to the clinic and thick white patch was present on her tongue. She was prescribed nystatin 4 cc on a swab. The mother was instructed to boil blttle nipples. She was instructed to call the clinic if it dose not clear within two weeks. On 11-APR-2008 the baby came to the clinic again. The mother thought she was fussy with bowel movement and felt that she had constipation. Mother reported that the baby was very irritable and screamed with bowel movement. She was advised to use 1-2 teaspoons of dark Karo syrup in every other bottle to see if it helps with the irritability and difficulty stooling. On 01-MAY-2008 baby had a visit to the clinic. On this visit mother reported that baby had watery left eye. It was reported that the baby recovered from constipation (date not reported). Her diaper area was reddened with multiple papules. No excess tearing from the eye noted in this visit. On 01-JUN-2008 the baby reported to have diaper candidiasis. She was called in clotrimazole cream to apply three times per day for ten days to the diaper area. It was discussed with mom other methods of improving diaper rash. Mom was concerned about a bump on baby's right hand. She wanted it to be checked. The

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 7/1/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336864-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	14-Nov-2007	25-Nov-2007	11	15-Dec-2008	14-Jan-2009	PA	WAES0803USA03041	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Constipation, Drug exposure during pregnancy, Premature labour, Vaginitis bacterial

Symptom Text: Initial and follow-up information has been received from a registered nurse and a nurse practitioner, for the Pregnancy Registry for GARDASIL, concerning a 19 year old female with a history of urinary tract infections, kidney infections, a previous pregnancy with an elective abortion, and an "abnormal pap with cryo" in December 2006, who on 14-NOV-2007 was vaccinated with her first dose of GARDASIL. On 21-JAN-2008, the patient was vaccinated with her second dose of GARDASIL. There was no concomitant medication. Subsequently, the patient became pregnant. No adverse symptoms were reported. The registered nurse stated that the patient was 12 weeks pregnant as of 18-Mar-2008. On an unspecified date, the patient took a urine pregnancy test which was positive. The date of last menstrual period was 23-DEC-2007 and the estimated delivery date was 28-SEP-2008. On 19-MAR-2008, the patient had a pelvic ultrasound with the normal result. On 25-MAR-2008 the patient had a maternal serum alpha-fetoprotein test for first trimester screening which was negative. On 26-APR-2008, the patient had an ultrasound for "anatomy" with "Echogenic Fetal Kidneys", results not provided. The dose of GARDASIL were administered at another site while the patient attended college. The patient sought unspecified medical attention in the office. On 10-OCT-2008, the nurse practitioner reported that the patient had her baby at the end of September or beginning of October. She did not have the patient's chart available at the moment so she wasn't sure of the exact date. She also reported that "nothing ever came of that" about the echogenic fetal kidneys that were seen during the 18 week 1 day anatomy scan on 26-APR-2008. The patient had undergone some genetic counseling/testing but everything was normal with the baby. There were no congenital anomalies and the baby was healthy when it was born. Follow-up information has been received from a completed questionnaire from a Certified Registered Nurse Practitioner. Other medication used d

Other Meds:

Lab Data: Ultrasound, 03/19/08, normal limit 12 wk 7 days; Ultrasound, 04/26/08, anatomy - 18 wk 1 day with echogenic fetal kidneys; Ultrasound, 05/06/08, Echogenic fetal kidney-anatomy screen: 0 problems; Diagnostic laboratory, ?/?/08, everything wa

History: Urinary tract infection; Kidney infection; Papanicolaou smear abnormal; Termination of pregnancy - elective

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336872-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Dec-2008	18-Dec-2008	3	09-Jan-2009	25-Jan-2009	WI		26-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2848AA	3	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0177X	1	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site rash, Injection site warmth

Symptom Text: Rec'd varicella and FLUZONE R arm 12/15/2008. Mother reports today an area " 3"x4", that is warm, red, hard and rashy" at the injection site R arm.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336873-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	10-Oct-2008	10-Oct-2008	0	09-Jan-2009	13-Feb-2009	MD		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Respiratory arrest, Syncope, Urinary incontinence

Symptom Text: Pt passed and approximately 15-30 sec after injection. Was assisted to prone position. No respiratory effort for approximately 30 seconds. Color remained pink. Pulse present , Chin - lift position to open airways and pt regained consciousness. Monitored x 30 min. Parents came to take pt home. Incontinent of urine during syncope episode.

Other Meds: Yasmin

Lab Data: None

History:

Prex Illness: No

Prex Vax Illns:

Vaers Id: 336887-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Feb-2008	07-Feb-2008	0	15-Dec-2008	14-Jan-2009	PA	WAES0803USA01873	17-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
MNQ	SANOFI PASTEUR	NULL	0	Unknown	Intramuscular	
VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bronchiolitis, Drug exposure during pregnancy, Urinary tract infection

Symptom Text: Information has been received from a physician for the Pregnancy Registry of GARDASIL concerning a 16 year old female who on 07-FEB-2008 was vaccinated with her first dose of GARDASIL (lot # not reported). Concomitant therapy included a dose of VARIVAX (lot number unknown). Other concomitant therapy included MENACTRA. On 19-FEB-2008 the patient had a positive pregnancy test. Her LMP was 25-JAN-2008. Follow-up information was received from the physician. The patient had medical history of depression. Concomitant medication during her pregnancy included KEFLEX for UTI (started on 11-JUN-2008) and ZITHROMAX for bronchiolitis (started on 08-SEP-2008). On 29-OCT-2008, the patient delivered a normal, health male baby (no congenital anomalies), weighing 7 pounds 14 ounces, 20 inch in length, with Apgar score 9/9 and head circumference 50.5 cm. There were no complication during labor or delivery. Additional information is not expected.

Other Meds: Unknown

Lab Data: Beta-human chorionic, 02/19/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/25/2008); Depression

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336888-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Oct-2007	16-Jan-2008	97	09-Jan-2009	13-Feb-2009	MI	WAES0803USA00533	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Cervicitis, Papilloma viral infection, Smear cervix abnormal, Urinary tract infection

Symptom Text: Information has been received from a Registered Nurse for the Pregnancy Registry for GARDASIL concerning an 18 year old female who on 11-OCT-2007 was vaccinated with the first dose of GARDASIL (lot number not provided) and on 06-FEB-2008 was vaccinated with the second 0.5 ml dose of GARDASIL (lot number not provided) and is now pregnant. There was no concomitant medications. The patient was not experiencing any known symptoms. Medical attention was sought in the practice. Patient outcome was unknown. No product quality complaint was involved. Follow-up information was received from another health professional who reported that on 06-FEB-2008 a PAP test showed atypical squamous cell of undetermined significance s/o HPV. She had the second dose of GARDASIL the same day. On 13-MAR-2008 the patient underwent colposcopy and was diagnosed with cervicitis, focal HPV changes. The patient received MACROBID 100 mg, twice a day for the treatment of urinary tract infection from 07-MAY-2008 to 14-MAY-2008. On 02-JUN-2008 an ultrasound was performed which was within normal limits and showed a fetal anatomy scan at 19 weeks. An MSAFP was declined. Patient declined genetic screening. This was the patient's first pregnancy. On 15-AUG-2008 (at 28 weeks) because she was Rh negative the patient received globulin, RHOGAM intramuscularly. The outcome of cervicitis and urinary tract infection was unknown. On 08-NOV-2008, at 40.5 weeks from LMP, the patient gave birth to a liveborn female infant weighing 5 pounds, 5 ounces, length was 18 inches, head circumference was 12 inches. Apgar score was 8. There were no complications during delivery. The infant was normal. There were no congenital anomalies or other complications or abnormalities. No further information is available.

Other Meds: None

Lab Data: Ultrasound, 06/02/08, within normal limits; Colposcopy, 03/13/08, cervicitis, focal HPV changes; Cervical smear, 02/04/08, ASCUS s/o HPV; Beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/16/2008)

Prex Vax Illns:

Vaers Id: 336890-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Aug-2007	16-Sep-2008	398	15-Dec-2008	14-Jan-2009	OK	WAES0802USA04438	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0388U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a Registered Nurse for the pregnancy registry for human papillommavirus vaccine concerning a female with a penicillin allergy who on 12-FEB-2007 was vaccinated with the first dose of GARDASIL (Lot #654741/1208F). The patient received the second dose on 01-MAY-2007 (Lot #655205/1426F) and the third dose on 15-AUG-2007 (Lot #657622/0388U). The patient became pregnant after her last menstrual period of 08-NOV-2007. No adverse effects were reported. Follow up information was received from a licensed practical nurse concerning a Caucasian female with no history of previous pregnancies, who on 12-FEB-2007, 01-MAY-2007 and 15-AUG-2007 was vaccinated with the first, second and third dose of GARDASIL respectively. Concomitant medication included TANDEM DHA. The LPN reported that on 06-MAR-2008 an ultrasound was performed for size and date. On 26-AUG-2008 the female patient gave birth to a normal male (weight 8 pounds 11 ounces and length 20.5 cm). It was reported that there were no complications during pregnancy and none during labor/delivery. The baby presented sleep apnea noted at 3 weeks. Last menstrual period was 08-NOV-2007. Estimated delivery date was 14-AUG-2008. No further information is available.

Other Meds: TANDEM DHA

Lab Data: Ultrasound, 03/06/08, for size and date

History:

Prex Illness: Pregnancy NOS (LMP = 11/8/2007); Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336891-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Oct-2007	01-Oct-2007	0	15-Dec-2008	13-Jan-2009	--	WAES0802USA00417	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Drug exposure during pregnancy, Gestational diabetes, Streptococcal identification test positive, Vaginitis bacterial

Symptom Text: Information has been received from a certified nurse midwife for the pregnancy registry for GARDASIL, concerning an approximately 19 year old female with diabetes, papilloma viral infection, successful smoking cessation at 27 weeks of gestation and thalassaemia minor and a history of depression, who in October 2007, was vaccinated with the first dose of GARDASIL and subsequently was determined to be pregnant. It was reported the patient has no previous pregnancies. On 31-Jan-2008, the patient was placed on therapy with prenatal vitamins (unspecified), PRN for the pregnancy and the treatment of anemia. Other therapies used in pregnancy included as follows: On 31-JAN-2008, the patient was placed on therapy with metronidazole, 500 mg twice a day for the treatment of bacterial vaginosis. On 04-FEB-2008, the patient was placed on ferrous sulfate, 325 mg twice a day for the treatment of anemia. On 04-FEB-2008, an ultrasound was performed and was found within normal limits. On 07-FEB-2008, therapy with metronidazole was discontinued. On 28-APR-2008, the patient was placed on therapy with glyburide, 2.5 mg twice a day for the treatment of gestational diabetes. On 09-MAY-2008, an ultrasound was performed and was found within normal limits. On 27-MAY-2008, an ultrasound was performed and a biophysical profile of 8/10 was found. Diagnostic laboratory tests during pregnancy also included a blood work for iron studies and a group B strep screen found positive. The patient's LMP was on 24-SEP-2007. On 11-JUN-2008, the patient delivered a 39 weeks healthy baby girl with an apgar score of 8 at one minute and 10 at 5 minutes. The estimated date of delivery was 18-JUN-2008. On 14-NOV-2008, the patient had a 5 month old visit and well child examination was found. Baby's growth and developed was considered normal. The baby was recommended for flu vaccine and scheduled for follow-up in two months. No further information is available.

Other Meds: Unknown

Lab Data: ultrasound 02/04/08 - OB within normal limits; ultrasound 05/09/08 - OB within normal limits; ultrasound 05/27/08 - BPP 8/10; Apgar score 06/11/08 - 8/10; vaginal Streptococcus - screen positive

History: Depression

Prex Illness: Pregnancy NOS (LMP = 9/24/2007) Thalassaemia minor; Diabetes; Papilloma viral infection; Smoker

Prex Vax Illns:

Vaers Id: **336892-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		15-Dec-2008	14-Jan-2009	--	WAES0801USA05865	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	HPV4

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Drug exposure during pregnancy, Fungal infection, Vaginal haemorrhage

Symptom Text: Initial and follow up information has been received from a nurse and a certified medical midwife for the Pregnancy Registry for GARDASIL, concerning a 23 year old female patient who smokes cigarettes, who in 17-DEC-2007 was vaccinated with the first dose of GARDASIL (Lot No 658563/1063U). In approximately 2008, the patient was vaccinated with the second dose of GARDASIL, 0.5 mL. Concomitant therapy included Depo-Provera on 17-DEC-2007 for contraception. On 17-DEC-2007, the patient took a pregnancy test which came back negative. Patient came back approximately a week later and was pregnant. The last date of menstrual period was on 22-NOV-2008 and the estimated delivery date was on 02-SEP-2008. On 11-JAN-2008, 17-APR-2008, 23-JUL-2008, 08-AUG-2008 some ultrasounds were performed to check the dates, survey and bleeding was found it. On 04-APR-2008 a serum alpha-fetoprotein test performed with negative results. The certified medical midwife reported that on 04-SEP-2008 the patient delivered a normal male baby, with no congenital anomalies, and with no known complication during labor/delivery. The patient had an obstetric history of one previous pregnancy with an spontaneous abortion and history of yeast during pregnancy. There was a complication during the patient's pregnancy with a vaginal bleeding at 36 weeks. Other medication used during pregnancy were prenatal vitamins (PVN), ferrous sulfate for anaemia, and Diflucan for yeast. The baby's weight was 6 pounds with 8 onz, with length of 18 1/2 cm a head circumference of 32 cm and an Apgar score of 9/9. No further information is expected.

Other Meds: Depo-Provera; Vitamins (unspecified)

Lab Data: Ultrasound, 04/17/08, dates, survey, bleeding; Ultrasound, 07/23/08, dates, survey , bleeding; Ultrasound, 01/01/08, dates, survey; Ultrasound, 08/08/08, dates, survey, bleeding; Beta-human chorionic, 12/17/07, negative; Beta-human chorioni

History: Abortion

Prex Illness: Pregnancy NOS (LMP = 11/22/2007); Smoker

Prex Vax Illns:

Vaers Id: **336893-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Sep-2007	12-Nov-2007	58	15-Dec-2008	14-Jan-2009	PA	WAES0810USA05569	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Staphylococcal infection

Symptom Text: Information has been received from a physician through the Pregnancy Registry for GARDASIL concerning an 18 year old female with a history of deep vein thrombosis at the age of 15 and no drug allergies, who in the middle of September 2007 was vaccinated intramuscularly in the left arm with the first dose of GARDASIL. The patient was vaccinated with a second dose of GARDASIL approximately from the middle to the end of November 2007. There was no concomitant medication. Subsequently, the patient was pregnant. The patient sought medical attention from her primary care physician. A urine pregnancy test was performed and was positive. The patient's last menstrual period was 12-NOV-2007 and her estimated delivery date was 18-AUG-2008. The patient contacted the physician for OB/GYN care. No problems were reported. At the time of the report, the outcome of the patient was unknown. No product quality complaint was involved. Follow-up information was received from a nurse practitioner and patient who reported that the patient delivered a normal healthy baby on 12-AUG-2008. The nurse practitioner reported that during the pregnancy the patient had a routine pregnancy ultrasound on 04-APR-2008, 23-JUN-2008 and 22-JUL-2008 and the results were normal. On 29-MAY-2008, the patient had a glucose screen and was normal. In further follow up, the patient reported that the baby was female and weighed 7 pounds, was 20 inches, the APGAR score was 8/9 and head circumference was 32. The infant was normal, with no congenital anomalies and there were no other complications. The patient had no complications during the pregnancy and labor/delivery. Infection during the pregnancy included a "staff" infection. The medications used during her pregnancy were LOVENOX, 40mg, daily (January to July 2008) and HEPARIN, 20mg, twice daily (July to August 2008) for the treatment of deep vein thrombosis. No further information is available.

Other Meds: None

Lab Data: Ultrasound, 04/04/2008, within normal limits; Ultrasound, 06/23/08, within normal limits; Ultrasound, 07/22/08, within normal limits; Urine beta-human, positive; Apgar score, 8/9; Serum glucose, 05/29/2008, within normal limits

History:

Prex Illness: Pregnancy NOS (LMP = 11/12/2007); Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336894-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	04-Jan-2008	04-Jan-2008	0	15-Dec-2008	13-Jan-2009	MI	WAES0801USA04765	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Drug exposure during pregnancy, Gestational diabetes

Symptom Text: Information has been received, for the Pregnancy Registry for GARDASIL, from a 24 year old female with a history of gestational diabetes who on 04-JAN-2008 was vaccinated with her first dose of GARDASIL. There was no concomitant medication. The patient reported that after receiving GARDASIL, she found out that she was 5 weeks pregnant. Her LMP was approximately 15-Dec-2007. A pregnancy test was performed. The patient did not seek medical attention. Follow-up information was received on 01-FEB-2008 via phone call from a person of a doctor's office indicating that they did not have any record of the patient ever receiving GARDASIL or any indication that she was pregnant. The patient was last seen in their office in November 2007. Follow-up information was received from a person of a doctor's office indicating that the Hispanic patient had 2 previous pregnancies and 2 pre-term deliveries. No birth defects occurred in previous pregnancies. The patient had pre-eclampsia and gestational diabetes in previous pregnancies. On 26-FEB-2008 an ultrasound was performed and the results were with normal limits. The patient was also placed on prenatal vitamins. Follow-up information was received on 03-NOV-2008 which confirmed that the patient had a past medical history of gestational diabetes. The patient developed insulin dependent diabetes during this pregnancy. She was treated with insulin human NOVOLIN (from 110JUL-2008 till EDC), 24 units, twice a day and insulin aspart NOVOLOG (from 11-JUL-2008 till EDC), 20/16 units, 20, every morning and 16, after supper. Other medication used during this pregnancy included prenatal vitamin (initialized on 20-MAY-2008), 1 mg, daily. On 02-SEP-2008, 37.3 weeks from her LMP, the patient delivered a normal male baby, weighing 7 pounds, 8 ounces. The baby's length was 19.5, head circumference was 13.5 and apgar score was 7/10. There were no congenital anomalies. There were no other complications or abnormalities. The patient had no complication during labor/delivery. Th

Other Meds:

Lab Data: beta-human chorionic - positive

History: Gestational diabetes; Pre-eclamsia

Prex Illness:

Prex Vax Illns:

Vaers Id: 336895-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	28-Aug-2007	04-Sep-2007	7	15-Dec-2008	14-Jan-2009	CA	WAES0712USA03771	03-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0245U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Drug exposure during pregnancy, Foetal disorder, Postpartum depression

Symptom Text: Initial and follow-up information has been received through Pregnancy Registry for a 22 year old female consumer with 2 previous full term deliveries who on 28-AUG-2007 was vaccinated with a first dose of GARDASIL vaccine (lot # 656050/0245U). There was no concomitant medication. On approximately 04-Sep-2007, the patient had a pregnancy test which was positive (LMP approximately 04-JUL-2007). The patient reported having an ultrasound; however, no additional information was provided. The patient sought unspecified medical attention. On 30-OCT-2007, the patient had a positive pregnancy test. The estimated conception date is 27-JUL-2007. The estimated date of delivery is 09-APR-2008. In further follow up, a nurse practitioner reported that the patient delivered a female baby on 23-MAY-2008. The baby weighed 10 pounds 2 ounces, was 20 inches, and the APGAR score was unknown. The infant was macrosomic and had no other abnormalities or complications. During pregnancy, the patient experienced anemia (HgE 10.9). The patient experienced failure to progress because of the large baby during the labor/delivery. On 14-DEC-2007, the patient had an ultrasound which was within normal limits. On an unspecified date, the patient had a positive alpha-fetoprotein test. There were no infections or illnesses during pregnancy. Follow-up information was received from a nursing supervisor who stated that the patient went to their offices on 11-JUN-2008 suffering post-partum depression and was referred to "psych". Additional information has been requested.

Other Meds: None

Lab Data: Ultrasound, 10/30/07, confirmation of pregnancy; Ultrasound, 12/14/07, within normal limits; Beta-human chorionic, positive; Serum alpha-fetoprotein, positive; Hemoglobin, 10.9

History:

Prex Illness: Pregnancy NOS (LMP = 7/4/2007)

Prex Vax Illns:

Vaers Id: **336896-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	11-Oct-2007	11-Oct-2007	0	15-Dec-2008	14-Jan-2009	AZ	WAES0710USA04313	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Initial and follow up information has been received as part of a Pregnancy registry for GARDASIL. A nurse practitioner and a certified medical assistant reported that a 25 year old female patient with no allergies and two previous pregnancies with full term deliveries and a bilateral tubal ligation (2006), on 11-OCT-2007 was vaccinated with GARDASIL. There was no concomitant medication. Subsequently the patient had a positive home pregnancy test. On 18-OCT-2007 the patient was seen in the office and underwent an ultrasound of the pelvis to confirm pregnancy. The patient's LMP was 01-SEP-2007 (EDD 29-MAY-2007). Follow-up information was received from a nurse who reported that the patient was scheduled at 39 weeks EGA for a repeat Cesarean section and delivered a healthy and normal male, weighing 7 lbs 3 oz. According to the nurse, the patient recovered postoperatively without problems. Additional information is not expected.

Other Meds: None

Lab Data: Unknown

History: Tubal ligation; Normal delivery

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336897-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	14-Sep-2007	14-Sep-2007	0	15-Dec-2008	14-Jan-2009	--	WAES0710USA03730	06-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vulvovaginal candidiasis

Symptom Text: Initial and follow up information has been received for the Pregnancy Registry for GARDASIL from a registered nurse concerning a 17 year old female with no known significant past medical history or no known concurrent medical condition, who on 14-SEP-2007 was vaccinated with the first dose of GARDASIL (Lot# 6585558/1061U), and was pregnant. On 14_SEP-2007, the patient experienced vaginal candida. Other medications used during the pregnancy was DIFLUCAN for vaginal candida. The patient's estimated LMP was 07-SEP-2007 and had a EDD of 14-JUN-2008. On an unknown date, the pregnancy was confirmed by a pregnancy test. The registered nurse wanted to have the patient added to the pregnancy registry. No further information is available.

Other Meds: Unknown

Lab Data: beta-human chorionic, positive.

History:

Prex Illness: Pregnancy NOS (LMP=9/7/2007

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336928-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Jan-2009	07-Jan-2009	0	09-Jan-2009	13-Feb-2009	TX		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Injection site haematoma, Injection site induration, Injection site pain, Musculoskeletal pain, Nausea, Pain in extremity

Symptom Text: pain from left elbow to left shoulder with pain/deep ache all around the left shoulder, and Nausea. She states the nausea started just shortly after receiving the injection, and the pain started two hours after receiving the injection. She states she hates shots and gets nervous; however, the nausea continued until the next day. the injection site is hard, sore to touch with mild bruising noted. No redness or heat noted. However, this time the band-aid did produce a local rash (in the shape of the Band-aid) it's the same type of band-aids i've applied to her skin with previous vaccinations.

Other Meds: Old med: "birth control pills" New Meds: "generic Prozac and Ambien for 6 weeks now"

Lab Data: None

History: depression

Prex Illness: none

Prex Vax Illns:

Vaers Id: **336933-1** **Related reports:** 336933-2; 336933-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	02-Aug-2007	02-Sep-2007	31	09-Jan-2009	03-Feb-2009	VA		09-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Aphthous stomatitis, Arthralgia, Exostosis, Lymphadenopathy, Oedema peripheral, Oral herpes, Pain in extremity, Polyarthritis, Rheumatoid arthritis, Synovitis

Symptom Text: HAD THE SERIES OF 3 GARDISIL VACCINES, HAVE BEEN EXPERIENCING PAIN IN FEET, HANDS, THEN OTHER JOINTS, BEEN TO DOCTORS, JUST BEEN TOLD MAY HAVE RHEUMATOID ARTHRITIS!! AT AGE 28. THESE SYMPTOMS STARTED AFTER THE VACCINE,BUT HAVE WORSENED OVER LAS 9-12 MONTHS!! I THNIK IT IS FROM THIS VACCINE! WHAT CAN WE DO? DON'T WANT MY DAUGHTER TAKING RA MEDS IF SOMETHING ELSE CAN HELP!! 2/2/09 Rheumatology consult received for eval of joint pain dated 12/19/08. Pt initially c/o sore feet, particularly in MTP joints x 2 yrs. Hand pain x 1 yr. Recent hand swelling jaw pain, and R shoulder, elbow and wrist pain with morning stiffness x 30 minutes. (+) canker sores and fever blisters. PE (+) for L posterior cervical lymph node, decreased thumb flexion, joint tenderness, synovitis, and swelling. Presntation c/w inflammatory arthritis such as RA.

Other Meds:

Lab Data: BLOOD WORK, XRAYS AT UVA, FONTAINE RESEARCH CENTER. Labs and Diagnostics: Anti-CCP (+), CRP 1.0. X-rays (+) for osteophytosis of the R foot, otherwise WNL. Complement CH 50 (H) at 386. UA (+) for 14 WBCs and few bacteria. ANA (+) at 1:640

History: NONE. PMH: 30 lb wt loss 2' to stress

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **336933-2** **Related reports:** 336933-1; 336933-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	21-Nov-2007	08-Jan-2009	414	14-Jan-2009	26-Jan-2009	--		04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Inappropriate schedule of drug administration, Pain in extremity, Rheumatoid arthritis

Symptom Text: Diagnosed with rheumatoid arthritis on 01/08/2009 by a rheumatologist at a research center. I am 28 years old, and first noticed pain in feet about 1 month after 2nd round of GARDASIL. I didn't think about any connection at the time, but joint pain, etc had worsened over the year, and my hands, fingers, shoulders, feet really hurt, so I finally went to rheumatologist, everyone saying it sounded like arthritis. There is not a history in my family of arthritis, and I am a healthy person, work as athletic trainer at university. After my feet started hurting, I switched shoes, got insoles, thought wearing flip flops a lot may be causing problem. Nothing has really helped. I had some blood work last summer, checking for some idea of the problem, no problems. I can't help fut feel there is a connection between my early onset of arthritis and this vaccine. I see other people have had similar problems. I just want to find out if there could be a conneciton, and possibly help with my diagnosis, recovery. I don't want to be on arathritis meds the rest of my life! Please contact me with any help in this matter if Merck has some suggestions to help me.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336933-3** **Related reports:** 336933-1; 336933-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	21-Nov-2007	Unknown		16-Mar-2009	31-Mar-2009	VA	WAES0903USA00087	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Rheumatoid arthritis

Symptom Text: Information has been received from a nurse concerning a 17 year old female who on 29-MAY-2007 was vaccinated with the first dose of GARDASIL (Lot # 657736/0389U), on 2-AUG-2007 was vaccinated with the second dose of GARDASIL (Lot # 657868/0523U), on 21-NOV-2007 was vaccinated with the third dose of GARDASIL 0.5ml (Lot # 659437/1266U). Concomitant therapy included oral contraceptive (manufacture unknown). Since then the patient had developed rheumatoid arthritis. The outcome of adverse event was unknown. It was reported that the patient sought unspecified medical attention. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 336937-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Oct-2007	25-Feb-2008	125	09-Jan-2009	14-Jan-2009	MA		27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	10110	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Chest discomfort, Deep vein thrombosis, Dizziness, Dyspnoea, Dyspnoea exertional, Familial risk factor, Headache, Hypercoagulation, Intensive care, Orthostatic hypotension, Pulmonary embolism, Pyrexia, Tachycardia, Tachypnoea

Symptom Text: Patient received HPV vaccine on 10/23/07 and 12/31/07. On 2/25/08 patient presented with breathing difficulty and was diagnosed with pulmonary embolism. Sibling and mother subsequently diagnosed with Protein S deficiency and patient presumed to have this as well. Patient began OCPs 10/07. Pulmonary embolism likely related to underlying hypercoagualability and use of OCPs, but we are reporting just in case HPV could also have been a factor. 01/26/09 Reviewed hospital medical records of 2/25-3/4/2008. FINAL DX: bilateral pulmonary emboli w/left common iliac DVT. Records reveal patient experienced DOE x 3 weeks & acute SOB w/chest pressure on 2/25. Fever & dizziness 2 weeks prior. Frontal HA 1 week prior. Seen by PCP 2/25 & found to have tachycardia, tachypnea, orthostatic BP. Admitted to PICU. Cardio, vascular surgery, Heme, Pulm consults done. Tx w/anticoagulant meds. D/C to home on continued anticoagulant meds w/thrombotic w/u to continue as outpatient in Hematology clinic. 4/24/09 Received Heme clinic med recs of 3/4/08-1/13/09. FINAL DX: PE assoc w/OCP Records reveal coumadin d/c 7/14/08 & covered w/lovenox to permit protein s testing. Patient self d/c coumadin as of 1/13/09 & no further medical records available.

Other Meds: Orthotricyclen prescribed 10/23/07

Lab Data: LABS: EKG abnormal w/biatrial enlargement w/RV strain. Troponin 2.13(H). Chest CT scan c/w large bilateral PEs. Echocardiogram abnormal w/RV enlargement, tricuospid regurg, pulmonary HTN.

History: PMH: BCP since 10/07. Preemie w/NICU & intubation. ITP at 2-3 yo. Sibling w/intrauterine CVA, cerebral palsy & protein s def; aunt w/DVT; parent & grandparent w/protein s deficiency; parent w/no hx of thrombosis & not on coumadin; grandparent w/recurrent thrombosis.

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336939-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Jan-2009	09-Jan-2009	1	09-Jan-2009	03-Feb-2009	TX		10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1391X	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2566AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0802U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Diarrhoea, Emotional distress, Fear of death, Injection site pain, Injection site swelling, Vomiting

Symptom Text: Mother of patient called immunization clinic at 1:15pm today 01/09/2009 asking for nurse who administered vaccination to her daughter. Mother claims daughter came home from high school today (01/09/2009) sick, having vomiting and diarrhea, with pain to the right upper arm and looked swollen. Mother believes child will die from the HPV ("the girls shot") due to information she gathered from her internet search. Mother stated "What should I do?". I expressed concern and needed more data from mother and crossed-check clients immunization consent form from 01/08/2009. It indicates that I was the administrator of the immunizations and that the HPV #1 dose was given on the Left Upper Deltoid (IM) and the Meningococcal Conjugate (MCV) on the Right Upper Deltoid (IM) with the Varicella #2 dose to Right lower arm Tricep (SQ). I strongly recommended Ice Pack or Ice Cubes inside a zip-lock bag as tolerated by client to Right Arm and/or what mother has previously given child for muscle discomfort, like Tylenol or Mortrin. If S/S continued next 24hours, mom would need to take daughter to ER of choice for follow-up. Mom agreed. 1/12/09 T/C to Mom states pt is no longer ill but mentally scared & will not go to school. Has not seen MD or gone to ER. Only researched on internet & is now afraid she is going to die. Not physically ill. Strongly encouraged Mom to have patient seen by MD or go to ER for reassurance & medical testing. Refuses. Gave Mom CDC NIP info phone # for additional info.

Other Meds: Unknown

Lab Data: Unknown

History: NKA, Last Menstrual Cycle :"12/22/2008" per mom and client statement.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336940-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	06-Jan-2009	07-Jan-2009	1	09-Jan-2009	13-Feb-2009	MO		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Erythema, Oedema peripheral, Pruritus, Rash

Symptom Text: 1/7/09@1000-Patient calls this office and speaks to this nurse. States that @ approx. 0630 today she woke up to itchy red bumps all over her (R) arm and (R) arm was swollen, when itched the rash left a greasy residue on her fingers and stated "it felt like my arm was on fire". Patient states @ this time the (L) arm that she got the gardasil injection in was not bothering her at all. Patient stated that she took benedryl (1)p.o. at approx 1100 and itching stopped shortly there after, but rash remained. Patient denies any S.O.B. scratchy throat, or any difficulty breathing. Instructed patient to take benedryl as directed on box and if symptoms worsened to contact Primary physician or Emergency room if needed. I requested at this time for her to come to the clinic for evaluation. 1/7/09@1300 Patient states that rash started on (L) forearm and started to itch and spread up to (L)deltoid. 1/7/09@1620 Patient is here at clinic raised red bumps are seen to (R) & (L) arm that cover the forearm and extend to the deltoid. Patient raised her shirt and no bumps are noted to her back, abdomen, or breast area. Does state that the back of lower (R) leg is itchy but I did not visually see this part and patient states that it is not bothering her like the arms are. Encouraged at this time to follow up with a primary care provider and to continue taking the benedryl as directed on the box. Also encouraged either calamine lotion or over the counter benedryl cream/spray to help with itching. Patient denies anything else new being introduced to her that could cause a reaction at this time. 1/8/09 Was contacted by RN, on this day. Patient states that there is no more itching and the red areas are almost gone.

Other Meds:

Lab Data: none...did not seek clinical evaluation by primary care physician

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **336945-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Aug-2008	31-Aug-2008	13	09-Jan-2009	03-Feb-2009	OH		04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	P0072X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Fatigue, Feeling cold, Gait disturbance, Headache, Hypersomnia, Hypoaesthesia, Paraesthesia, Sensation of heaviness

Symptom Text: Woke up that Sunday a.m. feeling very tired. Complained of arms feeling heavy and a headache. Later that day complained of numbness and tingling which progressed bilaterally up both her arms throughout that day and into the next several days. Complained of being cold. She slept up to 16 hours/day. Contacted the physician on-call on Monday (Labor Day) who suggested that we wait a week to see what course the symptoms took. Symptoms continued and progressed to complaints of difficulty walking due to heaviness of legs. Numbness and tingling progressed above elbows, but no further. No difficulty breathing. On Wednesday we went to see her primary care physician who felt she had mono, and that it was not related to the HPV vaccine. (patient had NO sore throat) Her doctor ran blood tests, but these returned negative for mono. Patient began to get less tired and less weak beginning on Friday, September 5th, during the day, but then returned to the weakened state on Saturday through Tuesday. And then rapidly recovered to her usual self by Saturday, September 13th. She has had no recurrence of the symptoms since. (NOTE: Her maternal grandfather was diagnosed with Myasthenia Gravis at age 70, and a cousin on her mother's side has Juvenile Rheumatoid Arthritis that first surfaced after a tetanus vaccine when she was 10 years old).

Other Meds: Nuvaring

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336947-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
31.0	F	08-Jan-2009	09-Jan-2009	1	10-Jan-2009	11-Feb-2009	TX		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Lymphadenopathy, Myalgia, Oropharyngeal pain, Pyrexia, Rhinorrhoea

Symptom Text: Low grade fever, sore throat, swollen neck lymph nodes, runny nose, muscle aches and fatigue. Taking ibuprofen.

Other Meds: Seasonale, zoloft 50mg

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336975-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	08-Jan-2009	08-Jan-2009	0	09-Jan-2009	11-Feb-2009	NY		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Immediate post-injection reaction, Syncope

Symptom Text: Patient given GARDASIL- fainted after getting it, patient complained of headache prior to fainting.

Other Meds: PROZAC; NUVARING

Lab Data:

History: AMOXICILLIN

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **336977-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	18-Mar-2008	22-Apr-2008	35	09-Jan-2009	11-Feb-2009	HI		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C2864AA		Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Mood swings, Muscle spasms, Smear cervix abnormal, Tachycardia, Tinnitus

Symptom Text: Dizzy, lightheaded, tachycardia, intermittent tinnitus. Cramps not related to monthly cycle. Mood swings, abnormal pap smear.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 337029-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Mar-2008	07-Mar-2008	0	12-Jan-2009	13-Jan-2009	FR	WAES0811AUS00009	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0784U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a health professional via CSL as part of a business agreement (manufacturer control # GARD 2008 10 30 002), with follow-up information received from the health professional, concerning an 18 year old female who on 07-MAR-2008 was vaccinated with the second dose of GARDASIL (Lot # 658275/0784U, Batch #J3206, Expiry date 22-MAR-2010). At the time of vaccination with her second dose, the patient was not aware that she was 10 weeks pregnant. On 17-SEP-2008 the patient delivered a normal, healthy female baby weighing 2.83 kilograms. The baby was reported to be healthy and no abnormalities were observed. Follow-up information was received from the reporting health professional, via CSL. The infant was born at 37 weeks gestation with APGAR scores of 9 and 10. The infant was admitted to hospital in the first few weeks of life due to sepsis. This was successfully treated with intravenous antibiotics. The reporter stated that it was uncertain whether the infant's sepsis was related to exposure to GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337030-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		12-Jan-2009	13-Jan-2009	FR	WAES0901CAN00018	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Muscle spasms, Paralysis

Symptom Text: Information has been received from a pharmacist concerning a female who was vaccinated with GARDASIL, dose and lot number(s) not available. Subsequently the patient some time after developed muscle spasms which then led to an almost total paralysis and muscle spasms which then led to an almost total paralysis (did not know how long after receiving the vaccine this occurred). On 16-DEC-2008 the patient was hospitalized. On 24-DEC-2008 the patient was discharged from hospital but it was reported that no medical diagnosis was given/made. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337031-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Nov-2008	24-Nov-2008	0	12-Jan-2009	13-Jan-2009	--	WAES0901USA00339	02-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypotension, Syncope vasovagal, Unresponsive to stimuli, Vaccination complication

Symptom Text: Information has been received from a registered nurse, for the Pregnancy Registry for GARDASIL concerning an 18 year old female who on 24-NOV-2008 was vaccinated with her initial dose of GARDASIL (lot # 661530/0575X) 0.5 mL intramuscularly in deltoid. On unknown date the patient had a severe reaction to the vaccination and went unresponsive. Her blood pressure was recorded at 54/30. The patient was sent to the local Emergency Room via ambulance. She was not admitted to the hospital and recovered from unresponsive. The last menstrual period was 21-OCT-2008 and estimated delivery date was 28-JUL-2009 (reported as "27-JUL-2009"). Upon internal review, went unresponsive was considered to be an important medical event. Additional information has been requested. 2/2/09 ER record received for DOS 11/24/08 with DX: Vasovagal episode. Pt was receiving immunizations when had a single episode of syncope. PE WNL in ER. D/C to f/u up with PCP.

Other Meds: Unknown

Lab Data: Blood pressure, 54/30. Labs and Diagnostics: CBC, Chem and EKG all WNL. Serum B-HCG (-).

History: PMH: none

Prex Illness: Pregnancy NOS (LMP = 10/21/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337032-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-May-2008	Unknown		12-Jan-2009	13-Jan-2009	TN	WAES0901USA00354	13-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Right arm	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Computerised tomogram, Nerve injury, Nuclear magnetic resonance imaging, Pain in extremity

Symptom Text: Information has been received from a physician concerning an 18 year old female who in May 2008 was vaccinated with the third dose of GARDASIL and within 1 week experienced right arm pain (2008). The patient saw an unspecified neurologist who said there of the vaccine was nerve damage. Lab diagnostics performed included MRI and CAT scan. All 3 doses were given in the right arm. Unknown if the patient had any problems with the first or second dose. The patient sought medical attention by visiting the physician's office. Nerve damage was considered to be disabling by the physician because the patient was on the golf team and was unable to participate. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337051-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	15-Dec-2008	16-Dec-2008	1	12-Jan-2009	21-Jan-2009	HI		26-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2806AA		Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2863AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Tenderness

Symptom Text: Right arm redness 7.5cm x 3.5cm, tender and itchy for 2 days. Rx'd Benadryl.

Other Meds: TB Test PPD JHP Pharm. 85857 ID/L Forearm

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **337062-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	09-Jan-2009	09-Jan-2009	0	12-Jan-2009	22-Jan-2009	MN		23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Dizziness, Feeling hot, Paraesthesia, Respiratory rate increased

Symptom Text: Patient felt hot, dizzy, lightheaded, hands were clammy, tight fisted, tingly and patient was breathing hard and fast

Other Meds:

Lab Data: BP: 130/84 P:80

History: Hyperglycemia, depression, allergies

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337133-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Dec-2008	29-Dec-2008	0	13-Jan-2009	23-Jan-2009	WA		27-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2829AA		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0651X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Immediate post-injection reaction, Pallor, Visual impairment

Symptom Text: Within 5 mins of receiving HPV injection pt became pale, lightheaded, vision became black, diaphoretic. Had pt wheeled to obs. room- monitored pt for 20 min - full recovery - discharged to Mom care.

Other Meds: No

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: 337144-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Dec-2008	26-Dec-2008	4	13-Jan-2009	23-Jan-2009	IL		23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0346X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted 4 days after vaccination per mom's report: with HPV vaccine patient was getting up from sitting down on couch when she fainted. Mom was in other room and heard her. Patient got up right away and has been acting fine. No fever, no cold symptoms.

Other Meds: FEXOFENADINE 180 mg daily

Lab Data:

History: Recurrent urinary tract infections.

Prex Illness: None

Prex Vax Illns: Fainting~HPV (no brand name)~2~18~In Patient

Vaers Id: **337154-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Feb-2008	14-Feb-2008	13	13-Jan-2009	14-Jan-2009	FR	WAES0804USA02623	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Complication of delivery, Drug exposure during pregnancy

Symptom Text: Information has been received from a general practitioner through the Sanofi Pasteur MSD pregnancy registry concerning a 17 year old female patient started a spontaneous pregnancy (estimated conception date: 15-Feb-2008) 5 days after receiving a dose of GARDASIL (batch number not reported) on 10-FEB-2008. The patient had no medical or obstetric history. Estimated delivery date was 15-NOV-2008. No adverse effect was reported. Follow-up information has been received through the Sanofi Pasteur MSD pregnancy registry initial questionnaire: Vaccination date was reported as 01-FEB-2008 (previously reported as 10-FEB-2008). Estimated date of conception was on 14-FEB-2008. Echographies at 12, 22 and 32 amenorrhea weeks were normal. The patient had no amniocentesis. Follow-up information received through the outcome pregnancy questionnaire on 08-JAN-2009: Case upgraded to serious. There was no complication during pregnancy. Diagnostics performed during pregnancy were normal. There was no infection and no disease during pregnancy. There were complications during the labour and the patient had a caesarean section on 30-OCT-2008. She gave birth to a normal baby girl at 38 amenorrhea weeks. Baby's height was 46 cm, weight was 2.835 kg, cranian perimeter was 33 cm. Other business partner numbers include E2008-02173. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, at 12, 22 and 32 amenorrhea weeks were normal

History:

Prex Illness: Pregnancy NOS (LMP = 09Feb08)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337155-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Oct-2008	23-Oct-2008	0	13-Jan-2009	14-Jan-2009	FL	WAES0901USA00452	14-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received for the pregnancy registry for GARDASIL from a physician concerning a 15 year old female who on 23-OCT-2008 was vaccinated with a third dose of GARDASIL (lot # 659184/0843X). It was reported that the patient was pregnant since August 2008 (LMP: August 2008). An ultrasound test was performed on 08-DEC-2008, which showed gestation of 22 weeks and 1 day. The physician reported that the patient had an elective termination of her pregnancy. The patient had no previous pregnancies. Upon internal review, elective termination of pregnancy was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, 12/08/08, Pregnant. 22 weeks, 1 day

History:

Prex Illness: Pregnancy NOS (LMP = 8/1/2008)

Prex Vax Illns:

Vaers Id: **337158-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	06-Jan-2009	07-Jan-2009	1	13-Jan-2009	23-Jan-2009	MN		23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Musculoskeletal stiffness, Myalgia, Pyrexia

Symptom Text: after first two HPV shots had muscle soreness and slight fever. After Shot #3 had severe whole body myalgias and stiffness "I can hardly move". Tender in all major trigger points. This report made by treating physician, vaccinating physician is patient's OBGYN, so I do not have vaccine lot number information

Other Meds:

Lab Data: Mild elevation of CK to 257.

History: Allergies to Fish and Shellfish

Prex Illness: none

Prex Vax Illns:

Vaers Id: 337160-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Jan-2009	12-Jan-2009	0	13-Jan-2009	11-Feb-2009	OK		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0702X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2660BA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2997AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyskinesia, Hypoxia, Immediate post-injection reaction, Loss of consciousness, Pallor, Syncope vasovagal, Urinary incontinence

Symptom Text: PT RECEIVED GARDASIL, MENACTRA AND ADACEL IMMUNIZATIONS ON 01-12-09. AFTER INJECTIONS, PT GOT DIZZY AND PALE WHILE SITTING UPRIGHT IN CHAIR IN EXAM ROOM. PT SLUMPED DOWN, HAD A BRIEF LOC WITH MILD IRREGULAR JERKING OF EXTREMITIES THAT LASTED APPROX 10 SECONDS. + URINARY INCONTINENCE. PT WOKE STARTLED AND SURPRISED ASKING "WHAT HAPPENED?" THE EPISODE WAS WITNESSED BY DR. DR. DOCUMENTED "THIS SEEMS TO HAVE BEEN A VASOVAGAL SPELL WITH A SUPERIMPOSED HYPOXIC SEIZURE."

Other Meds: BENADRYL

Lab Data:

History: ALLERGIC RHINITIS, ALLERGY-INDUCED ASTHMA

Prex Illness: PT PRESENTED TO OFFICE FOR A PHYSICAL. PT C/O BEING "TIRED MORE SINCE CHRISTMAS" WTH INCREASED SLEEPING DURING CHRISTMAS BREAK

Prex Vax Illns: NA~ ()~~0~In Patient|NA~ ()~~0~In Sibling|NA~ ()~~0~In Sibling

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337168-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Sep-2008	17-Sep-2008	1	13-Jan-2009	03-Feb-2009	FL		10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL	0	Unknown	Unknown	MEN
	HPV4	MERCK & CO. INC.	0571X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Arthralgia, Asthenia, Back pain, Cough, Dermatitis contact, Dizziness, Headache, Immunisation reaction, Musculoskeletal discomfort, Myalgia, Neck pain, Otitis media, Pain in extremity, Rash, Rash maculo-papular, Sinusitis, Upper respiratory tract infection, Vaccine positive rechallenge, Viral infection

Symptom Text: My daughter recived the first HPV guardasil shot on 9-16-2008. She received meningococcal vaccine at the same time. After the first shot she had a very unusual rash breaking out lasting for about 2 weeks. I did not make the connection until after the 2nd HPV shot on 11-19-2008 when it happened again. In addition this time she had severe neck and back pains severe stomach cramping dizey spells,and feeling weak. It has been 2 months since the 2nd shot. Her doctor has seen her still rash talked to her about her other symptoms that have for the most part cleared up. My daughter will be getting a barage of blood work tomorrow. She is a highly allergic child and had the CDC done a better job of educating parents on their pamplets I would have never never ever let my daughter get this shot. I do not believe children that are chemically sensitive dyes excetra should ever have this shot. To this day the CDC in their pamplet still says there are NO seriouse side effects. 2/24/09 MR received from PCP from 10/8/08 to 2/05/09. WCC 10/8/08 with normal exam. HPV#2 11/19/08. Returned 12/5/08 with c/o neck and back pain and URI sx. PE (+) for discomfort when palpating musculature of posterior neck along T-spine. Impression: URI. BSOM. Neck and Back pain-suspect muscular. Returned 1/9/09 with facial rash and intermittent R hip and leg pain, abdominal cramps on and off. PE (+) for mauculopapular rash face, chest & extremities. Impression: Contact dermatitis. R leg pain now resolved. Vaccination reaction per hx. Returned 2/5/09 with c/o H/A, joint pain, neck soreness and cough. Imp: viral syndrome. sinusitis.

Other Meds:

Lab Data: contact me in a week and I'll let you know Labs and Diagnostics: Insulin (H) 35.3. C-peptide 4.5. otherwise WNL.

History: Allergic to many things so much that the tests continue to come back inconclusive for which allergans. Has mild asma. Was born without left hand amniotic banding. Stopped breating in middle of MRI 15 seconds after dye gadoliom was administered last year. PMH: L hand absent 2' to amniotic banding

Prex Illness: none

Prex Vax Illns: none~ ()~~0~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337180-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Jan-2009	08-Jan-2009	2	13-Jan-2009	11-Feb-2009	NV		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Vaccine positive rechallenge

Symptom Text: Pt developed strong daily headaches. She reports a history of sever headaches in her past history. She noticed daily headaches after 1st Gardasil vaccine. The headaches subsequently subsided. She reports recurrence of headaches within days of 2nd Gardasil vaccine

Other Meds: Minocycline, celexa, Nuvaring

Lab Data: None

History: none

Prex Illness: none

Prex Vax Illns: Headaches~HPV (Gardasil)~1~18~In Patient

Vaers Id: 337182-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Jul-2007	16-Dec-2008	523	13-Jan-2009	23-Jan-2009	IL		23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0961F	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Genital herpes

Symptom Text: Patient developed genital herpes primary episode 12/16/08. Treated with hydrontisone prior to culture result. Resolved on own. Pt and her mother reported patient had never been sexually active or nude with a partner. Brother has hx cold sores.

Other Meds: Cephalexin;

Lab Data: 12/16/08, Positive HSV culture genitalia

History: Allergy Augmentin

Prex Illness: None

Prex Vax Illns: fainted~Tdap (no brand name)~6~14~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337242-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	15-Nov-2008		14-Jan-2009	15-Jan-2009	NM		29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Autopsy, Death

Symptom Text: My daughter had her 3rd GARDASIL vaccine in Sept. She was a very healthy young lady, she went to take a shower and died. Autopsy report states undermined death. There was no sign of trauma to the body to indicate a fall. She had pointed the shower head away from her and she got down on her knees and put her head on the edge of the tub and passed away. This has been a living nightmare for her family. She is not the only one to have had problems and death from this vaccine. Please I beg you to please take it off until it can be further tested. -not tested long enough to begin with- There will be others that will die if the cause is not found. 1/29/09-records received-COD-undetermined.

Other Meds:

Lab Data:

History: No medical problems-- no allergies -- No drug use, alcohol or smoking. Had all her medical check ups!!!

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337249-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	21-Nov-2007	08-Jan-2009	414	14-Jan-2009	26-Jan-2009	--		27-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Inappropriate schedule of drug administration, Pain in extremity, Rheumatoid arthritis

Symptom Text: Diagnosed with rheumatoid arthritis on 01/08/2009 by a rheumatologist at a research center. I am 28 years old, and first noticed pain in feet about 1 month after 2nd round of GARDASIL. I didn't think about any connection at the time, but joint pain, etc had worsened over the year, and my hands, fingers, shoulders, feet really hurt, so I finally went to rheumatologist, everyone saying it sounded like arthritis. There is not a history in my family of arthritis, and I am a healthy person, work as athletic trainer at university. After my feet started hurting, I switched shoes, got insoles, thought wearing flip flops a lot may be causing problem. Nothing has really helped. I had some blood work last summer, checking for some idea of the problem, no problems. I can't help fut feel there is a connection between my early onset of arthritis and this vaccine. I see other people have had similar problems. I just want to find out if there could be a conneciton, and possibly help with my diagnosis, recovery. I don't want to be on arathritis meds the rest of my life! Please contact me with any help in this matter if Merck has some suggestions to help me.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **337250-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	04-Dec-2008	Unknown		14-Jan-2009	26-Jan-2009	--		26-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	06050X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inflammation, Injection site pain, Local reaction, Musculoskeletal pain

Symptom Text: Pt describes onset of pain at R shoulder vaccination site @ 12/11/08 PM. Exam c/w localized inflammatory reaction at lateral aspect of deltoid. No sign of infection or systemic reaction.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **337298-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	28-May-2008	28-May-2008	0	14-Jan-2009	15-Jan-2009	FR	WAES0808USA04934	15-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a gynaecologist, for the Pregnancy Registry for GARDASIL, concerning a 20 year old female who on 28-MAY-2008 was vaccinated with a first dose of GARDASIL while she was pregnant. The patient started pregnancy on 30-MAR-2008, and received the second dose of GARDASIL on 04-AUG-2008. She discovered her pregnancy on 25-AUG-2008. At time of reporting, she had no adverse reaction. Follow-up information was received by phone from the reporter: Case was upgraded to serious. A voluntary termination of pregnancy was reported. No further information is available. The case is closed. Other business partner numbers included E2008-08038.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 30Mar08)

Prex Vax Illns:

Vaers Id: 337299-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	30-Jul-2008	30-Jul-2008	0	14-Jan-2009	15-Jan-2009	FR	WAES0810USA03043	15-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Tendonitis, Threatened labour

Symptom Text: Information has been received from a physician. The physician reported case of pregnancy through the Sanofi Pasteur MSD GARDASIL Pregnancy Registry on 10-OCT-2008. A female patient received first and second dose of GARDASIL, (batch number not reported) on unspecified dates while she was pregnant: the first dose was administered at 3 amenorrhea weeks and the second dose at 11.5 amenorrhea weeks. At time of reporting there was no adverse effect. Follow-up information received by phone from the reporter on 09-Jan-2009: Case upgraded to serious. The patient was 18 years old at time of events. Her last menstrual period was on 19-Apr-2008 and she started a spontaneous pregnancy. She had received a dose on 30-Jul-2008 at 11 and a half amenorrhea weeks. She discovered her pregnancy at 22 amenorrhea weeks on 07-OCT-2008. On 18-NOV-2008 she was hospitalized for a threatened premature labor and was prescribed LOXEN 50mg. She consulted on 19-DEC-2008 for a shoulder tendinitis. At time of reporting the outcome was not specified. The reporter did not follow her pregnancy but could provide more information if needed. Other business partner numbers include E200809458. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 19Apr08)

Prex Vax Illns:

Vaers Id: **337300-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Jan-2008	01-Jan-2008	0	14-Jan-2009	15-Jan-2009	FR	WAES0810USA04462	15-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Intra-uterine death

Symptom Text: Information has been received from a specialist concerning a female who on JAN-2008 was vaccinated with the first dose of GARDASIL (Lot and batch number not reported) while she was at 5 amenorrhea weeks. The patient ignored her pregnancy at time of vaccination. At time of reporting the patient had no adverse effect, echography during pregnancy was normal. The reporter did not see the patient yet she had just received a letter from the gynaecologist who followed her. The patient should give birth soon. This case was not enrolled in the Pregnancy Registry: patient's age was unknown. Other business partner numbers included: E2008-09680. Additional information was received from a specialist who reported that a corrective version was created on 12-Dec-2008 to enroll the patient in the Pregnancy Registry. Follow-up information received through the outcome pregnancy questionnaire on 06-Jan-2009: Case upgraded to serious. The patient was 18 years old. There was no congenital anomaly, no genetic problem in the family, no consanguinity with the partner. The patient had medical risk factor with smoking (10 cigarettes/day). There was no complication during this pregnancy. Diagnostics performed during pregnancy were normal. There was no infection and no disease during pregnancy. Pregnancy seemed to be not followed by the reporter. On 17-Sep-2008 at 17 amenorrhea weeks the patient suffered from an idiopathic early foetal death in utero. Products of conception were analyzed: there was a normal but sanguinolentis foetus. Died baby boy's weight was 0.3 kg, he was normal, without any post-natal complication and no congenital anomaly. The case was closed. No further information was expected.

Other Meds: Unknown

Lab Data: ultrasound, normal

History: Smoker

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337301-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Jan-2009	05-Jan-2009	0	14-Jan-2009	15-Jan-2009	PA	WAES0901USA00898	15-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a Licensed Practical Nurse concerning a 16 year old female who on 30-JUN-2008 was vaccinated with the first dose of GARDASIL. On 02-SEP-2008, the patient was vaccinated with the second dose of GARDASIL. On 05-JAN-2009, at 4:20 p.m. the patient was vaccinated with the third dose of GARDASIL (lot # 661764/0650X) IM in her left arm. The patient fainted as soon as the third dose was given, and had a seizure like symptom. Blood pressure was 102/60, and the pulse was OK. Half an hour later, the patient recovered from fainted and seizure like symptom. Upon internal review, seizure like symptom was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: blood pressure, 01/05/09, 102/60; total heartbeat count, 01/05/09, OK

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337302-1 (S)** **Related reports:** 337302-2; 337302-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Dec-2008	02-Jan-2009	2	14-Jan-2009	15-Jan-2009	--	WAES0901USA00986	11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Convulsion, Dyskinesia, Dyspnoea, Rash, Tremor

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female with no medical history and drug allergies who on 31-DEC-2008 was intramuscularly vaccinated with the third 0.5 ml dose of GARDASIL. She had no problems after receiving the 1st and 2nd doses of GARDASIL. At 22:30 on 02-JAN-2009, 48 hours later, the patient experienced seizure type activity and convulsions, 2 more occurred by 23:30 during which time she was taken to the hospital. It was decided in the emergency room to take the patient to a children's hospital early on 03-JAN-2009. The patient had a total 13 seizures type activities or convulsions but it was unclear the specific time frame. Laboratory tests included an magnetic resonance imaging, ultrasound of the kidney, and "lots of unspecified lab work" (one of the results were normal kidney function). The patient has one more episode after being discharged from the hospital on 04-JAN-2009. The patient was put on XANAX and her mother felt it had helped control the seizure type activity and convulsions. The patient started KEFLEX and AZO for urinary tract infection on 02-JAN-2009. The seizures type activities or convulsions was considered to be disabling. Additional information has been requested. 2/2/09-records received for DOS 1/3-15/09-DC DX: Spells. presented to ED with difficulty breathing, rash and episodic jerking. Rash on back, chest and neck and felt short of breath. Rash would come on with shaking and improve when shaking stopped.

Other Meds: Unknown

Lab Data: Unknown 2/2/09-records received-Renal ultrasound normal. Labs WNL. MRI brain normal.

History: None 2/2/09-records received- PMH: GTC seizure at 8 years of age andmultiple episodes of passing out with exercise and hypoglycemia. Urinary tract infection. Staph knee infection last year.

Prex Illness: 2/2/09-records received- Dysuria, left flank pain times 5 days. After first dose of Keflex felt lightheaded, fall to ground with

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337302-2 (S)** **Related reports:** 337302-1; 337302-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jan-2009	20-Jan-2009	--	WAES0901USA01615	05-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Kidney infection

Symptom Text: Information has been received from a registered nurse who reported that the one of her patient's mother reported that there was a female patient who was vaccinated with the third dose of GARDASIL (Lot and route unspecified) and three days later she had a seizure. The nurse reported that the patient was sent by ambulance to the hospital and was hospitalized (duration not reported). The nurse reported that the mother also mentioned that the patient, on an unspecified date, had kidney infection. It was unknown if the kidney infection occurred before the third dose of the vaccine or before of the GARDASIL. As of 13-JAN-2009 the outcome of the patient was unknown. Attempts are being made to verify the existence of an identifiable patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **337302-3 (S)** **Related reports:** 337302-1; 337302-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Dec-2008	02-Jan-2009	2	18-Feb-2009	20-Feb-2009	MO		20-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Convulsion, Electrocardiogram ambulatory, Palpitations

Symptom Text: Had convulsion 1/2/09 at 10:30 am. To ER, then another hospital by ambulance. Had undiagnosed kidney infection when received vaccine. Had total 14 convulsions - tried seizure meds - no help. Negative EEG. Heart palpitations - on holter monitor. To following up with doctor.

Other Meds:

Lab Data: EKG, Convulsions - Negative EEG

History: Hypoglycemia; family hx heart prob.

Prex Illness: Kidney infection

Prex Vax Illns:

Vaers Id: **337303-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	29-Oct-2008	25-Nov-2008	27	14-Jan-2009	15-Jan-2009	CT	WAES0901USA01014	23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	2	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Arthralgia, Wheelchair user

Symptom Text: Information has been received from a physician concerning a 12 year old female who on 29-OCT-2008 was vaccinated with the third dose of GARDASIL (lot # 659657/1487U). Concomitant therapy included Varicella virus vaccine (manufacturer unknown), hepatitis A vaccine (manufacturer unknown) and influenza virus vaccine (unspecified). On 25-NOV-2008 the patient came back with a severe hip pain. The pain started in her right hip and spread to both. The patient was sent to a rheumatologist and he performed multiple test and they all came back negative. The rheumatologist did mention that the patient was unable to walk and needed a wheelchair. The physician was informed on 15-DEC-2008 that the patient was walking without a limp. Severe hip pain and unable to walk and needed a wheelchair were considered to be disabling. Additional information has been requested.

Other Meds:

Lab Data: X-ray, negative; WBC count, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 337334-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Jan-2009	14-Jan-2009	1	14-Jan-2009	26-Jan-2009	MI		11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2670AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0279X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Back pain, Injection site swelling, Loss of consciousness, Musculoskeletal pain, Pain in extremity, Vision blurred

Symptom Text: Arm swelling (site of innoculation), arthralgias in knees and ankles bilaterally 2/9/09-records received for DOS 1/14/09-presented with C/O reaction to immunization received yesterday. Right arm sore with pain going up into shoulders and down left arm as well as into back. Progressed to legs and ankles and feet. Felt tired and weak. Fell and passed out. Prior to passing out felt tired and had blurred vision. Now C/O pain in knees and ankles bilaterally, feels tense in right arm and right hand. Pain is intermittent and stabbing.Assessnent likely to have serum sickness-like reaction to immunization. Joint arthralgia. Swelling at immunization site.

Other Meds: Bactrim for ingrown toenail

Lab Data: Pending labs currently are CBCPD, COMP, CRP, c3, c4, UA 2/9/09-records received-CRP increased .9, lymphocte % low 22.5, monocyte % high 14.6, neutrophil % increased 78.6, CAE total complement CH50 increased 129.

History: no 2/9/09-records received- Measles after first MMR.

Prex Illness: no 2/9/09-records received-Currently on Bactrim for ingrown toenail.

Prex Vax Illns: Measels~Measles + Mumps + Rubella (MMR II)~1~12~In Patient

Vaers Id: **337336-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Jan-2009	10-Jan-2009	1	14-Jan-2009	26-Jan-2009	MI		27-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2826CA	0	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0650X		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cellulitis, Erythema, Incorrect route of drug administration, Pain, Vaccination complication

Symptom Text: Given Meningococcal (MCV4) vaccine on 01/09/09 in left arm SC instead of IM. Pt was brought to Urgent Care on 01/11/09 with pain, erythematous in left upper arm. Dx with cellulitis, secondary to vaccine reaction. Rx for Bactrim DS 800 mg P.O. BID for 10 days and Medrol dosepak one tab P.O. for 5 days.

Other Meds: Motrin 800 mg TID, Lamictal 100 mg BID

Lab Data:

History: Allergy to Ceclor. Dx with Cerebral Palsy and followed by Dr.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **337337-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	14-Jan-2009	14-Jan-2009	0	14-Jan-2009	20-Jan-2009	KS		20-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Activities of daily living impaired, Anaphylactic reaction, Chest pain, Dyspnoea, Feeling hot, Hypersensitivity, Malaise, Nausea, Paraesthesia, Pruritus generalised, Throat irritation, Wheezing

Symptom Text: Sharp stomach pains within 2 hours of shot. Hands then became tingly and had"pins and needles", throat then had same feeling. Then had feverish feeling then nausea and itching all over. Then took Benadryl. Then "sick" feeling, then wheezing, then chest pain, then went to emergency room. Felt sick ,could not function. 2/17/09-records received for DOS 1/14/09-presented to ED with C/O difficulty breathing and wheezing, abdominal cramping . Allergic reaction to Gardasil Impression: anaphylaxis.

Other Meds:

Lab Data:

History: penicillin-all siblings have had reaction, told to avoid by physician

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337363-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	13-Jan-2009	14-Jan-2009	1	14-Jan-2009	26-Jan-2009	IN		26-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X		Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2800BA		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye swelling, Pruritus

Symptom Text: Patient eyes swollen shut, itchy. BENADRYL 2 Tsp PO Q6 PRN.

Other Meds:

Lab Data:

History:

Prex Illness: Well check

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337365-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Dec-2008	02-Jan-2009	4	14-Jan-2009	26-Jan-2009	IL		26-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Nausea

Symptom Text: Lower abdominal discomfort, onset 4 days after injection with nausea. Symptoms lasted X 5 days.

Other Meds: Mononessa 28's; Naprosyn

Lab Data:

History: Mild GERD; Dysmenorrhea

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337422-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	06-Jan-2009	06-Jan-2009	0	15-Jan-2009	26-Jan-2009	AZ		26-Jan-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1448U	0	Right arm	Intramuscular	
TYP	SANOFI PASTEUR	B0347	0	Left arm	Intramuscular	
YF	SANOFI PASTEUR	UF306AA	0	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drooling, Syncope, Tonic clonic movements

Symptom Text: Patient received yellow fever and typhoid injections without incident. Approximately 15 mins later GARDASIL inj given. Within mins patient had syncopal episode with tonic movements of both upper extremities and drooling. Treatment was supportive in nature-moved to supine position when LOC returned. Advised not to drive home. Rested approximately 30 mins.

Other Meds:

Lab Data:

History: Patient stated she was allergic to CECLOR

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337427-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	10-Oct-2007	20-Nov-2007	41	15-Jan-2009	26-Jan-2009	--		26-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fungal infection, Lymphadenopathy

Symptom Text: Prior to 3 doses of GARDASIL I had all normal pap tests between the years 2004 to 12-1-20066. After 3 doses of GARDASIL I had 2 abnormal pap tests. I also had a yeast infection on my right armpit, and on/ about 11-2008, I was seen by my OBGYN for a swollen gland in my groin area.

Other Meds:

Lab Data: PAP tests after GARDASIL: 11-20-07 = ASCUS; 5-21-08 = ASCUS; 12-3-08 = Normal

History: No Known

Prex Illness:

Prex Vax Illns:

Vaers Id: **337428-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-Feb-2008	07-Feb-2008	0	15-Jan-2009	26-Jan-2009	WA		26-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Dizziness, Dysstasia, Gait disturbance, Headache, Pyrexia

Symptom Text: After first shot of GARDASIL on 2-7-08 had dizziness, headache, missed school. Second shot 5-7-08 had dizziness and severe headache - missed school. Fever 3rd 9-29-08 major dizziness sever headache needed help getting up and walking missed school.

Other Meds: Allergic to most anti biotic

Lab Data:

History: Allergic to most anti biotics

Prex Illness: None

Prex Vax Illns: Dizziness~Varicella (no brand name)~1~5~In Patient

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337441-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Sep-2008	17-Sep-2008	1	15-Jan-2009	16-Jan-2009	FR	WAES0901USA01266	16-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	LG13640	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Hyperpyrexia, Hypotension

Symptom Text: Information has been received from a health authority (case n. 93469, local case n. IT005/09) on 08-JAN-2009, concerning a 12 year old female patient with no pertinent medical history, who on 16-SEP-2008 was vaccinated intramuscularly with the first (also reported as third) dose of GARDASIL (batch #LG13640). On 17-SEP-2008, 12 hours p.v., the patient presented with hyperpyrexia 40,5 C going down to 39 C that lasted 1,5 days. The patient was hospitalized. Also reported hypotension and feeling faint. The outcome was recovered on 19-SEP-2008. Other business partner numbers include E2009-00119. The case is closed. No further information is available.

Other Meds: Unknown

Lab Data: Body temp, 17Sep08, 40,5 C going down to 39 C

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 337442-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Jun-2008	03-Jun-2008	0	15-Jan-2009	16-Jan-2009	--	WAES0901USA00384	16-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received, for the Pregnancy Registry for GARDASIL, from a nurse practitioner concerning a 16 year old female with no pertinent medical history who on 03-JUN-2008, "while pregnant", was vaccinated with a first dose of GARDASIL. It was reported that the patient was hospitalized for delivery. On 14-SEP-2008 the patient delivered healthy, but premature twins. The babies were about 29 week gestation. It was reported that the babies were healthy, but had "typical premature problems". On 14-SEP-2008 the mother recovered. Follow-up information was received on 08-JAN-2008 via a telephone call from the N.P. in a pediatric practice where the mother was seen. On 03-JAN-2008 the mother received her first dose of GARDASIL (Lot #659180/1758U, expiration date 25-JUN-2010). The nurse was unaware if the patient received any subsequent doses of GARDASIL, there was no record of any further doses given in their office. The nurse did not have any specific information about the patient's obstetrical history, as the next time they saw the patient, she was there with the babies. The babies were born on 14-SEP-2008, both are male. There was no record of the mother's estimated conception date, but the babies were reported to have been delivered at 29 weeks gestation (delivery type was not reported). The nurse did not know if the patient's hospitalization was longer than a "typical" stay for a vaginal or C-section delivery. It was reported that baby "A" weighed 1420 grams and baby "B" weighed 1450 grams. Baby "A" spent one month in the Neonatal Intensive Care Unit and required one week on a ventilator. He had no bleeds, however was diagnosed with necrotizing enterocolitis, which resolved with a formula change. On 15-NOV-2008 baby "A" was re-admitted to the hospital for two days with pneumonia (no further details). Baby "B" was "OK" as far as the nurse knew, no ventilator and no bleeds. Upon internal review, "premature baby with 29 weeks gestation" was determined to be an other important medical event. Additional informa

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **337458-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Jan-2009	10-Jan-2009	1	15-Jan-2009	26-Jan-2009	NY		26-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2622AA	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1284X	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB257AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Joint swelling

Symptom Text: Patient states that right wrist was swollen on 01/10/09 about 24 hours after MENACTRA and HAVRIX was administered in right arm.

Other Meds: Contraceptive patch

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 337465-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Dec-2008	21-Dec-2008	4	15-Jan-2009	20-Jan-2009	MD		27-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Anorexia, Asthenia, Autonomic nervous system imbalance, Condition aggravated, Fall, Fatigue, Fibromyalgia, Gait disturbance, Gastrointestinal inflammation, Hypoaesthesia, Lethargy, Migraine, Muscle spasms, Myalgia, Pain, Pallor, Paraesthesia, Syncope, Vaccination complication, Vaccine positive rechallenge, Weight bearing difficulty

Symptom Text: Within 3 days of receiving the 2nd round of the HPV vaccination, my daughter began with severe pain in her arms, legs, and hips, difficulty walking which progressed to needing assistance, excruciating pain, numbness/tingling in her lower extremities/feet with weakness in her legs, inability to hold up her body weight, legs would buckle and she would fall when trying to stand, constant muscle cramps and charly horses just with normal movement, her skin was painful to touch, severe aching even with rest, fatigued, pale, lethargic, generalized weakness. 1/21/09 MR received for DOS 1/1-2/2009 with D/C DX: Fibromyalgia. L lens cataract s/p surgical correction. Idiopathic anaphylaxis. H/o syncopal spells. GERD. Migraine H/As. S/P T&A. H/o prematurity. Pt presented to ER with c/o generalized muscle pain, paresthesias and weakness since vax on 12/17/08. Pt has been "bed bound" except for trips to BR with assistance. Also reports generalized weakness, fatigue and anorexia. Currently tapering off steroids prescribed by PCP. PE (+) for antalgic gait and lower extremity pain. 2/20/09 MR received. Pt initially presented 12/26/08 with c/o pain all over since 2nd HPV shot. Had some aches after 1st but pain flared after most recent. Seen by GI for abdominal pain and given dx of inflammation if GI. Assessment: Adverse reaction to Gardasil flaring ANS.

Other Meds: Lyrica, Amytriptyline, Entocort, Birth control pill, Ultram

Lab Data: blood work, nerve conduction study. Labs and Diagnostics: CBC with WBC 13,940, RBC 5.28, Hgb 15.4. Hct 46.1. UA (+) for 52 WBCs. EMG/NCS WNL. ALT 54. AST 27. Alk Phos 80 (low). LDH 266. Ferritin low at 9.

History: Idiopathic Anaphylaxis, Fibromyalgia, GERD. PMH: NKA. prematurity. Congenital cataract. Fibromyalgia-dx 2/2008.

Prex Illness: None.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337467-1** **Related reports:** 337467-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Jan-2009	14-Jan-2009	0	15-Jan-2009	11-Feb-2009	WA		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651Z	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Fatigue, Lethargy, Nausea, Pyrexia

Symptom Text: High fevers 102+, Nausea, Dizzy, lethargic, weak & tired

Other Meds: none

Lab Data:

History: none

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337467-2** **Related reports:** 337467-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Jan-2009	14-Jan-2009	0	18-Feb-2009	20-Feb-2009	WA		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Nausea, Pyrexia

Symptom Text: High fever, Dizziness, Weak-ness, Nausea. CLARITIN + BENADRYL+TYLENOL.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **337490-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Jan-2009	14-Jan-2009	0	15-Jan-2009	11-Feb-2009	CA		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grip strength decreased, Injection site pain, Pain in extremity

Symptom Text: Complained of pain radiating from injection site in left deltoid down to her hand diminished grip strength, normal sensation. No s/s inflammation. Ibuprofen 400 mg of 8 hrs next 24 hrs. Follow up sooner if worsening pain or increasing weakness.

Other Meds: PROZAC 20 mg; VYVANSE 30 mg

Lab Data: None

History: ADHD, insomnia, allergic rhinitis, major depression

Prex Illness: None

Prex Vax Illns:

Vaers Id: **337545-1** **Related reports:** 337545-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Aug-2007	01-Oct-2007	40	16-Jan-2009	21-Jan-2009	MO		16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abscess, Alopecia, Anal fissure, Arthralgia, Asthenia, Blood corticotrophin increased, Blood glucose abnormal, Colonoscopy, Constipation, Contraception, Cough, Dehydration, Depression, Diabetes mellitus, Diarrhoea, Disorientation, Dizziness, Dysarthria, Dysuria, Ear pain, Educational problem, Fatigue, Folate deficiency, Head injury, Headache, Hyperinsulinism, Hypoaesthesia, Infectious mononucleosis, Joint effusion, Joint swelling, Lipohypertrophy, Multiple allergies, Nasal congestion, Neuropathy peripheral, Oropharyngeal pain, Paraesthesia, Pharyngitis, Polycystic ovaries, Pyrexia, Rash, Rash generalised, Rash pruritic, Rash pustular, Rectal haemorrhage, Respiratory tract infection, Rocky mountain spotted fever, Sinusitis, Skin striae, Snoring, Tonsillar disorder, Tremor, Urinary tract infection, Vision blurred, Vomiting, Weight decreased, Weight increased

Symptom Text: 10/07- Vomiting, Diarrhea Daily-No reason hospitalized for dehydration lost 30lbs. Continued to be sick- Colonoscopy, MRI problems with Blood sugar 12/08- Fluid on knees, All over rash, dizzy and disoriented, UTI's 1/21/09 Received ER medical records of 4/08 through 1/9/2009. 4/30/08 Seen for rectal bleeding probably due to hemorrhoids or anal fissure. Referred for colonoscopy. 6/25/08 ER visit for HA s/p struck on head accidentally by hand weight. CT scan WNL. Stable & d/c to home. 9/15/08 ER for fever/chills, cough, diarrhea rash, stuffy nose, ear pain, sore throat. Had recently been diagnosed w/diabetes & was on oral meds & BCP. 1/9/09 ER for tired, dizzy,numbness, shaking in knees & hands, burry vision, slurred speech. Had cough, fever, chills, intermittent abd pain, chronic diarrhea. Dx w/mononucleosis. 1/23/09 Received ER medical records of 12/18/2008. FINAL DX: records reveal patient see for diarrhea x 2 weeks, mild dehydration. Tx w/IVF & d/c to home. 2/2/09 Received ID & Immunology & Endocrine Clinic notes . Endocrine 9/30/2008 FINAL DX: hyperinsulinemia, oligomenorrhea likely POS, snoring, URI, abnormal weight gain Patient was on metformin at this time & checking blood sugars daily. ID & Immunology 1/20/2009 FINAL DX: severe chronic progressive fatigue syndrome w/chronic diarrhea & abd pain & vomiting, chronic HA, orthostatic dizziness, peripheral neuropathy symptoms, large joint arthralgia, patchy alopecia, weakness, folate deficiency, ?hyperinsulinemia, slight buffalo hump w/elevated ACTH, glucose metabolism abnormality Records indicate patient had fatigue x 2 mo, constant HA & diarrhea, frequent abdominal discomfort, arthralgias large joint w/occasional swelling. S/S present since 11/2007 following acute illness of vomiting & diarrhea requiring IVF. Illness lasted approx 1 mo & pt lost 25#. Since then had decreased energy & frequent URIs, academic decline, unable to participate in sports. Patches of hair loss, numbness & tingling LEs, intermittent itchy rash. Re

Other Meds: YASMINE

Lab Data: LABS: Blood work 1/20/09: ESR 32(H). CRP <0.5. CBC & chemistry WNL. ANA neg. IgA 73, IgG 1532, igM 105. CT 4/2008 c/w tonsillar abscess. MRI head 7/2008 WNL. Rocky Mountain spotted fever test (+). Abdominal x-ray revealed constipati

History: None PMH: UTIs, HA, dehydration, contraception irregular periodsrecently changed from depoprovera to yasmin

Prex Illness: None

Prex Vax Illns:

Vaers Id: **337545-2 (S)** **Related reports:** 337545-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Aug-2007	01-Oct-2007	40	03-Feb-2009	04-Feb-2009	--	WAES0901USA03671	04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Blood glucose abnormal, Dehydration, Disorientation, Dizziness, Nausea, Rash, Urinary tract infection, Vomiting

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female patient with no known drug allergies, who on 22-AUG-2007 was vaccinated with the first dose of GARDASIL (lot#657736/0389U) 0.5ml intramuscularly at the health department. In October 2007, the patient started experiencing nausea and vomiting, which required hospitalization twice for dehydration. The patient also experienced episodes of rash, dizziness, disorientation, "problems with blood glucose", and urinary tract infections. Patient sought medical attention by calling the health department. The patient has been evaluated by an unspecified endocrinologist but a diagnosis has not been made at the time of the report. A colonoscopy and other unspecified tests were performed which were negative. Patient received her second and third dose of GARDASIL on unspecified dates. At the time of this report the patient had not yet recovered. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: colonoscopy, negative; diagnostic pathological, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337546-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Aug-2008	28-Aug-2008	1	16-Jan-2009	11-Feb-2009	MO		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	62638AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	02889AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	174OU	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Myalgia, Pyrexia, Rash

Symptom Text: Within 24 hours of HPV dose given on 08/27/2008 - Had rash over trunk of body, Lasting 3 days did not seek medical attention. Within 24 hrs after 6/25/2008 vaccinations- had high fever, muscle aches 3-5 days, did not seek medical attention.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337589-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Oct-2008	15-Oct-2008	13	16-Jan-2009	20-Jan-2009	FR	WAES0901USA00866	20-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diabetes mellitus

Symptom Text: Information has been received from a Health Authority (HA ref. DK-DKMA-20083075) to a foreign agency. It was reported that a 14 year old female patient on 02-OCT-2008 was vaccinated IM with GARDASIL (batch number and site of administration not reported). There was no concomitant medication. On 15-OCT-2008 the patient developed diabetes. The patient was hospitalized (date and duration not reported). The patient had no relevant medical history. At the time of report, the patient had not recovered. Other business partner numbers included: E2009-00054. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 337590-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	07-Jan-2009	07-Jan-2009	0	16-Jan-2009	20-Jan-2009	IL	WAES0901USA01109	20-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Bronchospasm, Ocular hyperaemia, Rash

Symptom Text: Information has been received from a physician concerning a 22 year old female patient with no pertinent medical history and no known drug allergy who on 07-JAN-2009 was vaccinated with the first IM dose of GARDASIL (lot # 659184/0843X). Concomitant therapy included hormonal contraceptives (unspecified). On 07-JAN-2009 the patient experienced redness of the eye, bronchospasms and rash pennciallian. The patient went to ER (it was not known if the patient was admitted). At the time of this report, the physician stated that the patient was fine. Redness of the eye, bronchospasms and rash pennciallian were considered to be immediately life-threatening. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 337591-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-Dec-2007	08-Dec-2007	1	16-Jan-2009	20-Jan-2009	FL	WAES0901USA01201	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0188U	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Fibromyalgia, Insomnia, Myalgia, Pain

Symptom Text: Information has been received from a physician concerning a 15 year old female with no previous medical, family, or social history who on 19-NOV-2007 was vaccinated with a first dose of GARDASIL IM. The patient's mother told the physician that a few weeks after the GARDASIL, the patient had body aches and generalized pain. The patient was seen by her pediatrician and a neurologist, and they both thought that it was from GARDASIL. The neurologist had diagnosed the patient with fibromyalgia. CPK was elevated. At the time of reporting, the patient was being treated with cyclobenzapine hydrochloride (MSD), melatonin, imipramine, and chiropractic therapy for the pain and insomnia. The patient has missed many days from school and volleyball because of the fibromyalgia. At the time of reporting, fibromyalgia persisted. The reporter considered fibromyalgia to be disabling. Additional information has been requested. 1/29/09-According to the general practitioner, fibromyalgia persisted while insomnia was being controlled on medication (not recovered).Onset Date: Approximately December 2007 ("a few weeks after Gardasil", per pt's mother) 2/17/09-records received for DOS 7/23/08-neurology notes-C/O muscle aches and pains as well as sleep disturbance. Previously evaluated on 5/12/08, continues with pain on an almost daily basis. However no discomfort in past few days. Impression:history of severe pain in legs and arms and along cervical spine. Sleep disturbance resolved with use of Seroquel. No neurological cause of pain. No rheumatology consult at this time due to insurance issues.

Other Meds: Unknown

Lab Data: plasma creatine kinase, elevated 2/17/09-records received-MRI brain normal, MRI cervical spine minimal bulge at C5 to C6. Pseudotumor Chiari malformation and spinal instability ruled o ut. EMG and nerve conductions tudies normal. CPK sligh

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **337592-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	17-Dec-2008	17-Dec-2008	0	16-Jan-2009	20-Jan-2009	CA	WAES0901USA01203	23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	UNKNOWN MANUFACTURER	NULL		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0652X	0	Right arm	Intramuscular	
	MEN	UNKNOWN MANUFACTURER	NULL		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Feeling hot, Inappropriate schedule of drug administration, Loss of consciousness, No therapeutic response

Symptom Text: Information has been received from a health professional concerning a 19 year old female patient who on 17-DEC-2008 was vaccinated with the first dose of GARDASIL IM into her right arm (lot # 661766/0652X). On 17-DEC-2008 the patient also received MENACTRA and Tdap in her left upper arm. On 17-DEC-2008 ("a few seconds later") the patient experienced convulsed and passed out. The patient stated that she didn't feel funny after the first two shots. When she received GARDASIL she felt a rush of warmth in her arm then she experienced lightheaded and blacked out. At the time of reporting, the patient had recovered. It is unknown if the patient sought medical attention. Upon internal review, convulsed was determined to be an other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 337593-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	27-Oct-2008	06-Nov-2008	10	16-Jan-2009	20-Jan-2009	FR	WAES0901USA01274	20-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Joint swelling, Oedema peripheral, Pain in extremity, Spondylitis, Tenosynovitis

Symptom Text: Information has been received from a health authority concerning a 19 year old female adult who received on 27-OCT-2008 one intramuscular dose (0.5 mL) of GARDASIL (Lot number and site of administration not reported). On 06-NOV-2008, she noticed pain in her legs, distal of her knees with swelling in the ankle and the back of her feet. The pain was particularly pronounced in the evening and led to immobilization. The symptoms initially improved with therapy of mefenamic acid, but then turned back. The patient was hospitalized on 20-NOV-2008. In the area of the forefoot on both sides tendovaginitis was diagnosed, which improved initially after injection of steroids. In order to be pain free the patient was additionally treated with systemic NSAIDS. The laboratory and serological tests showed the following results: Leukocytes and CRP within the normal range, blood sedimentation rate of 14 mm slightly increased, HLA-B27, rheumatoid factors, anti CCP antibodies, antinuclear antibodies negative and virus serology negative. Complement reaction on Campylobacter jejuni with 1:30 reactive. A reactive tendovaginitis/arthralgia as well as a first episode of a seronegative spondylarthritis diagnosed by the HCP as probable causality. On 24-NOV-2008, the patient complaining discarded from hospital without symptoms. Other business partner numbers included: E2009-00095. Additional information has been requested.

Other Meds: Unknown

Lab Data: WBC count, normal range; Serum ANA, negative; Serum C-reactive protein, normal range; Serum Campylobacter jejuni Ab, complement reaction with 1:30 reactive; Serum cyclic citrulline peptide IgG Ab, negative; Serum rheumatoid factor, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337594-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		16-Jan-2009	20-Jan-2009	FR	WAES0901USA01344	20-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthritis, Chills, Juvenile arthritis, Polyarthritis, Rash

Symptom Text: Information has been received on 08-JAN-2009 from a health care professional concerning a 16 year old female patient who had received the second dose of GARDASIL (batch #, route and site unknown) on an unspecified date. A few weeks later, she experienced evanescent cutaneous eruptions, peripheral arthritis and chills without fever. Blood analysis: normal except inflammation markers and elevated white blood cell count. Skin biopsy consistent with Still's disease: Large number of neutrophils. The diagnosis of Still's disease has been established after other possibilities have been ruled out; diagnosis of exclusion. Treatment with Cortisones as from December 2008, patient not yet recovered. No reporter patient's medical history. First dose of GARDASIL administrated date unknown. The Health Care Professional considered Still's disease adult onset, chills, polyarthritis and skin eruption to be other important medical events. Other business partner numbers include E2009-00166 and BGAR2009-003. No further information is available.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, Blood analysis was Normal; diagnostic laboratory test, Blood analysis inflammation markers; skin biopsy, consistent with Still's disease: Large number of neutrophils; WBC count, elevated

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337616-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	04-Nov-2008	15-Dec-2008	41	16-Jan-2009	11-Feb-2009	AZ	AZ0901	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	4	Right arm	Intramuscular	HEPA MNQ TDAP

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Had 1st HPV on November 4th, 2008. she stated she didn't know she was pregnant. Had a miscarrieage in December. (Came in today becase she is due her 2nd dose.)

Other Meds: None

Lab Data: N/A

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337624-1 (S)** **Related reports:** 337624-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Aug-2007	15-Sep-2007	22	18-Jan-2009	23-Jan-2009	IA		30-Mar-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2392BA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1061U	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB186AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal discomfort, Activities of daily living impaired, Aggression, Alopecia, Arthralgia, Chest pain, Conversion disorder, Dehydration, Disturbance in attention, Dizziness, Dysmenorrhoea, Dysphonia, Dyspnoea, Ear pain, Fatigue, Feeling abnormal, Hypotension, Joint swelling, Menstruation irregular, Muscular weakness, Musculoskeletal discomfort, Myalgia, Nausea, Neurological examination normal, Oropharyngeal pain, Oxygen consumption decreased, Pain, Pallor, Patellofemoral pain syndrome, Personality change, Polydipsia, Syncope, Tremor, Viral infection, Viral upper respiratory tract infection, Vision blurred, Vomiting, Weight decreased

Symptom Text: Seizure activity, lower paralysis, exhaustion, nausea and vomiting, brain fog, difficulty concetrating, low blood pressure, Painful periods and off cycle, chest pain, joint pain, muscle pain and weakness, blurred vision, tremors, weight loss, personality change, dizziness, difficuly breathing, oxygen deprived, hair loss, Skin pale. 2/25/09 Received PCP medical records of 10/25/07-12/24/2008. FINAL DX: none provided Records reveal patient experienced good health on 10/25/07. RTC 11/15 w/sore throat, left ear pain & nausea x 1 wk. Dx w/viral URI. RTC 11/23/07 w/left knee pain/swelling x 5 yrs. Dx w/patellofemoral syndrome, tx w/meds & referred to PT. RTC 1/8/08 w/neck & throat discomfort. Dx w/voice weakness, probable strained cricopharyngial nerve. Tx w/meds & referred to ENT who dx w/dysphonia following likely vocal misuse. RTC 2/8/08 w/fatigue, upset stomach, weight loss, polydipsia & nausea x 1 wk. RTC 2/12/08 s/p fainting in school, lightheaded x 1 wk. Dx w/syncopal episode & possible dehydration, weight loss & fatigue. Tx w/IVF & meds. DM w/u neg. RTC 2/28 s/p ER visit for generalized pain. Had been hospitalized previous wk, dx w/pseudoseizure & followed by neuro. 3/27/09 Received Neuro consult medical records of 2/25-3/7/2008. FINAL DX: none provided. Consult states excessive tiredness, nausea & weight loss likely secondary to viral illness; intermittent weakness of legs posssibly due to dehydration vs presyncope; & recent onset of nonepileptic shaking events. Records reveal patient experienced fatigue during vacation out of state approx 3 wks prior to eval. Saw PCP after vacation for nausea, weakness. Hospitalized x 3 days. Eval by peds neuro at that time & dx w/syncope vs near syncope. Improved & d/c to home. Was able to return to school f/t & traveled out of state. Collapsed & had to be brought back home w/trembling of extremities. Admitted to hospital for further neuro eval. Exam & testing all WNL. D/C to home. Seen in ER x 2 for recurrence of shaking & aggressive behav

Other Meds:

Lab Data: PCOS LABS: video EEG, MRI brain & spine WNL. CPK WNL. Alk phos 51(L). PAP smear WNL.

History: Allergy penicillin PMH: Asthma, strep throat.

Prex Illness: none

Prex Vax Illns: severe fatigue~HPV (Gardasil)~1~16~In Patient

Vaers Id: **337624-2 (S)** **Related reports:** 337624-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Oct-2007	01-Nov-2007	31	20-Feb-2009	23-Feb-2009	--	WAES0902USA02613	23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Alopecia, Amnesia, Blood pressure decreased, Dyspnoea, Fatigue, Hypoaesthesia, Loss of consciousness, Malaise, Muscle spasms, Muscle twitching, Nausea, Paralysis, Tremor

Symptom Text: Information has been received from an internet report concerning a 16 year old female who in August 2007 received a first dose of GARDASIL and a dose of meningococcal vaccine (unspecified). In October 2007, the patient was vaccinated with a second dose of GARDASIL. The patient did not receive any other shots with her second dose of GARDASIL. It was a month or so after the second dose (in approximately November 2007) that the patient started getting sick. It was reported that the patient "played four sports, danced in her high school's show choir and earned top grades without even trying". The patient, at time of reporting, was exhausted all the time. She was nauseated. She passed out at show choir and blacked out at school. One day her legs went numb. She couldn't walk. It was reported that for a year, the patient had experienced four episodes of temporary paralysis, back spasms so painful "patient would tell her mom 'bye' and stop breathing", hospitalizations, "more 911 calls than the patient could count". Trip after trip to doctors who couldn't seem to find anything wrong. The patient's mother stated that she was convinced the vaccine "turned her perfectly healthy daughter into a chronically ill teenager". It was reported that the patient's hair fell out in clumps. Her nausea was ever present. Her blood pressure dropped dangerously low. She couldn't breathe. Most of the time, the patient couldn't remember what she had read from one day to the next. It was reported that when the patient tried out for basketball at her high school this year, her legs were shaking and she couldn't breathe after two drills. The patient was taking "a handful of pills every day and had to carry a special bag of medical supplies in case she had an 'episode'". It was reported that when the patient had good days, "she knew the twitches in her back and the funny feeling in the back of her head would come back, signaling another episode. Her blood pressure would plummet. She would hear her mother or her boyfriend talking to her, but she w

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337625-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	06-Jan-2009	07-Jan-2009	1	18-Jan-2009	11-Feb-2009	VA		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Chest pain, Headache, Immediate post-injection reaction, Muscular weakness, Nausea, Nodule, Pain in extremity, Pruritus, Rash

Symptom Text: Immediately after receiving shot,severe pain in injection arm.Had to rest for 10mins in office.Beginning the next day, had a painful knot in back, pain in left lung if deep breath is drawn, muscle weakness on left side from shoulder to fingertips all the way down to toes, muscle weakness, nausea, headache,rash on neck and itchiness on chest.These symptoms progressed and got worse and by Friday. Call Dr's office. Was told the symptoms I described had nothing to do with the Gardasil Shot. After I pressed the issue, the doctor returned my call, stated their office could do nothing and suggested I should see my primary care physician. The primary care doctor was booked solid so went to urgent care center. The doctor on duty did not know much about gardasil and suggested we go to the emergency room at another hospital if symptoms got worse. I took my daughter home and watched over her. She did begin to feel better and as of today the symptoms have subsided. This was her 2nd gardasil shot, the first was given 7/2008. She is scheduled to receive the 3rd shot on 2/3/2009. I am very afraid to have the 3rd shot administered because of the difficulty she experienced with the 2nd shot and the lack of support she received from her doctor and the urgent care doctor.

Other Meds: yaz birth control

Lab Data: A blood test was done at the urgent care office for any abnormality and results were okay.

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337628-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Jan-2009	19-Jan-2009	0	19-Jan-2009	29-Jan-2009	TN		29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	9725103		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: SYNCOPE

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337651-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Jan-2009	20-Jan-2009	--	WAES0901USA01615	21-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Kidney infection

Symptom Text: Information has been received from a registered nurse who reported that the one of her patient's mother reported that there was a female patient who was vaccinated with the third dose of GARDASIL (Lot and route unspecified) and three days later she had a seizure. The nurse reported that the patient was sent by ambulance to the hospital and was hospitalized (duration not reported). The nurse reported that the mother also mentioned that the patient, on an unspecified date, had kidney infection. It was unknown if the kidney infection occurred before the third dose of the vaccine or before of the GARDASIL. As of 13-JAN-2009 the outcome of the patient was unknown. Attempts are being made to verify the existence of an identifiable patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 337678-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-Sep-2008	19-Sep-2008	0	20-Jan-2009	29-Jan-2009	KY		06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Eyelid oedema

Symptom Text: Mother states "eye lids swelling, and severe stomach cramps". Was not seen by physician in office after symptoms occurred.

Other Meds: None

Lab Data:

History: NKA

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337685-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Jan-2009	15-Jan-2009	0	20-Jan-2009	29-Jan-2009	AL		29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1396X	1	Left leg	Unknown	
	HPV4	MERCK & CO. INC.	0575X	1	Right leg	Unknown	
	HEPA	MERCK & CO. INC.	0800U	0	Left leg	Unknown	
	MNQ	SANOFI PASTEUR	U2822AA	0	Right leg	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Immediate post-injection reaction, Skin discolouration, Urticaria

Symptom Text: red wheel apprx 3" immediately after receiving V2V- wheel baded after 24 hrs after 24 hrs - 3 days after a red/blue discoloration.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337693-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Jan-2009	16-Jan-2009	0	16-Jan-2009	11-Feb-2009	WI		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0702X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncopal episode following GARDASIL administration. Held in clinic for 15 min following incident, with BP initially 122/64 and 126/76 15 min later. Given 12oz apple juice while reclining.

Other Meds: None

Lab Data:

History: Allergic ICN, Augmentin

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337705-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Jan-2009	05-Jan-2009	2	20-Jan-2009	30-Jan-2009	MO	MO-2009-01	30-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea

Symptom Text: Headache in "forehead". Nausea - no vomiting. Onset 01/05/09

Other Meds: Vitamin, generic Zyrtec, oral contraceptives

Lab Data: N/A

History: seasonal allergies

Prex Illness: none

Prex Vax Illns:

Vaers Id: **337711-1** **Related reports:** 337711-2; 337711-3; 337711-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	28-Apr-2008	15-May-2008	17	20-Jan-2009	30-Jan-2009	LA		11-Mar-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0279X	0	Right arm	Intramuscular	MNQ
VARCEL	MERCK & CO. INC.	1584U		Left arm	Subcutaneously	TDAP
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B020AA	0	Left arm	Intramuscular	VARCEL
MNQ	SANOFI PASTEUR	U2551AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Balance disorder, Blood creatinine decreased, Dizziness, Electrocardiogram normal, Loss of consciousness, Syncope, Visual impairment

Symptom Text: I believe the symptoms started after the second dose. Delainey has been having fainting spells where she gets dizzy and sees black with white spots and she loses her balance. It only lasts a few seconds. It has happened at least 25 times or more. 2/23/09 PCP rec received for OV 12/15/08 with c/o black-out episodes x several months. Sees "spots" then blacks out. Reported loses vision x 4-5 seconds with slow return. PE WNL. Sent for labs and testing.

Other Meds: Motrin as needed

Lab Data: Her pediatrician has checked her vital signs, sent her for blood work, did an ultrasound on her heart, and a CT scan. All came back normal. Labs and Diagnostics: ECG WNL. Creatinine (L) 0.7. Head CT (-).

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **337711-2** **Related reports:** 337711-1; 337711-3; 337711-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	28-Apr-2008	15-May-2008	17	21-Jan-2009	02-Feb-2009	LA		05-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1740U	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B02DAA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1584U	0	Left arm	Subcutaneously	
MNQ	SANOFI PASTEUR	U21551AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Mom called 1/20/2009 to report patient has experienced 2-5-30 "dizzy, fainting spells" since may of 2008. No untoward reaction noted at time of administration for all 3 doses

Other Meds: None known

Lab Data: Per mom- Pediatrician running tests

History: None Known

Prex Illness: None Known

Prex Vax Illns:

Vaers Id: **337711-3** **Related reports:** 337711-1; 337711-2; 337711-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	--	WAES0901USA03465	09-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Syncope

Symptom Text: Information has been received from a nurse concerning a "less than 18 years old" female patient who was vaccinated with the third dose of GARDASIL (lot # not provided). Subsequently, patient fainted multiple times and became weak. Patient sought unspecified medical attention by seeing the nurse. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **337711-4** **Related reports:** 337711-1; 337711-2; 337711-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	28-Apr-2008	15-May-2008	17	18-Feb-2009	25-Feb-2009	--	WAES0901USA03153	09-Mar-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	1740U	0	Unknown	Intramuscular	
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a pharmacist concerning a 12 year old female patient who on 28-APR-2008 was vaccinated with the first dose of GARDASIL (Lot # 659962/1740U), intramuscularly. Concomitant therapy included diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid, VARIVAX and MENACTRA. The pharmacist reported that the patient had been experiencing dizzy spells since receiving her first dose of GARDASIL. The dizzy spells began on 15-05-2008 and she had had 25-30 dizzy spells since that time. The pharmacist reported that GARDASIL series had been completed, the dates of those immunizations was unknown by the pharmacist. At the time of the report, the patient had not recovered. The patient sought medical attention through an office visit. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337743-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	20-Jan-2009	20-Jan-2009	0	20-Jan-2009	29-Jan-2009	NY		05-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Felt faint 30 sec post injection, laid down that-ammonic inhalant. 15 min later again syncope episode ammonia, inhalants & crackers & juice given

Other Meds: TAZ

Lab Data:

History:

Prex Illness: NO

Prex Vax Illns:

Vaers Id: **337752-1** **Related reports:** 337752-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Feb-2008	28-Feb-2008	24	20-Jan-2009	25-Jan-2009	NY		18-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Cardiac monitoring normal, Chest pain, Dizziness, Dyspnoea, Erythema, Fatigue, Gaze palsy, Headache, Malaise, Memory impairment, Neck pain, Neurological examination normal, Pallor, Palpitations, Panic attack, Paraesthesia, Photophobia, Swelling, Syncope, Tonic clonic movements, Unresponsive to stimuli, Vision blurred

Symptom Text: 25 days after GARDASIL #3 developed syncopal episodes- recurrent, over course of 6 mos. Neuro and cardio work- ups WNL. 1/22/09 MR received from PCP including multiple neurology and cardiology consults from 8/07-1/13/09. OV 2/4/08 for recurrent sinusitis since 9/2007. HPV#3 given. Returned 3/3/08 with c/o H/As and dizziness as well as 1 fainting episode over past few days. Tx with abx for sinusitis and vasovagal syncope discussed. Pt fainted after blood draw in office with continued fuzzy vision and inability to get up. Unresponsive x 45 minutes.To ER. Received IVF which caused swelling. Still feeling unwell with photophobia, H/A, lightheadedness and neck soreness. No memory of ambulance ride. Still c/o H/A 3/6/08. Somewhat better 3/14/08 with exception of exhaustion. Several more episodes of H/A, fainting, chest ache with racing heart, stomachaches. Episode 9/17/08 face red, extremities grey with tonic-clonic movements of extremities and eyes rolling back. Unresponsive x 45 minutes. Referred to Neuro and Cardiology. Neuro consult 4/14/08 and 9/25/08 with normal exams. DX: Syncope. Panic attacks. Vasovagal syncope. Cardiolgy consult 10/2/08 for eval of syncope with shock-like, stabbing chest pain which self resolved. Subsequent episode with heart racing and difficulty breathing. No dx mde. Improved by 1/13/09.

Other Meds: BIAXIN

Lab Data: Labs and Diagnostics: CT scan (-). EKG WNL. Echo WNL. EEG WNL. MRI/MRA of brain WNL. Glucose tolerance test (-). Holter monitoring (-). Repeat EEG CMV IgG Ab (+), IgM (-). Mycoplasma pneumoniae IgG Ab 3.25 (H), IgM (-). Parvo B19 Ab IgG

History: PMH: kidney reflux as toddler. T&A age 4. Ovarian cyst. mild scoliosis. Apnea and reflux as infant. Allergy to sulfa

Prex Illness: Sinusitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337752-2** **Related reports:** 337752-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Feb-2008	28-Feb-2008	24	16-Mar-2009	25-Mar-2009	--	WAES0902USA02831	14-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 15 year old female who on 04-FEB-2008, was vaccinated with a dose of GARDASIL (lot# null). Concomitant therapy included BIAXIN. On 28-FEB-2008, 25 days after GARDASIL #3 developed syncopal episodes-recurrent, over course of 6 months. Neuro and cardio work-ups within normal limits. The original reporter was not provided. The VAER ID # 337752. No further information is available.

Other Meds: BIAXIN

Lab Data: Neurological examination, within normal limits; Cardiac monitoring, within normal limits.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337755-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	10-Jan-2009	11-Jan-2009	1	20-Jan-2009	29-Jan-2009	NJ		29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: 1/12/09 received call from mother she states that about 34 hours post vaccination hives appeared on arms, BENADRYL given with relief. On 1/12/09 hives appeared on face BENADRYL given. Upon returning home from school child had hives on torso, back and face. BENADRYL given. 1/13/09 child awoke with hives on face and arms BENADRYL given with no further outbreaks.

Other Meds: OTC for eczema

Lab Data:

History: Eczema

Prex Illness:

Prex Vax Illns:

Vaers Id: **337758-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Jan-2009	15-Jan-2009	0	20-Jan-2009	29-Jan-2009	CA		29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1156X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Patient had fainted about 2-4 min post vaccination with GARDASIL and VARIVAX. As family signed out in waiting room. Regained consciousness, 5 min post.

Other Meds: None

Lab Data: None

History: None; previous fainting on blood w/u

Prex Illness: None

Prex Vax Illns:

Vaers Id: 337761-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Jul-2007	20-Aug-2007	33	20-Jan-2009	30-Jan-2009	NM		09-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0960F	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Arthritis reactive, Cough, Decreased appetite, Dysstasia, Fatigue, Gait disturbance, Headache, Injection site pain, Joint range of motion decreased, Joint stiffness, Joint swelling, Mouth ulceration, Oropharyngeal pain, Pain, Pain in extremity, Petechiae, Polyarthritis, Pyrexia, Spina bifida occulta, Spondylolysis

Symptom Text: Week of 1/23/2007 pain at site of GARDASIL injection #2 5 week past GARDASIL. Myalgias, hip pain, elbow, wrist, hand, finger, knee, foot pain, fatigue, petechiae legs, decreased ROM, lab NL. Seen by rheumatology, resolved completely 4/3/08. Followed by rheumatology no reoccurrence as of 1/09. 1/29/09 Received PCP medical records which included Rheum & Ortho consults. FINAL DX: Polyarticular reactive arthritis Records reveal patient experienced usual state of good health on 5/18/07, day of HPV#1 & Varicella vaccinations. RTC 8/23/07 with symptoms x 3 days of pain & swelling of multiple joints; gen aching; fatigue; decreased appetite; difficulty standing, walking & making fist or extending fingers; low grade fever; oral ulcers; scattered petechiae of LEs; searing pain where HPV#2 given 7/18/07. 6/20-23 had illness w/cough, sore throat, fatigue, HA, fever, pain in hips/ankles, stiff joints. Rheum consult of 9/5/07, 4/3/08, 7/10/08 & 1/5/09. Ortho consult of 7/30/08. Referred to pulm & ID on 1/5/09.

Other Meds:

Lab Data: ANA, ASO, CRP, 3.5; RFU, negative; VaU, negative; CGB dip, negative; CMR, negative; ESR, negative LABS: CBC, chemistry, ESR, ANA, RF, & UA all WNL. CRP 3.5(H). Hip/pelvis x-ray & CT scan abnormal & revealed pars defects, spina bifida o

History: Laryngitis cough, 4/07 PMH: Mononucleosis. family hx: arthritis.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337776-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Jan-2009	Unknown		21-Jan-2009	11-Feb-2009	CO		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1070R		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Injection site warmth

Symptom Text: Received HPV vaccine on January 15. Aunt called on Jan. 16 and reported that her niece had swelling and redness from site of injection to her elbow. Area was warm to touch. Told to put ice on area and take Tylenol and call her Doctor. This is her 2nd HPV dose.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 337792-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	20-Jan-2009	21-Jan-2009	1	21-Jan-2009	03-Feb-2009	IL		09-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0029X	2	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Asthenia, Chills, Dizziness, Fatigue, Headache, Hyperaesthesia, Insomnia, Mood altered, Nervousness, Pain, Paraesthesia, Pyrexia, Reflex test normal, Rhinitis, Sensation of heaviness

Symptom Text: extreme weakness, fatigue, dizziness, severe mood changes, anxiety, low grade fever, severe headaches, chills 1/30/09 Received PCP medical records of 1/22-1/30/2009. FINAL DX: Records reveal patient experienced weakness, dizziness, moody, decreased energy after HPV #1 & #2 given 7/10/2008 & 9/11/08. Increased fatigue, moody, nervous, heaviness in legs, sensitive to touch, generalized aching, low grade fever, chills after HPV#3 1/20/09. RTC 1/30 symptoms except dizziness persist & now w/tingling in back & arms. Difficulty sleeping. DTRs WNL. Dx w/rhinitis & possible early sinusitis. Tx w/nasal spray & given Rx for antibiotics if symptoms persist.

Other Meds: none

Lab Data: LABS: WBC 13.1(H). ESR 4(N).

History: allergy to Bactrum and Ceclor PMH: bronchitis, pneumonia. Hives. Family hx: arthtis, DM, HTN.

Prex Illness: none

Prex Vax Illns: Lindsey D Hawkins~HPV (Gardasil)~2~25~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337796-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Jan-2009	05-Jan-2009	0	21-Jan-2009	11-Feb-2009	MO		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TD	UNKNOWN MANUFACTURER	?	2	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	?	0	Left arm	Unknown	
	HEPA	UNKNOWN MANUFACTURER	?	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Loss of consciousness, Myalgia, Pain

Symptom Text: Passed out immediately after HPV shot. Had stinging on right side above pelvic bone for a couple of days after. Had full body muscle soreness for a couple of days after. Had dizziness during first menstruation after.

Other Meds: None

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: **337797-1 (D)** **Related reports:** 337797-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	03-Jan-2007	31-Aug-2007	240	21-Jan-2009	22-Jan-2009	NM		08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0955F	0	Left arm	Intramuscular	FLU HPV4

Seriousness: DIED, SERIOUS

MedDRA PT Abnormal behaviour, Autopsy, Death, Dermatitis contact, Fatigue, Headache, Hypersomnia, Menorrhagia, Menstrual disorder, Metrorrhagia, Muscle spasms, Nasal congestion, Oropharyngeal pain

Symptom Text: Headaches, periods were very erratic. She would have them every 14 days @times, and others just spotting. Very bad cramps and periods were heavier after the 1st Gardasil shot. Wasn't her normal spunky and happy self. She was very tired and the last few weeks before she passed away, sheslept alot during the day which she never did. Never had any other problems prior to the Gardasil shots. She recieved all three shots in the series. Last shot was 5-2-2007. 2/9/09-autopsy report received-COD-undetermined by autospy and toxicology.3/18/09-records received-well visit C/O contact dermatitis, nasal congestion, itchy sore throat times 2-3days. HPV4 lot#1424 F received 1/3/07 in right deltoid. Lot #0384U received 5/2/07 left deltoid and 12/2/08 lot#0955F left deltoid.

Other Meds: Nasonex (Pseudovent 400 substituted for Entex 400 120 capsule),Claritan, Triamcinolene Acetonide cream for rash on wrist.

Lab Data: 4/7/09-path report received-multiple tissues with extensive autolysis and bacterial overgrowth. Molecular evidence of a Clostridium sp.

History: Seasonal allergies. None other.

Prex Illness: Went in for sinisitus, and had a sore throat. She had bad sinus allergies. But they still gave her the shots.

Prex Vax Illns: none~ ()~~0~Patient|none~ ()~~0~Sibling

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337797-2 (D)** **Related reports:** 337797-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-May-2007	31-Aug-2007	121	09-Mar-2009	10-Mar-2009	--	WAES0902USA03928	10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Abnormal behaviour, Death, Fatigue, Headache, Hypersomnia, Menorrhagia, Menstrual disorder, Menstruation irregular, Muscle spasms

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. On 01-NOV-2006, an 18 year old female with seasonal and sinus allergies, was vaccinated intramuscularly into the left arm with a first dose of GARDASIL (Lot # 653978/0955F) and was vaccinated with influenza virus vaccine (unspecified) (manufacturer unknown). Concomitant medications included: NASONEX, PSEUDOVEN substituted for ENTEX, CLARITIN and triamcinolene acetonide. It was reported that patient experienced headaches, periods were very erratic. She would have them every 14 days at times, and others just spotting. Very bad cramps and periods were heavier after the first GARDASIL shot. Was not her normal spunky and happy self. She was very tired and the last few weeks before she passed away, she slept a lot during the day which she never did. Never had any other problems prior to the GARDASIL shots. She received all three shots in the series. Last shot was 02-MAY-2007. Illness at the time of vaccination: It was reported that patient went in for sinusitis and had a sore throat. She had bad sinus allergies. But they still gave her the shots. Previous vaccinations illnesses: None. The listing indicated that one or more of the events resulted in death. A standard lot check investigation was performed. All in-process quality checks for the lot 653978/0955F were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the center and was released. No further information is available. The original reporting source was not provided. The VAERS ID # is 337797.

Other Meds: ENTEX (NEW FORMULA); PSEUDOVENT; CLARITIN; NASONEX; triamcinolone acetate

Lab Data: Unknown

History:

Prex Illness: Sinusitis; Sore throat

Prex Vax Illns:

Vaers Id: **337805-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Dec-2008	17-Dec-2008	0	21-Jan-2009	02-Feb-2009	NY		02-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Induration, Injected limb mobility decreased, Injection site pain, Pain

Symptom Text: Site never got swollen or red. Just very painful. Continues to throb, hurts to raise arm up above head after few seconds gets a shooting pain from the injection site to her finger tips.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 337812-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	19-Jun-2008	19-Jun-2008	0	21-Jan-2009	22-Jan-2009	MI	WAES0901USA01598	22-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse concerning a 22 year old female with penicillin and amoxicillin allergy who on 19-JUN-2008 was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (Lot # 660555/0279X) while she was pregnant. Concomitant therapy included ADDERALL TABLETS and oral hormonal contraceptives (unspecified). Her last menstrual period was 15-MAY-2008 and the expected delivery date was 19-JUN-2008. On 31-JUL-2008 the patient had a fetal ultrasound that showed a 10 week and 5 days gestational age fetus with positive cardiac activity. A pregnancy Ultra-screening test was performed with abnormal results. It showed an increased risk, 1 in 10, of having a baby with Down's syndrome. On an unspecified date, the patient elected to terminate this pregnancy. After the pregnancy was terminated, on 25-NOV-2008 the patient received the second dose of GARDASIL (Lot 661764/0650X). Upon internal review, the elected termination of pregnancy was determined to be another important medical event. Additional information has been requested.

Other Meds: Adderall tablets; Hormonal contraceptives

Lab Data: Ultrasound, 07/31/08, 10 week 5 day gestational age fetus with positive cardiac activity; Diagnostic laboratory, 07/31/08, abnormal pregnancy ultra-screen

History:

Prex Illness: Pregnancy NOS (LMP = 5/15/2008); Penicillin allergy

Prex Vax Illns:

Vaers Id: **337813-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Dec-2008	26-Dec-2008	3	21-Jan-2009	22-Jan-2009	FR	WAES0901USA01664	22-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Neurological examination, Petit mal epilepsy

Symptom Text: Information has been received from a gynecologist concerning a 17 year old female patient who was vaccinated with a second dose of GARDASIL (lot number not reported) IM into the upper arm on 23-DEC-2008. "After Christmas", exact onset not reported, she developed 6 to 7 episodes of petit mal epilepsy with "obstetrician's hand" {left hand} and absence attacks. The patient fully recovered from the episodes. To be noted that in October 2008, the patient underwent exhaustive neurological examinations (no results reported), the reason was unknown to the reporter. The first dose of GARDASIL, lot number not reported, administered on an unspecified date was well tolerated. Petit mal epilepsy was considered to be an other important medical event by the physician. Other business partner numbers included: E2009-00158. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 337814-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Jul-2007	01-Mar-2008	222	21-Jan-2009	22-Jan-2009	FR	WAES0901USA01666	03-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1518F	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Condition aggravated, Dissociative disorder, Facial pain, Headache, Sensory disturbance

Symptom Text: Information has been received from a foreign health authority (reference No. PEI2008021013) concerning a 15 year old female patient with history of headache (onset some years ago, at least since March 2007) and family anamnesis of migraine (patient's mother) was vaccinated with a first dose of GARDASIL (batch number NF2330, lot #1518F), route and site not reported on 23-JUL-2007, with a second dose of GARDASIL (batch #NG00010, lot # 1401F) on 27-OCT-2007 and with a third dose of GARDASIL (batch # NF58540, lot # 0253U) on 18-FEB-2008. The frequency of the pre-existing headache increased during the last years and the patient developed chronic headaches and took frequently analgesics. CCT in April-2008 showed normal results. Tension headache and development of headache due to analgesics were suspected. Atypical face pain and dissociative sensory disturbance were diagnosed when the patient presented at the physician practice for follow-up examination on 24-OCT-2008. EEG on 24-OCT-2008 showed no changes. MRI and x-ray cervical spine showed normal results. Examination at an ENT physician was pending at the time of reporting. As the sensory disturbance (hemihypaesthesia) was limited to the median area a psychogenic cause was suspected, but the final cause could not clarified. At a control on 28-NOV-2008 the physical examination revealed normal results. Several therapies including acupuncture and osteopathy have been tried, but without success. HA coded only cephalgia. File closed. Other business partner number include: E2009-00147. No further information is available.

Other Meds: Unknown

Lab Data: electroencephalography, 24Oct08, Showed no changes; Physical examination, 28Nov08, normal results; Magnetic resonance imaging, showed normal results; Spinal X-ray, showed normal results

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 337815-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	15-Feb-2008	03-Mar-2008	17	21-Jan-2009	22-Jan-2009	FL	WAES0804USA03264	22-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner and a certified nurse midwife, for the pregnancy registry for GARDASIL, concerning a 21 year old female with no medical history, no known drug allergies and with no history of previous pregnancies who on 15-FEB-2008 was vaccinated IM with the first 0.5 ml IM dose of GARDASIL (lot # 659962/1740U). The patient received the second 0.5 ml IM dose on 15-Apr-2008 (lot# 659962/1740U). There was no concomitant medication. On 15-APR-2008 the patient had a positive pregnancy test result. The patient's LMP was 03-Mar-2008 and an estimated delivery date is 08-Dec-2008. No other symptoms were noted. Patient sought medical attention via an office visit. Follow up information has been received from a certified nurse midwife, for GARDASIL, a Pregnancy Registry product, concerning a 21 year old female patient. In May 2008, the patient was seen due to a miscarriage. It is not known if the patient had received any prenatal care prior to the miscarriage. Upon internal review, miscarriage was determined to be an other important medical event. No further information is available.

Other Meds: None

Lab Data: Beta-human chorionic, 04/15/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = 3/3/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 337816-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Dec-2008	08-Dec-2008	4	21-Jan-2009	22-Jan-2009	FR	WAES0901USA01069	22-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Arthralgia

Symptom Text: Information has been received from a pediatrician that a 15 year old female patient was vaccinated with a third dose of GARDASIL (lot# not reported) approximately 4 weeks ago. "Shortly" p.v. the patient developed increasingly severe diffuse-spreading joint pain. Blood sample (not otherwise specified) showed normal findings. A rheumatological disease could be ruled out. The patient was remitted to a hospital for further clarification on 07-JAN-2009, symptoms were ongoing. Follow up information was received on 09-JAN-2009. The reporting form and laboratory findings were sent by the pediatrician: The patient with history of dysplasia of the elbows and wrists was vaccinated with a third dose of GARDASIL, lot #, site and route not reported, on 04-DEC-2008. On 08-DEC-2008 the patient developed joint pain of the large and small joints (knee, hip, shoulder, elbow, wrists and fingers). Symptoms increased and the patient was unable to walk. According to the reporter, the events occurred independently from the preexisting dysplasia of the elbows and wrists. Clinical findings were negative, no signs of inflammation, neither redness nor swelling. On 31-DEC-2008, Laboratory findings revealed normal values for ANA IgG (negative). RF (rheumatoid factor) -IgM (quantitative): 5.2 IU/ml (normal up to 15), Borrelia b. (Lyme) IgG and IgM antibodies: negative and Antistreptolysin (quantitative): 31U/ml (normal up to 150). Hemoglobin 12.1 g/dl (normal range 12.8-16.8 g/dl), LDH 148 U/L (normal range 160-278 U/L). Other routine laboratory findings showed normal results. Despite treatment with ibuprofen the patient has not recovered at the time of reporting. The first dose and the second dose of GARDASIL given on 12-JUN-2008 and on 12-AUG-2008 were well tolerated. Other business partner numbers include E200900064.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, showed normal findings; hemoglobin, 31Dec08, 12.1 g/dl; serum ANA, 31Dec08, IgG negative; serum B. burgdorferi Western blot IgG Ab, 31Dec08, negative; serum B. burgdorferi Western blot IgM Ab, 31Dec08, negative;

History: Dysplasia

Prex Illness:

Prex Vax Illns:

Vaers Id: 337817-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	12-Sep-2008	18-Nov-2008	67	21-Jan-2009	22-Jan-2009	CA	WAES0901USA01174	06-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Asthenia, Chest pain, Chills, Cough, Diarrhoea, Dizziness, Epigastric discomfort, Fatigue, Headache, Lymphadenopathy, Malaise, Migraine, Myalgia, Nausea, Neck pain, Oropharyngeal pain, Pallor, Vomiting

Symptom Text: Information has been received from a physician concerning a 11 year old female with no pertinent medical history who on 12-SEP-2008 was vaccinated intramuscularly with a first 0.5 ml dose of GARDASIL (lot #660618/0572X). There was no concomitant medication. "Three months after administration of her first dose of GARDASIL", on 12-DEC-2008 the patient experienced weakness, sore throat, nausea, vomiting, diarrhea, paleness and abdominal pain. "One month later", the patient's symptoms had not resolved and she was also experiencing chest pain, headaches, dizziness, swollen lymph nodes, chills and myalgia. The patient had office visits. "White blood cell differential count and white blood cell count" were normal. "Four weeks ago", on approximately 12-DEC-2008, the patient was prescribed PRILOSEC. At the time of the report, 09-JAN-2009, the patient had not recovered. Follow-up information received on 12-JAN-2009 from the physician via medical records indicated that on 18-DEC-2008 the patient was taken to the physician's office for follow-up. It was reported that the patient had a sore throat and abdominal pain which persisted one month. The patient vomited for four times on 08-DEC-2008 (previously reported as 12-DEC-2008) and had a diarrhea "last week". There was no blood. The patient was treated with omeprazole, 2-3 times daily for 3 weeks. At the time of the follow-up visit, the patient's abdominal pain worsened and she also had chest pain with deep breath, cough, headaches which happened "every day for one week" and cough. Lab tests performed on 18-DEC-2008 included: giardia antigen was negative, stool culture revealed no salmonella, shigella or campylobacter SP. isolated, white blood cell count and white blood cell differential count were normal, Epstein-Barr viral capsid antigen immunoglobulin M antibody was negative, EBV capsid antigen immunoglobulin G antibody and nuclear antigen immunoglobulin G antibody were positive. It was reported that the patient's mother was suspecting that her daughter's "r

Other Meds: None

Lab Data: Stool Giardia lamblia, 12/23/08, negative; WBC count, 12/18/08, 7.3 thou; Red blood cell count, 12/18/08, 4.73 mill; Hemoglobin, 12/18/08, 14.0 g/dL; Hematocrit, 12/18/08, 39.9%; Mean corpuscular volume, 12/18/08, 84 fL; Mean corpuscular, 1

History: None. PMH: none

Prex Illness:

Prex Vax Illns:

Vaers Id: **337827-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Jun-2008	23-Jul-2008	30	21-Jan-2009	02-Feb-2009	NJ		03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Left arm	Intramuscular	HPV4

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Muscular weakness, Musculoskeletal pain, Pain, Pain in extremity, Weight increased

Symptom Text: 1. Legs pain. 2. Some time weaken of lower limbs. 3. Some time numbness of lower limbs. 4. Shoulder pain once in a while. 5. Body ache- 3 weeks after #2 gardasil. 2/10/09 Received PCP medical records of 2/6/09. FINAL DX: none provided Records reveal patient experienced body aches, weakness & leg pain with intermittent leg numbness since 6/08 w/20# wt gain. Exam WNL.

Other Meds: EPIPEN; KRH; PENICILLIN; Allergy Bee Allopry

Lab Data: CBC with diff, ESR all pending. 2- ANA; Anti DNA; CPK; Chem screening LABS: all WNL

History: Allergy Penicillin; Bee sting; Asthma out grew PMH:multiple allergies. Acne. Trauma to hip by sibling jumping on her 6/08, seen in ER & x-rays WNL.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **337830-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Dec-2008	15-Dec-2008	0	21-Jan-2009	25-Feb-2009	MA		25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0513X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1311X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Injection site warmth

Symptom Text: Localized reaction to VARIVAX given SC to Left upper arm 12/15/08- 2x3 cm area arm sl, red, sl warm and swollen. Treatment: warm compress, OTC analgesics pm.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337950-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		22-Jan-2009	23-Jan-2009	--	WAES0901USA02129	23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Haemoglobin decreased, Transfusion

Symptom Text: Information has been received from a representative as reported by a colleague concerning a 13 year old female who on an unspecified date was vaccinated with a 0.5 ml dose of GARDASIL. It was reported that the patient developed low hemoglobin levels after receiving GARDASIL. She was taken to hospital where she received blood infusions. The outcome of the patient was not reported. The reporter considered "low hemoglobin levels" to be an other important medical event because the patient received blood infusion. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **337951-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jul-2008	01-Jul-2008	0	22-Jan-2009	23-Jan-2009	--	WAES0901USA02073	23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a 14 year old female who was vaccinated with her first 0.5 ml dose of GARDASIL towards the latter part of last year. The patient had a seizure "a couple days" after getting GARDASIL and had "several" seizures since then. The doctor's nurse said that the patient's father checked with a neurologist who said that the seizures were linked to GARDASIL. The outcome is unknown. The patient sought medical attention. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 337952-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	14-Jan-2009	14-Jan-2009	0	22-Jan-2009	23-Jan-2009	--	WAES0901USA01962	23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Anaphylactic reaction, Dyspnoea, Throat tightness, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female who on 14-JAN-2009 was vaccinated with a first and only dose of GARDASIL intramuscularly 0.5 mL. There was no concomitant medication. On the same day the patient experienced anaphylactic reaction. She experienced severe vomiting, abdominal pain within the hour of vaccination. She also had hard time breathing and sensation of the throat closing. She went to an emergency room and was given oxygen and intravenous steroids. The patient was discharged after the recovery (The outcome also reported as "recovering"). Anaphylactic reaction, abdominal pain and abdominal pain were reported to be immediately life-threatening. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **337953-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		22-Jan-2009	23-Jan-2009	CA	WAES0901USA01834	23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy, Hypoaesthesia, Paraesthesia

Symptom Text: Information has been received from a physician concerning a 19 year old female who in approximately 2009 was vaccinated with a 0.5 ml second dose of GARDASIL (no lot number provided). "Few weeks ago", after vaccination, the patient experienced tingling and numbness. One or two days later, unspecified medical attention was sought and she was diagnosed with Bell's palsy. At the time of the report, as 14-JAN-2009, the patient was being treated with steroids. Upon internal review, Bell's palsy was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 337954-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Jun-2008	13-Jul-2008	42	22-Jan-2009	23-Jan-2009	FR	WAES0901MYS00003	23-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Coma, Convulsion, Encephalitis

Symptom Text: Information has been received from a physician concerning a 12 year old female who in June 2008, was vaccinated with the first dose of GARDASIL. On 8-JULY-2008, the patient was vaccinated with the second dose of the vaccine. On 13-JUL-2008 the patient experienced seizure and went into a coma. The patient was hospitalized. MRI scan result showed that the patient had right temporal lobe encephalitis. The patient has no medical history of seizures. Subsequently, after two weeks, the patient was discharged. The patient has recovered from seizure, coma and right temporal lobe encephalitis. The reporter felt that seizure, coma and right temporal lobe encephalitis were not related to therapy with GARDASIL. Seizure, coma and right temporal lobe encephalitis were considered to be immediately life-threatening. Additional information is not expected.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, 13?Jul08, right temporal lobe encephalitis

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 337963-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	19-Sep-2008	25-Sep-2008	6	22-Jan-2009	27-Jan-2009	OR		04-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1702X	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Asthenia, Confusional state, Fatigue, Headache, Heart rate increased, Hyperglycaemia, Hypoaesthesia, Hyponatraemia, Leukocytosis, Malaise, Mental status changes, Oropharyngeal pain, Pyrexia, Vasculitis cerebral

Symptom Text: Soon after Gardasil, pt developed fever, malaise, confusion. Admitted to hospital and Dx'd with ADEM vs. cerebral vasculitis. Has made nearly full recovery. Question of Gardasil-induced vasculitis or immune-related acute CNS/systemic disorder. 3/3/09 MR received for DOS 9/25-29/2008 with D/C DX: ACute intracranial process, possible immunization related vs vasculitis vs diffuse encephalomyelitis. Recent Gardasil vaccination-uncertain relationship to this event. Leukocytosis-most likely r/t steroids. Mild hyponatremia during hospitalization. Hyperglycemia 2' to steroid use. Pt presented with c/o 1 1/2 wk hx fevers, weakness and altered mental status. Several ER visits prior to this admission. Pt reports sore throat, tiredness, fatigue, H/A, increased HR and bilateral foot numbness. Pt tx with steroids and d/c for outpt f/u.

Other Meds: Cymbalta - uncertain dates and doses

Lab Data: MRI showed numerous small white matter T2 lesions. ANA positive, elevated D-dimer, normal CSF. Labs and Diagnostics: CXR (+) for RLL pneumonia, later (-). WBC 19.7K. D-dimer 1661. CT angiogram of chest (+) for adenopathy. Chemistry WNL

History: History of depression. PMH: RAD. Seasonal allergies. depression. s/p sinus surgery. s/p tonsillectomy. Allergies to sulfa, NSAIDS.

Prex Illness:

Prex Vax Illns:

Vaers Id: **337965-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-Jan-2009	21-Jan-2009	0	22-Jan-2009	11-Feb-2009	NJ		11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	2	Left arm	Intramuscular	FLU HEPA MNQ

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Feeling hot, Immediate post-injection reaction

Symptom Text: ON 1/21/2009 APPROXIMATELY @ 9:20 PM PATIENT RECEIVED A SHOT OF GARDASIL 0.5 ML IM. PATIENT WAS ADVISED TO STAY FOR 20 MINUTES TO MAKE SURE SHE DID NOT HAVE ANY ADVERSE REACTION FROM RECEIVING THE GARDASIL. ONE MINUTE POST IMMUNISTRATION PATIENT REPORTED FEELING WARM ALL OVER THEN FELL OFF EXAM TABLE. PATIENT WAS OBSERVED FOR ANOTHER 20 MINUTES. PATIENT REPORTED WAS FEELING FINE. NO TREATMENT WAS NEEDED. BY LEFT OFFICE AT 9:50 PM WITH MOTHER.

Other Meds: NONE

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **337975-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Jan-2009	22-Jan-2009	0	22-Jan-2009	11-Feb-2009	KY		12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Patient fainted miniutes after the injection was given. Pt came to and we monitored pt and rechecked blood pressure and heart rate. Patient stayed at clinic for 25 min under observation.

Other Meds: none

Lab Data: monitored blood pressure and heart rate and monitored behavior

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337977-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Jan-2009	22-Jan-2009	0	22-Jan-2009	04-Feb-2009	WA		04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2829AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1968U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Hot flush, Hyperhidrosis, Vision blurred

Symptom Text: dizziness, hot flushing, sweating, blurry vision 5 minutes after vaccination. Pt did not pass out but did fall to ground. Pt felt better immediately upon being placed flat on ground (pt was also placed in trendelenberg position). Pt had not eaten prior to vaccination. Staff gave pt water & cookies & pt able to recover s incident.

Other Meds:

Lab Data:

History:

Prex Illness: none.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337981-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	31-Dec-2008	31-Dec-2008	0	22-Jan-2009	04-Feb-2009	MN		04-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
FLU	SANOFI PASTEUR	2810AA		Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0525U	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	033BA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2661AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Nausea, Pallor, Syncope

Symptom Text: Adolescent became lightheaded then fainted several minutes after receiving immunizations. LOC approx 1 min. and color pale. Remained nauseous and lightheaded 10 mins. Walked on own to parking lot accompanied by mother and nurse. Mother called 2 days later and stated adolescent fine after arriving home.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **337985-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Jan-2009	Unknown		22-Jan-2009	11-Feb-2009	KY		11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal pain, Pain in extremity

Symptom Text: Vaccine given 6 days ago Pt noticed soreness in shoulder to elbow area. Then spread to Flexor portion of Forearm only describes as "Arthritic. like pain". 0 numbness 0 tingling 0 loss of use of arm. Recommend Ibuprofen & follow-up in next few days in office on by phone

Other Meds: LEXAPRO; LODRANE-D

Lab Data: None

History: Depression; Amoxicillin Allergy

Prex Illness: Otalgia allergies

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338002-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Jan-2009	07-Jan-2009	2	22-Jan-2009	11-Feb-2009	NY		11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Joint swelling, Pruritus, Urticaria

Symptom Text: Swelling in both wrist, itching on palms of hands and soles of feet. Welts on hip bones and on one breast.

Other Meds:

Lab Data:

History: MINOCYCLINE (rash)

Prex Illness: None

Prex Vax Illns:

Vaers Id: 338049-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Nov-2008	Unknown		23-Jan-2009	26-Jan-2009	KY	WAES0901USA01809	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	HPV4

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Complex partial seizures, Conversion disorder, Dysgeusia, Electroencephalogram, Grand mal convulsion, Headache, Partial seizures, Status epilepticus, Tremor, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 13 year old female who was vaccinated with the first dose of GARDASIL, 0.5ml. Subsequently the patient experienced a shaking in her leg. After getting the second dose of GARDASIL 0.5ml the same experience occurred for almost 12 hours. The patient got checked for seizure activity however they did not diagnose her with that. The patient was hospitalized and the length of hospitalization was unknown. The patient did video EEG. At time of the report the patient was not recovered. Follow-up information has been received from a nurse concerning the patient who received two doses of GARDASIL. The nurse reported that the patient had a grand mal seizure (previously reported as the patient was not diagnosed with seizure activity) and was hospitalized. At time of the report the outcome of the patient was unknown. The patient had follow-up appointment scheduled with the physician on 21-JAN-2009. Additional information has been requested. 1/27/09 Rec vaccine records which did not include Lot #s. HPV #1 given 7/30/08; HPV #2 given 11/18/98. 1/27/09 Reviewed multiple hospital admit medical records: 12/15-12/16/2008 FINAL DX: status epilipticus Records reveal patient experienced seizure of approx 1 hour. Preceeded by HA & LLL shaking which proceeded to seizure. Pt w/history of seizures x 3 mo approx 2x/mo; rencently increased to daily & treated w/oral meds. Continued w/seizures while hospitalized & transferred to higher level of care. PMH: abnormal EEG & seizure disorder x 3 mos prior to current hospitalization. 1/4/-1/5/2009 FINAL DX: partial complex seizures. Tonic-clonic seizure activity began LLE & progressed to RLL & UEs x 10 min. Loaded w/antiseizure med, observed overnight & d/c to home 1/6-1/7/2009 FINAL DX: focal seizure disorder. Neuro consult done & patient transferred to higher level of care. 1/9-1/11/2009 FINAL DX: complex partial seizures Records reveal patient continued to experience seizures, metallic tast & HA. W/U at univers

Other Meds: Unknown

Lab Data: Unknown LABS: H/H 11.8/32.7(L). Chemistry WNL. Prolactin 37.46(H). Video EEG WNL.

History: Unknown PMH: Family hx: seizures.

Prex Illness:

Prex Vax Illns:

Vaers Id: 338050-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Jan-2009	12-Jan-2009	0	23-Jan-2009	26-Jan-2009	SC	WAES0901USA02024	29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Headache, Pyrexia, Rash maculo-papular

Symptom Text: Information has been received from a physician concerning a 17 year old female with no drug allergies who had recent urinary tract infection and completed a course of ciprofloxacin on 10-JAN-2009. She was intramuscularly vaccinated with the first 0.5 ml dose of GARDASIL on 12-JAN-2009. The patient developed a severe headache a few hours after receiving GARDASIL. The next day she developed a fever of 102F and a maculopapular rash on her face and trunk. On 14-JAN-2009 the patient developed abdominal cramping. She was examined in the office on 15-JAN-2009. A "rapid influenza test and monocyte test" were negative. Unspecified blood work was pending. The patient had been unable to attend school due to the severity of the headache. The patient did not recover at the time of reporting. No further information provided. Headache, fever, maculopapular rash and abdominal cramping was considered to be disabling. Additional information has been requested. 1/29/09-Follow-up from Merck on 1.28.09: PCP's nurse reported that the patient was given a Medrol Dose Pak and the symptoms of headache, rash, abdominal pain and fever resolved within a week

Other Meds: Ciprofloxacin

Lab Data: Diagnostic laboratory, 01/15?/09, rapid influenza test negative; Diagnostic laboratory, 01/15?/09, mononucleosis test negative; Temperature measurement, 01/12/09, 102 F

History:

Prex Illness: Urinary tract infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338051-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	30-Oct-2008	30-Oct-2008	0	23-Jan-2009	26-Jan-2009	FR	WAES0901USA02412	26-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1201U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menorrhagia, Vaccine positive rechallenge

Symptom Text: Information has been received from health authorities concerning a 13 year old female with no previous reactions to other drugs, without known clinical history, without history of thrombocytopenia, clotting disorders or irregular menstruation who on 30-OCT-2008 was vaccinated with a first dose of GARDASIL (lot #1201U, batch #NH00900) via intramuscular route. On 08-JAN-2009, the patient was vaccinated with a second dose of GARDASIL via intramuscular route. On 30-OCT-2008, the patient, menstruated, experienced menstruation increased until 30-NOV-2008. The adverse reaction evolved towards cured, without any specific treatment being given. The patient menstruated again in the middle of December 2008. There was a re-challenge with the suspect drug on 08-JAN-2009 with reappearance of the menstruation on 09-JAN-2009. She had menstruated 2 weeks before. At the time of reporting the patient had recovered. Re-challenge was positive. To be mentioned that menstruation anticipated was not coded however the health authorities considered it as a positive re-challenge being as if it were the same adverse effect (menstruation increased). The reporter considered the adverse reactions as an other important medical event and serious. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 338052-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	09-Jun-2008	09-Jun-2008	0	23-Jan-2009	26-Jan-2009	MO	WAES0901USA02577	26-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Pancreatitis, Parenteral nutrition, Pelvic pain

Symptom Text: Information has been received from a physician concerning a 15 year old female patient who on 15-DEC-2007 was vaccinated with the first dose of GARDASIL (lot# 655503/0012U). On 21-MAR-2008 she received her second dose of GARDASIL (lot# xxxxx) and on 09-JUN-2008 she received her third dose of GARDASIL (lot# 659962/1740U). On September 2008 the patient started to develop pelvic pain and was diagnosed of pancreatitis. Patient was hospitalized and received total parenteral nutrition and lipids and had an IV port. Pancreatitis was considered to be an other important medical event by the physician. Pancreatitis was considered to be disabling. At the time of this report the patient had not yet recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 338053-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-May-2008	21-Jul-2008	60	23-Jan-2009	26-Jan-2009	FR	WAES0901USA02689	26-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0354U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Facial palsy, Facial paresis

Symptom Text: Information has been received from a health authority on 15-JAN-2009 (HA reference no. PEI2009000323) concerning a 13 year old female patient who on 22-MAY-2008 was vaccinated intramuscularly with the first dose of GARDASIL (Lot # 0354U, Batch # NF58150) into the left deltoid muscle. On 21-JUL-2008 the patient was hospitalized. Two days prior to the hospitalization the patient was not able to close her left eye. Neurological examination revealed at admission: drooped corner of mouth, forehead was unforrowed and eye lid did not close on the left side. Idiopathic left peripheral facial paresis was diagnosed in hospital. For laboratory findings please see Lab comments. Ophthalmological examination on 22-JUL-2008: normal finding except incomplete eyelid closure. ENT examination: No otitis media, no indication for zoster oticus. The patient was discharged on 22-JUL-2008 and recovered completely within a not specified time. The 2 year old sister had fever and diarrhea 2 weeks ago. The mother had headache and stomach ache for two weeks. The twin sister was hospitalized for serous meningitis on 17-JUL-2008 (WAES # 0901USA02688). The second dose of GARDASIL was given on 18-AUG-2008. No adverse event was reported. This case is closed. This is one of several cases from the same source. No further information is available.

Other Meds: Unknown

Lab Data: neurological examination, 21Jul08, drooped corner of mouth, forehead was unforrowed and eyelid did not close on the left side. Idiopathic left peripheral facial paresis was diagnosed; ophthalmological exam, 22Jul08, normal finding except in

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338071-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Sep-2007	20-Sep-2007	1	23-Jan-2009	03-Feb-2009	MA		25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2395BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0387U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Condition aggravated, Depression, Diarrhoea, Dysmenorrhoea, Gastroenteritis viral, Nausea, Vaccine positive rechallenge, Vomiting

Symptom Text: Pt reports had significant vomiting day after HPV with all three administrations. 3/23/09 Received PCP medical records of 9/19/07- FINAL DX: viral gastroenteritis Records reveal patient experienced mild depression, received counseling & improved. Missed several days of school secondary to severe menstrual cramping. RTC 4/28/08 w/epigastric pain after eating, nausea, diarrhea x 5 da. Dx w/viral gastroenteritis. No further documentation of s/s.

Other Meds: None

Lab Data: None

History: None PMH: left axillary abscess, resolved; left ankle swelling; menstrual cramping. mild depression. HPV #2 given 7/18/08, lot # 0063X, IM/LA; HPV #3 given 12/2/08, lot# 0651X, IM/LA; MMR#2 given 12/2/08, lot # 1083X, SQ/RA.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338123-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Jan-2009	21-Jan-2009	5	23-Jan-2009	11-Feb-2009	OR		11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2820AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3028AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Urticaria

Symptom Text: She received her immunizations on 1/16 and developed urticarial rash 1/21. Patient had 0 previous hx of reactions to vaccinations and had 0 previous hx of Urticaria. Antihistamines were suggested.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **338217-1** **Related reports:** 338217-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Jan-2009	23-Jan-2009	0	26-Jan-2009	03-Feb-2009	MA		11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1398X	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1978U		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Erythema, Joint swelling, Joint warmth

Symptom Text: After waiting in office for 15 minutes after receiving GARDASIL vaccine. Patient complain of left knee feeling hot, painful. I assessed left knee, knee was red, swollen, warm to touch. Reported to Dr. 3/5/09 MR received from PCP. WCC 1/23/09 with normal exam. Several minutes after vax pt c/o knees feeling hot L>R. Knees erythemic and warm. Improving 30-40" later.

Other Meds:

Lab Data:

History: PMH: allergy to Flu vax.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **338217-2** **Related reports:** 338217-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Jan-2009	23-Jan-2009	0	18-Feb-2009	26-Feb-2009	MA	WAES0901USA03523	27-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1398X	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Joint swelling

Symptom Text: Information has been received from a Registered Nurse concerning a 14 year old female patient with Flu vaccine allergy and gastroesophageal reflux disease who on 23-JAN-2009 was vaccinated with first dose of GARDASIL vaccine (Lot # 659964/1978U) 0.5ml, intramuscularly and first dose VARIVAX vaccine (Oka/Merck) (Lot#662184/1398Xs). There were no concomitants medications. On 23-Jan-2009 approximately 20 minutes after the patient received vaccines she experienced red and swollen knee. There were no Laboratory diagnostics studies Performed. At the time of the report on 23-Jan-2009 the patient was not recovered. Patient sought medical attention was saw by a nurse. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Allergy to vaccine; Gastroesophageal reflux disease

Prex Vax Illns:

Vaers Id: **338232-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-Oct-2008	30-Nov-2008	39	26-Jan-2009	27-Jan-2009	FR	WAES0901AUS00087	27-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anaemia, Anaemia haemolytic autoimmune, Hyperbilirubinaemia, Neutropenia

Symptom Text: Information was obtained on request by the Company from the agency, via a Case Line Listing and Public Case Details form, concerning a 13 year old female who on 22-OCT-2008 was vaccinated with GARDASIL, intramuscularly, as prophylactic vaccination. On 30-NOv-2008 the patient developed autoimmune haemolytic anaemia and was hospitalised. It was described that the patient developed autoimmune haemolytic anaemia with mild anaemia and unconjugated hyperbilirubinaemia and transient neutropenia. A direct antiglobulin test (DAT) was positive, autoantibody with apparent anti Jka specificity. No evidence of viral infection, SLE or immune deficiency was identified. The patient was treated with oral prednisone. At the time of reporting to the agency on 13-NOV-2008, the patient had not recovered from autoimmune haemolytic anaemia. The agency considered that autoimmune haemolytic anaemia was possibly related to therapy with GARDASIL. The original reporting source was not provided by the agency. Additional information is not expected.

Other Meds: Unknown

Lab Data: direct antiglobulin test, results - positive, autoantibody with apparent anti Jka specificity. No evidence of viral infection.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338233-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		26-Jan-2009	27-Jan-2009	FR	WAES0901AUS00099	27-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Headache, Local reaction

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing concerning a 12 year old female who was vaccinated with GARDASIL. Other suspect therapy included RECOMBIVAX HB (manufacturer unknown) (duration and dose not reported). Subsequently after vaccination with GARDASIL and RECOMBIVAX HB (manufacturer unknown), the patient experienced convulsion, headache and local reaction. At the time of reporting to the agency on 14-NOV-2008, the outcome of convulsion, headache and local reaction was unknown. The agency considered that convulsion, headache and local reaction were related to therapy with GARDASIL and RECOMBIVAX HB (manufacturer unknown). The original reporting source was not provided. Upon internal medical review convulsion was considered an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 338235-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	18-Sep-2007	26-Aug-2008	343	26-Jan-2009	27-Jan-2009	FR	WAES0901USA02687	27-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cognitive disorder, Convulsion, Emotional disorder, Gliosis, Mental disorder due to a general medical condition, Psychotic disorder, Vasculitis cerebral

Symptom Text: Information has been received from the foreign Health Authorities (Reference no.: PEI2008021098), concerning a 17 year old female patient, who on 18-SEP-2007, was vaccinated with the first dose of GARDASIL (toleration was not reported); on 20-NOV-2007, was vaccinated with the second dose of GARDASIL (toleration not reported) and on 11-MAR-2008, was vaccinated with third dose of GARDASIL, intramuscularly (Lot # and injection site not reported). Starting mid-Jun-2008, the patient developed cerebral vasculitis with acute psychotic symptoms and seizures. Cerebral biopsy, performed on 26-AUG-2008, revealed astrocytic gliosis. Lab finding showed increased number of cells in cerebrospinal fluid (=CSF). Despite of therapies with cortisone, neuroleptics and antiepileptics, the patient only improved slowly from the severe organic brain syndrome with slowdown, cognitive disorders and emotional symptoms. The cause of cerebral vasculitis remained unexplained. The patient had not recovered. Other business partner numbers included (E2009-00275). No further information is available.

Other Meds: Unknown

Lab Data: brain biopsy, 26Aug08, reactive astrocytic gliosis; cerebrospinal fluid culture, increased number of cells

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: **338236-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Nov-2008	07-Dec-2008	36	26-Jan-2009	27-Jan-2009	FR	WAES0901USA02992	27-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Diplopia, Headache, Nasopharyngitis, Paresis

Symptom Text: Information has been received from Health Authority on 15-JAN-2009 (reference #2009-00031) concerning a 15 year old female adolescent who was intramuscularly vaccinated with the first 0.5 ml dose of GARDASIL (batch number not reported, site of administration not reported) in October 2008. In November 2008 she received the second 0.5 ml dose of GARDASIL, IM. From 07-DEC-2008 until 11-DEC-2008 she developed headache. On 11-DEC-2008 she noted a diplopia, which was progressive and she had symptoms of common cold. A paresis of the left abducent nerve was diagnosed. On 18-DEC-2008 an MRI showed hyperintense enhancement in the caudal salivary nucleus left. An acute disseminated encephalitis was diagnosed. Other business partner numbers include E2009-00291. No further information is available.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, 18Dec08, hyperintense enhancement in the caudal salivary nucleus left

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338247-1 (S)** **Related reports:** 338247-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Jan-2007	16-Jul-2007	174	26-Jan-2009	02-Feb-2009	NC		10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1209F	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0961F	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	U2107AA	0	Unknown	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Alopecia, Condition aggravated, Contusion, Cough, Diarrhoea, Dyspnoea, Ear infection, Influenza like illness, Lobar pneumonia, Nasopharyngitis, Pyrexia, Sinusitis, Vomiting

Symptom Text: 7/16/07 - Developed severe case of pneumonia with fever - no cough or cold prior. Was sent to hospital for chest x-ray. Was given inhalation therapy and prescribed cefdinir (300mg) and albuterol (90mg). 7/16/07 evening - went to emergency room when patient couldn't breath. Received inhalation therapy and z-pak 7/18/07 - checked at doctors' office for improvement 7/19/07 - was given additional albuterol (.83mg) and told to use one vial every 4 hours. 7/07 - given refill of z-pak. 9/28/07 - sinus infection and fever (has had for about 3 weeks) and is prescribed Z-pak 9/07 - begins losing substantial amounts of hair that continues for approximately 4 months. 3/7/08 - is seen for ear and sinus infection and fever and prescribed z-pak 12/19/08 - patient develops flu-like symptoms with vomiting, diarrhea, and fever. Is given phenergan (25 mg). Is sent to hospital when vomiting continues. Is given 3 bags of IV fluid and treated for vomiting and diarrhea. 1/20/09 - develops cold symptoms and fever. Chronic bruising. 2/13/09 Received ER medical records of 7/17/2007. FINAL DX: LLL pneumonia Records reveal patient experienced fever, cough, difficulty breathing, SOB. Had been seen by PCP 7/16 & dx w/pneumonia. Antibiotics & inhaler had not improved s/s. Exam revealed decreased LLL breath sounds. Tx w/nebs, IVF & oral antibiotics.

Other Meds:

Lab Data: chest x-rays and cbc LABS: CXR abnormal & c/w LLL consolidation. Blood c/s neg.

History: amoxycillin and augmentin PMH: pneumonia x 2. last one 3 yrs prior. Toxic synovitis at 3yo. Ear tube insertion.

Prex Illness: n/a

Prex Vax Illns:

Vaers Id: **338247-2** **Related reports:** 338247-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.9	F	23-Jan-2007	16-Jul-2007	174	03-Apr-2009	07-Apr-2009	NC		07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1209F	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0961F	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2107AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Pneumonia, Pyrexia

Symptom Text: Cough and fever. Developed pneumonia after HPV # 2. Antibiotics given.

Other Meds:

Lab Data: None @ our office except CXR

History: PCN

Prex Illness: Pneumonia - Improving

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338284-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	12-Aug-2008	13-Aug-2008	1	26-Jan-2009	04-Feb-2009	KS	KS200816	04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Fatigue, Headache, Pyrexia

Symptom Text: Headache, chills, fatigue, fever (highest 103.2 F). These symptoms lasted 4-5 days. Still had headache 8/18/08.

Other Meds:

Lab Data: None

History: Allergic to Penicillin

Prex Illness: None

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338290-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		26-Jan-2009	04-Feb-2009	FL		04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X2111	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site haemorrhage, Injection site vesicles

Symptom Text: Patient's mother reported that child had a small bleed after needle was removed pressure and cotton ball was applied by RN. The child removed band aid at 48 hrs, a small soft blister was seen approx 10mm away from injection site.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **338294-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Nov-2008	24-Nov-2008	0	26-Jan-2009	04-Feb-2009	KS	KS200824	06-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Left arm	Intramuscular	
	MMR	MERCK & CO. INC.	1120X	1	Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C2768BA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Gaze palsy, Heart rate decreased, Hypotonia, Oxygen supplementation, Pallor, Unresponsive to stimuli

Symptom Text: After giving MMR patient eyes rolled back, Pt slumped and became unresponsive and dusky. O2 put on Pt after trying to revive and EMS called. B/P 54/30 - Hr 55 and resp. 12.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338314-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Jan-2009	20-Jan-2009	1	26-Jan-2009	04-Feb-2009	IA	IA090001	04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	2	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2733AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Tinnitus, Vomiting

Symptom Text: C1 woke up at 5pm with vomiting. Feels like she could faint. Complains of ears ringing and continued nausea.-1.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: Fainting~HPV (no brand name)~1~15~In Patient

Vaers Id: **338317-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-Jan-2009	20-Jan-2009	0	26-Jan-2009	04-Feb-2009	MA		04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	5	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1531X	4	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Onset of nausea, dizziness within 30 sec of vaccine administration (HPV) symptoms persisted for full 48hrs per Pt symptoms were severe.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **338377-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	27-Feb-2008	27-Feb-2008	0	27-Jan-2009	28-Jan-2009	FR	WAES0807USA05472	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a physician concerning a 22 year old female with no relevant medical history and no previous pregnancy who on 27-FEB-2008 was vaccinated with a dose of GARDASIL. On 27-FEB-2008 the patient started her last menstruation period. The patient started a spontaneous pregnancy (estimated conception date on 12-MAR-2008). On 20-MAY-2008, she had a normal ultrasound. No adverse reaction was reported. The date of delivery was estimated on 03-DEC-2008. Follow up information received through pregnancy follow up on 21-JAN-2009: Case upgraded to serious-other medically important event. There was no congenital anomaly, no genetic problem in the family, no consanguinity with the partner. The patient was occasionally smoking. There was no complication during this pregnancy. Diagnostics performed during pregnancy were normal. There was no infection and no disease during pregnancy. On 16-DEC-2008 there was a foetal distress during labour leading to proceed to a cesarean section. She gave birth to a normal baby boy. Baby's weight was 4kg 180 kilograms, height was 56 cm. Apgar score was 10 at 1 mn and 10 at 5 mn. There was no post-natal complication and no congenital anomaly. The patient occasionally used paracetamol during her pregnancy. Other business partner number included: E2008-05386. No further information is available.

Other Meds: None

Lab Data: Ultrasound, 20May08, normal; Apgar score, 16Dec08, 10 at 1 mn and 10 at 5 mn

History:

Prex Illness: Pregnancy NOS (LMP = 27Feb08); Smoker

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338378-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Nov-2008	01-Nov-2008	0	27-Jan-2009	28-Jan-2009	FR	WAES0901AUS00105	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bradypnoea, Hypotonia, Loss of consciousness, Syncope

Symptom Text: Information was obtained on request by the Company from the agency, via a Case Line Listing and Public Case Details form, concerning a 25 year old female who on 01-NOV-2008 was vaccinated with her third dose of GARDASIL. Subsequently, on 01-NOV-2008 the patient experienced loss of consciousness and bradypnoea and was hospitalised. It was described that the patient was vaccinated with her third dose of GARDASIL at 10:52 am without any obvious side effects. At approximately 11:20 am the patient's husband brought her back to the physician's waiting room in a limp, unconscious state. The patient had collapsed 30 minutes after injection. The physician could not feel a pulse, however, a more senior physician could, and the patient's blood pressure was 110/70 and her respiratory rate was low. The patient was taken to the emergency department of hospital, where she was treated with oxygen. She was observed for a few hours and then discharged. On 01-NOV-2008 the patient recovered from loss of consciousness and bradypnoea. The agency considered that loss of consciousness and bradypnoea were probably related to therapy with GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: Blood pressure measurement, 01Nov08, 110/70, units not specified; Respiratory rate measurement, 01Nov08, low - bradypnoea

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 338379-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Nov-2008	22-Nov-2008	5	27-Jan-2009	28-Jan-2009	AZ	WAES0901USA02427	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLUN	MEDIMMUNE VACCINES, INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0070X	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Acute disseminated encephalomyelitis, Brain oedema, Chills, Cognitive disorder, Coma, Confusional state, Diarrhoea, Disseminated intravascular coagulation, Encephalitis, Endotracheal intubation, Extubation, Gait disturbance, Glossitis, Headache, Hemiplegia, Intensive care, Lethargy, Loss of consciousness, Miosis, Multi-organ failure, No reaction on previous exposure to drug, Ocular hyperaemia, Oral herpes, Photophobia, Posturing, Pyrexia, Rash, Renal failure acute, Respiratory failure, Septic shock, Sick relative, Strabismus, Toxic shock syndrome, Urosepsis, Vision blurred, Visual impairment, Vomiting

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 17-NOV-2008 was vaccinated with the second 0.5 ml dose of GARDASIL (lot #660553/0070X). Concomitant vaccine included FLUMIST intranasal (cold adapted Ann Arbor master strain). On 22-NOV-2008 the patient developed sepsis shock, high fever, acute renal failure and coma after getting the second dose of GARDASIL and was hospitalized. It was unknown how many days the patient stayed in hospital. Subsequently, the patient recovered on unspecified dates. It was also reported that the patient did not experience any AE after getting the first dose. No additional information was provided. Additional information has been requested. 3/9/09 Received PCP medical records of 11/17/08-12/19/08 as well as partial hospital records. FINAL DX: encephalitis, septic shock Records reveal patient had sore throat & dx w/URI on 11/17/08 when received HPV #2 & flumist vaccines. RTC 12/19 for hospital recheck w/residual hemipalsy. Hospital records of 11/22-12/3/2008: FINAL DX: toxic shock syndrome of unknown etiology, posibly menstrual associated vs post vaccination; acute disseminated encephalomyelitis. Records reveal patient had 2 siblings w/N/V/D 1 week prior to her experienced right frontal HA, chills, fever, bilious emesis, right monocular blurred vision, abdominal pain, diarrhea. Developed increasing confusion, lethargy, photophobia, emesis & became unconscious w/agonal breathing within 24 hours. Intubated by EMS for respiratory failure, temp 103.3, posturing, pinpoint unreactive pupils. Neuro, Neurosurgery, Ophtho, Heme & Renal consults done. Developed DIC likely related to urosepsis & multiorgan failure, acute renal failure, right hypertropia. Admitted to ICU & tx w/multiple IV antibiotics, steroids & pressors for low BP. Extubated 11/24. Remained febrile w/injected eyes, swollen red tongue, rsh & abdominal tenderness. Improved & transferred to inpatient neurorehab center. 3/12/09 Received additional hospital medical records of 1

Other Meds:

Lab Data: Unknown LABS: CT brain c/w cerebral edema. MRI brain abnormal & c/w ADEM. MRA head & neck & MRI of spine WNL. EEG abnormal. Renal US, visual evoked potentials, CT abdomen/pelvis WNL. CRP 1921, CK 1921, BNP 854, lactate 4.77, creatin

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338380-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-May-2008	08-Jul-2008	47	27-Jan-2009	28-Jan-2009	FR	WAES0901USA02688	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0354U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Facial paresis, Headache, Meningitis, Pleocytosis, Pyrexia, Vomiting

Symptom Text: Information has been received from a Health Authority (HA reference # PEI2009000322), concerning a 13 year old female, who on 22-MAY-2008, was vaccinated with the first dose of GARDASIL (Batch # NF58150, Lot # 0354U), intramuscularly in the left deltoid and on 18-AUG-2008, was vaccinated with the second dose of GARDASIL (Batch # NH17630, Lot # 1147U), intramuscularly in the left deltoid. On 08-JUL-2008, the patient developed headache and fever which lasted for 1 day. On 11-JUL-2008, she developed again severe frontal headache. On 14-JUL-2008, she vomited for several times a day. The symptoms recurred. The patient's siblings had a common cold at that time. The 2-year-old sister had fever and diarrhea 2 weeks ago. The mother had headache and stomach ache for two weeks. The twin sister was hospitalized for peripheral facial paresis on 21-JUL-2008. The patient was hospitalized on 17-JUL-2008. Clinical examination was normal as well as cranial MRI. CSF showed pleocytosis and elevated protein. Diagnosis of serious meningitis was established. The patient was treated symptomatically with Paracetamol and with penicillin for 3 days until suspicion of borreliosis was ruled out. The patient was discharged on 22-JUL-2008 at a stabilized condition, but not completely recovered. Exact duration of the symptoms and outcome is not reported. The second dose of the GARDASIL was administered into the left deltoid muscle on 18-AUG-2008. In October-2008, the patient developed right peripheral facial paresis. Follow-up examination on 15-NOV-2008 still showed mild facial paresis. Follow-up examination on 15-NOV-2008 still showed mild facial paresis. The patient had not completely recovered at the time of reporting. According to assessment of health authority, there is no causal relationship between the GARDASIL and the serious meningitis and the facial paresis. Therefore, there is no contraindication for administration of the third dose of GARDASIL. No further information is available. File Closed.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 17Jul08, influenza virus serology test: negative; diagnostic laboratory test, 17Jul08, TBE virus serology test: negative; diagnostic laboratory test, 17Jul08, VZV IgG serology test: positive; diagnostic laborator

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338382-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	26-Jun-2008	01-Aug-2008	36	27-Jan-2009	28-Jan-2009	FR	WAES0901USA03011	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Epilepsy, Familial risk factor, Intensive care

Symptom Text: Information has been received from a physician concerning a 16 year old female who was vaccinated with a third dose of GARDASIL (lot #, injection route and site not reported) on 26-JUN-2008. 2 months p.v. in August 2008 the patient experienced epilepsy. The patient was admitted to intensive care unit. Duration and outcome not yet reported. Medical history of the patient's aunt showed also epilepsy. Other business partner numbers include E2009-00297. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 338384-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Dec-2008	08-Jan-2009	21	27-Jan-2009	28-Jan-2009	FR	WAES0901USA03013	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chromaturia, Henoch-Schonlein purpura, Necrosis, Protein urine present, Scab, Skin discolouration, Wound

Symptom Text: Information has been received from a Health Authority (ref. DK-DKMA-20090077) and a physician concerning a 14 year old female who on 18-DEC-2008 was vaccinated intramuscularly with a first dose of GARDASIL (batch # and site not reported). On 08-JAN-2009, the patient developed Henoch-Shonlein purpura with universal spots. The spots developed to black necrotic wounds which subsequently formed scabs. The patient was hospitalized (date and duration not reported). Initially, protein urine was present and urine was discolored. On an unspecified date, the color of the urine became normal and either protein or blood in urine was no longer present. Dermatological examination and skin biopsy confirmed Henoch-Shonlein purpura. Various blood samples (not further specified) revealed no abnormalities. The patient received no concomitant vaccines or medications. At the time of reporting the patient was recovering. Other business partner numbers included E2009-00372. Additional information has been requested.

Other Meds: None

Lab Data: Skin biopsy, confirmed Henoch Shonlein purpura

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338386-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	25-Feb-2008	01-Aug-2008	158	27-Jan-2009	28-Jan-2009	FL	WAES0901USA03131	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Systemic lupus erythematosus

Symptom Text: Information has been received from a physician concerning a female patient who on 25-FEB-2008 was vaccinated with the third dose of GARDASIL. No lot number was provided. The physician reported that the patient had a positive lab test for lupus about six months (August 2008) after the date of the third dose of GARDASIL. Physician does not wish to be contacted. The patient sought unspecified medical attention. Upon internal review, lupus was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: LE cell, positive for lupus

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338387-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Oct-2008	05-Nov-2008	8	27-Jan-2009	28-Jan-2009	FR	WAES0901USA03202	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Juvenile arthritis, Pyrexia

Symptom Text: Case initially received from a health authority (reference # PEI2008021125) on 15-JAN-2009. It was reported that a 16-year-old female patient was vaccinated with a third dose of GARDASIL (lot# and injection site not reported) intramuscularly on 28-OCT-2008. On 05-NOV-2008 the patient experienced high fever, which initially could not be explained. Finally, diagnosis of Still's disease was established and treatment with prednisolone was started after 15 days. Then, the fever stopped. On an unspecified date, a blood sample was taken and showed leukocytemia (18.000, unit not reported) and elevated C-reactive protein (28 mg/dL). At the time of reporting to health authority (11-DEC-2008) treatment with prednisolone was ongoing. On the reporting form, the reporter is asking whether there could be a possible relation with GARDASIL. Other business partner numbers include E200900266. No further information is available.

Other Meds: Unknown

Lab Data: WBC count, 18000; Serum C-reactive protein, 28 mg/dl

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338414-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Sep-2008	15-Sep-2008	1	27-Jan-2009	28-Jan-2009	FR	WAES0901AUS00100	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hyperreflexia, Muscular weakness, Paraesthesia

Symptom Text: Information was obtained on request by the Company from the agency, via a Case Line Listing and Public Case Details form, concerning a 15 year old female, with a history of recurrent dislocation of her left knee, resulting in left knee surgery, who on 14-SEP-2008 was vaccinated with GARDASIL, intramuscularly. On 15-SEP-2008 the patient experienced muscular weakness, hyperreflexia and paraesthesia and was hospitalized. It was described that the patient experienced feet weakness, bilateral weakness to knees, with weakness ascending and tingling upper extremities. The patient was treated with cortisone injection. At the time of reporting to the agency on 11-NOV-2008, the patient had recovered from muscular weakness, hyperreflexia and paraesthesia. The agency considered that muscular weakness, hyperreflexia and paraesthesia were possibly related to therapy with GARDASIL. The original reporting source was not provided by the agency. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Knee operation; Dislocated knee

Prex Illness:

Prex Vax Illns:

Vaers Id: **338415-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	21-Aug-2007	Unknown		27-Jan-2009	28-Jan-2009	FR	WAES0901AUS00101	28-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Pancreatitis

Symptom Text: Information was obtained on request by the Company from the agency, via a Case Line Listing and Public Case Details form, concerning a 23 year old female who on 21-AUG-2007 was vaccinated with GARDASIL, intramuscularly. Other suspect therapy included MICROGYNON 30 ED, tablet, one dose daily (duration and indication not reported). Subsequently, the patient developed pancreatitis and was hospitalised. The patient was treated with morphine and metoclopramide. At the time of reporting to the agency on 18-NOV-2008, the patient had recovered from pancreatitis. The agency considered that pancreatitis was possibly related to therapy with GARDASIL and/or MICROGYNON. The original reporting source was not provided by the agency. Additional information is not expected.

Other Meds: MICROGYNON 30 ED

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338420-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Jan-2009	26-Jan-2009	0	27-Jan-2009	06-Feb-2009	NY		06-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Headache, Nausea, Syncope, Visual impairment

Symptom Text: About 7 minutes after patient had the shot, we were standing at the receptionist's area and she fainted and fell down. She remembers getting very dizzy and seeing black dots, but doesn't remember falling. She was awake by the time she was on the floor. We let her lie down, then she was able to walk into a room, and just sat, had water, and we were able to leave about 15 minutes later. Once at home, her head hurt from the fall, she rested, and seemed much better. At night, around 10 pm, she felt slightly nauseous, but then went to sleep for the night.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338424-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	10-Jul-2008	26-Sep-2008	78	27-Jan-2009	03-Feb-2009	TX		07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X		Left leg	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Autoimmune thyroiditis, Back pain, Fatigue, Kidney infection, Menstrual disorder, Pain, Pain in extremity, Sleep disorder, Urinary tract infection

Symptom Text: I had my first injection on 7/10/2008. Since my second injection (9/26/2008), I haven't had a regular menstrual cycle, even while on birth control. I am very tired and weak all the time. I was also diagnosed with autoimmune thyroiditis (10/20/2008). Prior to the injection, I had hypothyroidism. I have had urinary tract infections/kidney infections. I have had pain in my left hip area/leg and back. The pain shoots down my left leg, also injection leg. The pain is so annoying and constant it keeps me up at night. 05/07/09 Received Internal Medicine records 12/10/07-01/14/09 FINAL DX: Hypothyroidism Well patient visits. Adjustment of levothyroxine dosage

Other Meds: Armour Thyroid, Yasmin, Nuvaring

Lab Data: Bloodwork in October and December 2008 and January 2009 by Dr. Records received 05/07/09 - LABS: Thyroglobulin Antibodies = 188 IU/mL, Thyroid Peroxidase = 134 IU/mL

History: Hypothyroidism HPV #2 Lot # 0570X, given 9/26/08

Prex Illness: n/a

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338434-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	20-Sep-2008	12-Oct-2008	22	27-Jan-2009	06-Feb-2009	LA		06-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	?	3	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Fatigue, Injection site erythema, Injection site pain, Migraine, Nausea, Vaccine positive rechallenge, Vomiting

Symptom Text: approximately 3-6 wks after vaccination number 2 in september 2008. i had migraines, nausea, vomitting, fatique with no probable cause that lasted 3-4 times a week for about 3 months. followed by severe sob with no probable cause in jan 2009. i recieved vaccine number 3, 3 days ago and pain and redness at injection site.shortness of breath continues. no other symptoms have occured since 3rd vaccination

Other Meds: adderall 20 mg xr and femcon fe

Lab Data: quit taking all other medications and symptoms still persisted. lab work was done to draw igE levels to diagnosis shortness of breath as an allergic reaction. results were negative. no known cause of shortness of breath have been discovered

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338435-2** **Related reports:** 338435-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Jan-2009	24-Jan-2009	0	18-Feb-2009	20-Feb-2009	WA		25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1389X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site pruritus, Injection site swelling, Injection site warmth

Symptom Text: L upper arm became red, warm, swollen, painful and itchy 2hrs after varicella vaccine. Pt took BENADRYL po and topical and applied ice packs. Returned to clinic 1/26/09, seen by provider, given MEDROL dose pack.

Other Meds: BCP; IMITREX prn; VENTOLIN HFA

Lab Data: None

History: Migraines

Prex Illness: Non

Prex Vax Illns:

Vaers Id: **338447-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	08-Mar-2008	08-Mar-2008	0	28-Jan-2009	29-Jan-2009	FR	WAES0806USA08713	29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Gluteous maxima	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea, Drug exposure during pregnancy, Foetal growth retardation, Incorrect route of drug administration, Threatened labour, Vaginal haemorrhage

Symptom Text: Information has been received from a gynecologist, concerning a 20 year old female patient who was considered as non-enrolled as the vaccination was administered more than 1 month before the pregnancy start date (to be clarified). This is a case of misuse, is vaccine administered at inappropriate site. The patient started a spontaneous pregnancy (estimate conception date 15-APR-2008) 5 weeks after receiving on 08-MAR-2008 the first dose of GARDASIL (Lot #, Batch # not reported) in the buttock. Three days after vaccination (on 11-MAR-2008), the patient experienced vaginal bleeding. The outcome was not reported. absence of menstruations was noticed on 26-MAR-2008. The patient had concomitant contraception with DIANE 35. Conception date was estimated through dating ultrasound. Follow-up information on 24-JUN-2008 received by telephone: The reporter specified that the patient was 21 year old and that the vaccine was administered for a limit period of 1 month before the beginning of the pregnancy. The 15-APR-2008 was the pregnancy start date estimated by the ultrasound scan. Follow-up information was received on 31-JUL-2008 which reported that the patient is considered as enrolled in pregnancy registry as the vaccine was administered 5 weeks before conception date. Initials of the patient were modified. Patient's date of birth, height and weight were reported. On 15-APR-2008, the patient started a spontaneous pregnancy (estimated date by the ultrasound). The echography was normal. Estimated date of delivery on 15-JAN-2009. She had no previous pregnancy. Consent form was provided. Follow-up information was received on 20-JAN-2009 which reported that the patient had complications, abnormal diagnostic performed and infection or disease during her pregnancy: echography at 22 amenorrhea weeks revealed threatened premature labour, intrauterine growth retardation, and then there was a suspicion of pulmonary embolism (unspecified date). she gave birth to a normal baby girl on 12-DEC-2008 at 36 amenorrhea weeks. Baby's birth w

Other Meds: Diane 35

Lab Data: ultrasound, ??Oct?08, threatened premature labour; ultrasound, ??Oct?08, intrauterine growth retardation; ultrasound, Dating ultrasound: estimated conception date 15-APR-2008. Normal

History:

Prex Illness: Pregnancy NOS (LMP = 17Apr08)

Prex Vax Illns:

Vaers Id: **338448-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Apr-2008	15-Apr-2008	0	28-Jan-2009	29-Jan-2009	--	WAES0807USA01140	29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Inappropriate schedule of drug administration

Symptom Text: Information has been received through the Merck Pregnancy Registry from a healthcare worker concerning a female (age not reported) who on 02-JUL-2007 was vaccinated with a dose of GARDASIL (lot 657737/0522U). On 15-APR-2008 the patient was vaccinated IM with the second 0.5 mL dose of GARDASIL (lot 657737/0522U). Concomitant therapy included CLARITIN 10 mg PO q am. At the time of the second vaccination the patient was pregnant. The pregnancy was confirmed via a "pregnancy bloodwork." No adverse events were reported. The LMP was reported to be on 08-APR-2008. Follow up information indicated that on 12-JAN-2009 the 18 year old female patient delivered a baby by cesarean section (no details provided). The baby's weight was 8 pounds and 2 ounces with normal neonatal course. It was 39 weeks from last menstrual period. There were no past medical history and concurrent medical conditions. Upon internal review, the patient's delivery via cesarean section was considered an other important medical event. Additional information has been requested.

Other Meds: CLARITIN, 10 mg

Lab Data: Serum beta-human, positive

History:

Prex Illness: Pregnancy NOS (LMP = 4/8/2008)

Prex Vax Illns:

Vaers Id: **338449-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		28-Jan-2009	29-Jan-2009	FR	WAES0901CAN00076	29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactic shock

Symptom Text: Information has been received from a nurse concerning a patient who was vaccinated with GARDASIL, lot # not available. Subsequently the patient experienced anaphylactic shock. Upon internal review, anaphylactic shock was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338450-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Dec-2007	13-Dec-2007	0	28-Jan-2009	29-Jan-2009	FR	WAES0901USA00421	29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0276U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthma, Autonomic nervous system imbalance, Bronchial hyperreactivity, Depression, Disturbance in attention, Dizziness, Dyspnoea, Fatigue, Headache, Hypotension, Visual impairment

Symptom Text: Information has been received from a gynecologist concerning a 15 year old female patient who was vaccinated with the third dose of GARDASIL (batch # NF585S0; Lot # 0276U) I.M into upper arm on 13-DEC-2008. Since vaccination, the patient experienced alternating headache, dizziness, dyspnea and visual disturbance. Electroencephalography, cranial computed tomography and electrocardiogram were without findings. Epstein-Barr viral capsid antigen immunoglobulin G antibody test was positive on 04-DEC-2008, this result was assessed that there is no acute infection. At the time of reporting the patient had not recovered. Dose 1 of GARDASIL given on 30-MAY-2007 (batch # NE38100; Lot # 654948/0908F) and dose 2 of GARDASIL on 02-JUL-2007 (batch # NE45050; Lot # 655376/0572F) were well tolerated. Follow up information has been received concerning the patient. It was reported that at the beginning of 2008 the patient developed dizziness, dyspnea on effort, tiredness and impaired concentration. In April 2008 suspicion of vasovagal dizziness was diagnosed by a neurologist. Neurological examination and cranial MRI showed normal hyperreagibility by means of inhalative metcholine provocation, dyspnea on effort in the sense of asthma on effort, arterial hypotension, psychovegetative syndrome and suspicion of depressive syndrome were diagnosed. Dyspnea on effort started about 1 year ago especially during sports. Physical, cardiological examinations and pulmonary function showed normal results. The patient had not recovered at the time of reporting. The first dose of GARDASIL (batch # NE45050; Lot # 655376/0572F) was given on 02-APR-2007 and the second dose of GARDASIL (batch # NE38100; Lot # 654948/0908F) was given 30-MAY-2007. Dyspnea on effort was considered a symptom of asthma. Upon medical review this case was upgraded to serious because of long duration of the adverse event. The physician considered asthma, visual disturbance, headache, dizziness, tiredness, concentration impaired, psychovegetative syndrome, depressive syndrome

Other Meds: Hormonal contraceptives (unspecified)

Lab Data: Diagnostic laboratory test, 05Jan09, <1:20 U/ml, anti-EBNA EA IFT; Diagnostic laboratory test, 05Jan09, 5 IU/ml, MAK; Diagnostic laboratory test, 05Jan09, routine lab values: normal results; Diagnostic laboratory test, 05Jan09, <1.8 IU/L, T

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338451-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Dec-2008	01-Jan-2009	31	28-Jan-2009	29-Jan-2009	FR	WAES0901USA02649	29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ19750	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Facial paresis

Symptom Text: Information has been received from a health authority concerning a 12 year old female who on 01-DEC-2008 was vaccinated with a second dose of GARDASIL (batch # NJ19750 (not valid for GARDASIL) injection site and route not reported). On 01-JAN-2009 the patient developed right peripheral facial paresis. The patient was hospitalized on an unspecified date. Laboratory findings showed normal results. Borrelia serology was negative and borrelia DNA not detectable. Borrelia infection could be excluded. The patient had not recovered at the time of reporting. First dose of GARDASIL (lot# 0465U; batch # NG17850) was administered on 15-SEP-2008. Toleration was not reported. Other business partners numbers includes: E2009-00277. Additional information has been requested.

Other Meds: Unknown

Lab Data: laboratory test, normal; serum Borrelia burgdorferi antibody test, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338452-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-Oct-2008	30-Dec-2008	71	28-Jan-2009	29-Jan-2009	FR	WAES0901USA03040	29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1316U	1	Left arm	Intramuscular	

Seriousness: DIED, SERIOUS

MedDRA PT Autopsy, Death

Symptom Text: Information has been received from a health authority (reference # PEI2009000661) concerning a 15 year old female who on 20-OCT-2008 was vaccinated with the first dose of GARDASIL, lot #1427U (batch #NH15200) IM into the left upper arm. No information regarding toleration was given. On 29-DEC-2008, the patient was vaccinated with a second dose of GARDASIL, lot #1316U (batch #NH45640) IM into the left upper arm. On 30-DEC-2008 the patient died. According to the preliminary report, the autopsy showed no acute or chronic organic disease. The possibility of carbon monoxide intoxication was not yet ruled out. Investigation by public prosecution is ongoing. Lot checks have been requested. Other business partner numbers included: E2009-00404. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338454-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		28-Jan-2009	29-Jan-2009	LA	WAES0901USA03330	29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning an approximately 15 year old female patient who was mentally handicapped who in 2007 was vaccinated with all 3 doses of GARDASIL (Lot numbers not provided). The patient's mother told the physician that in late 2008, the patient was diagnosed with an abnormal PAP and possible cervical cancer related to HPV. As of 22-JAN-2009 the outcome of the patient is not recovered. Upon internal review, possible cervical cancer was considered to be an Other Important Medical Event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, ?/?/08, abnormal

History:

Prex Illness: Mental handicap NOS

Prex Vax Illns:

Vaers Id: **338455-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-Dec-2008	22-Dec-2008	0	28-Jan-2009	29-Jan-2009	FR	WAES0901USA03389	29-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ21180	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness, Nausea, Syncope, Vomiting

Symptom Text: Information has been received on 21-JAN-2009 from an Health Authority concerning a 13 year old female patient who received the first dose of GARDASIL (Lot #....., batch # NJ21180) via intramuscular route on 22-DEC-2008. 30 Seconds after vaccination, she lost consciousness with convulsion for 15 seconds. The patient did not experience sphincter incontinence. She woke up well, with space and time orientation but with nausea and vomiting. There was no specific treatment of the adverse reaction. The patient was under medical supervision and vital sign monitoring. There was no previous history of adverse reaction to other drugs. However, the patient had a history of loss of consciousness when blood analysis was conducted (one episode two years ago). Furthermore, she was concomitantly taking Paracetamol. There was no other known clinical history. At the time of reporting, the patient had recovered. Other business partner numbers include E2009-00496, L200901-159 and RA-002-2009. The health authority considered convulsion, fainting, and vomiting to be other important medical events. No further information is available. The case is closed.

Other Meds: Acetaminophen

Lab Data: Unknown

History: Loss of consciousness

Prex Illness:

Prex Vax Illns:

Vaers Id: 338475-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	06-Feb-2008	23-May-2008	107	28-Jan-2009	02-Feb-2009	OH		06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	1	Left arm	Unknown	HPV4

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hypoaesthesia, Multiple sclerosis, Neck pain, Paraesthesia, Post lumbar puncture syndrome, Viral infection

Symptom Text: I received 2 of the 3 Gardisil shots. One on 10/16/07 and one on 2/2/08. In April 2008 I had a virus that lasted for 4 weeks and was treated with antibiotics. On May 24th my left side went completely numb and I was diagnosed with Multiple Sclerosis on 5/25/09 and hospitalized for 5 days. I had another flare on 6/23/08 where i was hospitalized for 3 days. 3/4/09-records received for DOS 5/23/-5/27/08-DC DX:New diagnosis of multiple sclerosis.Cephalgia exacerbated by lumbar puncture., . Presented to ED with C/O 2 day history of neck pain, numbness and tingling in left upper and lower extremity.

Other Meds: Ortho Tri Sprintec

Lab Data: MRI, blood work and spinal tap 3/4/09-records received- MRI brain, cervical spine show multiple white matter lesions consistent with multiple sclerosis and demyelination.CSF lymphoctyes elevated 100, WBC elevated 7, olig none present, prot

History: n/a 2/17/09-records received:horse allergy-anaphylaxis. molds and nuts allergy-watering eyes and sneezing.

Prex Illness: Virus that lasted for 4 weeks then the onset of MS.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338491-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	06-Jan-2009	08-Jan-2009	2	27-Jan-2009	06-Feb-2009	NC	NC09008	06-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	UF456CA	5	Right leg	Intramuscular	
HPV4	MERCK & CO. INC.	G570X	0	Left leg	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB275BA	0	Left leg	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB53AA	1	Right leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: 12X12 can area of redness + swelling +warm painful to touch on Rt med thigh esp where TETNUS / ADACEL was given GARDASIL suspect + TDAP.

Other Meds: Toprimal Cariva BCP

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338495-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Oct-2008	27-Oct-2008	0	28-Jan-2009	09-Feb-2009	NC		09-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contusion, Injection site pain

Symptom Text: 1. Bruising x 3 weeks. 2. Local pain where shot or injection was given.

Other Meds:

Lab Data: Hematoma on left arm @ injection site.

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338496-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	26-Jan-2009	26-Jan-2009	0	28-Jan-2009	09-Feb-2009	TN		09-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Nausea, Vaginal infection, Vomiting

Symptom Text: Pt describes temp 102.2 F orally several hours after injection. Also complained of nausea and vomiting but was also taking Flagyl for Vaginitis.

Other Meds: Flagyl 500mg bidX7d

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **338500-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	20-Jan-2008		23-Jan-2009	13-Feb-2009	--		03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaginal discharge, Vaginitis bacterial

Symptom Text: I took the GARDASIL shot series. It didn't cause major problems, but when I took the second shot around the above date I noticed a change in my vaginal discharge. The shot caused me to get bacterial vaginosis. I had it for nine months till I figured out there was a problem because a month before hand I took myself off birth control and I thought my body was just going through changes. I talked to my doctor and he told me it wasn't the GARDASIL shot, so I took the third shot in the series. It immediately caused the bacterial vaginosis yet again. It's not that it's serious, but every woman should know that this is a possible side effect and may be they should prepare themselves.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338540-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Feb-2008	29-Feb-2008	0	20-Jan-2009	13-Feb-2009	CA	WAES0812USA02570	24-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1456U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Cough, Dyspnoea, Hypersomnia, Oxygen saturation normal, Sleep disorder

Symptom Text: Information has been received from a physician assistant concerning an 18 year old female who on unspecified dates was vaccinated with a first, second and third dose of GARDASIL, lot # unknown. It was reported that the patient had been short of breath since receiving her third dose of GARDASIL. At the time of reporting, the outcome of the event was unknown. 2/3/09 MR received from Pulmonary Med consults dated 9/9/08, 10/27/08 and 1212/10/08 with DX: Shortness of breath/chest tightness. Allergic rhinitis improved. Referred by PCP for eval of increasing SOB and chronic cough. Sleeping more lately and waking at night and unable to catch breath. PE WNL. O2 sat 96-98%. Referred for heart cath later in the yr to r/o pulmonary HTN.

Other Meds: Unknown

Lab Data: Unknown. Labs and Diagnostics: Stress test -no evidence for EIA or cardiac disease, but borderline VE and VC O2 suggesting possible early pulmonary vascular disease.

History: Unknown PMH: Mono 12/07. tonsillectomy 6/08. Allergy to PCN, metal

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338542-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		20-Jan-2009	13-Feb-2009	SC	WAES0812USA02379	10-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with the complete series of GARDASIL (lot not reported) when the vaccine was fairly new on the market and recently was found to had an abnormal PAP. The patient had HPV. At the time of reporting, 10-DEC-2008, the outcome of the patient was unknown. Additional information was unknown.

Other Meds: Unknown

Lab Data: Pap test, abnormal. The patient has HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338543-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		20-Jan-2009	13-Feb-2009	--	WAES0812USA02368	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, Skin discolouration

Symptom Text: Information has been received from a sonographer concerning her daughter, who an on unspecified date was vaccinated with the first dose of GARDASIL. On the same day, the patient was nauseous and turned green and within a few minutes after vaccination had recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338544-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Nov-2008	Unknown		20-Jan-2009	13-Feb-2009	IL	WAES0812USA02360	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site atrophy

Symptom Text: Information has been received from a nurse and later a physician concerning a 13 year old female patient with asthma and allergies to codeine, and shellfish who on 03-Nov-2008 was vaccinated intramuscularly with a 0.5 ml first dose of GARDASIL (lot# 660620/0571X). Concomitant therapy included ADVAIR, MSD and ZYRTEC. The physician stated that the patient received the vaccination with out incident but gradually noticed a "quarter-sized" indentation in the area of the deltoid that is obvious to visual inspection. No pain, erythema, limited movement, rash or other complaints were reported. The patient is schedule to be seen in follow-up next week. At the time of this report it is unknown if the patient recovered. Additional information has been requested.

Other Meds: Zyrtec; Advair; Singular

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity; Fish allergy; Shellfish allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338545-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Oct-2008	01-Oct-2008	-12	20-Jan-2009	13-Feb-2009	CO	WAES0812USA02344	04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1426F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician and a medical assistant concerning a 14 year old female with a history of asthma and recurrent otitis media; penicillin, KEFLEX, and sulfa drug allergies, who on 13-OCT-2008 was vaccinated with a first dose of GARDASIL (lot # 655205/1426P), intramuscularly. Concomitant therapy included medroxyprogesterone acetate DEPO-PROVERA. On October 2008 the patient experienced dizziness. She experienced the dizziness mainly in the in the morning but the dizziness is progressively getting worse and occurs during the day also. Laboratory diagnostics studies performed included a CBC, a complete metabolic panel and a TSH on 03-Dec-2008. The patient sought medial attention through an office visit. The patient had not recovered. Additional information has been requested.

Other Meds: DEPO-PROVERA mg

Lab Data: diagnostic laboratory 12/03/08 - complete metabolic panel plasma TSH 12/03/08 - complete blood cell 12/03/08 -

History:

Prex Illness: Asthma; Otitis media recurrent; Allergic reaction to antibiotics; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: 338546-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	28-Oct-2008	28-Oct-2008	0	20-Jan-2009	13-Feb-2009	CA	WAES0812USA02177	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Headache, Pain in extremity, Paraesthesia, Vision blurred

Symptom Text: Information has been received from a physician concerning a 26 year old female who on 28-OCT-2008 was vaccinated with the first dose of GARDASIL, lot number 661703/0651X. Within a week of receiving her first dose the patient experienced blurriness in the left eye, pain and tingling in her hands and feet, and joint pain and headache. The patient sought medical attention at the physician's office. Patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338547-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
40.0	F	01-Oct-2007	01-Oct-2007	0	20-Jan-2009	13-Feb-2009	CA	WAES0810USA05371	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Inappropriate schedule of drug administration, Nausea

Symptom Text: Information has been received a consumer through a Merck pregnancy registry concerning herself, a 41 year old female with allergies to Sulfa and iron supplements", who on 29-Apr-2008 was vaccinated IM with the third dose of 0.5 ml GARDASIL while she was pregnant. Her LMP was 27-Jan-2008. Expected date of delivery was 02-Nov-2008. The patient visited physician's office for medical attention. Prenatal testing included ultrasound for her has been normal. The patient had received the first dose of GARDASIL on 01-Oct-2007. Follow-up information has been received from a completed questionnaire. The patient was a Caucasian with no previous pregnancies. She also had Crohn's disease and multiple bowel excisions. Medications during her pregnancy included prenatal vitamins for routine use and REPLIVA 21/7 for anemia. She also had ZOFRAN for nausea on 13-March-2008. Ultrasound on 05-Jun-2008 was normal. On 13-Nov-2008, 41 weeks from her LMP, the patient delivered a live normal male infant weighing 6 pounds 3 ounces. The infant's Apgar score was 8/9 without congenital anomalies, complications or abnormalities. There were no complications, infections or illnesses during the patient's pregnancy and delivery. No further information is available.

Other Meds: Repliva 21/7, Zofran, Vitamins

Lab Data: Ultrasound normal - Prenatal testing including ultrasound has been normal. Diagnostic laboratory 04/11/08 - normal male.

History: Surgery

Prex Illness: Pregnancy NOS (LMP= 1/27/2008) Drug hypersensitivity: Crohn's disease

Prex Vax Illns:

Vaers Id: **338548-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	29-Jan-2008	03-Mar-2008	34	20-Jan-2009	13-Feb-2009	CA	WAES0809USA01795	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Fungal infection, Herpes simplex

Symptom Text: Initial and follow-up information has been received from a nurse practitioner concerning a 26 year old female patient with no pertinent medical history or concurrent conditions and no drug reactions/allergies, who on 29-JAN-2008 was vaccinated with the first dose of GARDASIL (lot # 655327/1287U) 0.5 mL, IM. On 03-MAR-2008, the patient received the second dose of GARDASIL (lot # 655604/0052X) 0.5 mL, IM. There was no concomitant medication. The patient was subsequently determined to be pregnant in April 2008. In April 2008, the patient's urine pregnancy test was positive for pregnancy. The patient sought medical attention with an office visit. The last menstrual period was on 09-FEB-2008. Therapy with GARDASIL was discontinued. The patient's estimate date of conception was 23-FEB-2008 and estimated date of delivery was 15-NOV-2008. No problems reported. Prenatal testing included. On 23-Apr-2008 ultrasound: Routine test - Within normal limits. On 16-Jun-2008 serum alpha-fetoprotein test: Negative. Time 4. Routine test. On 07-Jul-2008 ultrasound: Routine test. Within normal limits. The patient had five previous pregnancies and five (previously report that on 21-NOV-2008, the patient delivered a normal and healthy female baby weighing 8 lb and 14 oz and apgar score 9/10. No complications during the pregnancy and labor/delivery, no congenital anomalies, and no complications or abnormalities. During the pregnancy, prenatal laboratories were performed. There was infections or illness during the pregnancy, a laboratory test was positive for HSV I and II. The patient received prophylactic Valtrex, 500 mg, BID, started on 06-OCT-2008 to delivery day 21-NOV-2008. Other medications used during this pregnancy included Metronidazole 500 mg for 7 days on 20-OCT-2008 for bacterial vaginosis and Diflucan 150 mg one time oral dose that same day for a vaginal yeast infection. Additional information is not available.

Other Meds:

Lab Data: Ultrasound, 04/23/08, Routine test-Within normal limits; Ultrasound, 07/07/08, Routine test. Within normal limits; Urine beta-human, 04/??/08, positive; Serum alpha-fetoprotein, 06/16/08, Negative. Time 4. Routine test; Herpes simplex virus

History:

Prex Illness: Pregnancy NOS (LMP= 2/9/2008

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338550-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Feb-2008	29-Feb-2008	0	20-Jan-2009	13-Feb-2009	--	WAES0805USA00593	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Urinary tract infection

Symptom Text: Information has been received from a health care professional for GARDASIL regarding a 15 year old female who on 29-FEB-2008 was vaccinated with an unknown dose of GARDASIL (lot number unspecified). On 29-FEB-2008 the patient received vaccine when she was pregnant. The patient's LMP=11/21/07. The patient is not experiencing any known symptoms. Unspecified labs were performed on 02-MAY-2008. The patient sought unspecified medical treatment in the office. Follow up information was received from a health care professional who reported on 24-AUG-2008 the patient delivered a normal, healthy female baby weighing 6 pounds, 11 ounces at her 39 weeks and 4 days from LMP. The baby's apgar score was 9/9. It was also reported other medications used during pregnancy included MACROBID due to urinary tract infection from 09-MAY-2008 to 15-MAY-2008, biotin (+) carbonyl iron (+) ducosate sodium (+) folic acid (+) minerals (unspecified) (+) vitamins (unspecified) PRENATE ELITE and EXPEXTA LIPIL for prenatal vitamins from 02-MAY-2008. Additional information is not expected.

Other Meds: Unknown

Lab Data: Ultrasound, 5/2/08

History:

Prex Illness: Pregnancy NOS (LMP= 11/21/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338551-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	27-Dec-2007	11-Mar-2008	75	20-Jan-2009	12-Feb-2009	IL	WAES0804USA04002	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arrested labour, Drug exposure during pregnancy

Symptom Text: Initial Information and follow up has been received from a pharmacist and nurse for the Pregnancy Registry of GARDASIL concerning a 24 year old female with a history of 0 pregnancies and 0 live births who on 01-NOV-2007 was vaccinated with her first dose of GARDASIL (lot # not reported). On 27-DEC-2007 the patient was vaccinated with her second dose of GARDASIL (lot # not reported). Concomitant therapy included methyldopa, 500 mg BID for hypertension. The patient is now pregnant with an LMP date of 11-MAR-2008 and a delivery due date of 16-DEC-2008. No problems were reported. The patient is also taking 40mg daily of PROTONIX for gastrooesophageal reflux disease (GERD). The patient sought medical attention by contacting her physician on an unspecified date. Follow-up information was received from an RN for the Pregnancy Registry for GARDASIL. On 28-JUL-2008 and 12-SEP-2008, ultrasounds were performed for the evaluation of growth and date, and the results were within the normal limit. On 09-DEC-2008, the patient with chronic hypertension (CHTN) and gastrooesophageal reflux disease (GERD) gave birth to a 7 pounds 0 ounce male infant. The labor was forced for arrested descent. Apgar score was 8/9. The infant was normal without congenital anomalies. There was no infections or illnesses during pregnancy. No further information is available.

Other Meds: METHYLDOPA mg; PROTONIX mg

Lab Data: ultrasound, 9/12/08, within normal limit; ultrasound, 07/28/08, within normal limit

History:

Prex Illness: Pregnancy NOS (LMP = 3/11/3008) Hypertension; Dyspepsia

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338552-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
2.0	F	Unknown	Unknown		20-Jan-2009	12-Feb-2009	CA	WAES0804USA00010	16-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
MMR	MERCK & CO. INC.	NULL		Unknown	Unknown	
IPV	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	0928U	0	Unknown	Unknown	
HIBV	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event, Wrong drug administered

Symptom Text: Information has been received from a nurse practitioner (N.P.) concerning a 1 year old female who was inadvertently vaccinated with a first dose of GARDASIL (658554/0928U). Subsequently the patient experienced inappropriate age and inappropriate schedule of vaccine administered. No other information as available. Follow-up information was received on 26-DEC-2008 from the N.P. indicating that the patient is a 2 (previously reported as 1) year old female child with no pre-existing allergies, birth defects or medical conditions. On an unspecified date the patient was vaccinated with a dose of GARDASIL instead of a dose of POLIOVIRUS vaccine inactivated (unspecified). On the same day she also received a dose of VARIVAX virus vaccine live (Oka/Merck) (MSD), DTaP/Hib (manufacturer unknown), MMR II and VAQTA (manufacturer unknown). There was no illness at time of vaccination. It was reported that there was no adverse event.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **338553-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-May-2007	30-Jan-2008	245	20-Jan-2009	12-Feb-2009	KS	WAES0803USA00972	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Oedema, Pregnancy induced hypertension, Urinary tract infection, Vomiting

Symptom Text: Information has been received for the Merck Pregnancy Registry for GARDASIL from a health department nurse and from a registered nurse concerning a 15 year old female, with sulfonamide allergy, asthma, seasonal allergies and a history of smoking, who on 09-Aug-2006 was vaccinated with the first dose of GARDASIL, on 30-May-2007 was vaccinated with the second dose of GARDASIL and on 05-Dec-2008 was vaccinated with the third dose of GARDASIL (lot# 660616/0570X). Concomitant therapy included asthma medication, Meclizine, vitamins and ALLEGRA-D. The health department nurse reported that the patient was pregnant after receiving two doses of the HPV vaccine. The patient was seen at the Department on 06-Mar-2008 and a urine test was positive for pregnancy. The patient's date of last menstrual period was 30-Jan-2008. The estimated date of delivery was 05-Nov-2008, Ultrasounds were performed on 06-June-2008, 06-Aug-2008, 17-Sep-2008 and 14-Oct-2008 and results were within normal limits, small for dates, PIH and edema. A sonogram and a biophysical profile was also performed and resulted within normal limits. On 15-Oct-2008, the patient delivered a normal, healthy male baby weighing 5 pounds 3.7 ounces. There was no congenital anomalies. The baby's length was 18.5 inches and his Apgar score was 8/9 . the baby presented short foreskin. Complications during pregnancy included UTI, edema, increased blood pressure and hyperemesis. Complications during delivery included PIH and vacuum delivery. No further information is available.

Other Meds: Allegera-D; Meclizine; Vitamins

Lab Data: Ultrasound, Biophysical profile, within normal limits; Ultrasound, 10/14/2008, within normal limits, small for dates, PIH, edema; Urine beta-human, 03/06/2008, positive

History: Smoker

Prex Illness: Pregnancy Nos (LMP = 1/30/2008); Asthma; Sulfonamide allergy; Seasonal allergy

Prex Vax Illns:

Vaers Id: 338554-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	08-Nov-2007	18-Dec-2007	40	20-Jan-2009	12-Feb-2009	CA	WAES0802USA04664	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1209U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Fungal infection

Symptom Text: Information has been received from a medical assistant and a nurse practitioner, for the pregnancy registry for GARDASIL, concerning a 23 year old female patient with Glioblastoma multiforme in 2007, cholecystectomy in 2001, history of smoking and asthma, and with a history of 4 pregnancies and a 4 full term deliveries, who on 08-NOV-2007 was vaccinated the first 0.5 ml dose of with GARDASIL (Lot #654540/1209U). The patient became pregnant after receiving the vaccination. Her LMP was 18-DEC-2007. Estimated conception date was 15-DEC-2007 and EDD was 26-SEP-2008. Other medications used during pregnancy included MONISTAT on 11-apr-2008 for yeast and prenatal vitamins 7 tablets once a day on 11-APR-2008. Prenatal care panel were performed. On 07-FEB-2008 ultrasound was performed for SGA with the result of pregnancy 5 week 6/7 day; on 25-APR-2008 amniocentesis was performed for SGA with the result of pregnancy 5 week 6/7 day; on 25-APR-2008 amniocentesis was performed for SGA with the result of pregnancy 17 week 2/7 day, and MSAFP was performed for screening with the result of Neg x4. On 24-SEP-2008 the patient had a normal female infant (6 pounds, 10 ounces) with no congenital anomalies. Other complication was choroid plexus cyst. There was not complication during pregnancy and labor/delivery, and not infections or illness during pregnancy for the patient. BS monitoring per 6 AM was performed during pregnancy. Follow up information was received from a nurse practitioner. She reported that the fetal choroid plexus cyst was noted only prenatally on a mid-trimester ultrasound. On 10-JUN-2008, at 25 weeks EGA, the patient had a follow up sonogram with a perinatologist who said the cyst had resolved. No further testing was done or needed. The reporter also noted that the baby was fine with no problems and no anomalies. Additional information is not expected.

Other Meds: Unknown

Lab Data: Diagnostic laboratory, pre natal care panel; Ultrasound, 02/07/08, 5 week 6/7 day; Amniocentesis, 04/25/08, 17 week 2/7 day; Ultrasound, 6/10/08, fetal choroid plexus cyst resolved; Ultrasound, fetal choroid plexus cyst; Serum alpha-fet

History: Cholecystectomy; Smoker; Glioblastoma multiforme

Prex Illness: Pregnancy NOS (LMP = 12/18/2007); Asthma

Prex Vax Illns:

Vaers Id: **338559-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		29-Jan-2009	30-Jan-2009	--	WAES0901USA03646	30-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a pharmacist concerning a female who in 2008 was vaccinated with a dose of GARDASIL. The patient experienced seizure after receiving the GARDASIL. At the time of this report the patient had recovered. Upon internal review seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 338560-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	22-Jan-2009	22-Jan-2009	0	29-Jan-2009	30-Jan-2009	OH	WAES0901USA03508	10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	2	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain lower, Abdominal tenderness, Deep vein thrombosis, Fallopian tube disorder, Gastrointestinal hypomotility, Immunisation reaction, Malaise, Migraine, Nausea, Pain, Pancreatitis, Phonophobia, Photophobia, Salpingitis, Thrombosis, Visual impairment

Symptom Text: Information has been received from a physician concerning a 24 year old female who on 22-JAN-2009 was vaccinated with a 0.5 mL third dose of GARDASIL (lot # 661046/0381X). On 22-JAN-2009 the patient experienced pancreatitis and was hospitalized. Additional information has been requested. 2/13/09 MR received for DOS 1/23 with D/C DX: Psuedointestinal Obstruction, S/P stomach, intestine, pancreas and liver transplantation on Immunosupression. GERD. Mild Pancreatitis probably 2' to Gardasil Administration, although the cause effect of this intervention is not proven. Pt presented with intestinal abdominal pain, achiness and generalized malaise. PE (+) for abdominal tenderness. No sign of obstruction found. D/C and transferred to higher level of care. MR received for DOS 1/24-30/2009 with D/C DX: S/P Multivessel transplant. R Femoral vein DVT. Abdominal pain r/t dilated Fallopian Tube. Pt presented 1/24/09 with c/o abdominal pain. Some nausea. Pain is in lower abd and crampy. Tx: IVF and D/C to f/u with gyn. 2/23/09 PCP records received including some hospital records. Seen 10/23/08 for migraine with light sensitivity. Worst H/A ever had. Seen again 1/19/09 for migraine x 1 week with phono/photophobia and visual changes. 3/3/09 GYN records received for f/u visit 2/18/09 for salpingitis, now resolved. Of note: pt received 2nd HPV in 8/2008. Thrombic events in upper extremity noted.

Other Meds: Unknown

Lab Data: Unknown. Labs and diagnostics: CT abdomen (+) for ? liver bilomas. Transvaginal US (+) for dilated L Fallopian Tube. US pelvis (+) for dilated Fallopian tube. CT head (-). BUN 25 down to 21 by d/c. Creatinine 1.9. EKG (+) for sinus bra

History: Unknown. PMH: Congenital malformation and lack of rotation of intestines. Transplant of intestines, pancreas, stomach and liver. Allergies to Vanco, Cipro sumatriptin and metoclopramide. Previously on OCP which were d/c due to thrombic events.

Prex Illness:

Prex Vax Illns:

Vaers Id: **338561-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	27-Dec-2008	01-Jan-2009	5	29-Jan-2009	30-Jan-2009	FR	WAES0901USA03398	30-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: DIED, HOSPITALIZED, SERIOUS

MedDRA PT Arrhythmia, Atrial fibrillation, Autopsy, Cyanosis, Death, Dyspnoea, Hyperthermia, Hypothermia, Intensive care, Leukocytosis, Lung disorder, Malaise, Multi-organ failure, Mydriasis, Tachycardia, Tremor, Ventricular hypokinesia

Symptom Text: Information has been received from a specialist and from the health authority, concerning a 20 year old female with asthenia, anxiety/overwork syndrome and psychologic fragility since May 2008 and a history of cardiac murmur during childhood, who in OCT-2008 was vaccinated with the first dose of GARDASIL. The patient had no adverse effects after this dose. Concomitant therapy included BUSPAR, LEXOMIL, magnesium (unspecified) (+) pyridoxine hydrochloride and hormonal contraceptives (unspecified). On 27-DEC-2008 the patient was vaccinated with the second dose of GARDASIL, batch number not reported. It was reported that 3 days after the second dose of GARDASIL, i.e. in JAN-2009 the patient presented with hyperthermia at 38 C associated with breathlessness. After a malaise during shopping on 01-JAN-2009 the patient consulted her general practitioner; she had tremor and tachycardia. Blood analysis was performed on 03-JAN-2009 and revealed a slight hyperleukocytosis (12.4 103/mm3). By the evening on 03-JAN-2009 the patient presented with a malaise again but with no dyspnea and after taking BUSPAR. 2 hours later the intervention of EMUR (emergency medical mobile unit) could lead to recuperate a sinusal rhythm. Continuous arrhythmia with atrial fibrillation was diagnosed. The patient was transferred to medical intensive care service: she presented with bilateral mydriasis, hypothermia at 33.7 C, the result of measure of sugar in her blood was increased at 3.18 and she had cyanosis of face, ears, and extremities. Radiological examinations revealed a pneumopathy of the right middle pulmonary lobe and septal hypokinesia with paradoxical septal. There was no cocaine and no benzodiazepines. The patient presented with multiorgan failure under high dose of amines and then she dies in spite of the cardiopulmonary by-pass and extra corporeal oxygenation assistance. An autopsy was performed (unspecified date) and found no cause of death, also reported as information on autopsy was still awaited. Other business partner numbers incl

Other Meds: BUSPAR; LEXOMIL; hormonal contraceptives (unspecified); magnesium (unspecified) (+) pyridoxine hydrochloride

Lab Data: electrocardiogram, 03Jan09, arrhythmia with atrial fibrillation; X-ray, 03Jan09, pneumopathy of right middle pulmonary lobe and septal hypokinesia; body temp, 01?Jan09, 38 C; WBC count, 03Jan09, 12.4.103/mm3; body temp, 03Jan09, 33.7 C; blo

History: Cardiac Murmur

Prex Illness: Asthenia; Anxiety; Overwork; Psychological disorder NOS

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338563-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		29-Jan-2009	30-Jan-2009	--	WAES0901USA02709	30-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Convulsion, Loss of consciousness, Pain, Tremor, Vomiting

Symptom Text: Information has been received from a consumer concerning the 15 year old daughter of her friend who "months an months ago" was vaccinated with GARDASIL (route and site not reported). Subsequently the patient experienced vomiting, seizures, shakes, black out, abdominal pain and excruciating pain from head to toe and was hospitalized in and out. Per caller, the last time she spoke to the patient's parents, the patient was at home but they are thinking of bringing the patient to another hospital. Per caller, the patient's vomiting, seizures, shakes, black out, abdominal pain and excruciating pain from head to toe persisted. Attempts to verify the existence of an identifiable patient have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338564-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	13-May-2008	12-Dec-2008	213	29-Jan-2009	30-Jan-2009	FR	WAES0808USA05282	30-Jan-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1049U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arrested labour, Caesarean section, Drug exposure during pregnancy, Induced labour, Postmature baby

Symptom Text: Information has been received from a gynecologist for the pregnancy registry for GARDASIL concerning an 18 year old female who was vaccinated with the third dose of GARDASIL (Lot # 1049U Batch # NG46500) into the deltoid muscle on 13-MAY-2008. On 08-APR-2008 the patient already received a booster dose RECOMBIVAX HB (Lot # 654829/0335F Batch # NF24490) into the deltoid muscle. On 12-JUN-2008 pregnancy in 14th gestation week was detected. Date of last menstrual period (LMP) is unknown. Estimated outcome pregnancy (EOP) will be 13-DEC-2008. At the time of reporting no adverse event occurred. The first and second dose of GARDASIL and RECOMBIVAX HB were well tolerated. Follow-up information received on 16-JAN-2009. Upon medical review the company upgraded the case to serious because of caesarian section. It was reported by the gynecologist that the patient had a normal course of pregnancy. Medical induction of labor was performed on the 9th day due to postmaturity. Caesarian section was performed due to interrupted labor and the patient gave birth to a normal baby on 21-DEC-2008. The Apgar score was 9/10/10. The postnatal examination of the mother and child showed no pathologies. Other business partner number included (E2008-05526). No further information is available. Case closed.

Other Meds: Unknown

Lab Data: Apgar score, 9/10/10

History: Immunisation

Prex Illness:

Prex Vax Illns:

Vaers Id: **338572-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Dec-2008	11-Dec-2008	0	20-Jan-2009	12-Feb-2009	ID	WAES0812USA03380	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hyperventilation, Vomiting

Symptom Text: Information has been received from a physician concerning an 18 year old female patient who on 11-DEC-2008 was vaccinated with the second dose of GARDASIL (lot # not provided). After receiving the dose the patient was left alone to have some privacy in the room, and then someone came to check on her and she had vomited, felt light headed, dizzy and was hyperventilating. Patient sought unspecified medical attention. No lab diagnostics

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338573-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	11-Dec-2008	11-Dec-2008	0	20-Jan-2009	12-Feb-2009	VA	WAES0812USA03339	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Axillary pain, Chest pain, Oedema peripheral, Pain in extremity

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female patient with asthma and no known allergies who on 11-DEC-2008 was vaccinated with the first dose of GARDASIL vaccine 0.5 ml intramuscularly. Concomitant therapy included ADACEL and HAVRIX. On 11-DEC-2008 the patient experienced left arm pain, arm pit pain, left sided chest pain and swelling of her left arm. The patient sought medical attention at the office. At the time of report the patient was recovering. Additional information has been requested.

Other Meds:

Lab Data: None

History:

Prex Illness: Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338576-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Jul-2007	01-Aug-2007	31	20-Jan-2009	12-Feb-2009	--	WAES0812USA03231	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Facial pain, Hypoaesthesia, Pain in extremity

Symptom Text: Information has been received from a nurse practitioner concerning a 19 year old female patient who 1.5 year ago, approximately in July 2007, was vaccinated with the first dose of GARDASIL vaccine 0.5 mL IM. Approximately thirty days after received GARDASIL vaccine, in approximately August 2007, the patient experienced bilateral facial pain, numbness of her feet and hands, pain in her hands and gastrointestinal upset. It was noted

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338577-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	21-Nov-2008	12-Dec-2008	21	20-Jan-2009	17-Feb-2009	IL	WAES0812USA03225	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0137U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a pharmacist, concerning a female patient with hyperlipidaemia and no known drug reactions or allergies, who on 11-SEP-2008 was vaccinated with the first dose of GARDASIL, 0.5ml, intramuscularly and on 21-NOV-2008 was vaccinated with the second dose of the HPV vaccine (Lot # 655165/0137U), 0.5ml, intramuscularly. Concomitant therapy included LIPITOR and clobetasol propionate

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338578-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	12-Nov-2008	12-Nov-2008	0	20-Jan-2009	12-Feb-2009	NJ	WAES0812USA02823	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass

Symptom Text: Information has been received from a registered nurse concerning a 23 year old female patient with drug hypersensitivity who a month ago was vaccinated with GARDASIL intramuscularly, lot # 661764/0650X. The patient reported to the nurse that she developed a lump at the injection site where the HPV vaccine was given. At the time of reporting, the patient had not recovered. Additional information has been requested. This is one of several reports received from the same source.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **338579-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	04-Oct-2008		20-Jan-2009	12-Feb-2009	NJ	WAES0812USA02818	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site irritation, Injection site pruritus, Injection site swelling, Oedema peripheral, Pruritus

Symptom Text: Information has been received from a registered nurse concerning a 22 year old female with no medical history and allergy to KEFLEX, who on 02-OCT-2008 was vaccinated with a 0.5ml first dose of GARDASIL (lot# 660612/0229X), intramuscularly. On 4-OCT-2008 the patient developed a raised, "gum ball sized", itchy, burning area at the injection site. The reaction resolved without treatment. On 11-Dec-2008 the patient received the deltoid muscle of the right arm and later that night developed itchiness and swelling of both hands. The patient contacted the office by phone on 12-Dec-2008 and was prescribed BENADRYL. There were no laboratory diagnostics performed. The patient had not recovered for the itchiness and swelling of both hands. The patient sought medical attention through a phone call to the doctor's office. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338580-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Dec-2008	05-Dec-2008	0	20-Jan-2009	12-Feb-2009	--	WAES0812USA02787	04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	FLUN	MEDIMMUNE VACCINES, INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pyrexia, Vomiting

Symptom Text: Information has been received for the Merck Pregnancy Registry for GARDASIL from a Registered Nurse concerning a 14 year old female patient who on 05-DEC-2008 was vaccinated with first dose of GARDASIL (Lot # not provided). Concomitant therapy included Diphtheria Toxoid (+) PERTUSSIS ACELLULAR vaccine (unspecified) (+) TETANUS TOXOID (manufacturer unspecified), FLUMIST and MENACTRA . After the patient received the vaccines she went to the Emergency Room with a fever of 102.6F and vomiting. It was at this time she discovered she was about 8 to 12 weeks pregnant. Additional information has been requested.

Other Meds:

Lab Data: body temp - fever of 102.6F

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **338581-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Nov-2008	01-Nov-2008	0	20-Jan-2009	12-Feb-2009	WA	WAES0812USA02632	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning an approximately 15 year old female who in November 2008, was vaccinated with a dose of GARDASIL vaccine, lot# not reported. It was reported that the patient received the GARDASIL vaccine and waited for 20 minutes and was fine, however she left to the pharmacy and felt light headed and she had to sit down. The physician stated that the patient was fine and was released home after 20 minutes of observation. Patient recovered the same day. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338582-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	Unknown	01-Nov-2008		20-Jan-2009	12-Feb-2009	TX	WAES0812USA02627	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 24 year old female who "more than a year ago" was vaccinated with GARDASIL, 0.5 mL, intramuscularly. Concomitant therapy included NUVARING. It was reported that the patient was tested for HPV prior to HPV vaccination: DNA negative for HPV and had a normal PAP smear. The patient completed her series about a year ago. The physician stated that at the end of NOVEMBER 2008 the patient had a HPV test, and was positive for the HPV in the high risk panel. At the time of the report the patient was not recovered. Additional information has been requested.

Other Meds: NUVARING

Lab Data: diagnostic laboratory - DNA negative for HPV diagnostic laboratory - 11/??/08 - HPV test positive Pap test - normal

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338583-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	13-Nov-2008		20-Jan-2009	12-Feb-2009	CA	WAES0812USA02624	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia, Syncope

Symptom Text: Information has been received from a physician concerning a 15 year old female patient, who was vaccinated with the first dose of GARDASIL, 0.5ml. The physician reported that after receiving the HPV vaccine, the patient fainted. Since then, the patient had been consistently feeling a tingling sensation throughout her body. The patient sought unspecified medical attention. At the time of the report, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338584-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	06-Oct-2007	Unknown		20-Jan-2009	12-Feb-2009	CA	WAES0812USA02612	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse, for the Pregnancy Registry for GARDASIL concerning a 23 year old female patient who on 06-APR-2007 was vaccination with the first dose of GARDASIL 0.5 ml intramuscularly. On 06-JUN-2007 the patient received the second dose of GARDASIL 0.5 ml intramuscularly and the third dose of GARDASIL 0.5 ml intramuscularly was administered on 06-OCT-2007. The patient had an abnormal Pap smear result on 01-OCT-2008. Also the patient was currently pregnant. Second Pap smear results are pending. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test 10/01/08 - abnormal; Pap test - 2nd pap smear results are pending

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 338585-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	06-Nov-2008	06-Nov-2008	0	20-Jan-2009	12-Feb-2009	CA	WAES0812USA02603	11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Areflexia, Asthenia, Back pain, Dyspnoea, Fatigue, Headache, Hypoaesthesia, Hypokinesia, Hyporeflexia, Local reaction, Malaise, Muscular weakness, Neurological examination, Nuclear magnetic resonance imaging, Peripheral sensory neuropathy, Pyrexia, Sensation of heaviness, Sensory disturbance, Sensory loss

Symptom Text: Information has been received from a physician concerning a 13 year old female patient who was vaccinated with the third dose of GARDADIL vaccine (lot# was not available) on unspecified date and played a "vigorous volleyball" using the same arm where she received the vaccine the following day after receiving the vaccine. There was no concomitant medication. The physician reported that on 06-NOV-2008 the patient experienced "serious malaise after vaccination" and on 17-NOV-2008, the patient brought to the hospital and was admitted for a "couple of days", Lab diagnostics Studies Performed included neurological tests when the patient was in the hospital including MRI. The patient sought medical attention through the physician. At the time of report the patient was recovering. Additional information has been requested. 2/23/09 MR received for DOS 11/15-xxxx with DX: S1 distribution sensory neuropathy. Lower extremity weakness and altered sensation. No D/C information available. Pt presented with 1 wk hx of weakness and fatigue. Had local reaction to recent HPV vax 11/6/08 with fever. Pt describes heaviness of extremities and difficulty lifting them. Low grade temp with mild intermittant H/As, numbess in foot and toes and low back pain. Seen by outpt neurologist and found to be areflexic. Instucted to go to ER with worsening sx. Presented for eval following an episode of dyspnea which self-resolved. Neuro exam (+) for loss of sensation on the back and decreased in extremities. DTRs and strength WNL. Abdominal reflexes absent. Admitting DX: S1 sensory neuropathy. LE weakness and altered sensation. 2/26/09 Neurology consult received dated 11/14/08 with DX: Generalized weakness with depressed ankle jerks. S/P Vaccination. R/O GBS despite normal NCS/EMG. PE (+) for decreased strength, depressed reflexes in upper extremities and ankles, normal sensation. Instructed to go to ER for further progression of sx which pt did.

Other Meds:

Lab Data: Unknown Labs and Diagnostics: CBC WNL. CRP (-). LP with normal cell count, protein and glucose. CSF cx (-). MRI of lumbar, throacic and sacral spine (+) for L4-5 disc bulge. EBV IgG and IgM (+) Labs and Diagnostics: EMG/NCS WNL but l

History: Unknown. PMH: none

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338586-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	28-Apr-2008	Unknown		20-Jan-2009	11-Feb-2009	FL	WAES0812USA02593	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Information has been received from a healthcare worker concerning a 20 year old female patient with no pertinent medical history and with allergic reaction to CECLOR who on 28APR-2008 was vaccinated with the first dose of GARDASIL (lot# 655604/0052X), on 30-JUN-2008 was vaccinated with the second dose of GARDASIL (lot# 0152X) and on 10-Nov-2008 she received third dose of GARDASIL (lot# 0250X). Concomitant therapy included YAZ. It was reported that the patient was diagnosed with Bell's palsy after receiving the third dose of GARDASIL. It was reported that the patient had not recovered at the time of the report. The patient sought medical attention with a different physician. Follow up information was received on 15-DEC-2008 from a medical assistant who stated that the patient went to the emergency room. Follow up information was received on 15-DEC-2008 from the medical assistant who stated that on 10-DEC-2008 went to the emergency room and diagnosed Bell's palsy by the physician. Additional information has been requested.

Other Meds: YAZ

Lab Data: Unknown

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338587-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	12-Dec-2008	12-Dec-2008	0	20-Jan-2009	12-Feb-2009	DE	WAES0812USA04118	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash, Rash

Symptom Text: Information has been received from a physician concerning a 20 year old female who on 12-DEC-2008 was vaccinated with a second dose of GARDASIL vaccine. Subsequently, the patient developed a rash at injection site. As of approximately 18-DEC-2008, the patient's rash had spread to her face. No reactions were reported after the first dose was given. The patient contacted the physician for medical attention. At the time of this report, 18-DEC-2008, the events persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338588-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Dec-2008	17-Dec-2008	8	20-Jan-2009	12-Feb-2009	--	WAES0812USA04111	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Pain

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female with no medical history of allergies, who on 09-DEC-2008 was vaccinated with a 0.5 mL first dose of GARDASIL vaccine, intramuscularly. There was no concomitant medication. On 17-DEC-2008 the patient developed widespread achiness and joint pain. The patient consulted her unspecified pediatrician but no treatment was prescribed. There were no laboratory diagnostics studies performed. The patient had not recovered. The sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338589-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	14-Oct-2008	14-Oct-2008	0	20-Jan-2009	12-Feb-2009	--	WAES0812USA04110	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	661046/0546X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Urticaria

Symptom Text: Information has been received from a nurse practitioner concerning a 21 year old female with a penicillin allergy and no medical history who on 14-OCT-2008 was vaccinated with a 0.5 mL first dose of GARDASIL (lot # 661046/0546X), intramuscularly in the deltoid. There was no concomitant medication. After received the vaccine the patient experienced a rash on her back that lasted for 2.5 weeks. There were no laboratory studies performed. Follow up information received on 18-DEC-2008 at 13:00 stated that "the patient was actually in the office about to get the second of GARDASIL and reported that after the first dose she developed a welt in the area of the bra strap at the cup part of the bra". Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **338590-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Dec-2008	18-Dec-2008	0	20-Jan-2009	12-Feb-2009	MI	WAES0812USA04104	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Underdose

Symptom Text: Information has been received from a healthcare worker concerning an 18 year old female with no medical history and allergies, who on 18-JUN-2008 was vaccinated with a first dose of GARDASIL. There was no concomitant medication. On 18-DEC-2008 the patient received a partial dose of GARDASIL (lot # 661530/0575X), intramuscularly, the patient pulled away saying "ouch, ouch." She did not get another dose yet. The outcome is unknown. The outcome is unknown. The patient sought medical attention through an office visit. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **338591-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	M	03-Dec-2008	03-Dec-2008	0	20-Jan-2009	17-Feb-2009	FL	WAES0812USA03784	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No adverse event, Off label use

Symptom Text: Information has been received from a physician concerning a male patient who on approximately 03-DEC-2008 was vaccinated with 1 dose of GARDASIL vaccine and was referred to his primary physician for completion of the series. No adverse effects were reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338592-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Dec-2008	15-Dec-2008	6	20-Jan-2009	12-Feb-2009	NY	WAES0812USA03782	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Fatigue, Pain in extremity, Swelling

Symptom Text: Information has been received from a 16 year old female patient with no drug reactions/allergies, who on 09-DEC-2008 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. On 15-DEC-2008 the patient experienced joint pain, swelling fatigue and pain in her legs. The patient spoke to the physician, At the time of reporting, the patient had not recovered. Additional information has been requested.2/5/09-records received-12/9/08 received 1st Gardasil injection in left deltoid. No C/O illness or fever. Parent on 12/23/08 stated child might have mono.2/4/09 called MD office C/O possible reaction to vaccine, seen by pediatrician with C/O joint pain, fatigue, pain and swelling of legs.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338593-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	29-May-2008		20-Jan-2009	12-Feb-2009	AL	WAES0812USA03779	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle spasms, Myalgia, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female patient with idiopathic thrombocytopenia and no drug reactions/allergies, who on 29-MAY-2008 was vaccinated intramuscularly on her arm with the first 0.5 mL dose of GARDASIL vaccine. On the same day the patient experienced severe muscle pain and spasm in her back and buttocks. There was no concomitant medication. On 28-JUL-2008 was vaccinated intramuscularly on her arm with the second 0.5 mL dose of GARDASIL vaccine and experienced severe muscle pain and spasm in her back and buttocks several hours later. All symptoms resolved within few days after the vaccination. The patient did not seek medical attention. The patient had not received the third dose. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Idiopathic thrombocytopenia

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338598-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Jan-2009	28-Jan-2009	2	29-Jan-2009	03-Feb-2009	NC		10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2686AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2997AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0546X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Depressed level of consciousness, Disorientation, Eye pain, Headache, Hypoaesthesia oral, Lip swelling, Nausea, Paraesthesia, Vomiting

Symptom Text: 01/28/2009 pt report n&v, confussion,HA,lip swelling & numbness. 2/23/09 MR received for several OVs beginning 1/8/09. Seen prior to vaccine for viral URI and rash. Returned 1/28/09 with c/o swollen lips with numbness, nausea and headache. At school became had H/A at R temple with R eye pain and slightly disoriented. Still slow to respond and confused in office, had difficulty following commands. Assessment: H/A. paresthesia. Nausea. Confusion. Sent for labs and CT.

Other Meds: lamictal, synthryoid, zyrtec

Lab Data: cbc,cmp,tsh,glucose finger stick,CT scan. Labs and Diagnostics: Head CT WNL. CBC & CMP unremarkable. Granulocyte % (H) 81.6%. Lymph % (L) 13.2%. TSH 0.72.

History: epilepsy, hypothyroid , allergic rhinitisis. PMH: remote hx of seizure- lat 2 yrs ago

Prex Illness: none

Prex Vax Illns:

Vaers Id: **338602-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-Jan-2009	20-Jan-2009	0	29-Jan-2009	03-Feb-2009	AL	AL0901	10-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC5213030AA	5	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHBUB527AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1448U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Adverse reaction, Asthenia, Dizziness, Headache, Pallor, Photophobia, Vertigo

Symptom Text: On 1/20/09 after clinic visit, and @ 7:30p felt dizzy, faint, sensitive to light and mom states pt. got really pale. Mom gave tylenol and went to sleep. When getting up this am, feels dizzy, faint when standing up headache enc to seek pmd care. Saw Dr. P/c attempted 4x's. No answer. 2/3/09 MR received from PCP for OV 1/21/09 for c/o dizziness, H/A and weakness x 1 day since receiving shots. Took first OCP that day as well. Reports light sensitivity, spinning sensation. PE WNL. Impression: Dizziness/ Vertigo. Suspected adverse reaction to either HPV or OCP. Tx: Meclizine

Other Meds:

Lab Data:

History: Acid Reflux

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338604-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-Jan-2009	14-Jan-2009	1	29-Jan-2009	11-Feb-2009	WA		11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysphagia, Lip swelling, Swollen tongue

Symptom Text: Lip swelling for 12 hours. 10 days later subjective sx of swollen tongue and difficulty swallowing. Did not seek medical care for condition.

Other Meds: none

Lab Data: n/A

History: none known

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338605-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Jan-2009	28-Jan-2009	6	29-Jan-2009	11-Feb-2009	NY		11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Bell's palsy 1 week after HPV #3 vaccine

Other Meds:

Lab Data:

History: peanuts

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338643-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	17-Jun-2008	17-Jun-2008	0	20-Jan-2009	12-Feb-2009	PA	WAES0812USA03770	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Headache, Influenza like illness, Nausea, Pyrexia, Vaccine positive rechallenge, Vomiting, Weight decreased

Symptom Text: Information has been received from a physician concerning a 20 year old female patient who on 17-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine intramuscularly. Concomitant therapy included hormonal contraceptives (unspecified). On 17-JUN-2008 the patient experienced flu like symptoms, fever, stomach ache, stomach pain, nausea, vomiting and headache, she lost 23 pounds after receiving the vaccine. The patient's symptoms went away and came back after the second dose GARDASIL vaccine intramuscularly. The patient's flu like symptoms, fever, stomach pain, nausea, vomiting, headache and weight loss persisted. On unspecified date the patient had an Endoscopy done (results not provided). Additional information has been requested.

Other Meds: Hormonal contraceptives.

Lab Data: Endoscopy

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338644-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Aug-2008	Unknown		20-Jan-2009	12-Feb-2009	CA	WAES0812USA03750	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysmenorrhoea, Menorrhagia

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who on 14-AUG-2008 was vaccinated with the first dose of GARDASIL (lot# 660612/0229X) 0.5 ml intramuscularly. After receiving the first dose patient experienced bad cramps and heavy bleeding during her menstrual period. Patient sought unspecified medical attention. Patient informed physician about this experience when she came back to receive her second dose of GARDASIL 24-NOV-2008. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338645-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Apr-2008	09-Apr-2008	0	20-Jan-2009	12-Feb-2009	UT	WAES0812USA03738	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning an 18 year old female patient who on 6-DEC-2007 was vaccinated with the first dose of GARDASIL (lot # not provided). On 09-APR-2008 the patient received the second dose of GARDASIL (lot # not provided). A colposcopy done approximately on 3-DEC-2008, "2 weeks ago", showed the patient was high risk HPV. Possible exposure to HPV through her boyfriend. Patient went to the doctor's office. At the time of the report the patient had not yet recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Colposcopy, 12/03/08, results showed high risk HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 338646-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-Apr-2008	26-Nov-2008	233	20-Jan-2009	12-Feb-2009	PA	WAES0812USA03713	27-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Arthralgia, Fatigue, Headache, Neck pain

Symptom Text: Information has been received from an office manager at the physician's office, concerning a female patient, who was vaccinated with first, second and third doses of GARDASIL (dose, route, lot # not reported). The office manager reported that the patient completed her GARDASIL vaccination series a couple of months ago and started experiencing hip pain and headaches. At the time of the report, the patient had not recovered. Follow up information was received from the Registered Nurse on 23-DEC-2008 which reported: The patient was vaccinated with three doses of GARDASIL on 19-SEP-2007, 29-NOV-2007 and 03-APR-2008 respectively. The patient experienced hip pain, headaches, and stomach pain and that were all still ongoing. The patient also experienced fatigue but that has resolved. Follow up information has been received from a Registered Nurse on 30-DEC-2008 which reported that the lot number that was administered was: 660387/19670. The patient was administered the vaccine at her pediatrician's office. The patient was also administered varicella virus vaccine live (Oka/Merck) (MSD) and hepatitis B virus vaccine rHBsAg (yeast) (MSD) on the same day the patient received her third dose of GARDASIL. Additional information has been requested. 2/4/09-records received-presented on 11/17/08 with C/O run down, tired. 11/24/08 still very fatigued, dizzzy, occasional. 12/16/08 C/O headache. Possibility treated by another physician prior to presenting on 11/17/08. 2/23/09-records received-office visit 1/20/09-C/O headache, neck in pain for past 3 months. Holter monitor supraventricular ectopic beats noted. 12/30/08 increasing headaces.

Other Meds: Unknown

Lab Data: Unknown 2/4/09-records received- HA. Holter monitor normal EEG normal with mild swelling of background. Chemistry normal. Chest x-ray no evidence of infiltrate or pleural effusion.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338648-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	11-Jan-2007	Unknown		20-Jan-2009	12-Feb-2009	CA	WAES0812USA03685	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1264U		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Vomiting

Symptom Text: Information has been received from a medical assistant concerning a 23 year old female with no medical history, allergies or drug reactions who on 11-JAN-2007 was vaccinated with the first dose of GARDASIL vaccine (lot no. 658488/1264U) 0.5 ml, IM. Concomitant therapy included hormonal contraceptives (unspecified). On an unknown date, the patient experienced nausea, vomiting and light headedness after getting the first dose of the vaccine. Subsequently, the patient recovered from nausea, vomiting and light headiness. No laboratory test was performed. Additional information has been requested.

Other Meds: Hormonal contraceptives.

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338649-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	17-Sep-2008	Unknown		20-Jan-2009	12-Feb-2009	NJ	WAES0812USA03609	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Menstruation delayed, Vaginitis bacterial

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female patient with seasonal allergy and no known pertinent medical history who on 17-SEP-2008 was vaccinated with first dose of GARDASIL (Lot # 659184/0843X) 0.5ml, intramuscularly. The patient's last menstrual period was 10-NOV-2008. The patient was in the office to received the second dose of GARDASIL and she mentioned she was 10 days late getting her period. The second dose of GARDASIL was not given to the patient. Although the patient's urine HCG test was negative the physician instructed the patient to wait 1 or 2 days to see if she gets her period. If the patient does not get her period she was instructed to call the office to arrange for blood test for pregnancy. On 17-DEC-2008 the patient was treated with Clindesse for bacterial vaginosis. At the time of report on 17-DEC-2008 the patient was not recovered. Additional information has been requested.

Other Meds: Clindesse

Lab Data: Urine beta-human, Negat

History:

Prex Illness: Seasonal allergy

Prex Vax Illns:

Vaers Id: **338650-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		20-Jan-2009	12-Feb-2009	VA	WAES0812USA03414	01-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	UNK	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Pain in extremity

Symptom Text: Information has been received from a nurse concerning a 129 year old female patient who was vaccinated with the first dose of GARDASIL vaccine (no lot # provided) intramuscularly. "Patient received two other unspecified vaccines in her opposite arm". Subsequently the patient experienced pain underneath her arm and into her chest. Subsequently, the patient recovered from pain underneath arm and pain into her chest. patient sought unspecified medical attention. At the time of the report the patient's symptoms had resolved. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338651-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		20-Jan-2009	12-Feb-2009	OR	WAES0612USA03385	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with no known drug reactions or allergies, who in 2008, "a few weeks ago", was vaccinated wit the first and only dose of GARDASIL (no lot # provided). There was no concomitant medication. On the same day of the vaccination the patient passed out. Patient saw the physician. No lab diagnostic studies were performed. The patient recovered after a few minutes. No further information is available.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338652-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		20-Jan-2009	12-Feb-2009	TX	WAES0812USA04585	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a physician concerning an adolescent female patient who on an unspecified date, was vaccinated with GARDASIL vaccine. The physician reported that the patient experienced injection site pain. The outcome is unknown. This is one of several cases from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338653-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		20-Jan-2009	12-Feb-2009	TX	WAES0812USA04584	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister, Injection site pain

Symptom Text: Information has been received from a physician concerning an adolescent female patient who on an unspecified date, was vaccinated with GARDASIL. The physician reported that the patient experienced injection site pain and blisters under eye. the outcome is unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338654-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	28-Sep-2008		20-Jan-2009	12-Feb-2009	--	WAES0812USA04554	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Musculoskeletal chest pain, Nausea, Pain in extremity

Symptom Text: Information has been received from a registered nurse concerning a 26 year old female who on 25-SEP-2008 was vaccinated with a first dose of GARDISIL vaccine. After the first dose of GARDASIL vaccine she felt pain in the muscles around her chest but they resolved in three days. Concomitant therapy included vitamins (unspecified) and OMEGA-3. On 18-dec-2008 the patient received a second dose of GARDASIL vaccine and later that day called the nurses and stated that she experienced slight nausea, pain in her left arm and pain in the muscles around the chest not her heart. The nurse also reported that she advised the patient after she told her the experience with the second dose to seek further medical attention, but the patient said she would not since it happened with the first dose and it resolved. The nurse at this time is unsure if the patient had recovered. The patient sought medical attention through a call to the nurse. Additional information has been requested.

Other Meds: OMEGA-3, vitamins (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338655-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		20-Jan-2009	17-Feb-2009	MD	WAES0812USA04543	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a physician concerning a 21 year old female patient with no pertinent medical history and no drug reactions/allergies, who in approximately October 2008, a few months ago (exact date unspecified) was vaccinated with an initial dose of GARDASIL vaccine. There was no concomitant medication. Since receiving the GARDASIL vaccine, coincidently the patient had not had her period the past 2 months. The patient was not pregnant and not in a relationship. The patient had no underlying medical conditions that would explain this as she exercised regularly but not to excess, she was thin but not underweight, and she did not have a medical issue such as PCOS (polycystic ovary syndrome). She had an upcoming appointment with her gynecologist. No other symptoms were present. As of 22-DEC-2008, the patient's outcome was unknown. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338656-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		20-Jan-2009	17-Feb-2009	CO	WAES0812USA04513	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Behcets syndrome

Symptom Text: Information has been received from a physician concerning a patient who on an unknown date was vaccinated with a dose of GARDASIL, (site, route and lot no. not reported). The patient experienced bipolar aphthosis. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338657-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Sep-2008	01-Sep-2008	0	20-Jan-2009	17-Feb-2009	VA	WAES0812USA04291	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Information has been received from a medical assistant concerning a 25 year old female patient who in approximately September 2008, was vaccinated with her second dose of GARDASIL (Lot not provided). Following the vaccination the patient experienced tingling from her elbow to her pinky intermittently (off and on for several months). As of 19-DEC-2008 the patient's symptoms persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338658-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	15-Dec-2008	19-Dec-2008	4	20-Jan-2009	17-Feb-2009	--	WAES0812USA04284	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypersensitivity, Injection site swelling, Local swelling, Oedema peripheral, Swelling face

Symptom Text: Information has been received from a registered nurse concerning of her 22 year old daughter with no known allergies and a history of contact dermatitis who on 15-DEC-2008 was vaccinated with the first dose of GARDASIL (Lot not reported). Concomitant therapy included hormonal contraceptives (unspecified). On 19-DEC-2009 the patient developed what appears to be an allergic reaction. The patient developed swelling of her injection arm that had progressed up her arm to her neck and face. The patient took Benadryl and Hidroxyzine (Unspecified) (left over from a recent bout of contact dermatitis that "got out of hand"). As of 19-DEC-2008 the patient had not recovered. Additional information has been requested.

Other Meds: Hormonal Contraceptives

Lab Data: Unknown

History:

Prex Illness: Dermatitis contact

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338659-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Dec-2008	18-Dec-2008	0	20-Jan-2009	17-Feb-2009	GA	WAES0812USA04280	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Injection site reaction, Injection site swelling, Injection site warmth

Symptom Text: Information has been received from a registered nurse concerning a 12 year old female patient with no known allergies and sickle cell anemia who 10-JUL-2008 was vaccinated with first dose of GARDASIL. On 18-DEC-2008 the patient was vaccinated with 0.5ml of her second dose of GARDASIL (lot# 66174/0650X) intramuscularly. Concomitant therapy included influenza virus vaccine and pneumococcal 23v polysaccharide vaccine. On the same day, 18-DEC-2008, the patient developed painful local injection site reaction after vaccination. The reaction consisted of warm, tender and swelling around two inches at the injection site. The patient went to the emergency room and later additional information has been requested.

Other Meds: Influenza virus vaccine

Lab Data: Complete blood cell

History:

Prex Illness: Sickle cell anemia

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338660-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Nov-2008	01-Nov-2008	0	20-Jan-2009	17-Feb-2009	--	WAES0812USA04272	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Pain, Pain in extremity

Symptom Text: Information has been received from a registered nurse concerning her 23 year old daughter who "about one month ago" was vaccinated with the first dose of GARDASIL. After receiving the vaccine the patient developed shooting and burning pain in the arm the injection was given down to fingertips. At the time of reporting it is unknown if the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 338661-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Jul-2008	05-Sep-2008	50	20-Jan-2009	17-Feb-2009	CA	WAES0812USA04270	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hallucination, auditory, Hallucination, visual, Syncope

Symptom Text: Information has been received from a physician concerning a 15 year old female patient with no pertinent medical history, no drug reactions/allergies; who on 17-JUL-2008 was vaccinated with the second dose of GARDASIL. There was no concomitant medication. On 05-SEP-2008, about 5 weeks after vaccination, the patient developed hallucinations, both visual and auditory. The patient had also had syncope. The patient was seen in the office and was treated with KEPPRA with no effect. In the beginning of December 2008, the patient had recovered. Additional information has been requested.

Other Meds: None

Lab Data: Magnetic resonance; diagnostic laboratory, blood tests; electroencephalography; cerebrospinal fluid

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338662-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		20-Jan-2009	17-Feb-2009	IN	WAES0812USA04263	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, General symptom

Symptom Text: Information has been received from a nurse concerning a female patient who was vaccinated with a dose of GARDASIL (lot # not provided). Subsequently the patient experienced chest pain and mild unspecified symptoms. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338663-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	21-Nov-2008	21-Nov-2008	0	20-Jan-2009	17-Feb-2009	IL	WAES0812USA04143	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site pain, Nodule

Symptom Text: Information has been received from a physician concerning a 25 year old female with no pertinent medical history or allergies who on 21-NOV-2008 was vaccinated intramuscularly in her right deltoid with 0.5 ml third dose of GARDASIL (lot # 660557/0072X). Concomitant therapy included an unspecified birth control medication. On 21-NOV-2008 the patient developed an induration "about the size of a dime" at the injection site of the right deltoid muscle. The area was painful to touch, The physician added that the patient had a similar knot near her vagina. The patient contacted the office via phone. No laboratory or diagnostics test were performed. At the time of this report, as 18-DEC-2008, the events persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **338664-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Dec-2008	17-Dec-2008	0	20-Jan-2009	17-Feb-2009	PA	WAES0812USA04134	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X		Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Hypotension, Skin laceration, Syncope

Symptom Text: Information has been received from a licensed practical nurse concerning a 11 year old female patient with no drug/reactions allergies, who on 17-DEC-2008 was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL (Lot # 660555/0279X). Concomitant therapy included HAVRIX and MENACTRA. The patient fainted and fell about 5 minutes after receiving GARDASIL vaccine causing a laceration on her chin. The patient came to immediately. It was not known what the patient hit when she fainted. The patient's blood pressure was low. It took about 30-45 minutes until her blood pressure and color returned to normal. The patient received stitches for the laceration in an emergency room. At the time of reporting, the patient was recovering. Additional information has been requested.

Other Meds:

Lab Data: blood pressure - was low

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **338665-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		20-Jan-2009	17-Feb-2009	DE	WAES0812USA04131	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Information has been received from a physician concerning a 14-15 year old female. On an unknown date, the patient was vaccinated with her first dose of GARDASIL 0.5ml (route and site not reported). After vaccination, the patient experienced a pain in her hip. The pain went away and then the patient received her second dose of GARDASIL and the pain in her hip reappeared. Patient went to physical therapy however she did decline to receive the third dose. No lot number was provided. The patient recovered from pain in her hip. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338666-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Aug-2008	Unknown		20-Jan-2009	17-Feb-2009	NY	WAES0812USA04119	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fungal infection, Injection site pruritus, Injection site rash, Injection site swelling, Rash erythematous, Rash papular

Symptom Text: Information has been received from a physician concerning an 18 year old female who on 14-AUG-2008 was vaccinated with a second dose of GARDASIL (lot #660393/0067X) in the left arm. "The patient developed a rash at the injection site shortly after receiving the vaccine. The rash was itchy and swollen and continued to spread into fungal infection. The rash was described as a papular erythemic rash". The patient had not recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338674-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	31-Oct-2008	01-Nov-2008	1	20-Jan-2009	17-Feb-2009	PA	WAES0812USA05232	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a physician concerning a 12 year old female patient with no pertinent medical history who in the end of October 2008 was vaccinated with the second dose of GARDASIL vaccine. There was no concomitant medication. The physician reported that patient has been having temporal headaches on right side of her head since 3 days after receiving the HPV vaccine. A computed axial tomography or magnetic resonance

Other Meds: None

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **338675-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
0.6	M	Unknown	Unknown		20-Jan-2009	17-Feb-2009	WI	WAES0812USA05223	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Information has been received from a patient's mother concerning her 7 month old son who was vaccinated with a dose of GARDASIL instead of the flu vaccine by mistake. No adverse event reported as a result. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338676-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Mar-2007	01-May-2007	39	20-Jan-2009	17-Feb-2009	MA	WAES0812USA05222	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1888U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain lower, Alopecia, Bradycardia, Headache, Mass, Menstruation irregular, Oropharyngeal pain, Pharyngeal erythema, Pharyngitis, Weight decreased

Symptom Text: Information has been received from a registered nurse and the patient's mother concerning a 14 year old female patient with no allergies and no pertinent medical history who on 23-MAR-2007 was vaccinated with the first dose of GARDASIL (date also reported as 22-MAR-2007 by the patient's mother), on 23-MAY-2007 the patient received the second dose of GARDASIL the patient's mother reported that in approximately may 2007, the patient experienced severe hair loss. On 24-SEP-2007, the patient was vaccinated with the third dose of GARDASIL. Concomitant therapy included vitamins (unspecified). In July 2008, the patient came into the doctor's office and stated that her hair started to fall out and she had had dramatic weight loss (onset date not reported). The nurse reported that the patient was going to have various test done. As of 30-DEC-2008, the patient had not recovered. Additional information has been requested. 2/9/09 PCP records received. 2/6/08 WCC with Impression: Well Teenager. (Some records illegible) Seen 3/27/08 for bradycardia. OV 4/24/08 with c/o sore throat and H/A. Throat hyperemic on PE. Imp: Pharyngitis. OV 7/7/08 with c/o losing hair x 1 month, facial hair x 1 month, irregular periods with R sided pain, R foot lump, lump on coccyx, and significant weight loss (169 in 2/08 to 146). Sent for labs. Returned 12/31/08 for f/u of hair loss. No dx noted.

Other Meds: Vitamins (unspecified)

Lab Data: Unknown. Labs: Strep test (-). CBC and Chem unremarkable. TSH normal at 2.13. AM Cortisol low at 7.1. Lyme (-). ACTH WNL at 12.2.

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **338677-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Dec-2008	10-Dec-2008	0	20-Jan-2009	17-Feb-2009	--	WAES0812USA05150	19-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Mobility decreased, Pain in extremity

Symptom Text: Information has been received from a nurse practitioner concerning an 18 year old female patient who on 10-OCT-2008 was vaccinated with first dose of GARDASIL (Lot # number not reported) 0.5ml, intramuscularly in deltoid. On 10-DEC-2008 she received second dose of GARDASIL (lot # number not reported) 0.5ml, intramuscularly in deltoid. After the patient received the vaccine she developed pain at the injection site which radiates down her arm. The pain has impaired mobility and the pain has persisted for the past 19 days. There were not laboratory diagnostics performed. At the time on the report on 29-DEC-2008 the patient was not recovered. The patient sought medical attention in the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338678-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	07-Oct-2008	08-Oct-2008	1	20-Jan-2009	17-Feb-2009	--	WAES0812USA05125	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy, Rash

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female patient with hypothyroidism and no know allergies who on 07-AUG-2008 was vaccinated with the first dose of GARDASIL. On 08-OCT-2008 the patient was vaccinated with 0.5 ml of her second dose of GARDASIL intramuscularly. Concomitant therapy included "thyroid medication". On 08-OCT-2008 the patient developed unilateral rash on the left side of her neck along with inflamed lymph nodes. The rash disappeared 3 weeks later, on approximately 29-OCT-2008. The rash re-occurred on the same area (2008) and again lasted for 3 weeks (recovered , 2008). The patient had not received the third dose. On an unspecified date the patient recovered (2008). Additional information has been requested.

Other Meds: Thyroid

Lab Data: None

History:

Prex Illness: Hypothyroidism

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338680-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	08-Dec-2008	23-Dec-2008	15	20-Jan-2009	17-Feb-2009	PA	WAES0812USA05115	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Rash

Symptom Text: Information has been received from a medical assistant concerning a 19 year old female patient for the pregnancy Registry for GARDASIL with no known allergies and a history of papanicolaou smear abnormal who on 08-DEC-2008 was vaccinated with 0.5 ml of the first dose of GARDASIL (Lot: 658563/1063U) intramuscularly. There was no concomitant medication. On 09-DEC-2008, the patient broke out in a rash on the chest and both shoulders. The patient's rash disappeared on an unspecified date in December 2008. The patient was seen by the doctor on 29-DEC-2008 and there was no terrace of the rash. The patient found out that she was pregnant on 23-DEC-2008. The gestation was on to two weeks. Additional information has been requested.

Other Meds: None

Lab Data: Serum beta-human, 12/??/08, Positive

History: Papanicolaou smear abnormal

Prex Illness:

Prex Vax Illns:

Vaers Id: 338681-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	13-Aug-2008	27-Nov-2008	106	20-Jan-2009	17-Feb-2009	--	WAES0812USA05114	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Unknown	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: Information has been received from a medical assistant concerning a 19 year old female patient with no pertinent medical history and a history of an allergic reaction to Amoxil (reaction unspecified), who on 13-JUN-2008 was vaccinated with her first dose of GARDASIL (Lot: 659962/1740U). On 13-AUG-2008 received the second dose of GARDASIL (Lot: 660393/0067X) and 19-DEC-2008 received the third dose of GARDASIL (Lot: 660393/0067X). On 27-NOV-2008 the patient developed swollen lymph nodes on her neck. The patient sought medical attention with her primary physician. MRI and CT scan were negative. As of 29-DEC-2008 the patient's symptoms persisted. Additional information has been requested. 2/5/09 Received GYN vaccine & medical records of 6/13-12/29/2008. FINAL DX: lymphadenopathy Records reveal patient experienced good health on 6/13 1st HPV. Received call form parent 12/29 about painful neck lymphadenopathy since week of Thanksgiving. Had seen PCP & tx w/antibiotics. Improved initially but then recurred. Had been referred to ENT who had CT/MRI done which revealed benign lymph nodes.

Other Meds:

Lab Data: Magnetic resonance, ?/?/08, negative results; computed axial, ?/?/08, negative

History: Penicillin allergy PMH: constipation. Yaz contraception. Allergy: amoxil. Pap smears normal. Family hx: DM, osteoporosis, blood clotting disorder, heart disease, cancer. HPV #3, lot # 0067X given LA on 12/19/08

Prex Illness:

Prex Vax Illns:

Vaers Id: **338682-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	29-Nov-2008	Unknown		20-Jan-2009	17-Feb-2009	NJ	WAES0812USA05103	04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Disturbance in attention, Dizziness, Lymphadenopathy, Malaise, Tremor

Symptom Text: Information has been received from a physician concerning a 23 year old female patient with depression, who on an unspecified date, was vaccinated with the first dose of GARDASIL and on approximately 29-NOV-2008 was vaccinated with GARDASIL. Concomitant therapy included TRAZODONE HC1, CLONAZEPAM, METHYLPHENIDATE and YASMIN. The physician reported that the patient reported feeling weak, dizzy, tremulous over her entire body and her subclavian lymph node was enlarged on the same side where the vaccine was received. The physician reported that the patient experienced the same reaction after both doses of the GARDASIL vaccine. The symptoms were more severe after her 2nd dose. Exact dates of vaccinations were not available. It was 4 four weeks post dose 2 and patient still did not "feel herself". The patient reported she still felt weak and is unable to concentrate. At the time of the report, the patient had not recovered. The patient sought medical attention and was seen at the physician's office. Additional information has been requested.

Other Meds: CLONAZEPAM; YASMIN; METHYLPHENIDATE; TRAZODONE HYDROCHLORIDE

Lab Data: Unknown

History:

Prex Illness: Depression

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338683-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	18-Dec-2008		20-Jan-2009	17-Feb-2009	MI	WAES0812USA05034	04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site irritation

Symptom Text: Information has been received from a healthcare worker concerning that "many patients complained of burning at the injection site whey they get a dose of GARDASIL vaccine. Follow up information received on 30-DEC-2008 stated that the healthcare worker did not know the names of the other patients. Attempts are being made to obtain additional identifying information to distinguish the individual patients. This one of two reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338684-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Dec-2008	23-Dec-2008	0	20-Jan-2009	17-Feb-2009	--	WAES0812USA04902	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female with asthma and no allergies who was vaccinated with the the third dose of GARDASIL (lot # 659182/1757U) on 23-DEC-2008. Concomitant therapy included ALBUTEROL and fluticasone propionate (+) ADVAIR. After the patient received GARDASIL and 5 minutes later she fainted. The patient recovered from faint on 23-DEC-2008. The patient was seen in the office for medical attention. Additional information has been requested.

Other Meds: ALBUTEROL; ADVAIR

Lab Data: None

History:

Prex Illness: Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338685-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		20-Jan-2009	17-Feb-2009	IN	WAES0812USA04828	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Sexually transmitted disease

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with GARDASIL (dose, site and route not reported) on unspecified date. The patient tested positive for a sexually transmitted disease after received the vaccine. At the time of reporting the outcome was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338686-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	18-Dec-2008	19-Dec-2008	1	20-Jan-2009	17-Feb-2009	MA	WAES0812USA04823	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral

Symptom Text: Information has been received from a registered nurse concerning a 24 year old female patient with no known drug reactions/allergies or medical history who on 09-OCT-2008 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL (lot # 658556/1060U) and on 18-DEC-2008 with the second dose of GARDASIL (lot # 661044/0548X). Concomitant therapy included LEXAPRO. On 19-DEC-2008 the patient developed swollen feet. The patient was told to take BENADRYL and to go to the emergency room if her symptoms worsened. The nurse did not know the patient's present status but said, "The patient was told that if her symptoms did not improve then she should call the office. The nurse had not heard from her so she assumed the patient was recovered". Additional information has been requested.

Other Meds: LEXAPRO

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **338687-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	08-Nov-2007	Unknown		20-Jan-2009	03-Feb-2009	AZ	WAES0812USA04815	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1424F	0	Unknown	Intramuscular	HEPA HPV4 MNQ VARCEL

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Breast cyst, Breast mass, Breast tenderness, Dysmenorrhoea, Fibrocystic breast disease, Hemicephalalgia, Melanocytic naevus, Pain

Symptom Text: Information has been received from a registered nurse concerning a 13 year old female patient with no previous medical history reported who in 2007 was vaccinated, from another office, with the first and second dose of GARDASIL. As of 23-DEC-2008, the patient had not received the third dose. There was no concomitant medication. Subsequently, the patient developed headaches after her first dose of GARDASIL. The headaches are unilateral on the left side of her head and occur daily. The patient was referred to a neurologist. The patient's headaches persisted. The patient sought medical attention at office visit. Additional information has been requested. 2/3/09 Received OB/GYN medical records of 12/22/2008. FINAL DX: fibrocystic disease Patient had experienced enlarging right breast mass w/tenderness x 1 year. During discussion of completing HPV vaccinations (had not had #3) patient revealed also had HA for approx 1 year. 3/11/09 Received PCP medical records of 7/19/07-11/1/2008. FINAL DX: fibrocystic breast disease; dysmenorrhea Records reveal patient experienced good health on 7/19. RTC 10/25 w/sports injury & dx w/sprained right knee. RTC 11/8/07 w/improving right knee. RTC 6/20/08 for skin eval of moles on neck whose size had incresed x 1 year & were tender w/stinging sensation. Dx w/pigmented nevus & referred to Derm for eval. RTC 8/13/08 w/right breast lump that was tender esp during menses. Dx w/fibrocystic breast disease & dysmenorrhea. RTC for breast pain recheck but patient refused exam. No further records available.

Other Meds: None

Lab Data: None LABS: MRI & US of bilateral breasts c/w right cyst

History: None PMH: Asthma in childhood, appy, umb. hernia repair. Allergy: naprosyn. Family hx: DM, HTN, breast ca.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338688-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	05-Nov-2008	Unknown		20-Jan-2009	17-Feb-2009	MD	WAES0812USA04777	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Fatigue

Symptom Text: Information has been received from a physician for GARDASIL vaccine, concerning an 18 year old female patient with no previous medical history reported who on 09-SPR-2008 was vaccinated with the first dose of GARDASIL. On 15-JUN-2008 the patient was vaccinated with the second dose of GARDASIL and on 05-NOV-2008 with the third dose of GARDASIL. On 04-DEC-2008, a home pregnancy test was performed and the result was positive. The patient reported to the physician that she was tired. The patient sought medical attention, by phone call. Additional information has been requested.

Other Meds: Unknown

Lab Data: Beta-human chorionic, 12/04/08, positive, home pregnancy

History:

Prex Illness: Pregnancy, NOS (LMP= unknown)

Prex Vax Illns:

Vaers Id: **338690-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-Jan-2009	20-Jan-2009	0	30-Jan-2009	11-Feb-2009	FL		11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB329AA	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	D072X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Gaze palsy, Loss of consciousness, Tremor

Symptom Text: Passed out, tremors, eyes rolling in the back of her head Client sent to ER via ambulance.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338699-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	04-Aug-2008	04-Aug-2008	0	20-Jan-2009	17-Feb-2009	CA	WAES0901USA00023	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Local swelling

Symptom Text: Information has been received from a medical assistant concerning a 20 year old female patient with no pertinent medical history, no drug reactions/allergies, who on 04-AUG-2008 was vaccinated intramuscularly with the 0.5 mL first and only dose of GARDASIL vaccine (Lot # 660391/0063X). There was no concomitant medication. On the same day, the patient experienced swelling on her neck. On 08-AUG-2008, the patient recovered. The

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **338700-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	29-Dec-2008	Unknown		20-Jan-2009	17-Feb-2009	MO	WAES0901USA00012	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Information has been received from a healthcare worker concerning a 25 year old female patient who received second dose of GARDASIL and was found to have genital warts. The patient has stated to the physician that she was not sexually active. Follow up information received on 31-Dec-2008 from the healthcare worker who reported the patient received her first dose of GARDASIL (lot# 660398/1968U) on 30-Oct-2008 and the second dose of GARDASIL (lot#660389/1958U) on 29-Dec-2008. At the time on the report on 31 Dec-2008 the patient was not recovered The patient sought medical attention was seen in the office. Additional information has been requested

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338701-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		20-Jan-2009	17-Feb-2009	CT	WAES0812USA05266	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site extravasation

Symptom Text: Information has been received from a medical assistant concerning a patient who may had received a partial dose of GARDASIL. The patient did not report any pain upon injection and some vaccine ran down her arm. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338702-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Dec-2008	30-Dec-2008	0	20-Jan-2009	17-Feb-2009	--	WAES0812USA05263	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Muscle twitching, Syncope, Tonic clonic movements

Symptom Text: Information has been received from a nurse practitioner concerning a 14 year old female who on 30-DEC-2008 was vaccinated with the first dose of GARDASIL (Lot # 660616/0570X) 0.5 ml via IM route into her deltoid. The patient fainted immediately after receiving the vaccine. She also displayed twitching with tonic-clonic motions of her upper extremities. This reaction resolved spontaneously. It was also noted that the patient did not eat breakfast. Unspecified medical attention was sought in the office. The patient was observed resting for about 20 minutes after the episode and given a popsicle. No other treatment and patient was considered fully recovered. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338703-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	30-Dec-2008	30-Dec-2008	0	20-Jan-2009	17-Feb-2009	NE	WAES0812USA05239	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Consciousness fluctuating, Nausea, Paraesthesia, Syncope

Symptom Text: Information has been received from a nurse concerning a 19 year old female with asthma, hirsutism and polycystic ovarian syndrome and no known drug allergies, who 2 years ago was vaccinated with a first dose of GARDASIL. On 30-DEC-2008 the patient received a 0.5 mL second dose of GARDASIL (lot # 659184/0843X), intramuscularly. Concomitant therapy included Ocella. Ten minutes after the administration of the second dose the patient experienced syncope. The patient was "in and out of consciousness" for 4 to 5 minutes. She also experienced nausea and tingling sensation in her arm. There were no laboratory diagnostics studies performed. At the time of the report the patient was recovering. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Ocella

Lab Data: None

History: Asthma; Hirsutism; Polycystic ovarian syndrome

Prex Illness:

Prex Vax Illns:

Vaers Id: 338733-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Feb-2008	07-Feb-2008	0	01-Feb-2009	05-Feb-2009	NY		30-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Left arm	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abnormal behaviour, Aggression, Agitation, Akinesia, Anxiety, Asthenia, Back pain, Confusional state, Decreased appetite, Dizziness, Educational problem, Encephalitis, Endotracheal intubation, Fatigue, Grand mal convulsion, Headache, Hyperreflexia, Injection site pain, Lethargy, Malaise, Mood swings, Muscle twitching, Nausea, Pain, Personality change, Postictal state, Posturing, Retching, Skin papilloma, Status epilepticus, Tremor, Vomiting, Weight decreased

Symptom Text: February 2008 first shot experienced headaches, dizziness, back pain, soreness at injection site (still feels pain in arm today). April 2008 after second infection in addition to above symptoms, confustion, lethargic, gagging, nausea, vomiting, massive warts on the bottom of feet, mood swings, altered personality, shaking. In May 2008 was brought to the hospital had a MRI and cat-scan both normal. The doctor said she was experiencing headaches. In June 2008 she woke up with a headache and vomiting, collasped into a grand-mal seizure. Tranferred to a hosptal. Went through every test possible and came home for a few days. Went into another grand-mal seizure that lasted about three hours, had to be intabated again and transported to the hospital again where they did another MRI, EEG, Spinal Tap and more and more blood tests. Her protein level in her Spinal Tap was very high (159). We are still dealing with a very ill child. On Christmas day she had a seizure and back to hospital which is two and a half hours away from where we live. She takes 14 pills a day with really no answers to why she is ill. Her immune system is confused, confusing her brain. Her life has changed dramatically as she is unable to do the things a healthy 17 year old should be able to do. 2/17/09 Neuro consult dated 1/2/09 received with dx: probable Hashimoto's Encephalopathy. Report reveals pt had 2 prolonged seizures in summer 2008 with behavioral and mood changes. Dx with Hashimoto's Encephalopathy and tx with steroids x 3 mon which were tapered off. On 12/25/09 pt woke feeling nauseous and gagging, tremoulous, and feeling sick. Felt like face "was pulling off". Unable to yell or move. Found by parents seizing ~ 10 minutes. Diastat administered. Transferred to hospital. Post-ictal then later combative and agitative. Pt reports being tired and achey since 11/08. Neuro exam WNL. 3/19/09 Additional records received from 7/23/08, 8/26/08 and 2/20/09 Neuro consults as well as rheum consult 2/20/20009 as well. Pt hospitalized in June

Other Meds: none at time of vaccinaion

Lab Data: Spinal Tap protein 159 very high. Labs and Diagnostics: CSF protein increased, then repeat CSF WNL. Anti-thyroid peroxidase Ab 107 (H). TSH WNL. T4 WNL. EEG abnormal x 3. Lipase increased. ANA 1:80. Lupus anticoags (-).

History: Never been ill

Prex Illness: none (never been ill) very healthy until GARDISL

Prex Vax Illns: ~HPV (Gardasil)~2~0~In Patient

Vaers Id: **338762-1 (S)** **Related reports:** 338762-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	20-Sep-2007	20-Sep-2007	0	02-Feb-2009	09-Feb-2009	MA		02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Bruxism, Constipation, Headache, Migraine, Nausea, Pain, Post lumbar puncture syndrome, Pyrexia, Temporomandibular joint syndrome, Vomiting

Symptom Text: I got the first HPV vaccine, and 1 hr later, I developed a fever of 102.0, was vomiting, and had a severe headache. Ever since 9/20/07, I have had a chronic, 24 hr/day headache. I have seen my PCP, neurologist, and many ER visits. It has been concluded that this occurred from the HPV vaccine. After doing extensive research about GARDASIL, and being advised by healthcare professionals, I got the first dose on 9/20/2007. About an hr later, I got a fever of 102.2, was vomiting, and had a severe headache. Eventually, the other symptoms went away, but the headache continued. It was an intense headache that lasted 24hrs/a day. I saw my PCP several times, and was referred to a neurologist. In the meantime, I got the second dose on 11/14/2007. I did not put two and two together. Since there was a long wait to see the neurologist, I ended up in the emergency room twice in 12/07. The first visit, an MRI, CT, and Lumbar Puncture were performed. I ended back in the ER a few days later for observation. All of the tests came back normal, but the pain was unbearable. I was put on IV MORPHINE, which had little affect. I then got an urgent appt with my neurologist in 12/07. Since 9/07, my life has been turned upside down. I have missed work, had to switch jobs, and have struggled to finish nursing school. I was 100 percent healthy before this immunization I have spent thousands of dollars on medications, copays, alternative options, such as chiropractic care, acupuncture, and massage. I simply can't afford it. I have been on more Rx in the last year and a half than most people have in a lifetime. At 21 years old, I should be able to live a normal life. Within the past month, I have been back in the ER three times. The only thing that "took the edge off" was IV DILAUDID. I have tried basic OTC such as ADVIL, TYLENOL, ALEVE, EXCEDRIN, Rx NSAIDS, PREDNISONE, muscle relaxers, anticonvulsants, and tricyclic antidepressants. Caffeine and antihistamine, narcotics, and just about anything else you can of, I have tried. Still, nothing has

Other Meds: At the time, just oral contraceptives 2/17/09-records received-Current medications Necon and Lorazepam.

Lab Data: Several tests, including extensive blood work; Cat Scan; MRI; and Lumbar puncture. 2/17/09-records received-CSF pressure 120-130, protein 31.2 and glucose 61, cutlure negative. CBC showed elevated WBC 10,300. Urinalysis revealed 1+ protein

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **338762-2 (S)** **Related reports:** 338762-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	20-Sep-2007	20-Sep-2007	0	16-Mar-2009	07-Apr-2009	MA	WAES0902USA01132	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Headache, Pain, Pyrexia, Vomiting

Symptom Text: Information has been received from a 20 year old female patient with no pre-existing physician-diagnosed allergies, birth defects or medical conditions who at 10:00 on 20-SEP-2007 was vaccinated with the first dose of GARDASIL in her arm (lot #658558/1061U) after doing extensive research about GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). There was no illness at the time of vaccination. At 11:00 on 20-SEP-2007 ("about an hour later") the patient experienced a fever of 102.2, vomiting and a severe headache, and was hospitalized for two days. Subsequently, the other symptoms went away but the headache persisted. It was an intense headache that lasted 24 hours a day. The patient saw her PCP several times and was referred to a neurologist. On 14-NOV-2007, the patient received the second dose of GARDASIL in her arm (lot # 658560/1062U). In December 2007 the patient went to the emergency room twice. At the first visit, MRI, CT and lumbar puncture were performed. The patient ended back in the ER a few days later for observation. All of the tests were normal, but the pain was unbearable. The patient was given IV morphine which had little effect. Then in December 2007 the patient got an urgent appointment with the neurologist. She noted that her life had been "turned upside down", and the patient had missed work, had to switch jobs and had struggled to finish nursing school. She also indicated that she was 100% healthy prior to the vaccinations. The patient had been on more therapy in the last one year and a half, and has been in the ER three times again "within the past month". The only thing that "took the edge off" was IV DILAUDID. She had tried basic OTC such as ADVIL, TYLEND, ALEVE, EXCEDERIN, nonsteroidal anti-inflammatory drug (unspecified), PREDNISONE, muscle relaxes, anticonvulsants, tricyclic antidepressants, caffeine, antihistamine, narcotic, and just about anything else. Still nothing had worked. The patient's doctor had concluded she had a serious reaction from GARDASIL. A feve

Other Meds: hormonal contraceptives

Lab Data: magnetic resonance, normal; computed axial, normal; spinal tap, normal

History: None

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338782-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	05-Oct-2007	19-Apr-2008	197	02-Feb-2009	03-Feb-2009	PA	WAES0901USA03970	03-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse for the Pregnancy Registry for GARDASIL concerning a 28 year old female patient with no pertinent medical history, no drug reactions/allergies, who on 03-AUG-2007 was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL (Lot # 658222/0927U). There was no concomitant medication. On 05-OCT-2007 the patient was vaccinated intramuscularly with the second 0.5 mL dose of GARDASIL (Lot # 658563/1063U). The patient became pregnant after receiving her second dose of GARDASIL. Her LMP was on 19-APR-2008 and estimated date of delivery was 24-JAN-2009. On 19-JAN-2009 the patient delivered by caesarean section. Upon internal review, patient delivered by caesarian section was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 4/19/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338783-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jan-2009	01-Jan-2009	0	02-Feb-2009	03-Feb-2009	FR	WAES0901PHL00007	03-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician concerning a female who in January 2009, was vaccinated with GARDASIL. The patient has received the second dose when patient became pregnant. On January 2009 the patient experienced vaccine exposure during pregnancy and abortion. Upon internal medical review, abortion was considered an other important medical event. No further information is available. The physician was not available to give additional information.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338784-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Aug-2008	14-Aug-2008	13	02-Feb-2009	03-Feb-2009	FR	WAES0809USA04068	03-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received on 14-AUG-2008 from a gynaecologist, concerning a 16 year old female who was vaccinated with GARDASIL (lot #, route and site not reported) on an unspecified date. At the time of reporting, the patient was in the 5th month of pregnancy (22nd week of pregnancy). No adverse effect was reported. Follow-up information received via the pregnancy follow-up reporting form on 20-JAN-2009 and by phone call on 21-JAN-2009. Upon medical review the company upgraded the case to serious because of induced abortion. It was reported by the gynaecologist that the patient consulted him on 14-AUG-2008 in 22nd weeks of gestation. Thereafter she underwent voluntary termination of pregnancy (induced abortion) between 15-AUG-2008 and 20-AUG-2008. The patient was vaccinated with a third dose of GARDASIL, lot # not reported on 20-JAN-2009 which was well tolerated. Case closed. Other business partner numbers include E2008-07749.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 01Apr08)

Prex Vax Illns:

Vaers Id: **338839-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Jun-2008	03-Jun-2008	0	03-Feb-2009	04-Feb-2009	--	WAES0901USA03921	04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female patient who on 03-JUN-2008 was vaccinated with a dose of GARDASIL. Concomitant therapy included MENACTRA. On 14-SEP-2008 the patient delivered at 29 weeks pregnant. The status of the baby is unknown. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338840-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		03-Feb-2009	04-Feb-2009	TX	WAES0901USA03924	04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received for the pregnancy registry for GARDASIL from a 20 year old female patient who was vaccinated with the first dose of GARDASIL (lot# not provided) when she was "around one month pregnant". Subsequently the baby had some complications and when patient was three months pregnant she terminated the pregnancy due to the complications. Patient was then referred to another physician (name not provided) who told the patient that the complications she had with the baby were probably related to GARDASIL. Upon internal review, the termination of the pregnancy was considered an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 338841-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	08-May-2008	01-Jun-2008	24	03-Feb-2009	04-Feb-2009	TN	WAES0901USA03994	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain lower, Activities of daily living impaired, Anxiety, Decreased appetite, Dehydration, Endometriosis, Muscle spasms, Nausea, Pelvic pain, Tenderness, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 10 year old female patient with anterior and posterior endometriosis and SYNAREL allergy and a history of laparoscopic band surgery (2007) who on 08-MAY-2008 was vaccinated with first dose of GARDASIL (Lot # not reported). Concomitant therapy included LUPRON DEPOT on 06-NOV-2008, in December 2008 and January 2009. In June-2008 after administration of vaccine the patient experienced intermittent lower anterior abdominal pain on left and right side. The pain was below umbilicus more midline than lateral. Patient had lower abdominal wall tenderness. She also experienced anxiety, nausea and decrease in appetite. She was hospitalized in June of 2008 for a few days due to dehydration and abdominal pain. She did not experience pain in July and August of 2008. On 03-JUL-2008, the patient was vaccinated with the second dose of GARDASIL (lot # not reported). In September of 2008 abdominal pain returned. She was hospitalized 16-SEP-2008 to 18-SEP-2008 and then again in October of 2008. On 03-NOV-2008, the patient was vaccinated with the third dose of GARDASIL (lot # not reported). On 22-JAN-2009 to 23-JAN-2009 she was hospitalized for dehydration. She was unable to attend college because of her symptoms. She was being treated with PERCOCET and DILAUDID but was not currently taking either medication. In September 2008 laparoscopy was performed (results not reported). Also colonoscopy, computed axial tomography, sonogram and complete blood cell count were performed (results not reported). At the time of the report on 27-JAN-2009 the patient was recovering. The patient sought medical attention office visit. The physician considered intermittent lower anterior abdominal pain on left and right side, anxiety, nausea and decrease in appetite to be disabling. Additional information has been requested. 2/10/09 Received hospital medical records of 9/16-9/18/09. FINAL DX: pelvic pain, endometriosis Records reveal patient experienced lower abdominal pain, cramping since

Other Meds: LUPRON DEPOT

Lab Data: Colonoscopy; Computed axial; Ultrasound; Laparoscopy, 09/??/08; Complete blood cell LABS: CT & US neg.

History: Laparoscopic surgery PMH: anxiety, gastric band surgery & sinus surgery.

Prex Illness: Endometriosis; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **338842-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Jun-2008	01-Sep-2008	66	03-Feb-2009	04-Feb-2009	FR	WAES0901USA04005	04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eczema, No reaction on previous exposure to drug, Rheumatoid arthritis

Symptom Text: Information has been received from a Health authority concerning a 15 year old female patient who on 27-JUN-2008 was vaccinated with the first dose of GARDASIL (lot# 1477U, batch# NH16170). On 25-AUG-2008, the patient was vaccinated with a second dose of GARDASIL (lot# 1427U, batch# NH15200). There was no concomitant medication. At the end of September 2008, the patient developed rheumatoid arthritis and eczema of the anticubital fossa (bilateral). The patient had not recovered as of 23-JAN-2009. The first dose was well tolerated. Rheumatoid arthritis and eczema were considered to be another important medical event by the health authority. Other business partner numbers include: E2009-00555, PEI2009000869. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 338843-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Oct-2008	22-Nov-2008	31	03-Feb-2009	04-Feb-2009	FR	WAES0901USA04297	04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1941U	3	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dialysis, Face oedema, Inappropriate schedule of drug administration, Localised oedema, Oedema peripheral, Renal failure, Systemic lupus erythematosus

Symptom Text: Initial case was reported on 27-JAN-2009 by Health Authority (ref. number DK-DKMA-20082812). This case is an overdose case. It was reported that a 16-year-old female patient was vaccinated with GARDASIL (lot#1941U, Batch# NJ01850 site of administration not reported) intramuscularly on 22-OCT-2008. It was reported that the patient previously had received 3 vaccinations with GARDASIL (batch#, route and site of administration not reported). One month later, on 22-NOV-2008, the patient developed neck oedema, oedema face and leg oedema. On 24-NOV-2008, the patient was seen by a physician (GP). Urine strip test revealed blood and protein present in urine. Blood pressure was 160/90 mmHg. Streptococcus A test was negative. The patient was admitted to hospital on 24-NOV-2008. The patient was diagnosed Systemic Lupus Erythematosus. As a consequence of systemic lupus erythematosus, the patient experienced renal insufficiency that required dialysis treatment. At the time of report the patient had not recovered and received immune suppressive treatment (not further specified). The patient had a medical history of episodes with intermitting eye oedema during the past 2-3 years. This was interpreted as unspecified allergy. The patient had received 3 vaccinations with GARDASIL (batch number, route and site of administration not reported) previously. Vaccination dated not reported. No reaction was reported in connection with these vaccinations. Relevant test/laboratory data: On 24-NOV-2008 urine strip test revealed blood and protein present in urine. Blood pressure was 160/90 mmHg, and streptococcus A test was negative. Other business partner numbers include: E2009-00647. No further information is available.

Other Meds: Unknown

Lab Data: blood pressure measurement, 24Nov08, 160/90 mmHg; urinalysis, 24Nov08, blood and protein present; Streptococcus group A culture, 24Nov08, negative

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

Vaers Id: **338853-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	12-Dec-2008	Unknown		03-Feb-2009	04-Feb-2009	FR	WAES0901USA03801	04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Pain, Pericarditis

Symptom Text: Information has been received from a female patient with attention deficit/hyperactivity disorder; hyperactivity due to treatment with CERAZETTE and deafness unilateral (cytomegalovirus or waardenburg's syndrome) from birth who on 12-DEC-2008 was vaccinated with the first dose of GARDASIL (lot # not reported). Concomitant therapy included alprazolam (manufacturer unknown) and ABILIFY. Few days after vaccination, first symptoms occurred with breathlessness. As the reaction was very painful, corrective treatment with ASPIRIN 3 gram was taken. At cardiology consultation, the patient was diagnosed with a small pericarditis sicca. Electrocardiography and echocardiography were normal. A follow up was not planned. At the time of the report, the outcome was unknown. The case was not medically confirmed. Pericarditis sicca was considered to be another important medical. Other business partner numbers include: E2009-00655. No further information is available.

Other Meds: ABILIFY; CERAZETTE; alprazolam

Lab Data: Electrocardiogram, normal; Echocardiography, normal

History:

Prex Illness: Deafness unilateral; Attention deficit/hyperactivity disorder; Adverse drug reaction

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338854-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	07-May-2008	19-Dec-2008	226	03-Feb-2009	04-Feb-2009	FR	WAES0901USA03788	04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Information has been received from a physician concerning a 24 year old white female patient with no pertinent medical history who on unspecified dates received the first and second doses of GARDASIL. On 07-MAY-2008 was vaccinated with the third dose of GARDASIL. There was no concomitant medication. On 19-DEC-2008 the patient experienced genital warts. The patient's last PAP test on 19-MAR-2008 was a normal smear, class 1. The patient's genital warts persisted. Genital warts were considered to be another important medical event by the physician. No further information is available.

Other Meds: None

Lab Data: Pap test, 19Mar08, Normal smear class I

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 338855-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	02-Jul-2008	01-Aug-2008	30	03-Feb-2009	04-Feb-2009	FR	WAES0901USA03763	04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Erythema nodosum, Incorrect route of drug administration

Symptom Text: Information has been received form a Foreign Health authorities concerning a 15 year old female patient with a medical history of fracture, joint ligament rupture and rhinitis allergic who received the first and second doses of GARDASIL (batch numbers not reported) via an inappropriate route of vaccination i.e. subcutaneous route instead of intramuscular route respectively on 02-JUL-2008 and 30-AUG-2008. At the end of August 2008, she presented with erythema nodosum which worsened after the second dose of GARDASIL. Several consultations were needed and the patient was hospitalized on an unspecified date. Aetiological, infectious, medicated and inflammatory work-up were negative on 07-JAN-2009. At the time of the report, the patient had not recovered. According to Foreign Health Authorities, there were no other triggering factors identified as GARDASIL and the third dose was not contra-indicated. The Foreign Health Authorities assessed the causal relationship between the reported reaction (s) and vaccination as doubtful according to the Foreign method of assessment. The case is closed. Other business partner numbers include E2009-00653, LM20090060 and LM900021.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 07Jan09, etiological, infectious, medicated and inflammatory check-up negative

History: Joint ligament rupture; Fracture

Prex Illness: Rhinitis allergic

Prex Vax Illns:

Vaers Id: **338856-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	24-Nov-2008		03-Feb-2009	04-Feb-2009	--	WAES0901USA03679	04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a licensed practical nurse for the pregnancy registry for GARDASIL concerning a pregnant female patient with herpes simplex type II who was vaccinated with GARDASIL. Concomitant therapies included VALTREX and prenatal vitamins (unspecified). No complications during the pregnancy. On 24-NOV-2008 the patient's baby was having non reassuring fetal heart tones, and patient delivered her baby via cesarean section. Infant was born normal, without congenital anomalies 40 weeks from LMP. Baby is a 6 pounds male with an Apgar score of 7/8. Upon internal review, non reassuring fetal heart tones and cesarean section was determined to be an other important medical event. No further information is available.

Other Meds: VALTREX, mg; Vitamins (unspecified)

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 2/18/2008); Herpes simplex type II; Pregnancy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338858-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Apr-2008	Unknown		03-Feb-2009	04-Feb-2009	FR	WAES0901USA03395	04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Type 1 diabetes mellitus

Symptom Text: Information has been received initially on 22-JAN-2009 from a pharmacist concerning a 17 year old female patient who in April 2008, was vaccinated with the first primary dose of GARDASIL (Batch #, route and site of administration not reported). The patient's mother reported to the pharmacist that her daughter experienced juvenile diabetes (unspecified timeline). It was unknown whether or not the patient had received other doses of vaccine. This case was assessed as serious by the pharmacist as medically significant. Other business partner numbers include E2009-00517. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **338867-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-Oct-2008	08-Nov-2008	18	03-Feb-2009	04-Feb-2009	CT	WAES0901USA01798	04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse and the patient's mother for the pregnancy registry for GARDASIL, concerning a 15 year old female with Amoxicillin allergy and psoriasis who on 21-OCT-2008 was vaccinated with the first dose GARDASIL (Lot not provided). Concomitant therapy included hepatitis A virus vaccine (unspecified). On 23-DEC-2008 the patient received the second dose of GARDASIL (Lot not provided). Subsequently the patient discovered that she was pregnant via pregnancy test (LMP: 08-NOV-2008, EDD: 15-AUG-2009). As of 15-JAN-2009 the patient was fine. Follow up information has been received on 29-JAN-2009 from the patient's mother concerning her 15 year old daughter who on 25-JAN-2009 had a miscarriage. Upon internal review, miscarriage was considered to be an Other Important Medical Event. Additional information has been requested.

Other Meds:

Lab Data: beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 11/8/2008); Penicillin allergy; Psoriasis

Prex Vax Illns:

Vaers Id: **338868-1 (S)** **Related reports:** 338868-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Dec-2008	22-Dec-2008	4	03-Feb-2009	04-Feb-2009	--	WAES0901USA03674	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Unknown	Intramuscular	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Back pain, Constipation, Dyspepsia, Fatigue, Headache, Musculoskeletal pain, Myalgia, Nausea, Pain in extremity, Pneumonia, Sleep disorder, Vomiting, Weight increased

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female patient who on 16-OCT-2008 was vaccinated with the first dose of GARDASIL (lot# 659184/0843X) 0.5ml intramuscularly. Subsequently the patient developed sharp, intermittent abdominal pain, which resolved without treatment in an unspecified length of time. On 18-DEC-2008 the patient received her second dose of GARDASIL (lot# 659184/0843X) 0.5ml intramuscularly. On 22-DEC-2008 patient developed intense abdominal pain as well as pain in her lower extremities. Patient's parent sought medical attention by calling the health department. The nurse is unsure if the pain had resolve at the time of this report. On 05-JAN-2009 patient was hospitalized with a diagnosis of pneumonia and was discharged on 07-JAN-2009. This is one of several reports received from the same source. Additional information has been requested. 3/23/09 Received ER & Clinic medical records of 1/19-2/26/2009. FINAL DX: constipation; chronic abdominal pain Records reveal patient experienced crampy intermittent severe abdominal pain & nausea since 10/08 which had worsened in 12/08 & now included muscle tenderness when seen in ER 1/19/09. Had been using narcotic pain meds, dx w/constipation, & tx w/laxative. Had missed several days of school due to pain & the pain would awaken her at night. Seen in GI clinic 1/19/09. Tx w/laxative & enema w/resolution of abd pain. Psych counseling started. RTC 1/26 dx w/functional dyspepsia & meds adjusted. RTC 2/4/09 w/right back/shoulder pain, vomiting, HAs, abdominal pain improved, classes 1/2 days & exhaustion when completed. RTC 2/26 w/20# weight gain, continued missed school although abdominal pain & HA less but continued daily.

Other Meds: Unknown

Lab Data: Unknown LABS: Abdominal US neg. CT abdomen c/w pneumonia. KUB revealed constipation. Upper endoscopyWNL. Throat c/s neg.

History: Unknown PMH: T&A. Tension HAs. Allergy: PCN, rash. Family hx: IBS, SLE, herpetic whitlow, CNS glycolysis.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338868-2** **Related reports:** 338868-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Dec-2008	22-Dec-2008	4	18-Feb-2009	19-Feb-2009	MO		10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Back pain, Neck pain, Pain in extremity, Pneumonia

Symptom Text: HPV #1 on 10/15/08- within 1wk- sharp, midsection abdominal pain that would come and go. 12/22/08 Same abdominal pain with greater severity. Pain in upper back and neck radiating down arms. Pain upper thigh down legs. Hospitalized 1/5/09-1/7/09 for pneumonia unable to attend school.

Other Meds: None

Lab Data: Negative Strep; MONO; CBC within normal limits

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338869-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Dec-2008	29-Dec-2008	7	03-Feb-2009	04-Feb-2009	FL	WAES0901USA03680	04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Nausea, Syncope

Symptom Text: Information has been received from a healthcare worker concerning a 17 year old female patient with no known drug reactions/allergies and medical history who on 15-OCT-2008 was vaccinated intramuscularly with the first dose 0.5 ml dose of GARDASIL (Lot #660618/0572X), and on 22-DEC-2008 with the second dose of GARDASIL (Lot #661044/0548X). There was no concomitant medication. On 29-DEC-2008 at home the patient experienced syncope and possible seizure. The patient was evaluated at a local emergency room and a CT scan of the brain and Electrocardiogram were normal. Since then, the patient had experienced persistent dizziness, headaches, and nausea. The patient was examined in the office and was prescribed PREVACID. An Electroencephalogram was normal. The stool was positive for occult blood so the patient was referred to an unspecified gastroenterologist. An abdominal ultrasound and endoscopy had been scheduled. The patient sought medical attention. At the time of reporting the patient was not recovered. Upon internal review seizures were considered to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: computed axial, normal; electrocardiogram, normal; electroencephalography, normal; stool occult blood, positive

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338870-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Oct-2008	16-Oct-2008	0	03-Feb-2009	04-Feb-2009	--	WAES0901USA03777	04-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dyspnoea, Familial risk factor

Symptom Text: Information has been received from the mother concerning her 13 year old daughter who on 16-OCT-2008 was vaccinated with a dose of GARDASIL. On 16-OCT-2008 the patient experienced severe breathing problems and was hospitalized. At the time of reporting the patient was not recovered. The patient's sibling experienced heart problems after vaccination with GARDASIL (MSD WAES 0901USA03550). This is one of two reports received from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: cardiac disorder~HPV (Gardasil)~1~14~In Sibling

Vaers Id: 338907-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Jan-2009	23-Jan-2009	2	03-Feb-2009	12-Feb-2009	WI		03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Asthenia, Constipation, Diarrhoea, Dyspnoea, Dysuria, Eye discharge, Gastritis, Gastroenteritis, Heart rate increased, Hypophagia, Nausea, Pallor, Pollakiuria, Pyrexia, Similar reaction on previous exposure to drug, Vomiting

Symptom Text: FATHER REPORTS CHILD DEVELOPED MIDABDOMINAL PAIN, DIARRHEA, AND VOMITED ONCE STARTING 1/23/09. IT BECAME INCREASINGLY WORSE AND SHE BECAME PALE ON 1/25/09. PARENTS TOOK HER TO THE EMERGENCY ROOM AND SHE WAS GIVEN IV FLUIDS, BLOOD TESTS, AND URINE TESTS. ALL TESTS WERE NORMAL. FATHER IS CONCERNED AS HE BELIEVES IT IS RELATED TO THE GARDISIL VACCINE. 2/23/09 Received ER medical records of 2/1/2009. FINAL DX: gastroenteritis Records reveal patient experienced nausea, vomiting, diarrhea, abdominal pain, fever, oral intake reduced, urinary frequency, dysuria, eye drainage, SOB, increased heart rate, weakness x 3 days. Patient had similar experience after initial HPV vaccine. Tx w/antinausea meds & IVF. Improved & d/c to home. 2/26/09 Received PCP medical records of 8/30/07-12/8/08. FINAL DX: epigastric pain, likely gastritis Records reveal patient experienced abdominal pain intermittently x several months when seen 12/3, 12/7 & 12/8/2008. Tx w/meds.

Other Meds: UNKNOWN

Lab Data: LAB WORK, AND URINE TESTS LABS: CBC, BMP & UA WNL. Abdominal x-ray c/w constipation. CT abdomen/pelvis WNL. ER LABS: BUN 9(L), lipase & amylase WNL. neutros 69%(H).

History: NONE PMH: anxiety

Prex Illness: NONE

Prex Vax Illns: SAME SYMPTOMS~HPV (Gardasil)~1~12~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338911-1** **Related reports:** 338911-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Dec-2007	28-Dec-2007	4	03-Feb-2009	13-Feb-2009	WI		17-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NOT AVAILABLE	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Diarrhoea, Diplopia, Disturbance in attention, Dizziness, Fatigue, Headache, Memory impairment, Nausea, Photophobia, Tension headache, Weight decreased

Symptom Text: Severe, chronic headaches that began very soon (within days) after first vaccination of Gardasil. Headaches became progressively worse and currently continue daily- one year later. Referral was made for vision testing, CT Scan and MRI, with no underlying cause of headaches determined. Numerous different prescription drugs were prescribed with no effect until current prescription, taken twice daily, was found to help subdue the headaches- though they have not been eliminated. At their worse, the headaches were debilitating- rendering my daughter unable to function at school with some days missed and numerous visits to the nurses office and then to the doctors office. At home, she would just curl up into a ball many days- unable to function whatsoever. The headaches begin when she wakes in the morning and persist throughout the day- every day. 3/13/09 OV dated 12/24/07 received from PCP for 16 yr WCC. Impression: Acne. Sent to derm. Left SI joint pain and R lower rib tenderness. HPV vax given. 3/16/09 Neurology consults received dated 3/14/2008 to 2/2/2009. Initially seen 3/14/08 for c/o 8-9 wk hx of H/A. Pt reports double vision, dizziness, nausea and lightheadedness with H/A. Recent 6lb weight loss. PE WNL. DX: Chronic Tension H/A. Rx meds. F/u 6/2/08 with no improvement,H/A now daily. Meds increased. F/u 8/1/08 H/A now with photophbia and nausea. 8/8/08 Mom reporting memory difficulties x several weeks. 9/2008 started Cymbalta with some improvement in H/A, however having diarrhea and tiredness. Changed to Zoloft.

Other Meds: Minocycline

Lab Data: Vision screening, CT Scan, MRI, blood tests. Labs and Diagnostics: MRI/MRA brain WNL. EKG abnormal-borderline QT wave.

History: none PMH: none

Prex Illness: none

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338911-2** **Related reports:** 338911-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Dec-2007	Unknown		16-Feb-2009	17-Feb-2009	WI		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Patient's mother reports that patient has had daily headaches since around the time she got 1st GARDISIL injection. She is unsure if it is related to injection but feels strongly that it could be and should be reported for knowledge.

Other Meds: MINOCYCLINE

Lab Data: Has been seeing Neurology for headaches

History: Acne

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338941-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-Jul-2008	08-Jul-2008	1	30-Jan-2009	17-Feb-2009	AZ	AE0824	19-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	TD	MASS. PUB HLTH BIOL LAB	TD196		Unknown	Intramuscular	
	PNC	WYETH PHARMACEUTICALS, INC	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Injection site erythema, Wrong technique in drug usage process

Symptom Text: Patient developed induration and redness at injection site, and a headache. Follow up on 10/28/08: As the patient did not return to the medical office, the reporter considered her recovered. Reporter attributed reaction to an incorrect administration technique. The reporter did not have additional details on the administration of the vaccine, vaccine was administered IM in a deltoid.

Other Meds: unknown

Lab Data: unknown

History: unknown

Prex Illness: unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338979-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-May-2008	Unknown		04-Feb-2009	05-Feb-2009	FR	WAES0901USA04470	05-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bronchitis, Fatigue, Generalised oedema, Glomerulonephritis chronic, Hypotension, Proteinuria, Toxoplasmosis

Symptom Text: Information has been received from a physician concerning a 17 year old female with pneumopathy, otospongiosis, allergic asthma, and a history of allergy to graminaceae and acarus (which was former and had resolved) who on 17-MAY-2008 was vaccinated with a third dose of GARDASIL. Concomitant therapy included desensitization treatment. In June 2008, the patient complained of unusual fatigue. During the summer, she developed bronchitis and toxoplasmosis. Late in august 2008, she experienced generalized oedema. There was no hematuria, but there was proteinuria. The patient had no hypertension but hypotension. Renal biopsy revealed chronic glomerulonephritis with mild glomerular lesions. Corrective treatment with high dose of corticosteroids, 55 mg per day was given and a strict diet without salt and sugar was prescribed, and symptoms oedema resolved. A good prognosis was given because of the age, the response to treatment and the early diagnosis. Hypotension, generalised oedema and bronchitis were considered symptoms of chronic glomerulonephritis. The events were considered to be other important medical events. Additional information has been requested. Other business partner numbers included E2009-00825.

Other Meds:

Lab Data: Renal biopsy, chronic glomerulonephritis with mild glomerular lesions

History: Allergy to plants; Acaridae allergy

Prex Illness: Pneumopathy; Otosclerosis; Allergic asthma

Prex Vax Illns:

Vaers Id: **338980-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		04-Feb-2009	05-Feb-2009	FR	WAES0901AUS00177	05-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from a neurologist via an other company representative via CSL as part of a business agreement (manufacturer control # 2009 01 28 RB1) concerning a 14 year old female who was vaccinated with GARDASIL. Subsequently the patient was diagnosed with multiple sclerosis several days post vaccination with GARDASIL. At the time of reporting , the neurologist had advised that this case was due to be reported to the agency by the following day. Upon internal medical review, multiple sclerosis was considered to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **338981-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		04-Feb-2009	05-Feb-2009	FR	WAES0901USA04498	05-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Colitis ulcerative

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with the dose of GARDASIL. Following the vaccination, the patient was diagnosed with ulcerative colitis confirmed by a gynecologist. At the time of reporting, the outcome was not reported. The event was considered to be an other important medical events. Additional information has been requested. Other business partner numbers included E2009-00749.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **339034-1 (S)** **Related reports:** 339034-2; 339034-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	09-Sep-2008	12-Sep-2008	3	04-Feb-2009	11-Feb-2009	CA		13-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Amyotrophic lateral sclerosis, Asthenia, Balance disorder, Blood product transfusion, Extensor plantar response, Gait disturbance, Hypoaesthesia, Hyporeflexia, Muscle atrophy, Muscle spasms, Neuropathy peripheral, Paraesthesia, Peroneal nerve palsy, Polyneuropathy, Sensory loss, Syncope, Tachycardia

Symptom Text: Progressive weakness and muscle atrophy in lower extremities, L>R with intermittent parathesias. 3rd vaccine given around Sept. 9 and unusaly gate noticed shortly after. 2/23/09-records received-presented on 11/25/08-with C/O left lower extremity tightness, tingling and leg cramps. Limping. Fainted prior to 12/23/08, weak spells, left leg continue to have tingling.PE developing cavus deformity of foot and muscle wasting of left calf. initial complaint 9/12/08. Now blance difficulties. Neurolgoy consult 1/20/09-presented with C/O foot weakness and 4 month history of balance problems. Gait changes, waddling. C/O loss of sensation at left big toe, increasing clumisness while walking, including tripping and rolling her ankle. Episode of numbness and tingling of hands when rock climbing, muscle cramps in legs. PE: revealed heel cord tightening, left foot drop.Treated with IVIG. 2/11/09-neurolgoy follow-up, decreased DTRs, positive Babinksi and heel cord tightening. Hospital records for DOS 1/21-1/25/09-DC DX: Inflammatory polyneuropathy. 2/11/09-follow-up visit, No progressive weakness over last 2 months with no change in symptoms. Hospital records for DOS 1/21-1/25/09-DC DX: Inflammatory polyneuropathy. 2/11/09-follow-up visit, No progressive weakness over last 2 months with no change in symptoms. 2/11/09-follow-up visit-over last 2 months has shown no progressive weakness no change in symptoms, wearing ankle-foot orthotics. Feeling well able to walk easier not running. PE: decreased DTRs, positive Babinski and evidence of hell cord tighetening . IVIG treatments monthly. Office 3/4/09-Holter monitor showed episode of asymptomatic tachycardia. Impression acquired immune neuropathy versus genetic diseases. 4/13/09 CDC staff, FDA staff and UCSF neurologists reviewed VAERS # 339034 and have concurred that their patient originally diagnosed as CIDP is really juvenile ALS.

Other Meds: None

Lab Data: EMG showed asymmetric motor>>sensory axonal>demyelinating neuropathy. CPK 620. CSF protein 62, otherwise negative. 2/23/09-records received-MRI lumbar spine no abnomality. MRI throacic spine normal. EMG showed asymmetric motor>>sensory

History: None known 2/23/09-records received-PMH: asthma, attention deficit hyperactivity disorder.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **339034-2 (S)** **Related reports:** 339034-1; 339034-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		19-Mar-2009	20-Mar-2009	--	WAES0903USA02542	24-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Gait disturbance, Mobility decreased, Neuromyopathy, Orthosis user, Walking aid user

Symptom Text: Information has been received from a patients mother concerning her 12 year old daughter who, on an unknown date, was vaccinated with a dose of GARDASIL. Subsequently the patient experienced an "unknown neuromuscular condition" and was hospitalized. The patients mother reported that her 12 year old daughter was now crippled with a neuromuscular disorder caused from the HPV vaccines. She wears braces on both legs and uses a walker to walk with. She hardly moves or walks at all. She has been in the hospital twice in 6 weeks and was to go back into the hosp "this week" for a few days. The patients mother felt that the "unknown neuromuscular condition" was related to therapy with GARDASIL. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339034-3 (S)** **Related reports:** 339034-1; 339034-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	19-Sep-2008	30-Sep-2008	11	04-Apr-2009	06-Apr-2009	CA		06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Balance disorder, Chronic inflammatory demyelinating polyradiculoneuropathy, Gait disturbance, Muscle atrophy, Syncope, Walking aid user

Symptom Text: loss of balance, muscle atrophy, syncope spells, CIDP, inability to walk without aid of walker/leg braces

Other Meds: none

Lab Data: labs, LP, EMG/NCV, MRI

History: asthma-outgrown, no longer using medications

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339038-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Feb-2009	04-Feb-2009	0	04-Feb-2009	16-Feb-2009	PA		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	0933X	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0650X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Immediate post-injection reaction

Symptom Text: HEPATITIS A VACCINE WAS ADMINISTERED IN LEFT ARM, THEN GARDASIL VACCINE WAS ADMINISTERED IN RIGHT ARM AND APPROXIMATELY 5 SECONDS AFTER ADMINISTRATION OF SECOND VACCINE PATIENT HAD A SEIZURE.

Other Meds:

Lab Data: PATIENT HAD PREVIOUS SEIZURE/VASOVAGAL INCIDENT DURING DENTAL PROCEDURE, WE ARE REFERRING HER TO NEUROLOGY FOR WORK UP.

History: H/O EXERCISE INDUCED ASTHMA

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339041-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Feb-2009	04-Feb-2009	0	04-Feb-2009	16-Feb-2009	AZ		16-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB2244BA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	065X	2	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2669AA	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	UF452AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted after vaccines

Other Meds: None

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339051-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	30-Jan-2009	01-Feb-2009	2	04-Feb-2009	16-Feb-2009	WA		16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Rash pruritic, Skin warm

Symptom Text: 48 degrees after vaccine given (given 1/30/09). On 2/1/09 pt. developed "hot, itchy, burning flue rash on thighs, abdomen & back of knees- Denies any throat swelling or SOB.

Other Meds: Oral contraceptive; Multi-vit

Lab Data: None at this time

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 339091-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Jun-2008	20-Jun-2008	10	05-Feb-2009	06-Feb-2009	FR	WAES0902USA00088	06-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1475F	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Demyelination, Dysaesthesia, Hypoaesthesia, Motor dysfunction, Multiple sclerosis, Pain, Paraparesis, Vaccine positive rechallenge

Symptom Text: Information has been received from a health agency (case # 94191) concerning a 16 year old female patient who on 10-JUN-2008 was vaccinated intramuscularly with the first dose of GARDASIL (batch # NF35170; lot # 1475F). On 20-JUN-2008 she presented with algia, dysesthesia, motor impairment and hyposthenia of the upper right limb. The family physician advised treatment with OKI after which there was an initial improvement (after 7/10 days), but the symptoms reoccurred in July 2008, as hyposthenia of the right limbs worsening for about 2 weeks and then spontaneously resolving, with the exception of the impairment to the fine motility of the right hand. On 18-AUG-2008 the patient was vaccinated with the second dose of GARDASIL (batch # NF35170; lot # 1475F). On 01-SEP-2008 she went to the hospital because of the impairment to the fine motility of the right hand. She was admitted to the hospital on 01-SEP-2008 and discharged on 06-SEP-2008 with the diagnosis "suspected multiple sclerosis". Investigations performed during admission: brain MRI with contrast, showing demyelinization with active plaque; cervical MRI with contrast showing demyelinating active plaque. Evoked potentials within normal limits. CSF testing within normal limits, CSF isoelectrofocusing: presence of 16 oligoclonal bands IgG, Link's index = 28 (normal range 0.30 - 0.70). After discharge the patient returned to the hospital on 13-OCT-2008 for a worsening paraparesis (mainly affecting the left side) and she was treated with SOLU-MEDROL I.V. for 5 days. In December 2008, the diagnosis of multiple sclerosis was confirmed and she has been in treatment with Interferon beta I a (unspecified) since. At the time of reporting the patient had not recovered. This case is linked with WAES #0902USA00339, reported by the same physician with the same lot number. Other business partner numbers included E200900775 and IT03209. Additional information has been requested.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 01Sep08, cervical with contrast: demyelinating with active plaque; somatosensory evoked potential, 01Sep08, within normal limits; brain imaging, 01Sep08, with contrast: demyelinization with active plaque; cerebro

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **339092-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	27-Jan-2009	27-Jan-2009	0	05-Feb-2009	06-Feb-2009	FL	WAES0901USA04400	06-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a 19 year old female patient who on 27-JAN-2009 was vaccinated with first dose of GARDASIL (Lot # not reported). On 27-JAN-2009 after she received the vaccine she fainted immediately. As she was coming to she could hear the nurse yelling that she was having a seizure and she then fainted a second time. She came to and fainted a few more times, then she went to the emergency room in an ambulance. She was not admitted to the hospital and was released a few hours after she had received the vaccine. On 27-JAN-2009 the patient was recovered. Patient sought medical attention was at emergency room. The patient considered seizure and fainted was determined to be other important medical events. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339107-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	22-Jan-2009	24-Jan-2009	2	05-Feb-2009	09-Feb-2009	PA		09-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2670AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0960F	1	Left arm	Intramuscular	
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	89976	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Pyrexia, Urticaria

Symptom Text: Parent reports adolescent having hives on hands,knees and feet that began approximately 2-3 days past receiving vaccines on 1/22/09. Also reports fever for one day when hives began. Using topical benadryl cream with no relief. Hives and c/o itching remain. Hives seen by RN in clinic today. Referred to primary physician.

Other Meds: NONE

Lab Data: NONE

History: NONE PER PARENT

Prex Illness: NONE

Prex Vax Illns: NONE~ ()~NULL~~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339110-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	03-Feb-2009	03-Feb-2009	0	05-Feb-2009	16-Feb-2009	MN		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Spoke with pt on Tuesday 2/3/09 she was administered the HPV vaccine about 4 hours later a rash devloped on her back that grew to cover the majority of her back. She feels that today it is not spreading and she feels it is getting better she dose not tolerate benadryl so that was not advised. No SOB, pain, fever, hives. Advised pt she should not continue with the HPV series as there is really no way of telling how she may react. She was in agreement with this. Pt will call back if any other symptoms devlope or rash dose not continue to improve over the next few days

Other Meds: Flonase, Synthroid, Yasmin

Lab Data: per pt the rash is getting better.

History: NO

Prex Illness: no

Prex Vax Illns:

Vaers Id: **339111-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Dec-2008	08-Dec-2008	0	05-Feb-2009	16-Feb-2009	MO		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1423X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Patient complains of severe pain in left arm when lifts the arm, since first injection given

Other Meds: Desogen

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **339131-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Dec-2008	30-Dec-2008	0	05-Feb-2009	16-Feb-2009	NH	NH0815	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope vasovagal

Symptom Text: Patient experienced a vasovagal response to HPV. Duration was 4-6 seconds. BP at 09:30 60/40 pulse-50, at 9:45 62/40 p-52, BP at 10:00 72/40 p-60 and at 10:15 80/44 p-68.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339147-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Dec-2008	01-Dec-2008	0	06-Feb-2009	09-Feb-2009	FR	WAES0812USA02252	09-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	DT	SANOFI PASTEUR	NULL		Unknown	Unknown	
	IPV	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy, Menstruation delayed

Symptom Text: Case of pregnancy follow-up received from a general practitioner on 08-DEC-2008. A 18-year-old female patient started a spontaneous pregnancy and received an injection of REVAXIS (batch # not reported) and the first dose of GARDASIL (batch # not reported) on 01-DEC-2008 while she was pregnant. Her estimated date of last menstrual period was on 31-DEC-2008. At the time of reporting the patient had no adverse effect. During the consultation with the physician and after the vaccination the patient complaint with delayed menstrual period and to be a little puffy since few days. Beta human chorionic gonadotropin test revealed her pregnancy. She wanted to keep the baby. A correction version was created on 23-DEC-2008 to code "vaccine exposure during pregnancy" in accordance with the specific rules of the GARDASIL pregnancy registry. Follow-up information received through the initial pregnancy questionnaire on 02-FEB-2009: Case upgraded to serious. There was a voluntary termination of pregnancy not other wise specified. No more information was provided. This case is closed. Other business partner numbers include E200811440. No further information is available.

Other Meds: Unknown

Lab Data: Beta-human chorionic gonadotropin (unsp), pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 31Oct08)

Prex Vax Illns:

Vaers Id: 339148-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	27-Oct-2006	02-Mar-2007	126	06-Feb-2009	09-Feb-2009	NE	WAES0901USA03519	12-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Hypoaesthesia, Paraesthesia, Pruritus, Restless legs syndrome, Upper respiratory tract infection, Viral infection

Symptom Text: Information has been received from a Registered Nurse concerning her 22 year old daughter who on 27-OCT-2006 was vaccinated with first dose of GARDASIL (Lot# 653937/0637F) intramuscularly right deltoid. Concomitant therapy included influenza virus vaccine (unspecified). On 02-MAR-2007 "she developed restless leg syndrome". The restless leg syndrome resolved but recurred in May 2007 and it was no know if she had recovered. The patient sought unspecified medical attention. Follow up information has been received from a Registered Nurse concerning a 21 years old female patient with colitis ulcerative and scoliosis. Illness at time of vaccination included a slight cold. The patient was taking NYQUIL which she had used before. Other concomitant medications included hormonal contraceptives (unspecified). On 02-MAR-2007 patient experienced tingling, itching, restless feeling where legs and arms had to keep moving and it was reported that it lasted all night until 03-MAR-2007 (am). She went to the emergency Room and was diagnosed with possible restless leg syndrome. On approximately 09-MAR-2007 the patient was seen by Neurologist and ruled out a stroke. On approximately 07-MAR-2007 she recovered. In approximately May 2007, the patient experienced a reoccurrence of the events. Blood test and neurologic exam were performed at Emergency Room (results were not showed). The registered nurse considered possible restless leg syndrome to be an other important medical event and also disabling as it reoccurred 2 to 3 months later. Additional information is not expected. 3/4/09 Received Neuro medical records of 3/2-3/19/2007. FINAL DX: probable post-viral syndrome Records reveal patient experienced pruritis & tingling of extremities x 2 days when hospitalizeed 3/2-3/4/2007. Had similar symptoms briefly & intermittently x 2 mo. Had URI approx 2 wks prior to hosp admit. When seen as outpatient 3/19/07, resolved intermittent pins/needles of legs 3-4 days s/p hospital d/c. 3/4/09 Received ER medical records of 3/2/2007. FI

Other Meds: VICKS NYQUIL SINUS; hormonal contraceptives

Lab Data: diagnostic laboratory, Blood test; neurological, Blood test LABS: CBC, CMP, CRP & UA WNL.

History: PMH: ulcerative colitis. contraception, HA.

Prex Illness: Cold; Colitis ulcerative; Scoliosis

Prex Vax Illns:

Vaers Id: **339149-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		06-Feb-2009	09-Feb-2009	--	WAES0902USA00303	09-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a doctor of pharmacy for the pregnancy registry of GARDASIL concerning a female patient who on an unspecified dates was vaccinated with an unknown number of doses of GARDASIL. It was reported that the patient was pregnant and the fetus had fluid in the brain and heart. It was reported that the patient had four days to decide whether to continue or terminate the pregnancy. The patient sought medical attention with the physician. Upon internal review hydrocephalus was considered to be a congenital anomaly. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 339170-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	20-Aug-2007	20-Aug-2007	0	06-Feb-2009	11-Feb-2009	OH		20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0212U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal tenderness, Amnesia, Confusional state, Convulsion, Depressed level of consciousness, Disturbance in attention, Dizziness, Dry mouth, Educational problem, Epigastric discomfort, Fatigue, Flushing, Grand mal convulsion, Headache, Immediate post-injection reaction, Joint crepitation, Laceration, Malaise, Myalgia, Nausea, Paraesthesia, Postictal state, Sensory disturbance, Syncope, Tenderness, Tremor, Unresponsive to stimuli

Symptom Text: Patient fainted immediately after first shot. Has experienced extreme fatigue,memory loss, trouble concentrating and after the third shot started experiencing seizures. 2/13/09 MR received for multiple DOS. Pt seen in ER 4/14/08 following apparent seizure. Pt found unresponsive in bed. Difficult to arouse and confused. Post ictal upon arrival to ED. Small lac on lip. Later, a H/A. Neuro consult with PE (+) for epigastric tenderness and tenderness of the paracervical and shoulder muscles and intrascapular region. Event suggests nocturnal seizure. Returned 7/20/08 following grand mal seizure in bed. Post ictal upon arrival in ED. Both seizures following start of new antidepressant. Impression: Breakthrough seizure. Returned 11/14/08 with c/o shakiness, lip and chin quivering and an abnormal sensation like being unable to feel touch. Now having seizures every few weeks. Recently has been feeling ill, with face flushing, muscle aches and joint cracking. Final impression: Paresthesia and tremor. Seizure d/o. 3/11/09 Neuro consults received beginning 5/12/2008-12/29/08. Records reveal nocturnal seizure 10/15/08 where pt bit tongue. Seizures seem to be around time of menses. Pt c/o episodic dizziness. Neuro exam WNL. Started on Lamictal. Seizure 11/14/08. H/As in good control on Lamictal. 3/17/2009 MR received from PCP. Pt seen 4/18/08 with multiple c/o since about 10/2007. Recently hospitalized above for syncope/seizure. Since 10/2007 pt not acting herself, grades have dropped, diffuse H/A, overwhelming fatigue, puffy face. Seen in 6/08 with anxiety, fatigue. Requests meds for "nerves"-given. Assess: Abnormal results thyroid funtion study, syncope and collapse, anxiety state. By 8/08 feeling dizzy, nauseated with dry mouth.

Other Meds: birth control pills lexapro

Lab Data: MRI, CAt scans, ambulatory EEG, thyroid tests,blood tests. Labs and Diagnostics: Ambulatory EEG (+) for frontotemporal slowing. MRI brain (+) for mesial temporal lesions bilaterally. ? mesial temporal sclerosis. Head CT WNL. Thyroid s

History: PMH: Anxiety & depression/ Bipolar d/o. EIA. T&A. Ear tubes. Allergies: sulfa. Ceclor.

Prex Illness: nons

Prex Vax Illns: seizures~HPV (Gardasil)~3~22~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339171-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Oct-2007	01-Jun-2008	236	06-Feb-2009	17-Feb-2009	SC		16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	2	Right arm	Intramuscular	HPV4

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Acne, Chills, Dysmenorrhoea, Ear pain, Menstruation irregular, Oral herpes, Oropharyngeal pain, Pharyngitis, Pyrexia

Symptom Text: None at time of Gardasil vaccine, but one year later adverse immununе system problems that included strep throat, urinary tract infections,treated for mono symptoms,rheumatoid arthritis and tonsillitis 2/16/09 Received PCP medical records of 3/20/07-6/2/08. FINAL DX: none provided Records reveal patient experienced irregular periods, menstrual cramps, acne, fever blisters. Tx w/meds & BCP starting 5/2/07. RTC 6/2/08 w/chills, fever, ear ache, sore throat. Dx w/pharyngitis & tx w/antibiotics. Referred to ENT after labs w/WBC increase.

Other Meds: Birth control, acne medication

Lab Data: LABS: CBC done 7/9/08: WBC 20.8, bands 25%(H), lymphs 15%(L). Monospot neg.

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339178-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	10-Jan-2008	Unknown		09-Feb-2009	17-Feb-2009	CA		12-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Anxiety, Asthma, Blindness transient, Condition aggravated, Conjunctivitis, Contraception, Cough, Dysphagia, Fatigue, Feeling cold, Headache, Immune system disorder, Localised infection, Pain, Panic attack, Presyncope, Pyrexia, Sinus headache, Swelling face, Tension, Tremor, Upper respiratory tract congestion, Weight decreased

Symptom Text: I have lost at least 25% of my hair. I have never experienced this type of hair loss before the shot, and am not under any major stress. I had my last shot about one year ago, and have noticed a lot of shedding of my hair since then. It is just now to the point that other people are noticing how wide my part is getting. Not to mention the fact that I have had other strange symptoms. Sometime after my second shot, I ended up in the hospital with what the doctors called a "panic attack". I have no previous history of panic attacks and was not under any real stress at the time. Furthermore, I have had extreme headaches, near fainting spells with partial loss of vision for a few hours at a time. To add to that, I have developed immunity deficiencies. Before this vaccine, I was perfectly healthy. Now, I have spent hundreds and hundreds of dollars trying to figure out what is wrong with me. This is physically and emotionally damaging, and I hope no one else has to experience this. 2/11/09 Received ER medical records of 8/23/2007. FINAL DX: panic attack; possible med side effect Records reveal patient experienced shakiness, difficulty swallowing with sudden onset after taking bactrim for facial infection. Felt facial swelling. Tx w/antihistamine, improved & d/c to home. 3/10/2009 Received PCP medical records of 1/29/08-1/14/2009. FINAL DX: Records reveal patient experienced: asthma, sinus HA, chest congestion, cough, fever, body aches, URI, asthma exacerbation, BCP use, tension & difficulty relaxing, weight loss, feeling cold, anxiety, fatigue, conjunctivitis, HA w/temporary left lateral vision loss 11/08, alopecia 12/08. Tx w/meds.

Other Meds: Yasmin, albuteral, singular

Lab Data: Had a normal blood test before shot, and after shot tested for immune deficiencies. LABS: CT head WNL., ANA 1:40.

History: Asthma, allergies (not to food or medications)

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339236-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	Unknown	Unknown		09-Feb-2009	10-Feb-2009	FR	WAES0902AUS00004	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from a physician, via CSL as part of a business agreement (manufacturer control No. 2009 02 04 JV1), concerning a 24 year old female who was vaccinated with her second dose of GARDASIL (date not reported). Subsequently, the day after her second vaccination with GARDASIL, the patient developed MS-like symptoms. Subsequently the patient recovered and then again developed MS-like symptoms one month later. The patient had experienced lesser MS symptoms prior to vaccination with GARDASIL. The reporting physician did not mention anything pertaining to the patient's first dose of GARDASIL Upon internal review, both episode of MS-like symptoms were considered to be Other Important Medical Events. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Multiple sclerosis-like syndrome

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339249-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Dec-2008	Unknown		09-Feb-2009	10-Feb-2009	--	WAES0902usa00465	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Facial bones fracture, Syncope

Symptom Text: Information has been received from a physician's assistant concerning a 17 year old female who "within the last month and a half", on approximately 22-DEC-2008, was vaccinated with the first 0.5 ml dose of GARDASIL (lot number not provided). It was reported that after receiving GARDASIL, the patient fainted and broke her nose on the floor. Unspecified medical attention was sought. It was reported that the vaccine was discontinued "within the last month and a half". The outcome of the patient was not reported. The reporter considered the patient's events to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **339250-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	11-Jan-2009	18-Jan-2009	7	09-Feb-2009	10-Feb-2009	GA	WAES0902USA00416	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0702X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Injected limb mobility decreased, Oedema peripheral, Pain in extremity, Paraesthesia

Symptom Text: Information has been received from a certified medical assistant concerning a 22 year old female allergic reaction to LEVAQUIN who on 17-NOV-2008 and 11-JAN-2009 was intramuscularly vaccinated with a first and second doses of GARDASIL (both lots #0702X), respectively. There was no concomitant medication. On 18-JAN-2009 the patient developed left arm pain and swelling and difficulty moving her left arm after receiving her second dose of GARDASIL. The patient also experienced tingling in her left hand. The patient sought medical attention via an office visit. She did not recover at time of reporting. The patient's left arm pain and swelling and difficulty moving her left arm and tingling in her left hand were considered to be disability. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: 339251-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-May-2008	04-Jan-2009	220	09-Feb-2009	10-Feb-2009	FR	WAES0902USA00339	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1475F	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Ataxia, Demyelination, Dysaesthesia, Headache, Paresis, Vertigo, Vision blurred, Vomiting

Symptom Text: Information has been received from Health Authority on 28-JAN-2009. A 14 year old female was intramuscularly vaccinated with the third dose of GARDASIL (lot #1881U, batch n. NJ03030) on 04-DEC-2008. It was also reported that the patient was vaccinated with the first dose of GARDASIL (lot #1475F, batch n. NF35170) on 29-MAY-2008 with no adverse effect. The second dose of GARDASIL (lot #1475F, batch n. NF35170) was administered on 29-JUL-2008. On 05-AUG-2008 the patient presented with blurred vision in the left eye and dysesthesia in the third finger of the right hand for one week. She was evaluated by an ophthalmologist on 08-AUG-2008 and resulted within normal limits. On 04-JAN-2009 she presented with headache, vomiting, subjective vertigo, worsening ataxia, left crural paresis and she was admitted to the hospital. Investigations performed during admission included: 16-JAN-2009, brain MRI with contrast: diffused demyelinization with active plaques. 19-JAN-2009 evoked potentials: PEV normal in morphology and with, latency slightly above the norm in the right eye response. Stimulation in the left eye evoked morphologically normal response, with latency markedly above the norm and width significantly reduced in comparison to the right eye. PEA bilateral latency increased along the central acoustic ways with significant increase in the peak I-III and I-V. 21-JAN-2009 evoked potentials: PES upper limbs stimulation of the median nerve at the wrist evoked latency responses within normal limits at Erb and Cv7. Cortical response appeared asymmetric in latency (Left > right) with N20 on the left at the limits of the norm and discretely disgregated on the right. The morphology of the sub-cortical complex P14-N18 on th right appeared disgregated as well. On 17-JAN-2009 CSF exam: isoelectrofocusing presence of about 12 oligoclonal bands IgG type. Link's index=2.41. Chloride 109 meq/L, LDH 3 IU/L. She was diagnosed with "acute demyelinating disease". At the time of reporting her condition had improved. The final outcome was no

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 16Jan09, Brain MRI with contrast: diffused demyelination with active plaques; diagnostic laboratory test, 17Jan09, 109 meq/L, CSF chloride; diagnostic laboratory test, 17Jan09, 2.41, CSF link's index; diagnostic

History: Vision blurred; Dysaesthesia

Prex Illness:

Prex Vax Illns:

Vaers Id: **339252-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	26-Jul-2007	01-Aug-2007	6	09-Feb-2009	10-Feb-2009	FR	WAES0901CAN00049	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Alopecia areata, Hypothyroidism, Type 1 diabetes mellitus

Symptom Text: Information has been received from a physician concerning a 9 year old female who on 26-JUL-2007 was vaccinated with the first dose of GARDASIL, lot # not available. There was no concomitant medication. In July 2007 the physician reported that patient had a C & S negative for vaginitis before vaccine started. In approximately August 2007, the patient experienced hypothyroidism. On 14-AUG-2007 the patient was diagnosed with insulin dependent diabetes mellitus (IDDM). In November 2007, the patient experienced alopecia areata. Subsequently the patient experienced tummy ache. On 31-JAN-2008 the physician reported that the patient had her third dose of GARDASIL, lot # not available. IDDM, hypothyroidism and alopecia areata were considered to be permanent or substantial disabilities by the physician. Additional information has been requested.

Other Meds: None

Lab Data: vaginal culture, ??Jul07, negative for vaginitis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 339253-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	31-Aug-2007	09-Apr-2008	222	09-Feb-2009	10-Feb-2009	IL	WAES0809USA02697	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Intra-uterine death

Symptom Text: Information has been received from a nurse and a physician for the pregnancy registry for GARDASIL concerning a 15 year old female student with no pertinent medical history and no allergies who on 31-AUG-2007 was vaccinated with the first dose of GARDASIL IM 0.5 ml in the deltoid. On 03-JUN-2008 the patient was vaccinated with the second dose of GARDASIL IM 0.5 ml in the deltoid (lot # 660391/0063X). Concomitant therapy included prenatal vitamins. The patient was 23 weeks gestation. The patient's last menstrual period was 09-APR-2008. The estimated due date is 14-JAN-2009. No adverse symptoms. The patient sought medical attention in the office visit. The urine pregnancy test was performed. Follow-up information has been received from the physician from questionnaire. On 02-OCT-2008 ultrasound was performed for routine with normal results at 19 weeks 6 days. On 25-NOV-2008 serum alpha-fetoprotein test was performed with fetal demise at 24.3 weeks. It was reported that the patient was 24.3 weeks by ultrasound date but was 28 plus weeks by first ultrasound date. On 27-NOV-2008 the patient with 0 previous pregnancy underwent induction for fetal demise at 24.3 weeks. The fetus was normal with no autopsy done. There was no complication during pregnancy. Upon internal review, fetal death was determined to be an other important medical event. Additional information is not expected.

Other Meds: Vitamins (unspecified)

Lab Data: ultrasound, 10/02/08, normal 19.6 weeks; urine beta-human, pregnancy; serum alpha-fetoprotein, 11/25/08; fetal demise at 24.4 weeks

History:

Prex Illness: Pregnancy NOS (LMP= 4/9/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339256-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	20-Jan-2008		09-Feb-2009	17-Feb-2009	--		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaginal discharge, Vaginitis bacterial

Symptom Text: I took GARDASIL shot series, It didn't cause major problems, but when I took the second shot around the above date I noticed a change in my vaginal discharge. The shot caused me to get bacterial vaginosis. I had it for nine months till I figured out there was a problem because a month before hand I took myself off birth control and I thought my body was just going through changes. I talked to my doctor and he told me it wasn't the GARDASIL shot, so I took the third shot in the series. It immediately caused the bacterial vaginosis yet again. It's not that it's serious, but every woman should know that this is a possible side effect and may be they should prepare themselves.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339257-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Feb-2009	03-Feb-2009	0	09-Feb-2009	17-Feb-2009	--		25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Back pain, Depression, Headache, Menstruation irregular, Nausea, Night sweats, Vomiting

Symptom Text: Daughter had second shot of GARDASIL and is having bad headaches, pain in the abdomen, nausea, night sweats, depression, lower back pain. Her first shot she vomited once, but no other side effects. 2/12/09 Office note received from PCP dated 12/17/08 for 16 yr WCC. Normal exam. Assessment: Well Adolescent. Possible pregnancy (due to LMP 2 months ago-normally irregular) Pt not seen for OV since 12/17/08. Only in for vax 2/3/09. No further info available.

Other Meds:

Lab Data: None

History: Smokes 5-7 cigarettes a day. PMH: smoker

Prex Illness:

Prex Vax Illns:

Vaers Id: **339260-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
1.3	M	19-Jan-2009	19-Jan-2009	0	09-Feb-2009	17-Feb-2009	WV		17-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0570X	0	Right leg	Intramuscular	
VARCEL	MERCK & CO. INC.	1525X	0	Left leg	Subcutaneously	
DTAP	GLAXOSMITHKLINE BIOLOGICALS	AC14B085AA	3	Left leg	Intramuscular	
HIBV	SANOFI PASTEUR	UF519AA	3	Right leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Wrong drug administered

Symptom Text: Evening of vaccination developed rash on trunk. Parent thought possible hives. Advised BENADRYL po dose. No other symptoms. Rash resolved in 24 hours. Inadvertently received GARDASIL dose.

Other Meds: None

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339264-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	26-Jan-2009	28-Jan-2009	2	09-Feb-2009	17-Feb-2009	WI		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2688AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0652X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal pain, Pain in extremity

Symptom Text: Alicia had complained of pain in her R arm with pain radiating from shoulder to hand the morning of 1/28/09. This pain is still present > 1 week after vaccination. Mother gave IBUPROFEN which helps but not completely. Mother will call pediatrics Dept @ the end of 2 wks. if pain has not resolved.

Other Meds: Recently completed antibiotics for strep throat.

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: 01/28/2009~HPV (Gardasil)~2~11~In Sibling

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339265-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	26-Jan-2009	28-Jan-2009	2	09-Feb-2009	17-Feb-2009	WI		11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2688AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0652X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Daughter complained of pain in her entire R arm the afternoon of 1/28/09, approx 2 days after vaccination. No radiating pain-just persistant pain in her entire arm. Sibling was vaccinated with same vaccines @ same time also has R arm pain. IBUPROFEN is somewhat helpful. Mom will call MD by 2 wks post vaccination if pain persists.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns: 01/28/2009~HPV (Gardasil)~2~17~In Sibling

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339266-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-Jan-2009	21-Jan-2009	0	09-Feb-2009	17-Feb-2009	WA		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Wrong technique in drug usage process

Symptom Text: I took patient to receive the 3rd shot of GARDASIL. The person who administered the shot squeezed patient's arm and stuck the needle in her arm and the needle almost went out her arm the other part of her skin. Like she was sewing a piece of fabric.

Other Meds: None

Lab Data:

History: None

Prex Illness: Aches in joints

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339285-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Jan-2009	22-Jan-2009	0	09-Feb-2009	17-Feb-2009	WI		25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Chest pain, Headache, Hypersomnia, Hypoaesthesia, Pain in extremity, Paraesthesia, Sleep disorder

Symptom Text: Persistent headaches and numbness in left arm, fingers, chest and leg starting after HPV #1(7/8/08), which were annoying but tolerable. Now experiencing persistent intolerable painful tingling and numbness with headaches over past 2 weeks after receiving HPV#2 (1/22/09). These symptoms are interfering with her ability to sleep and participate in college activities. 2/11/09 MR received for ER visit 2/7/09 with DX: Left Arm/Leg Pain. Numbness. Pt presented with 6 month hx of intermittent, worsening numbness and tingling which began in the chest and L arm, now involving bilateral upper and lower extremities. Happening now several times/day and lasting hours at a time. Currently with chest and arm pain. Sleeping more. HPV vax in July 2008 and January 2009. PE WNL. W/U (-). D/C.

Other Meds:

Lab Data: Chest xray & Head CT WNL 2/7/09. CBC w/ diff & CMP WNL 2/7/09. TSH reflex and Vit D serum tests from 2/9/09 pending. Head MRI being performed 2/9/09, pending. Labs and Diagnostics: CXR (-). EKG WNL. Head CT WNL. CBC and Chem WNL.

History: Penicillin allergies. Lumbar pain after motor-vehicle accident 2002. PMH: none. Allergic PCN

Prex Illness: none

Prex Vax Illns: Tingling & Numbness~HPV (Gardasil)~1~18~In Patient

Vaers Id: **339304-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	06-Feb-2009	06-Feb-2009	0	09-Feb-2009	17-Feb-2009	NM		03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope vasovagal

Symptom Text: During administration the patient had a vasovagal response. She was sitting on an exam table was brought to a recombant position and recovered within a few minutes.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 339305-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	04-Feb-2009	05-Feb-2009	1	09-Feb-2009	17-Feb-2009	CO		04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Injection site pain, Injection site swelling, Musculoskeletal pain, Pain, Pain in extremity, Sleep disorder

Symptom Text: Pt contacted clinic on 2/6/09 (injection given on 02/4/09) stating after third HPV injection she experienced mild swelling @ site with moderate pain and bilateral shoulder , elbow, and wrist join pain (no recent trauma noted), throbbing in (R) side down to fingers, cannot sleep on (R)Side.

Other Meds: LEVORA; Fluoxetine; DEMEROL

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339306-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Jan-2008	15-Jan-2008	0	09-Feb-2009	17-Feb-2009	NH		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522LL	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Injected limb mobility decreased, Pain in extremity

Symptom Text: Patient states she had a S/E of right arm pain from upper arm down her arm which lasted 5 days, It was hard for her to lift her right arm over her shoulder. This started at night on 1-15-08 and was worse in the arm 1-16-08, she also had dizziness X2 days. Ice and Tylenol helped the arm pain.

Other Meds: BCP (Trinessa 28 0.035 mg)

Lab Data: none

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **339312-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	13-Mar-2008	28-Mar-2008	15	09-Feb-2009	10-Feb-2009	--	WAES0902USA01054	10-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0277U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Activities of daily living impaired, Aggression, Anorexia, Aphasia, Arthralgia, Asthenia, Asthma, Cough, Diarrhoea, Disturbance in attention, Dizziness, Dyspnoea, Ear pain, Eczema, Enteritis, Gastrointestinal pain, Headache, Hypoacusis, Hypoaesthesia, Impaired driving ability, Listless, Lymphadenopathy, Memory impairment, Metrorrhagia, Mood altered, Oropharyngeal pain, Pain in extremity, Presyncope, Pruritus generalised, Sleep disorder, Weight decreased

Symptom Text: Information has been received from a gynecologist, concerning a 21 year old female patient with history of pollinosis who was vaccinated with a third dose GARDASIL (Lot number 0277U, Batch number NG00020, injection route and site not reported) On 13-MAR-2008. On 28-MAR-2008, the patient developed gastrointestinal cramps with postprandial diarrhea for, the first time. She recurrently complained of abdominal cramps with diarrhoea. After one of these episodes, in September 2008, she went to the emergency room. Clinical examination, lab tests and abdominal sonography were without pathologies. Suspected diagnosis was enteritis. During months she had a weight loss of 5 kg of weight. Within a few months p.v. the patient also experienced generalized itching and an eczema on the right hand. The patient additionally complained of impaired memory, amnesic aphasia, concentration impairment, bad mood, aggression, listlessness, arthralgia, headache, pain and numbness in the whole left arm (from shoulder to fingertips) so that temporarily driving a car was not possible. Also, the patient experienced intermenstrual bleeding, sleeping disorder because of pain in legs, dizziness, feeling of weakness and near fainting, loss of appetite, sore throat with dizziness, feeling of weakness and near fainting, loss of appetite, sore throat with lymphadenopathy followed by ear pain and reduced hearing. In June 2008, the patient consulted a pneumologist because of frequent dyspnoea and unusual cough. Diagnosis of allergic bronchial asthma was diagnosed for the first time (long time history of pollinosis). Treatment with beclometasone and salbutamole inhalatives was started. The outcome was not reported. Upon internal review report considered medically significant. Other business partner numbers included: E2009-00384. Additional information has been requested.

Other Meds: Unknown

Lab Data: Abdominal ultrasound, 09/??/08, without pathologies; diagnostic laboratory 09/??/08, without pathologies

History:

Prex Illness: Pollinosis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339333-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-Nov-2008	07-Nov-2008	0	10-Feb-2009	11-Feb-2009	FR	WAES0902USA00843	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1201U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a nurse via the health authority (reference #C200902-483) concerning a 13 year old female who on 07-NOV-2008 was vaccinated with a dose (number in series unspecified) of GARDASIL (lot #1201U, batch #NH00900) via intramuscular route. A short time later the patient presented with cutaneous eruptions on face and thorax. Previous reactions to the same vaccine and to other drugs were unknown. On an unspecified date, the patient recovered from the events. No further information is available. The case is closed. Other business partner numbers included E2009-01009.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339334-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Aug-2008	30-Nov-2008	106	10-Feb-2009	11-Feb-2009	NJ	WAES0902USA00587	24-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest X-ray normal, Convulsion, No reaction on previous exposure to drug

Symptom Text: Information has been received from a physician concerning a female patient who on unknown date was vaccinated with the second dose of GARDASIL. It was reported that after the appointment, possibly on the same day, the patient developed seizures. She went to the emergency room but was not admitted. The physician stated that the patient had no problems with the first dose of GARDASIL. At the time of reporting the patient has completely recovered. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested. 3/16/09-records received-vaccine administered on 8/16/08-. On 12/1/08 sudden onset of seizures-Neurolgoy consultation 1/13/09-PE WNL. Impression seizure episode.

Other Meds: Unknown

Lab Data: Electroencephalography, negative; Computed axial, negative; Neurological, negative 3/16/09-records received-EKG WNL, chest x-ray negative.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339335-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		10-Feb-2009	11-Feb-2009	TX	WAES0902USA00564	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Circulatory collapse, Headache, Migraine

Symptom Text: Information has been received from a nurse who reported that she received an email from a former employee of theirs, who stated in the email that "a high school student received one or more doses of GARDASIL and after vaccination the patient experienced severe migraines/headaches and then had to hospitalized because the patient also had to have a venous port put in her because her veins kept collapsing". The email did not mention how long the patient was in the hospital or any of the hospital information. Attempts are being made to verify the existence of an identifiable patient. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339336-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		10-Feb-2009	11-Feb-2009	PA	WAES0902USA00449	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Meningism, Pyrexia

Symptom Text: Information has been received from a physician concerning a 14 year old female who was vaccinated with the first dose of GARDASIL. Subsequently the patient went to the emergency room with the symptoms of meningitis, including a high fever. The patient recovered on an unspecified day. The patient did not plan on receiving the second or third doses. The physician considered the symptoms of meningitis, including a high fever was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **339337-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-Nov-2008	06-Nov-2008	1	10-Feb-2009	11-Feb-2009	FR	WAES0901USA04296	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1882U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gait disturbance, Hemiparesis, Pain

Symptom Text: Information has been received on 27-JAN-2009 from a Health Authority concerning a 13 year old female patient with asthma who received the first dose of GARDASIL (Lot # 1882U, batch # NJ04160) via intramuscular route on 05-NOV-2009. On the twenty-four hours after the administration of the vaccine, the patient "felt her body stuck on the left side for two days". She also felt pain on the left side of the body and limped on the left leg. Health Authority did not see the patient and could no better define reaction. Health Authority was only informed on 05-JAN-2009. There was no specific treatment for the adverse reaction. At the time of the report, the patient recovered. The health authority considered pain, weakness left or right side and limping to be an other important medical events. Other business partner numbers include E2009-00758 and L200901-254. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339338-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		10-Feb-2009	11-Feb-2009	FR	WAES0901CZE00003	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dyspnoea, Erythema, Hypersensitivity, Swelling

Symptom Text: Information has been received from a physician concerning a young female who was vaccinated with GARDASIL. Subsequently the patient experienced allergic reaction, erythema, swelling and breathing difficulties and was hospitalized in emergency department. Subsequently, the patient recovered from allergic reaction, erythema, swelling and breathing difficulties. The reporter felt that allergic reaction, erythema, swelling and breathing difficulties were related to therapy with GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339339-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	28-Feb-2008	28-Feb-2008	0	10-Feb-2009	11-Feb-2009	FR	WAES0805USA05541	11-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1201U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical incompetence, Drug exposure during pregnancy, Premature baby, Premature labour

Symptom Text: Information has been received from a gynaecologist concerning a 24 year old female patient who on 28-FEB-2008 was vaccinated with the third dose of GARDASIL (lot no. 1201U, batch no. NG29050) via the intramuscular route into the upper arm. On 28-FEB-2008 the patient experienced vaccine exposure during pregnancy. No adverse effect after vaccination. The date of last menstrual period was 11-FEB-2008. No detailed information about first and second vaccination. Follow-up information was received on 03-FEB-2009. This case has to be upgraded to serious because of premature birth. It was reported by the gynaecologist that the patient experienced premature birth after a normal course of pregnancy cervical incompetence due to premature labour. Premature birth took place on 21-OCT-2008 (in 36+1 weeks of pregnancy). The patient gave birth to a normal and sound baby on 21-OCT-2008. Weight at birth was 2585 g and height at birth was 49 cm. Apgar score was 6/7/8. The postnatal examination of mother and child showed no pathologies. The first three obligatory primary infant's examination showed normal results. Premature birth was considered to be an other important medical event by the business partner. Other business partner numbers included: E2008-03922. The case is closed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 11Feb08)

Prex Vax Illns:

Vaers Id: 339351-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	30-Aug-2007	01-Sep-2007	2	10-Feb-2009	17-Feb-2009	NY		27-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0962F	0	Left arm	Unknown	
MNQ	SANOFI PASTEUR	U2367AA	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Depression, Headache, Lymphadenopathy, Major depression, Migraine, Occipital neuralgia, Pain, Photophobia, Sinusitis, Vision blurred, Visual impairment

Symptom Text: Chronic headache pain. 2/18/09MR received from PCP including vax rec and numerous consultations. Initially c/o with visual changes 10/3/07. PE (+) for R posteriar auricular node. Dx: Lymphadenopathy. Multiple OVs 1/2008-1/2009 for H/A with increasing freqeuncy and severity. Occur daily with blurry vision. Dx: Chronic H/A, Migraine. Back and leg pain noted 1/29/08 with photophobia. Sinusitis with Sinus surgery 4/08 and 5/08. Nothing helping H/A pain by 12/08 despite Botox, steroids and analgesics.DX: Intractable H/A pain. Depression and Anxiety noted 1/20/09. Multiple consults beginning 2/2008. ENT consult-severe cephalgia-out of proportion with sinus disease. ? Migraine. Neuro consult 2/26/08 -H/A- multifactorial. F/U 8/25/08. Recent psych admission for Major Depressive Episode with med adjustment. Pain mgmt consult 10/3/08 for constant H/A. Chronic Daily H/A with tension-type H/A features and occipital neuralgia. Occipital nerve blocks helped temporarily. Multiple F/Us. Scalp muscles possibble as source of pain. Accupucture started 2/09.

Other Meds: PROZAC; Doxycycline; ASTELIN; NASONEX; CLARINEX

Lab Data: CT; MRI. Labs and Diagnostics: CT scan (+) for sinus disease. MRI brain WNL.

History: Seasonal allergies. PMH: ADD. Asthma. Seasonal allergies. Acne

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339366-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
35.0	F	28-Jan-2009	06-Feb-2009	9	10-Feb-2009	13-Feb-2009	GA		12-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Lymph node pain, Lymphadenectomy, Lymphadenopathy

Symptom Text: Left axillary lymphadenopathy: swollen, tender. There was no source of infection, so I had mammogram plus ultrasound done. Multiple suspicious nodes on US. Pathologists recommended a biopsy. Had core bx which failed, so went to OR to have 2 lymph nodes removed for diagnosis on 2/8/09. All path was benign. 3/6/09-records received for DOS 1/28/09-received Gardasil vaccine. No C/O at time of visit. 3/11/09-records received-abnormal lymphadenopathy left axilla. Excision on 2/10/09-

Other Meds: doxycycline 40mg PO q day

Lab Data: pathology including flow cytometry of LNs were negative. 3/11/09-records received-pathology report no abnormality identified.

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **339367-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Jan-2008	17-Jan-2008	0	10-Feb-2009	13-Feb-2009	TX		31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal discomfort, Asthma, Condition aggravated, Dizziness, Dyspnoea, Fungal infection, Hypoaesthesia, Paraesthesia, Pelvic pain, Rash, Upper respiratory tract infection, Urinary tract infection

Symptom Text: Patient began having frequent UTI's after first HPV. Then after second got yeast infections every 2 weeks and tingling in fingers and toes. After third vaccine, has worse tingling in fingers and feet fall asleep, shortness of breath with exertion, rash on face and pelvic pain. 2/16/09 PCP records received beginning 6/19/08. Pt seen multiple times for recurring UTI's and yeast infections. URI with asthma exacerbation 10/28/08. Returned 2/5/09 with c/o dizziness, tingling in arms and feet, SOB, R sided abdominal pressure since most recent (3rd) HPV vax. Tingling in toes and fingers noted after 2nd vax, now up to the ankles and elbows. Intermittant in nature. Feet feel like asleep but if attempts to stand will fall over. New onset SOB. Becomes dizzy, releived with deep breathing. Pink area on L eyebrow appeared after #2 vax, now pink area on R chin. PE WNL. Referred to neurologist and pulmonologist. 3/25/09 Recs received from OBGYN vax provider. Normal exam 1/17/08. 1st Gardasil given. Yeast infection dx 12/11/08 on date of 3rd vax. Had sx x 3 days.

Other Meds: albuterol and flovent

Lab Data: Work-up in progress. Labs and diagnostics: UC (+) for Group B strep and E coli. GC (-). Chlamydia (-). UA abnormal. CXR WNL.

History: Amoxicillin. PMH: asthma, bladder infections. Allergies to Amoxicillin. PCN.

Prex Illness:

Prex Vax Illns:

Vaers Id: 339371-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	09-Feb-2009	09-Feb-2009	0	10-Feb-2009	13-Feb-2009	OH		16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Disorientation, Dizziness, Immediate post-injection reaction, Pain in extremity, Vision blurred, Visual impairment

Symptom Text: Severe pain after injection. Few minutes later severly dizzy and disoriented. Blurred, splotchy vision. Still have pain in arm to which it was administered

Other Meds: Synthroid, Buspar

Lab Data:

History:

Prex Illness: n/a

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339374-1** **Related reports:** 339374-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	26-Jan-2009	26-Jan-2009	0	11-Feb-2009	17-Feb-2009	OH		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Balance disorder, Dehydration, Headache, Malaise, Pyrexia, Vomiting

Symptom Text: My dughter became very ill when we left the office. Complained of headache, stomache ache, had a fever, could not keep balance. Within 8 hrs I had to take her to ER, she was vomiting, temp of 101, she had dehydrated so bad they said her veins had colapsed. Dr. had checked her prior to the shot and she was fine. Also her throat had turned yellow, she was given an IV and sent home, where she stayed sick in bed not eating for 3 days.

Other Meds:

Lab Data: Dr. done throat cultures. Hospital done blood work and said she has mono. (No one else in house got sick)

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339374-2** **Related reports:** 339374-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	26-Jan-2009	26-Jan-2009	0	12-Feb-2009	13-Feb-2009	OH		02-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope, Vomiting

Symptom Text: Taken to ER for syncope and vomiting shortly after receiving shot. Needed I/V fluids

Other Meds:

Lab Data:

History:

Prex Illness: Epstein Barr

Prex Vax Illns:

Vaers Id: **339375-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	15-Jan-2009	28-Jan-2009	13	10-Feb-2009	12-Feb-2009	--		20-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ40730	0	Right arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Areflexia, Asthenia, Ataxia, Blood product transfusion, Dizziness, Guillain-Barre syndrome, Headache, Nausea, Nuclear magnetic resonance imaging brain normal, Scan brain, Vertigo, Vomiting

Symptom Text: In Spanish: The HPV vaccine Gardasil was administered on January 15, 2009. Thirteen days later and for 3 days has vomit, dizziness and cephalgia, later vertiginous sensation. On January 31 present a frank ataxic gait and progressive loss of strength in lower and upper extremities almost totally in the following 3 days with loss of osteotendinous reflexes. We had taken a normal brain CT scan a normla MRI and nerve conduction studies compatible with GBS. Started treatment with Immunoglobulin with a response in 72 hours and almost total recovery of the motor function, vertiginous felling and cephalgia still persists. 2/18/09-hospital records received-all information in Spanish.

Other Meds: NO

Lab Data: Nerve conduction studies compatible with GBS

History: Allergy to Ampicillin Sulbactam

Prex Illness: NO

Prex Vax Illns:

Vaers Id: **339390-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Jul-2008	01-Nov-2008	113	10-Feb-2009	13-Feb-2009	MI		04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2635AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Arthralgia, Asthenia, Fatigue, Tension headache

Symptom Text: Pt seen for headaches on 1/21/09 - Seen again on 2/7/09 when mother told dr she is concerned this is related to the HPV vaccine. got related information from the internet 2/13/09 Received PCP medical records of 1/21-2/10/2009. FINAL DX: tension/stress HA Records reveal patient experienced HA on 1/21 occurring 4-5x/wk over 2 mo period. Usually starts in afternoon. Tiredness, stomach pain. Tx w/meds. RTC 2/7 w/worse HA unrelieved by meds along w/joint pain, low energy, stomach ache. CT scan & labs ordered.

Other Meds:

Lab Data: Head CT Scheduled for 2/13/09

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339400-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Feb-2009	03-Feb-2009	1	10-Feb-2009	13-Feb-2009	LA		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dry mouth, Immediate post-injection reaction, Injection site pain, Nausea, Pain in extremity, Vomiting

Symptom Text: Reported back to clinic with report of "some pain at (L) arm site" immediately after second injection + "around" 2am this morning (2-3-09) - Pt c/o onset of sharply -type pain/(L) arm with radiation to hand, also nausea/vomiting, weakness + mouth dryness approx 5am given TYLENOL + codeine tabs per father. Pt. present in clinic, Pt alert and oriented, with guarding noted per (L) arm - noted no swelling, redness or induration of (L) arm-ADVIL with warm compresses-See PCP, if symptoms worsen.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 339413-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Nov-2008	04-Feb-2009	78	11-Feb-2009	12-Feb-2009	FR	WAES0902USA01131	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1282U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Convulsion, Dizziness, Endotracheal intubation, Eye movement disorder, Intensive care, Loss of consciousness, Myoclonus, Pyrexia, Sedation, Tremor, Trismus

Symptom Text: Information has been received from the health authority and a physician who was treating the patient, concerning a 14 year old female who on 18-NOV-2008 was vaccinated with the first dose of GARDASIL, (lot # 1282U, batch # NH45150), which was well tolerated. On 04-FEB-2009 the patient was vaccinated with the second dose of GARDASIL, (lot # 1647U/batch #NH52670), route and site not reported. It was reported that ten minutes after vaccine administration the patient presented with fever (maximum temperature recorded, 38.5 C), dizziness, convulsions and loss of consciousness. In order to treat the adverse event, the patient was given several doses of VALIUM in the health center where she was vaccinated. The patient did not improve with this treatment therefore she was transferred by an ambulance to the hospital where she was admitted to the pediatric intensive care unit. Once in the hospital, the patient was treated with a bolus of DIAZEPAM. The seizures did not remit, thus she was administered another bolus of diazepam. The patient continued presenting myoclonic movements especially in the lower limbs. The patient also presented with trismus and ocular deviation. The patient was given DEPAKINE, phenytoin and midazolam by perfusion to treat the adverse events. The patient was intubated and then induced into a barbiturate coma. On 05-FEB-2009 treatment with sedatives, midazolam, was stopped. DEPAKINE and phenytoin by perfusion treatment continued. Extubation was attempted while the patient remained semi-conscious. During the extubation attempt, the patient had another seizure. Consequently the patient was sedated and inbutated once again. Several tests have been performed on the patient. The nuclear magnetic resonance imaging (MRI) appeared to be normal. Lumbar puncture was also normal. Electroencephalography results were pending. The reporting investigator considered convulsion, dizziness, loss of consciousness, pyrexia and tremor to be life threatening. A lot check has been initiated. Other business partner numbers

Other Meds: Unknown

Lab Data: magnetic resonance imaging, 04?Feb09, appeared to be normal; spinal tap, 04?Feb09, normal; electroencephalography, 04Feb09, results pending; body temp, 04Feb09, 38.5 c

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **339414-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	13-Aug-2007	01-Dec-2007	110	11-Feb-2009	12-Feb-2009	--	WAES0902USA01069	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Affective disorder, Mental disorder

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female patient with no pertinent medical history and allergic reaction to AUGMENTIN, CECLOR, and sulfonamide allergy who on 13-AUG-2007 was vaccinated with the first dose of GARDASIL (Lot # 658554/0928U) intramuscularly. On 29-FEB-2008 the patient received the second dose of GARDASIL (Lot # 660557/0072X). Concomitant therapy included LOESTRIN 24. It was reported that in December 2007 the patient developed mental illness which consisted of mood disorder after receiving GARDASIL. It was reported that the patient had not yet received the third dose. A serum level test for aluminum was performed (result not provided). It was reported that the patient had been hospitalized due to the disorder, but the reporter did not know the duration of the hospitalization. Additional information has been requested.

Other Meds: LOESTRIN 24 FE

Lab Data: Serum Al

History:

Prex Illness: Allergic reaction to antibiotics; sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339415-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	29-May-2007	01-Jul-2007	33	11-Feb-2009	12-Feb-2009	NM	WAES0902USA01095	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pulmonary embolism

Symptom Text: Information has been received from a nurse concerning a female "born in 1983" with no pertinent medical history who on 29-MAR-2007 was vaccinated with the first dose of GARDASIL (lot# not provided), and on 29-MAY-2007 was vaccinated with the second dose of GARDASIL (lot# not provided) 0.5ml intramuscularly. Concomitant therapy included ORTHO TRI-CYCLEN LO. In July 2007 the patient experienced pulmonary embolism and experienced a second one in August 2007. Patient sought unspecified medical attention. At the time of this report the patient's condition was unknown. Upon internal review, the pulmonary embolism was determined to be an other important medical event. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN LO

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339416-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	03-Dec-2008	04-Dec-2008	1	11-Feb-2009	12-Feb-2009	FR	WAES0902USA01023	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0467U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Myalgia, Myositis, Rhabdomyolysis

Symptom Text: Information has been received initially on 29-JAN-2009 from a school physician concerning a 10 year old female patient who on 03-DEC-2008 was vaccinated into the arm with the first dose of GARDASIL (Batch # NG14300 Lot # 0467U) (route not reported). On 09-DEC-2008 the female patient came for examination due to persistent muscle pain in the area of both thighs, incipient 24 hours post vaccination. It was reported that the injection site was not inflammatory and the female patient reported about persistent pain in both thighs during going and running, and in the area of the left hip. At the area of both quadriceps musculature local pain without external abnormality. It was reported, that as the female patient was sportive and trained (wrestler) a blood test (CPK-Creatinphosphokinase, CRP-C reactive protein) on an unspecified date the family doctor was initiated to exclude an iatrogenic rhabdomyolysis. Results were only reported for CK-NAC. As well, the female patient was examined at the emergency department and the pediatric department to exclude a coxitis fugax. An ultrasound examination of the hip was performed, results without finding. The diagnosis of a reactive myositis of both quadriceps muscles was reported. The lab was inconspicuous, except for a heightened CK NAC (263), ranges not reported. A lab control in January 2009 was performed. The CK NAC value decreased to 98, as well as the other parameters, inconspicuous. The physician observed, that the CK heightening was due to the local injection or activated due to concomitant reaction of musculature. Therefore the physician decided not to vaccinate the female patient with the second dose of GARDASIL, as she could not exclude an iatrogenic activated rhabdomyolysis. A treatment with antiphlogistics was unknown. The female patient recovered after about 2 weeks. Upon internal review suspicion of rhabdomyolysis was considered a medically significant event. Other business partner numbers include E2009-00844. Additional information is not expected. The case is clos

Other Meds: Unknown

Lab Data: Ultrasound, results without finding; Serum creatine kinase, ??Jan09, 98, CK-NAC value decreased; Serum creatine kinase, 263, Heightened CK-NAC

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 339417-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Aug-2007	01-Dec-2008	467	11-Feb-2009	12-Feb-2009	OR	WAES0902USA00873	20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	0495A	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0927U	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2232AA	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Cerebellar infarction, Cerebral haemorrhage, Cerebrovascular accident, Chills, Cranial nerve paralysis, Diabetes mellitus, Diplopia, Dysphagia, Headache, Hemiplegia, Hyperglycaemia, Hyperhidrosis, Hypoaesthesia, Inappropriate schedule of drug administration, Intracranial venous sinus thrombosis, Lumbar puncture, Nausea, Neck pain, Neuralgia, Nuchal rigidity, Paraesthesia, Pyelonephritis, Pyrexia, Thrombocytopenia, Vomiting

Symptom Text: Information has been received from a Certified Medical Assistant concerning an 18 year old female who on 22-AUG-2007 was vaccinated with a first dose of GARDASIL (lot #658222/0927U) intramuscularly. On 26-JUN-2008, the patient was vaccinated with a second dose of GARDASIL. The patient was started on an unspecified birth control pill sometime after receiving both doses but prior to having the stroke. On an unspecified date, the patient had stroke when attending school and then was hospitalized. The patient is currently taking COUMADIN. The patient called the reporter's office, but had not been seen yet. At the time of reporting, the patient was recovering from stroke. The patient's stroke was considered to be life-threatening. Additional information has been requested. 3/12/09 Received hospital medical records of 12/4-12/8/2008. FINAL DX: diabetes; right cerebellar infarct w/hemorrhagic conversion; right transverse sinus thrombosis; superior sagittal sinus thrombosis. Records reveal patient experienced HA, nausea, vomiting, fevers, chills & sweats x 4 days. Saw PCP, dx w/pyelonephritis & tx w/oral antibiotics. Symptoms persisted & developed nuchal rigidity & pain. Admitted directly for possible meningitis. LP done. Developed numbness, tingling, difficulty swallowing & double vision. Neuro, neurosurg consults done. Developed possible heparin induced thrombocytopenia. Transferred to higher level of care. 3/18/09 Received Rehab hospital medical records of 12/17-12/24/2008. FINAL DX: RUE hemiplegia; diplopia; cranial nerve VII palsy, left side; neuropathic pain; hyperglycemia.

Other Meds: Unknown

Lab Data: Unknown LABS: WBC 12.6, H/H decreased. Glucose 200 (H). HgA1c 7.1(H). CSF: WBC 8 & RBC 3540(H), protein 41 WNL, glucose 97(H). MRI brain & c-spine abnormal. CT brain angiogram abnormal. Platelets 76K (L).

History: None PMH: BCP. Amblyopia in childhood. 06/06/2008 Received Hep A #2 GSK lot # AHAVP230BA, IM/LA; and HPV#2, lot #0279X, IM/LA

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339418-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		11-Feb-2009	12-Feb-2009	PA	WAES0902USA00919	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Pyrexia

Symptom Text: Information has been received from a healthcare professional concerning her 20 year old daughter who was vaccinated with all three doses of GARDASIL. One week after receiving the third dose the patient experienced spiking a 104 degree fever and sometime after that the patient experienced a seizure/seizure like activity. Two weeks after the seizure like activity the patient saw a neurologist. At the time of this report, the outcome was unknown. Upon internal review, seizure/seizure like activity was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339419-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Jan-2009	29-Jan-2009	0	11-Feb-2009	12-Feb-2009	FR	WAES0902USA01022	12-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1114U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Malaise, Pallor

Symptom Text: Information has been received on 04-FEB-2009 from a Health Care Professional concerning a 16 year old female patient who received the first dose of GARDASIL (Lot # 1114U, batch # NH10940), on 29-JAN-2009. On 29-JAN-2009, post vaccination, the patient felt faint, dizzy, pale and unwell. The patient recovered 40 minutes later. The Health Care Professional considered the event to be serious. The Health Care Professional considered faint, dizzy, pale and unwell to be an other important medical event. Other business partner numbers include E2009-01057. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **339420-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Oct-2007	31-Oct-2007	0	11-Feb-2009	12-Feb-2009	OH	WAES0901USA00170	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0955F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Complication of delivery, Condition aggravated, Drug exposure during pregnancy, Failed trial of labour, Foetal disorder, Premature rupture of membranes, Urinary tract infection

Symptom Text: Information has been received from a medical assistant and a pediatrician concerning a 17 year old female patient for the pregnancy registry for GARDASIL with no pertinent medical history and no known drug allergies, who on 31-OCT-2007 was vaccinated with the first dose of GARDASIL (lot# 653978/0955F) 0.5 ml intramuscularly. There was no concomitant medication. It was reported that the patient found out she was pregnant in "December 2008" after receiving the first dose of GARDASIL. Patient sought medical attention from unspecified OB. On 29-AUG-2008 the patient received the second dose of GARDASIL (lot# 660553/0070X) 0.5 ml intramuscularly after delivering a healthy baby on June 2008. Follow-up information received from the medical assistant who reported that the patient has had a history of 1 previous pregnancy and 1 full term delivery. The infant was born 30-JUN-2008, Apgar score of 1, normal, with no congenital anomalies and with no other complications or abnormalities. Follow up information received on 06-FEB-2009 from a pediatrician who reported that the patient has a history of mononucleosis and UTI. Number of previous pregnancies is 0 (previously reported as 1); number of previous live births is 0 (previously reported as 1). The date of the last menstrual period is 08-OCT-2007. On 24-NOV-2007 patient was on treatment with KEFLEX 500 mg twice a day, for 5 days for the treatment of urinary tract infections. Ultrasounds performed on two different occasions with normal results. On 27-JUN-2008 a biophysical profile was performed. Complications during pregnancy included premature rupture of membranes and irregular fetal heart rate, fetal arrhythmia. Failure to progress during labor/delivery therefore a cesarean section was performed. The baby was born 37 weeks from LMP, weighed 6 pounds 11 ounces and was 19 inches tall. Infant was normal with no congenital anomalies. No further information is available.

Other Meds:

Lab Data: ultrasound, normal; ultrasound, normal; diagnostic laboratory, 06/27/08, byophysical profile

History: Urinary tract infection; Infectious mononucleosis

Prex Illness:

Prex Vax Illns:

Vaers Id: 339421-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	22-Apr-2008	23-Apr-2008	1	11-Feb-2009	12-Feb-2009	CA	WAES0804USA05621	17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Caesarean section, Drug exposure during pregnancy, Face presentation, Failed trial of labour

Symptom Text: Information has been received from a registered nurse (R.N.), for GARDASIL, a Pregnancy Registry product, concerning a 15 year old female patient, who on 23-APR-2008 was vaccinated with the first dose of GARDASIL. On the same day, the patient also visited the OB/GYN, and had a positive pregnancy test. Details of the pregnancy and gestation were not reported. Follow-up information was received on 05-FEB-2009 indicating that on 22-APR-2008 (previously reported as 23-APR-2008), the patient with behavioral problem and school problem and a history of varicella disease was vaccinated intramuscularly in the right deltoid with a first dose of GARDASIL (Lot #659439/1267U). It was reported that the patient had 0 previous pregnancies. An ultrasound performed on 25-JUN-2008 revealed possible brachycephaly. Amniocentesis performed on 27-AUG-2008 showed no brachycephaly. Maternal serum alpha-fetoprotein (MSAFP) on 07-JUL-2008 was negative. It was reported that the patient developed anemia during pregnancy. There were no infections or illnesses during pregnancy. On 16-NOV-2008, 38 weeks from LMP, the patient had a cesarean section for occiput posterior descent, and delivered a normal male baby, weighing 6 pounds 10 ounces. The baby's length was 20 inches, head circumference was 13 inches and apgar score was 8/9. There were no congenital anomalies, other complications or abnormalities. Upon internal review, "cesarean section for failure to progress" was determined to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: ultrasound, 06/25/08, possible brachycephaly; amniocentesis, 08/27/08, no brachycephaly, beta-human chorionic, 04/23/08, pregnant; serum alpha-fetoprotein, 07/07/08, negative x4

History: Varicella

Prex Illness: Pregnancy NOS (LMP=Unknown); Behaviour disorder

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339431-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Feb-2009	09-Feb-2009	0	11-Feb-2009	13-Feb-2009	IA		16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	MERCK & CO. INC.	0062X	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0652X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2664AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Bradycardia, Hyperhidrosis, Pallor, Syncope

Symptom Text: 1-2 minutes after receiving vaccine Pt. was getting ready to walk out the door with parent - and fainted - Able to keep standing and assisted into chair. Upon exam , NP noted mild diapheresis, Pallor, bradycardia. Responded with supine position and oral beverages. Discharged in stable cond. with limited activity x 24 hrs

Other Meds:

Lab Data: NP exam, repeated vitals, no studies.

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339449-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Feb-2009	10-Feb-2009	0	11-Feb-2009	13-Feb-2009	PA		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2726AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0653X	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3057AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Loss of consciousness, Pallor

Symptom Text: Patient was in office for routine visit. Pt was ordered HPV vaccine, menactra (meningococcal) vaccine, and adacel (tdap) vaccine. Gave all three immunizations and right after giving the HPV vaccine, patient stating she felt like she was going to pass out. Patient leaned forward onto her mom while sitting on exam table and passed out, became very pale. Pt did not fall off table. Myself and another nurse immediately laid pt back on table. Pt awoke after only 1-2 seconds. We elevated pt's legs and had pt lay there while monitoring her for approximately 10 minutes. Pt was awake, alert, and oriented. At that time we gave her a small cup of orange juice and elevated pt's head. Pt laid there for approximately 10 more minutes and then we had the doctor check the pt. Pt was stating she was feeling fine, awake, alert, and oriented/walking around in room. Dr. gave the okay for pt to go home.

Other Meds: none

Lab Data: n/a

History: no known allergies, no documentation of any birth defects or medical conditions

Prex Illness: none

Prex Vax Illns:

Vaers Id: 339457-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Mar-2007	02-May-2007	35	11-Feb-2009	13-Feb-2009	MN		25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0244U	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Back pain, Confusional state, Diplopia, Disorientation, Dizziness, Encephalitis, Fatigue, Headache, Hypersomnia, Mental disorder, Post lumbar puncture syndrome, Visual impairment, Vomiting

Symptom Text: Developed symptoms of severe headache, fatigue, dizziness, abnormal vision and excessive sleeping on about 5/2/2007, 5 weeks after receiving HPV #1 and about 1 week after diagnosis of acute Group A strep throat on 4/26/2007. She continued to have prolonged symptoms and MRI of brain was performed on 5/23/07 and was consistent with Acute disseminating encephalomyelitis. She was hospitalized for several days and treated with IV steroids and bed rest. She had a prolonged convalescence but for the most part all symptoms had completely resolved by August 2007 except for continued headaches for which she takes amytriptline rather regularly. She continues to have psychologic issues, but these pre-dated HPV vaccine and I do not think they are the result of HPV. She sees a psychologist regularly. She has not received any further HPV due to concern about possible connection with her A.D.E.M. 2/24/09-records received for DOS 5/30-6/2/07-DC DX:post lumbar puncture headache. Acute disseminated encephalomyelitis (ADEM). One month prior received treatment for infectious cerebellitis and a diagnosis of ADEM 2-3 weeks prior to admission. Prior to lumbar puncture C/O confusion and disorientation. Presented with vomiting and headache. Lower back pain. Blood patch performed. Eye consult 5/23/07-C/O sudden onset horizontal diplopia, dizziness and movement of the environment. 3/23/09-additional information recieved-presented on 5/30/07- with C/O headaches after lumbar puncture. 2-3 weeks ago developed diplopia and a gait imbalance,

Other Meds:

Lab Data: MRI of brain consistent with A.D.E.M. 4/24/09-records received-MRI abnormal signal in brainstem without regional mass effect. Compatible with demyelinating disease. T2 signal abnormality. MRI showed ADEM. Follow-up MRI yesterday showed imp

History: Adjustment reaction with depressed mood 2/24/09-records received-PMH: Chronic tension headaches, neck and shoulder tension. Headaches for many years but now worse. Double vision. Stated always had tracking issues with reading. Strep throat 5/7/07.Allergy to penicillin.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339467-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Feb-2009	11-Feb-2009	0	11-Feb-2009	13-Feb-2009	VA		13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breath sounds abnormal, Cyanosis, Dizziness, Erythema, Muscle contracture, Muscle rigidity, Mydriasis, Respiratory arrest, Retching, Unresponsive to stimuli

Symptom Text: Pt was sitting on exam table after vaccine and she felt dizzy. She was assisted to lying position on table by mother. A few seconds later nurse arrived in room and pt had rigid posture. Her face was red, then blue, and patient had ragged breathing. Her third and fourth fingers of her right hand were clenched, and her right arm was contracted. Pt's eyes fully dilated. Another nurse elevated pt's legs. A few seconds later Pt stopped breathing for about 5 seconds and nurses performed vigorous sternal rub, causing patient to resume ragged breathing. A few seconds later, Pt heaved, but did not vomit, was then turned to her left side. A few seconds later, pt started kicking for a few seconds, then relaxed, and was immediately responsive. Pt stated her name when asked, and was breathing calmly and normally. No loss of bladder or bowel function. Total non-responsive time was about 45 seconds. Pt was then kept supine for 5-10 minutes, then sitting for 5 minutes, then standing. No further loss of consciousness. Multiple sets of BP and pulse, and O2 sats obtained immediately after episode.

Other Meds: none

Lab Data: immediately after episode: BP 112/48, HR 91, O2 98% 5 min after episode: BP 104/52, HR 90, O2 99%

History: renal glucosuria

Prex Illness: none

Prex Vax Illns: fainting~Varicella (Varivax)~2~13~In Sibling1

Vaers Id: 339471-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Nov-2006	06-Feb-2007	77	11-Feb-2009	16-Feb-2009	MD		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Unknown	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Acne, Back pain, Dizziness, Hypophagia, Ocular icterus, Orthostatic hypotension, Rash, Road traffic accident, Syncope

Symptom Text: RASH ON HANDS< AND OVER FOURTY PERCENT OF BODY AFTER VACCINE>>NOW HAVE GUILLIAN BARRE SYNDROME> 12/13/09-office notes received for DOS 11/21/06-well visit-mild acne-received 1st Gardasil vaccine. Office visit 2/6/07-C/O scleral icterrus past few weeks, comes and goes 2nd Gardasil vaccine. Office visit 7/31/07-2 episodes of syncope in last few days, fluid intake decreaed. Dizziness. Office visit 7/23/08-well visit. Office visit 8/1/08-dizziness, blood pressure standing 104/54, blood pressure lying 120/58. DX: Orthostatic hypotesion. Plan increase fluids. Office visi 12/30/08-C/O back pain, involved in an auto collision. No significant injury.

Other Meds: None

Lab Data: BLOOD WORK AND PHYSICAL OBSERVATION 2/13/09-records received-CBC normal.

History: NONE

Prex Illness: NONE

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339474-1 (S)** **Related reports:** 339474-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
30.0	F	20-Jan-2009	03-Feb-2009	14	11-Feb-2009	16-Feb-2009	VA		16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Arthralgia, Convulsion, Diarrhoea, Haemoptysis, Headache, Hypoaesthesia, Nausea, Paraesthesia, Systemic lupus erythematosus, Vomiting

Symptom Text: Patient received Merck's Gardasil vaccine 2 weeks ago and since has been experiencing a variety of symptoms, headaches, seizures, tingling, numbness, joint pain, diarrhea, n/v, coughing up blood, etc. etc. She was seen by the PCP and in the ER twice. Labs revealed elevated lymphocytes, an elevated ANA, and an abnormal antibody response. She has since been dx with Lupus. The GYN has contacted Merck and we are continuing with the recommended course of treatment however the symptoms have not subsided.

Other Meds: None

Lab Data: Elevated lymphocytes, an elevated ANA, and an abnormal antibody response. EEG and Rheumatology consult are ordered for next month.

History: None

Prex Illness: None, prophylactic

Prex Vax Illns:

Vaers Id: **339474-2 (S)** **Related reports:** 339474-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Feb-2009	Unknown		13-Feb-2009	17-Feb-2009	NC		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Arthralgia, Convulsion, Diarrhoea, Disturbance in attention, Fatigue, Haemoptysis, Migraine, Nausea, Neurological symptom, Systemic lupus erythematosus, Vomiting

Symptom Text: Two weeks following the administration of Merck's GARDASIL vaccine, my sister has been diagnosed with Lupus. She has been in and out of the PCPs office for 2 weeks with 2 ER visits for vague neurological symptoms, seizures, coughing up blood, joint pain, diarrhea, fatigue, n/v, inability to concentrate, migraines, etc, etc. After multiple test, the diagnosis of Lupus was been made 2nd to an elevated ANA level and multiple antibody elevations. All symptoms and lab findings occurred following the administration of the vaccine. Her GYN, which administered the vaccine, is contacting Merck for he feels it is related to this vaccine; as do we.

Other Meds:

Lab Data: Elevated Lymphocytes and ANA as well abnormal antibody responses consistent with Lupus.

History: NKDA, NKMA. No previous auto-immune disorders, system failures, takes no medications. No pertinent or relevant PMH.

Prex Illness:

Prex Vax Illns:

Vaers Id: **339489-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	10-Apr-2008	15-Apr-2008	5	12-Feb-2009	13-Feb-2009	FR	WAES0811USA03598	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0510U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Inflammatory bowel disease, Nausea

Symptom Text: Case was initially reported by Health Authority (PEI2008014571). Information has been received from a gynecologist concerning a 14 year old female patient who on 10-APR-2008 was vaccinated with the second dose of GARDASIL into the deltoid muscle (Batch #NG20180, lot # 0510U). On 15-APR-2008 the patient developed abdominal pain and nausea especially postprandial. Gastroscopy and colonoscopy showed no pathological findings. The patient was tested for food allergy, the results were no available at the time of reporting. The patient had not recovered at the time of reporting (28-JUL-2008). The first dose of GARDASIL was given on an unknown date and was well tolerated. The reporter assessed the relation to the vaccine as unlikely but the mother insisted on reporting. The file was closed. Follow up information was received on 09-FEB-2009: this case had to be upgraded due to long persistence of symptoms. It was reported that the patient underwent a colonoscopy on an unspecified date and an inflammatory bowel disease was diagnosed. The health authority considered inflammatory bowel disease to be an other important medical event. The file was closed. Other business partner numbers include E2008-10095. No further information is available.

Other Meds: None

Lab Data: Gastroscopy, no pathological findings; Colonoscopy, no pathological findings; Allergy test, food allergy test; Colonoscopy, inflammatory bowel disease

History: None

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339490-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	Unknown	Unknown		12-Feb-2009	13-Feb-2009	AR	WAES0902USA01085	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Systemic lupus erythematosus

Symptom Text: Information has been received from a physician concerning a 10 year old female patient who was vaccinated with a dose of GARDASIL (lot# not provided) 0.5ml intramuscularly. Subsequently the patient developed lupus. Patient sought unspecified medical attention and is currently under the care of a pediatric rheumatologist. Upon internal review lupus was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339491-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	06-Feb-2009	06-Feb-2009	0	12-Feb-2009	13-Feb-2009	FR	WAES0902USA01482	13-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1647U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Coma, Convulsion, Dizziness, Hypertonia, Loss of consciousness, Myoclonus

Symptom Text: Information has been received from a health professional concerning an adolescent female (exact age not reported) who on an unknown date was vaccinated with the first dose of GARDASIL. On 06-FEB-2009 at 9:30, the patient was vaccinated with the second dose of GARDASIL, (lot # 1647U/batch # NH52670), route and site not reported. It was reported that 1 hour after vaccine administration while the patient was at school she started with dizziness, loss of consciousness and a hypertonic crisis. The patient was transferred to the hospital. During the transferral to the hospital the patient presented with myoclonic movements in her right leg and she was admitted to the pediatric intensive care unit. During her admission to the hospital the patient had another convulsive crisis. It was reported that the patient was induced into a barbiturate coma. This is one of 2 reports from the same source. Other business partner numbers include: E2009-01135. A lot check has been initiated. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **339504-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Jul-2008	15-Jul-2008	0	12-Feb-2009	17-Feb-2009	WA		06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DTAP	UNKNOWN MANUFACTURER	NULL	1	Unknown	Intramuscular	
	HEPA	UNKNOWN MANUFACTURER	NULL	1	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Chest pain, Dizziness, Heart rate irregular, Hyperhidrosis, Pallor, Palpitations, Unresponsive to stimuli

Symptom Text: After the third dose my daughter got very pale, sweaty, aand dizzy. The nurse and I layed her back on the exam table. She became unresponsive for 10-20 seconds and stayed laying down for about 10 minutes after that until she was no longer dizzy. My daughter started having heart palpitations after this and still has them today. Starting in February 2009, they are accompanied by chest pains. 4/8/09 PCP records received from 7/15/08 to 2/10/09. Seen for 14 yr WCC on 7/15/08 with c/o heavy periods. ROS (+) for headaches QOD. PE WNL with acne. Started on Concerta of ADD and OCs to regulate periods. Seen again 9/9/08 and 9/12/08 with c/o racing heart and irregular heartbeats associated with some anxiety. PE WNL. HR 95-105. Assess: Palpitations and/or tachycardia while on Concerta. Nausea from OCPs. Referred to cardiology for Holter. Returned 2/10/09 for c/o chest pain with skipped beats and feeling like the heart is beating hard. 4-6 episodes in last 2 weeks. Assessment: Likely precordial catch syndrome. Palpitations. Holter to be scheduled. 4/29/09 Received Cardiology medical records of 10/7/08-3/5/2009. FINAL DX: Palpitations Records reveal patient experienced palpitations w/chest pain & dizziness. Concerta had been d/c approx 1 mo prior to initial eval & palpitations had improved; however, patient needed to restart meds to maintain academic performance. When seen 3/5/09 palpitations had recurred while on Concerta esp when exercising. No further records available.

Other Meds: Concerta 27mg, Fexofenadine 30mg, Flonase

Lab Data: LABS: EKG & Holter monitor WNL

History: seasonal allergies, ADD PMH: acne, irregular heavy menses, OCPs, headaches, palpitations x 2 yrs. Family hx: MVP.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339516-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Jan-2009	06-Feb-2009	16	12-Feb-2009	17-Feb-2009	WA		25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Depressed level of consciousness, Headache, Hypokalaemia, Insomnia, Loss of consciousness, Presyncope, Vomiting

Symptom Text: 2/6/2009 7:00 p.m. To E.R. by ambulance for sudden onset altered loss of consciousness. Obtained labs, CT, lumbar puncture. Had been c/o insomnia over 3 weeks prior to event, but also documented in pt. record as having 'troubles getting to sleep at night' in 4/2008. 3/23/08 MR received for ER visit 2/6/08 with DX: Vomiting, unclear etiology. Altered LOC, unclear etiology. Pt presented with acute onset of vomiting with altered LOC. Pt recently reporting H/As and near syncopal episode. PE WNL. Given KCl for mild hypokalemia and d/c home for outpt f/u.

Other Meds: 1. Amitriptyline 10 mg. 1 pill p.o. night before event. 2. Flexeril 10 mg. q8 hrs. prn back spasms.

Lab Data: CSF - neg. CBC - WNL UA - WNL, + for Tricyclics CT/head - no acute intracranial abnormality. Labs and Diagnostics: CBC WNL. Tox screen (-) for drugs of abuse. CT brain (-). K+ 3.1. BS 142. CSF WNL. CSF cx (-).

History: scoliosis, headaches, muscle spasms in lumbar area. PMH: difficulty falling asleep 4/2008

Prex Illness: none

Prex Vax Illns:

Vaers Id: **339525-1 (S)** **Related reports:** 339525-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Dec-2008	19-Dec-2008	1	12-Feb-2009	17-Feb-2009	OK		04-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	2	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Acute myeloid leukaemia, Anaemia, Blood product transfusion, Bone pain, Chemotherapy, Conjunctival haemorrhage, Continuous haemodiafiltration, Contusion, Dehydration, Dyspnoea, Encephalopathy, Endotracheal intubation, Enterococcal infection, Fatigue, Influenza like illness, Intensive care, Mechanical ventilation, Metabolic function test abnormal, Nausea, Neutropenia, Pallor, Pancytopenia, Peritoneal dialysis, Petechiae, Pneumonia, Pyrexia, Renal failure, Respiratory distress, Respiratory failure, Thrombocytopenia, Tracheostomy, Transfusion, Tumour lysis syndrome, Vomiting

Symptom Text: 12/17/08 mom took patient to ER for nausea and vomiting. 12/19/08 mom took patient to ER for shortness of breath. Diagnosed with acute myeloid leukemia. 2/18/09 Received ER medical records of 12/17/2008. FINAL DX: vomiting w/o dehydration. Records reveal patient experienced N/V x 3 days, no BM x 2 days. Able to tolerate oral fluids. Tx w/antinausea meds & d/c home on additional antinausea meds. 3/23/09 Received hospital medical records of 12/19/08-remains inpatient. FINAL DX: acute myeloblastic leukemia; respiratory failure; severe thrombocytopenia & anemia w/severe neutropenia; pneumonia; renal failure. Records reveal patient experienced flu-like symptoms, bone aching, bruising & petechial rash, pale, fatigue, SOB, low grade fever & abdominal pain w/vomiting x 3-5 days w/conjunctival hemorrhage. Developedencephalopathy, respiratory distress, renal failure, tumor lysis syndrome, metabolic derangements, ARDS, labile BP. Heme/onc, Pulm, ID, Nephro consult. Admitted PICU, intubated followed by tracheostomy, initially CVVH followed by peritoneal dialysis, multiple transfusions, antibiotics, chemotherapy. Developed pancytopenia secondary to chemotherapy.

Other Meds: CLONIDINE; ALBUTEROL; MONTELUKAST

Lab Data: LABS: CXR w/infiltrates. WBC 170,000, Hgb 4.1(L), plts 10K (L). Potassium (H), Uric acid 10.5(H). Creatinine 1.3. Urine c/s (+) enterococcus faecium.

History: Asthma; ADHD; MR PMH: intrauterine growth retardation, NICU, developmental delays, learning disability, amenorrhea.

Prex Illness: None reported

Prex Vax Illns:

Vaers Id: **339525-2 (S)** **Related reports:** 339525-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Dec-2008	19-Dec-2008	1	09-Apr-2009	10-Apr-2009	--	WAES0903USA04987	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Acute myeloid leukaemia, Dyspnoea, Nausea, Vomiting

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 16 year old female with asthma and attention deficit/hyperactivity disorder and a history of "MR" (not otherwise specified) on 18-DEC-2008 was vaccinated intramuscularly with a third dose of GARDASIL (lot number 661703/0651X) in the left arm. Concomitant therapy included clonidine, albuterol and montelukast. On 17-DEC-2008 the patient experienced nausea and vomiting. The patient's mother took the patient to the emergency room. On 19-DEC-2008 the patient's mother took the patient to emergency for shortness of breath. The patient was diagnosed with acute myeloid leukemia. The listing indicated that one or more of the events required hospitalization, was considered to be immediately life-threatening. No further information is available. The original reporting source was not provided. The VAERS ID # is 339525. A standard lot check investigation was performed. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center and was released.

Other Meds: Albuterol; clonidine; montelukast

Lab Data: Unknown

History:

Prex Illness: Asthma; Attention deficit/hyperactivity disorder

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339526-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Feb-2009	12-Feb-2009	0	12-Feb-2009	17-Feb-2009	NC		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Patient fainted within 2 minutes of vaccine administration. Patient obs x 45 minutes. BP checked after 10min. BS checked-88. Drank water. Walked out of office escorted

Other Meds:

Lab Data:

History:

Prex Illness: Here for c/o HA's

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339545-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	06-Feb-2009	07-Feb-2009	1	13-Feb-2009	17-Feb-2009	VA		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1189X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Lacrimation increased, Rash

Symptom Text: Patient developed rash on neck, face on 2/9. Also had some shortness of breath and "watery eyes" on 2/8. Rash on inner arms, back, chest, per nurse. Took BENADRYL 50mg with minimal improvement.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **339552-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	19-Jan-2009	19-Jan-2009	0	13-Feb-2009	16-Feb-2009	FR	WAES0902USA01025	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0779X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bradycardia, Dizziness, Hypoglycaemia, Hypotension, Pallor, Similar reaction on previous exposure to drug

Symptom Text: Information has been received from a Health Authority (Ref. No. L200901-487) on 05-FEB-2009 and transmitted under local reference number RA-006-2009. A 13 year old female patient experienced dizziness, pallor, Hypotension at 90/50 mmHg, bradycardia and hypoglycemia around 60 mg/dl with a duration of 40 minutes, ten minutes after she had received the second dose of GARDASIL (batch no. NJ32820; lot no. 0779X) via intramuscular route on 19-JAN-2009. There was no specific treatment for the adverse reaction. To be noted that when she had received the first dose of GARDASIL (batch no. not reported) on an unspecified date, the patient had shown the same symptoms and had fainted. The patient had no known clinical history. History of adverse reactions to previous other drugs was unknown. The patient recovered without specific treatment on unspecified date. The case is closed. The patient's experience was considered serious as an other important medical event. Other business partner numbers included: E2009-01092. Additional information is not expected.

Other Meds: Unknown

Lab Data: Blood pressure measurement, 19Jan09, 90/50 mmHg; Serum glucose, 19Jan09, 60 mg/dl

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339553-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	20-Apr-2007	01-Aug-2008	469	13-Feb-2009	16-Feb-2009	FL	WAES0902USA01061	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Carcinoma in situ, Cervical dysplasia, Smear cervix abnormal, Uterine dilation and curettage

Symptom Text: Information has been received from a physician concerning a 24 year old patient with a history of papanicolaou smear abnormal who on 20-FEB-2007 was vaccinated with the first dose of GARDASIL (lot no. 656049/0187U), second dose of GARDASIL (lot no. 657621/0387U) was given on 20-APR-2007 and third dose on 20-AUG-2007 (lot no not reported). In August 2008 the patient was diagnosed with carcinoma in situ. A colposcopy was performed and result was high grade squamous epithelial lesions. On an unknown date a uterine dilation and curettage was performed. It was also reported that a cervical cone biopsy was made (results not provided). Upon internal review, the patient's carcinoma in situ was considered an other important medical event. The patient's sister had a similar adverse experience following vaccination (WAES 0902USA00938). Additional information has been requested. 2/25/09 GYN records received from 11/2005 to 12/2008. Seen 2/9/07 for annual exam. Normal PAP. HPV vax series started. Returned 8/7/08 for exam. PAP (+) for mild dysplasia. Colposcopy 9/2/08. Cone bx (+) for carcinoma in situ and severe dysplasia.

Other Meds: Unknown

Lab Data: Colposcopy, high grade squamous epithelial lesions; Cervical smear, ascus pap smear. Labs: PAP (+) for ASCUS, HPV (+). Cervical cone bx (+) for carcinoma in situ with extensive glandular involvement. Repeat (-) for malignancy.

History: PMH: anorexia-past. hernia repair

Prex Illness:

Prex Vax Illns: High grade squamous; Papilloma viral infection~HPV (Gardasil)~UN~24~Sibling

Vaers Id: 339554-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Oct-2007	15-Dec-2007	61	13-Feb-2009	16-Feb-2009	FR	WAES0902USA01538	16-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0253U	2	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hypoaesthesia, Paresis, Sensory disturbance, Somatoform disorder

Symptom Text: Information has been received from a general practitioner on 05-FEB-2009 who also sent a hospital discharge report concerning a 14 year old female patient who was vaccinated with a third dose of GARDASIL (lot #0253U, batch #NF58540, injection route not reported) into the left upper arm on 15-OCT-2007. On 15-DEC-2007 the patient developed hypaesthesia and paresis of the right hand. The patient was hospitalized from 17-DEC-2007 until 20-DEC-2007. Hypaesthesia and paresis of the right hand were diagnosed. Cranial and cervical MRI were normal as well as neurography, AEP and routine lab findings (not otherwise specified). VEP showed a slight delay on the right side. CSF was not examined. According to a neurological examination on 18-JAN-2008 the patient had not recovered and persisting sensory disturbance of the right hand was diagnosed. A somatoform origin of the complaints was suspected and a psychiatric examination planned. On the reporting form it was mentioned that the patient developed during the course about 6 weeks later also sensory disorder and paresis of the right and left foot. Hypaesthesia of the right hand and right foot were persisting at the time of reporting. The first and second dose of GARDASIL (both lot# not reported) administration on 01-JUN-2007 and 24-AUG-2007 into the left upper arm were well tolerated. Other business partner numbers include: E2009-01038. No further information is available. File closed.

Other Meds: None

Lab Data: magnetic resonance imaging, ??Dec07, cranial and cervical MRI were normal; Auditory evoked potential, ??Dec07, normal; Visual evoked potential, ??Dec07, slight delay on the right side; Diagnostic laboratory test, ??Dec07, neurography normal

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339570-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	11-Feb-2009	11-Feb-2009	0	13-Feb-2009	17-Feb-2009	GA		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NA	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Asthenia, Blindness, Deafness, Diarrhoea, Dysgeusia, Dyspnoea, Feeling cold, Injection site pain, Injection site swelling, Nausea, Pallor, Syncope, Tinnitus, Visual impairment

Symptom Text: I received the Gardasil vaccine and walked out of the room. As I exited I lost vision and hearing and collapsed, still conscious and very nauseated. Difficulty breathing occurred once vision returned. Hearing did not return for 10 minutes and I heard a ringing, metallic sound every time I talked. Vision was yellow and green, and my face had lost all color (pale/green). 15 minutes after the shot I had abdominal cramps and diarrhea. I drank some water and was then freezing cold and very weak. I felt more normal by the end of the day. On the second and third day, I had swelling and tenderness at the injection site.

Other Meds: Birth control (depo provera)

Lab Data:

History: none

Prex Illness: None

Prex Vax Illns:

Vaers Id: 339581-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Apr-2008	09-May-2008	24	13-Feb-2009	17-Feb-2009	AL		11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Fibromyalgia, Gait disturbance, Joint swelling, Juvenile arthritis, Mobility decreased, Musculoskeletal stiffness, Myofascial pain syndrome, Neck pain, Pain in jaw, Paraesthesia, Stiff-man syndrome, Tendonitis

Symptom Text: 1st Gardasil vaccination on 2/19/08. Second Gardasil vaccination April 2008. 3 weeks later, on May 9, she came home from school complaining of soreness in all her joints. She had no fever or any other flu-like symptoms. Medical tests have consistently been negative for arthritis, lupus or any other autoimmune disease the doctors could think of. Neurological tests revealed no neurological source of the soreness and stiffness. Nine months later, she is still experiencing joint pain. 2/20/09 MR received from PCP. In for 14 yr WCC on 2/19/08 with dx: Well adolescent. Next OV 5/9/08 with c/o joint pain and swelling x 2 days. PE (+) for swollen ankles. Dx: arthralgia. Returned 5/12/08 with increasing pain and swelling jaws, neck, knees, wrists and ankles. Tingling in feet. NSAIDS not helping. Swollen joints on PE with decreased strength- 4/5 ankles, knees and wrists. Labs WNL. Medrol rx with some improvement, with return of pain/stiffness after. Walking stiff legged 5/16/08. 2/27/09 MR received from neurologist dated 6/25/08 with DX: Pain, joint, musculotendonous, connective tissue. Etiology unknown. MR received from rheumatologist dated 12/9/08 and 2/3/09 with DX: Enthesitis related JIA and Fibromyalgia temporally associated with Gardasil vaccine. Another consult noted discusses amplified musculoskeletal pain syndrome. ? idiopathic variant of stiffman syndrome. Pt reports continued stiffness, joint pain and decreased mobility. More fatigue. Restarted Methotrexate and Humira 2/3/09

Other Meds: NONE

Lab Data: MRIs, Bone Scan, X-Rays, Echocardiogram, Bloodwork. Labs: CRP, ESR, ANA, RF, mono, Complement C3 and C4 all (-). Labs: EMG/NCS WNL. MRI brain WNL. MRI spine (-).

History: NONE. PMH: none noted. allergy to PCN

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **339589-1 (S)** **Related reports:** 339589-3; 339589-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Aug-2008	03-Sep-2008	16	14-Feb-2009	17-Feb-2009	NC		31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Activities of daily living impaired, Condition aggravated, Convulsion, Decreased appetite, Depression, Diarrhoea, Disability, Gastroenteritis viral, Headache, Hypophagia, Mental impairment, Migraine, Nausea, Pain, Panic reaction, Pharyngitis, Pyrexia, Vaccine positive rechallenge, Viral infection, Weight increased

Symptom Text: Patient given 1st dose of Gardasil Lot # 14484 on 2/4/08. Patient became ill with Severe Adominal Pain and Nausea. Patient given 2nd dose of Gardasil Lot # 17574 on 4/16/08. Patient because ill with Severe adominal pain, and Nausea and treated at pediatricans office on 5/1/08. Patient given 3rd dose of Gardasil Lot # 0067X on 8/18/08. Patient returned to Pediatrician on 9/3/08 with Severe adominal pain, severe nausea, and brain freezes or seizure complaints. Since September of 2008, patient has been placed on a modified school schedule and is being treated by Hospital with little to no improvement. Student is unable to attend school except for an average of 2 days per week. Student has become disabled because of pain, nausea, and seizure effects. 2/19/2009 MR received from PCP which include multiple consults and ER visits. Seen 2/4/08 for c/o congestion, H/A, fever and abd pain. Assess: Sinustis. Vax given. WCC 4/16/08 with normal G&D. PE WNL. Vax given. Returned 5/1/08 with c/o fever, diarrhea, decreased appetitie and po intake. Assess: Pharyngitis. Viral syndrome. OV 6/4/09 for nausea and migraine. Assess: VGE. OV 9/3/08 for H/a, nausea, stomach pain. Assess: VGE. Returned 9/15/08 with RUQ pain and diarrhea. Rx: Prilosec. Similar sx 9/22/08, 9/25/08 with fever. Seen 11/10/08 with for daily "brain freeze' where pt can't think clearly, panics, with H/A after. Missed 20 days of school this yr. Sx continue to present. Referred to GI 10/6/08 with multiple consults for abd pain with no clear dx-likely functional. Depression noted 1/13/09. Weight gain 2' to eating to lessen pain. IBS dx 2/16/09 2/26/09 Hospital records received for ER visit 9/29/08 and later diagnostic studies with DX: Abdominal pain. Pt presented with several week hx of RUQ abdominal cramping with nausea. Severity 4-9/10. PE WNL. Referred for out pt tx.

Other Meds:

Lab Data: Large battery of tests performed by Medical Center . Labs and diagnostics: Duodenal bx (-). Stomach bx (+) for chronic gastritis. Esophagus bx (-). H. pylori (-). Biliary patency study WNL. KUB (+) for moderate stool burden. Labs: Str

History: None PMH: none

Prex Illness: None. Seen 2/4/08 for c/o congestion, H/A, fever and abd pain. Assess: Sinustis. Vax given.

Prex Vax Illns:

Vaers Id: **339589-3** **Related reports:** 339589-1; 339589-4

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	04-Feb-2008	Unknown		02-Mar-2009	05-Mar-2009	--		09-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	14484	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Convulsion, Disability, Malaise, Nausea, Thinking abnormal, Vaccine positive rechallenge

Symptom Text: Patient given 1st dose of GARDASIL Lot # 14484 on 2/4/08. Patient became ill with Severe Abdominal Pain and Nausea. Patient given 2nd dose of GARDASIL Lot # 17574 on 4/16/08. Patient became ill with Severe abdominal pain, and Nausea and treated at pediatricians office on 5/1/08. Patient given 3rd dose of GARDASIL Lot # 0067X on 8/18/08. Patient returned to Pediatrician on 9/3/08 with Severe abdominal pain, severe nausea, and brain freezes or seizure complaints. Since September of 2008, patient has been placed on a modified school schedule and is being treated at Medical Center with little to no improvement. Student is unable to attend school except for an average of 2 days per week. Student has become disabled because of pain, nausea, and seizure effects.

Other Meds:

Lab Data: Patient Treated multiple Times and multiple tests performed at Medical Center, under the care of pediatricians at Medical Center. Patient Treated multiple Times and multiple tests performed at hospital under the care of doctor.

History: No previous medical issue history prior to use of GARDASIL vaccine.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339589-4** **Related reports:** 339589-1; 339589-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Apr-2008	Unknown		22-Apr-2009	08-May-2009	--	WAES0903USA01126	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Metal poisoning

Symptom Text: Information has been received from a school nurse (registered nurse) concerning a middle school aged female who was vaccinated with a dose of GARDASIL. On an unspecified date, after receiving GARDASIL, the patient developed aluminum poisoning. The patient sought unspecified medical attention. Additional information was received from the school nurse and an office manager concerning the 13 year old middle school female who on 4-FEB-2008 was vaccinated with the first dose of GARDASIL, on 16-APR-2008 was vaccinated with the second dose and on 16-AUG-2008 was vaccinated with the third dose (lot #: 660393/0067X). On an unspecified date, after administration of GARDASIL, the patient developed aluminum poisoning. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339594-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		16-Feb-2009	17-Feb-2009	--		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Cold sweat

Symptom Text: About 2 minutes after the shot I walked out of the doctors office and into the lobby, and all of a sudden I lost all energy in my body. Literally, I felt as though if I were to take one more step I would collapse. I did not have the energy to put my hand up and ask the clerk for help, and she was only a few feet away. Not knowing what else to do, I laid down on the floor in the lobby and tried to sleep. Probably soon after a medical assistant brought me back into the office and gave me some water. She said I looked "clammy" and I felt a cold sweat. After I drank the water I laid down on one of the beds in the small offices. I have not gone back to get the other two shots. I am a 19 year old female.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339615-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Feb-2009	13-Feb-2009	0	13-Feb-2009	17-Feb-2009	GA		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction

Symptom Text: Minutes after vaccine admin., pt. walked back into the waiting room complaining of dizziness. Assisted into a chair with mother at side. Several attempts at a BP (auto and manual) made. Called Dr. BP 51/21. Ordered to call 911 & admin 0.3 ml epi. EMT arrived & epi admin into right thigh. EMT @ side. BP 100/50 & pt more conscious. Reported to Dr Pt mother refuse ambulance but would take daughter to ER. Pt walks out with mother and EMTs.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339617-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Nov-2008	Unknown		13-Feb-2009	17-Feb-2009	PA		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C3032AA		Left arm	Unknown	
	MNQ	SANOFI PASTEUR	02731AA		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Pt had Px exam 11-25-08. GARDASIL #1, MENACTRA & ADACEL given to update imms- Pt has since learned that she was pregnant at time of vaccine administration (2 weeks pregnant), unaware of any adverse reaction

Other Meds: SINGULAER 10 mg daily

Lab Data:

History: Asthma; Heart murmur

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339625-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Feb-2009	05-Feb-2009	1	13-Feb-2009	17-Feb-2009	GA		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	0	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1183U	1	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site swelling

Symptom Text: Redness, swelling to site, itching. (Varicella).

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339652-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jan-2009	02-Feb-2009	31	16-Feb-2009	18-Feb-2009	MO		10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Back pain, Blood potassium decreased, Convulsion, Dyskinesia, Headache, Influenza like illness, Muscle contractions involuntary, Muscle spasms, Nausea, Pain

Symptom Text: Headaches starting January 3rd. Nausea and flu-like symptoms starting around January 15th. Low back pain started early January. February 2, patient had one "violent seizure-like episode" with strong involuntary muscle contractions at school. Ambulance was called, patient went to ER. Diagnosed with low potassium. February 3, patient had several more episodes at school. Ambulance was called again, patient went to ER and had several more episodes in the ER, and admitted to hospital. Possible dystonia? Several more episodes in the hospital with total lab and diagnostic test work-up. Discharged February 8 with diagnosis of anxiety. Was given Kepra which took her from 30 seizures a day to 15 a day. Patient taking 500 mg bid. Back pain remains at an 8 which increases to 10 right before an episode. Patient is aware and alert during seizure-like episodes and states they are extremely painful muscular contractions. Has follow-up testing with pediatrician and ob-gyn, and has been referred to specialist.2/27/09-records received-for DOS 2/3-/2/8/09-presented with back spasms after 1 day history of multiple episodes of flexing back and flexing hands foreward and flexing legs backwards with severe pain.

Other Meds: Oral contraceptives

Lab Data: EEG, EKG, CT Scan, MRI, X-ray of back, extensive blood and urine work-up. Video x24 hours with EEG. 2/27/09-records received EEG negative. Labs WNL. CT of head and MRI WNL.

History: Allergic to Penicillin. Seasonal allergies. 2/27/09-records received- History of panic attacks and anxiety.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339656-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Aug-2008	28-Sep-2008	51	16-Feb-2009	17-Feb-2009	LA		13-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Bronchitis, Chills, Chronic fatigue syndrome, Cough, Dyspnoea, Ear pain, Headache, Hypersensitivity, Hypoaesthesia, Lip swelling, Lymphadenopathy, Oropharyngeal pain, Otitis media, Pharyngitis, Pyrexia, Respiratory tract congestion, Sinusitis, Upper respiratory tract infection, Wheezing

Symptom Text: Patient received 1st dose of Gardasil vaccine on 8/8/08 in Dr. office, since having the vaccine she has had recurring headaches, severe joint pain, chronic fatigue syndrome, and chronic swollen glands, chills, fever, sore throat, ear pain, numness in arms. On 12/2/08 she received her 2nd MMR and Menoccical vaccine at her pediatrician. 3/11/09 MR received from PCP from 8/7/08-2/15/09. Seen 9/28/09 with c/o sore throat and congestion. DX: sinusitis. Pharyngitis. Seen again 10/6/08 after falling off horse with c/o neck pain. DX: Spasm-R SCM muscle. URI and BSOM 10/13/09. Sinusitis 11/12/08. MCV4 and MMR given 12/2/08. Seen again 2/5/09 for c/o ear pain, chills, fever with congestion. DX: allergy. RSOM. Seen 2/12/09 for c/o fever, scratchy throat,cough, lip swelling,congestion and achy joints. DX: Pharyngitis. Bronchitis. Seena 2/15/09 with c/o difficulty breathing, cough, wheezing, H/A. DX: URI.

Other Meds: Synthroid 50 mg

Lab Data: flu test, CBC, Chem profile. Labs and Diagnostics: CXR WNL. T4 high at 15.4. CBC WNL.

History: Penicillin, Advil PMH: OCs.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **339659-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Feb-2009	16-Feb-2009	0	16-Feb-2009	17-Feb-2009	--		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Malaise, Syncope

Symptom Text: My daughter received Gardisil vaccine today..Number 3, and she fainted about 8 minutes after the shot. She was okay..nurse kept us a few minutes to be sure, but then walking to the check out desk she said she didn't feel well and fainted onto the floor (I caught her on the way donw)She had no reaction to the first 2 doses, but fainted after this one.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **339660-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Dec-2008	29-Dec-2008	28	16-Feb-2009	17-Feb-2009	CO		31-Mar-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0548X	0	Right arm	Intramuscular	FLU
TDAP	SANOFI PASTEUR	C3027AA	0	Unknown	Intramuscular	VARCEL
MNQ	SANOFI PASTEUR	U2812AA	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Back pain, Clonus, Constipation, Dizziness, Dyspnoea, Enema administration, Gastroenteritis, Headache, Hot flush, Mechanical urticaria, Musculoskeletal pain, Nausea, Orthostatic hypotension, Posturing, Rash, Syncope, Tachycardia

Symptom Text: Patient experiences severe flushing episodes, nausea, severe abdominal pain, back pain, difficulty breathing. Several physicians and tests find nothing causing it. Alls symptoms developed after the first Gardasil injection. Symptoms still present two months later. /24/09 Received vaccine records & PCP medical records of 12/1/08-2/17/2009. FINAL DX: likely dermatographism Records reveal patient experienced HA & dizziness intermittently x 2 yrs. Meds had been d/c'd but HA & dizziness persisted. Missed school due to HAs. Allergy consult done 2/2/09 due to rash & flushing episodes since 12/29/08. Allergy testing neg except for cedar pollen. Tx w/antihistamine. Had been hospitalized w/RLQ pain & dx w/constipation, treated w/enema & diet. RTC 2/17/09 w/dizziness, flushing, abdominal pain. Exam revealed orthostatic BP w/tachycardia. Referred to known Neuro for additional w/u. 3/30/09 Received ER & Outpatient clinic records of 1/25/08-2/11/2009. FINAL DX: convulsive syncope Records reveal patient experienced continued dizziness, HA. Had outside MRI considered to be abnormal & had been referred to Neuro. RTC 9/08 off meds & mood markedly improved. Continued w/HA, dizziness followed by syncope & tonic posturing w/some clonic jerks, last episode 8/08 & occurring approx q6mo, lasting approx 30-60 secs. Seen in ER 1/13/09 for intermittent RUQ abdominal pain, right shoulder & shoulder blade pain; hot flashes & nausea x 1-2 wks. Dx w/acute gastroenteritis & constipation. Tx w/fluids & enema. Seen in GYN clinic 2/11/09 for recurring hot flashes, felt to be neurologic rather than GYN in origin as exam WNL.

Other Meds:

Lab Data: LABS: UA, US abd WNL. Abdominal x-ray c/w constipation. Food allergy tests neg.

History: PMH: partial seizures since 2 yo, remission since 10/06;migraine HAs; asthma; heart murmur; overweight. Allergy: PCN, cephalosporins, adhesive tape, mountain cedar tree pollen.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339662-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	06-Feb-2009	06-Feb-2009	0	16-Feb-2009	17-Feb-2009	WY		03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	2	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Arthralgia, Asthenia, Dysphagia, Fatigue, Headache, Hypersensitivity, Muscular weakness, Nausea, Pain, Pain in extremity, Pyrexia, Swelling face, Vaccination complication, Viral infection

Symptom Text: Fever, headache, nausea, joint pain, unusual tiredness/weakness, aching muscles, muscle weakness, bad stomach ache. 2/18/09 Received vaccine records & PCP medical records of FINAL DX: viral syndrome & vaccine allergic reaction Records reveal patient experienced left arm pain s/p vaccination w/fever, HA, facial swelling, difficulty swallowing, gen aching, nausea, & seen in ER 2/6/09. Tx w/IVF & meds, imiproved & d/c to home. Missed 3 days of school.

Other Meds: Zovia

Lab Data: Urine sample.

History: NA PMH: abnormal pap smear; LEEP/LEETZ; bilat breast augmentation; allergies/hay fever; GERD; contraception.

Prex Illness: NA

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339681-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Feb-2009	16-Feb-2009	0	16-Feb-2009	17-Feb-2009	NY		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Consciousness fluctuating, Dizziness, Dyskinesia

Symptom Text: Pt c/o feeling dizzy after shot. Pt told to sit- down - given a cold compress. Pt LOL for under 1min with some jerking movements ammonia inhalant used with little effect Pt cont. to go in and out of consciousness. MD call to Pt. 911 called as per MD. O2 given. Pt taken to hospital via amb.

Other Meds: DDAUP

Lab Data: Temp 97.8; BS 93; Pulse OX 96%

History: Enuresis

Prex Illness: None

Prex Vax Illns:

Vaers Id: **339683-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	11-Feb-2009	11-Feb-2009	0	16-Feb-2009	17-Feb-2009	AZ		17-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Injection site rash, Injection site swelling, Urticaria

Symptom Text: Rash. swelling pain @ injection site hives present both arms.

Other Meds: ORTH TRI CYCLEN

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **339684-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Dec-2008	25-Dec-2008	2	17-Feb-2009	18-Feb-2009	FR	WAES0902USA01285	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1941U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal neoplasm, Azotaemia, Chemotherapy, Coma, Haemorrhage, Rhabdomyosarcoma, Surgery

Symptom Text: Information has been received from a Foreign Authority (reference number DK-DKMA-20090203) concerning a 15 year old female patient who was vaccinated intramuscularly with the first dose of GARDASIL (lot # 1941U, batch # NJ01850, site of administration not reported) on 23-DEC-2008. It was reported that the patient experienced rhabdomyosarcoma on 25-Dec-2008. She was diagnosed with rhabdomyosarcoma (date of diagnose not reported). The sarcoma presumably had its origin in the patient's uterus (not confirmed). The patient was hospitalized (date not reported) and placed in coma (date not specified) at the hospital intensive unit. The patient's abdomen was opened due to an inoperable, rapidly growing tumor which at the time of acute operation had grown rapidly to the size of a full term pregnancy (date not specified). The patient received chemotherapy (onset date not specified) and experienced complications in form of uraemia and bleeding (not further specified). The course of the disease was reported as unexpectedly fast and aggressive. Initially, before the expansion of the abdomen, the adverse event was interpreted as appendicitis. At the time of report to the Health Authorities the condition of the patient was stable and she was scheduled to be taken out of coma the next day (date not reported). It was reported that the patient was healthy and did not suffer from any known diseases at the time of vaccination. The patient received no concomitant vaccinations or medication. At the time of report the patient had not recovered. Other business partner numbers include: E2009-01070. No further information is available.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339686-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Aug-2008	01-Aug-2008	0	17-Feb-2009	18-Feb-2009	--	WAES0902USA01640	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Electroencephalogram

Symptom Text: Information has been received from a Nurse Practitioner concerning a female who approximately 6 months ago was intramuscularly vaccinated with the third dose of GARDASIL, shortly after which the patient experienced seizures. The patient's mother is still taking the patient to the doctor a lot. Electroencephalography (EEG) was performed but the result was unspecified. At the time of reporting, the patient's outcome was unknown. The nurse practitioner did not administer any of the vaccinations. Upon internal review, seizures was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 339687-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jan-2008	01-Apr-2008	90	17-Feb-2009	18-Feb-2009	IA	WAES0902USA01693	10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1264U	2	Left arm	Unknown	HPV4

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Dyskinesia, Headache, Loss of consciousness, Muscle twitching, Myoclonic epilepsy, Neurological examination abnormal, Photophobia, Tremor

Symptom Text: Information has been received from a Registered Nurse (R.N.) concerning a 17 year old female with no family history of seizures or drug allergies who received all three doses of GARDASIL and then experienced seizures. All 3 doses were administered at a different facility and the patient just started coming to the nurse's office in December 2008 so the dates or lot number of the GARDASIL administered were not available. The patient was vaccinated with the third dose of vaccine in mid-January 2008. The seizures began in April 2008. In December 2008 the seizures became consistent and occurred daily. Starting 09-FEB-2009 the patient experienced blackouts. A neurologist determined the patient was having monoclonic seizures and prescribed KEPPRA and DILANTIN. The KEPPRA would be discontinued and replaced with LAMICTAL. Neurological tests indicated abnormal electroencephalogram. The nurse also mentioned that the patient has been experiencing headaches but had no further information about them. At the time of reporting the patient was getting worse. The patient was hospitalized and was seen by a neurologist. Additional information has been requested. 2/24/09 Received hospital medical records of 12/10-12/11/2008. FINAL DX: myoclonic seizures Records reveal patient experienced HA, photophobia x 2 days then had involuntary jerking/shaking/twitching episode while in class 12/9. Neuro consult done. Tx w/meds. 3/5/09 Received Neuro medical records of 1/15/09 FINAL DX: seizure disorder, generalized, myoclonic Records reveal meds were adjusted.

Other Meds: None

Lab Data: electorencephalography, abnormal LABS: CBC WNL, plts 423(H). CO2 14(L), total protein 5.7(L) EEG abnormal. Brain MRI WNL.

History: None PMH: chronic HAs, shaking/jerking episode 4/08, ADHD, possibly bipolar disorder. Family hx: Factor XI elevated, DVT, PE, meningioma, lung & brain cancer.

Prex Illness:

Prex Vax Illns:

Vaers Id: **339688-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Jan-2009	16-Jan-2009	1	17-Feb-2009	18-Feb-2009	FR	WAES0902USA01719	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	US30960		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Feeling cold, Injection site pain, Musculoskeletal stiffness, Pyrexia

Symptom Text: Information has been received from Health Authority (reference no. 2009-00428) on 05-FEB-2009 concerning a 15 year old female adolescent who on 15-JAN-2009 was vaccinated intramuscularly with a dose of GARDASIL (batch #US30960, site of administration not reported). After 24 hours the patient developed fever (39 degrees Celsius), fatigue, neck stiffness, feeling cold and injection site pain. A meningism was excluded in the physical examinations of the patient. A blood count was unremarkable, the C-reactive protein increased to 27 and a serology for influenza A and B was also negative. After 4 days the patient recovered without damage. Fever, fatigue, feeling cold, injection site pain and neck stiffness were considered to be important medical events. Other business partner numbers included E2009-01067. No further information is available. Case is closed.

Other Meds: Unknown

Lab Data: body temp, 39 C; serum C-reactive protein, 27; Serum influenza A virus Ab, negative; serum influenza B virus Ab, negative; complete blood cell count, unremarkable

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **339693-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	Unknown	Unknown		17-Feb-2009	18-Feb-2009	FR	WAES0902KOR00007	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cardiogenic shock

Symptom Text: Information has been received from a health professional (a nurse) via a company representative (sales) concerning a teenage female who was vaccinated with the first dose of GARDASIL. This is a hearsay report in the absence of an identifiable patient. Attempts are being made to verify the existence of a patient. The reporting nurse (outpatient injection room) heard this case from another nurse in a general ward. The patient was vaccinated with the first dose of GARDASIL (the date of vaccination was not reported). Subsequently the patient experienced cardiogenic shock. The patient received CPR in ER due to cardiogenic shock. The outcome and the causality with GARDASIL was not reported. The patient's cardiogenic shock was considered as an other important medical event. The company representative asked to PV staff whether there have been adverse events of cardiogenic shock after vaccination of GARDASIL. The company representative also suspected that this case might be rumor. Attempts have made to receive additional information by telephone but information has not received at the time of this report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **339694-1** **Related reports:** 339694-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Aug-2008	01-Sep-2008	27	17-Feb-2009	18-Feb-2009	--	WAES0902USA02156	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Convulsion, Dizziness, Eating disorder, Gastric disorder, Gastrointestinal disorder, Headache, Loss of consciousness, Tremor, Weight decreased

Symptom Text: Information has been received from a kindergarten teacher concerning her husband's relative's churchmember's daughter's friend at school, a girl who in August 2008 was vaccinated with the third dose of GARDASIL. The patient developed similar symptoms as her friend (WAES #0902USA01121) noted below, most of which started in September 2008. Headache, seizures, quit eating, passed out, lost weight, gastric disorder, blood pressure dropping extremely low, dizziness, tremors, and digestive disorder. It was also noted that this patient's digestive tract issues were worse. At the time of the report, the patient had been out of school about the same amount of time as her friend, approximately 8 or 9 weeks. The reporter considered both girls' symptoms to be due to the vaccine. Attempts are being made to verify the existence of an identifiable patient and reporter. Upon internal review, seizures is considered to be an other important medical event.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339694-2** **Related reports:** 339694-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		26-Feb-2009	04-Mar-2009	NM		06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness, Migraine, Pain

Symptom Text: Black outs, migraines, unexplained body aches. Progression to seizures in FEB, 2009. Dates vaccine given: 1st unknown, 2nd 3/08 and 3rd 8/08

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339695-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Nov-2007	16-Nov-2007	0	17-Feb-2009	18-Feb-2009	MI	WAES0711USA06688	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received through the Merck pregnancy registry from a physician concerning a 17 year old female who on 16-NOV-2007 was vaccinated with the first dose of GARDASIL. Subsequently, the patient learned that she is pregnant. The pregnancy was confirmed by a pregnancy test. Concomitant therapy included injection with the first dose of VARIVAX on 16-NOV-2007. Other concomitant therapy included HAVRIX and MENACTRA. No adverse side effects were reported as a result of this exposure. The patient sought unspecified medical attention. Follow up information was received from the nurse via phone call. It was reported the baby was "fine", healthy and normal. The reporters now see the baby was well. The baby was born by C-section (Caesarean-section) with no complications but the reporter did not know the indication for the C-section. The baby weighed 7 lbs 9 oz and was 18 and a half inches long. Upon internal review, "the baby was born by C-section" was determined to be an other important medical event. No further information was available.

Other Meds:

Lab Data: Beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 10/19/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339696-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	03-Jan-2009	Unknown		17-Feb-2009	18-Feb-2009	FR	WAES0902USA01427	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Aphonia, Dysphonia, Inappropriate schedule of drug administration, Stress, Vocal cord atrophy, Vocal cord disorder

Symptom Text: Information has been received from a pharmacist concerning a 29 year old female who on 03-JAN-2009 was vaccinated with a second dose of GARDASIL (batch number not reported). Several months later, the patient experienced dysphonia, characterized by a hoarse voice and aphonia. She had a work interruption during 3 weeks. In January 2009 she consulted two otorhinolaryngologists who did not make a diagnosis, and a phoniatrician who diagnosed compressed vocal cords. The patient was treated with cortisone and anti-inflammatory drugs. It is noteworthy that the patient was under antidepressants treatment, that she was a light smoker and did not take any alcohol. Furthermore, there was a possible context of stress. At the time of reporting, the outcome was not reported. Dysphonia and vocal cord atrophy were considered to be medically significant (other important medical events). Other business partner numbers included E2009-01100. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Smoker

Prex Vax Illns:

Vaers Id: 339697-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Apr-2008	01-Oct-2008	168	17-Feb-2009	18-Feb-2009	--	WAES0902USA01700	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	2	Left arm	Intramuscular	HPV4 MNQ

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Balance disorder, Convulsion, Depersonalisation, Dizziness, Fall, Fatigue, Hypoaesthesia, Muscular weakness, Nausea, Restless legs syndrome, Syncope, Urinary incontinence, Vestibular neuronitis

Symptom Text: Information has been received from a Registered Nurse concerning her daughter (a 15 year old female) who in August 2008 was vaccinated with the third dose of GARDASIL (lot number was not available). The patient experienced leg weakness, dizziness, fatigue and syncope after receiving her third dose of vaccine. At the time of reporting the patient was not recovered. Follow-up AE Information was received from the Registered Nurse by phone concerning her daughter with no pertinent medical history and drug allergies who was vaccinated with her third dose of GARDASIL in April 2008 (not August 2008 as previously reported). Date of birth of the patient is 19-JUN-1993. Patient is not pregnant. Lot #s of GARDASIL are unspecified. Her symptoms began in October 2008. In addition to leg weakness, dizziness, fatigue and syncope the patient has also been experiencing seizure-like activity. No other vaccinations was administered with GARDASIL. Patient is on AVIANE birth control. The patient has seen a neurologist and has had an EEG, EMG of lower extremities and MRI of brain, MRI of abdomen and lab work. All tests have all come back negative. Dose 1 was administered on an unspecified date and dose 2 was administered on 09-SEP-2007. The patient's symptoms are getting worse. The syncope and seizure-like activity are occurring more often. No hospitalization, not life-threatening, not a significant disability. No treatment and no medication have been prescribed at this point. Upon internal review, seizure-like activity was determined to be an other important medical event. The patient sought medical attention. Additional information has been requested. 2/24/09 Received PCP medical records of 11/7/08, Records reveal patient experienced abdominal pain, dizziness, numbness & urinary incontinence x 1. Refered to Neuro. 3/4/09 Received Neuro medical records of 11/18/2008-2/12/2009. FINAL DX: right peripheral vestibular dysfunction, vestibular neuronitis & restless leg syndrome Records reveal patient experienced episodes of diseq

Other Meds: Aviane

Lab Data: Electroencephalography, 10/??/08, negative; Electromyography, 10/??/08, for lower extremities: negative; Magnetic resonance, 10/??/08, for brain: negative; Magnetic resonance, 10/??/08, for abdomen: negative; Laboratory test, 10/??/08, nega

History: None PMH: aching, cramping,numbness, tingling of LEs w/urge to move legs for several years, esp at night. Depo-provera./

Prex Illness:

Prex Vax Illns:

Vaers Id: **339698-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Mar-2008	Unknown		17-Feb-2009	18-Feb-2009	CA	WAES0902USA01836	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a female with penicillin and sulfa allergy and a history of knee surgery and tube placed in her ear as a child who in March 2008, was vaccinated with a first dose of GARDASIL 0.5 mL and in May 2008 was vaccinated with a second dose of GARDASIL. The reporter was unaware if patient received her third dose. Concomitant therapy included "birth control". On unknown date, the patient experienced seizures. It was unknown after what dose seizures occurred. The patient sought unspecified medical attention. At the time of reporting, the outcome was unknown. Upon internal review, seizures was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Joint disorder; Ear disorder

Prex Illness: Penicillin allergy; Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339701-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	01-Jan-2009		17-Feb-2009	18-Feb-2009	FR	WAES0902USA01540	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts

Symptom Text: Information has been received from a physician general practitioner concerning a 14 year old female patient who developed a condyloma in January 2009 after she had received the third dose of GARDASIL (batch # not reported) via intramuscular route on an unspecified date in 2008. The patient was going to undergo surgical excision of the lesions. At the time of reporting, the outcome was not provided. Condyloma was considered to be an other medically important event as it was medically significant. Other business partner numbers include: E2009-00995. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339702-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Feb-2009	18-Feb-2009	FR	WAES0902USA01056	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from a pharmacist concerning a female patient (age unspecified) who developed a beginning of multiple sclerosis on an unspecified onset of time after she had received the three doses of GARDASIL (batch # not reported) on unreported dates. There was no other information. At the time of reporting, the outcome was not provided. The reporter considered multiple sclerosis to be an other important medical event as it was medically significant. This is one of several reports from the same source. Other business partner numbers include: E2009-01096. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339703-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Oct-2008	27-Oct-2008	0	17-Feb-2009	18-Feb-2009	FR	WAES0902USA01539	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Condition aggravated, Convulsion, Dizziness, Pain, Syncope, Urinary incontinence, Vomiting

Symptom Text: Information has been received from a health authority under reference number of DK-DKMA-20092932 concerning a 15 year old female with a history of fainting following a pain, who on 27-OCT-2008 was vaccinated with a dose of GARDASIL IM. After vaccination, the patient fainted with urinary incontinence and convulsions. The patient experienced dizziness that lasted hours after vaccination. The patient also experienced vomiting. The patient was admitted to hospital on the same day, and the patient recovered from all symptoms on the same day. Duration of hospitalization was not reported. Additional information has been requested. Other business numbers included E2009-01136.

Other Meds: Unknown

Lab Data: Unknown

History: Syncope

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339704-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Aug-2008	Unknown		17-Feb-2009	18-Feb-2009	FR	WAES0902USA01861	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rheumatoid arthritis

Symptom Text: Information has been received from a physician concerning an 18 year old female who in August 2008, was vaccinated with GARDASIL (number in series unspecified, batch # not reported). On unknown date, the patient experienced rheumatoid arthritis. At the time of reporting, the outcome was not provided. Rheumatoid arthritis was considered to be medically significant (an other important medical event). Other business partner numbers included E2009-01227. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **339706-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	31-Dec-2008		17-Feb-2009	18-Feb-2009	--	WAES0902USA01121	18-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Asthenia, Blood pressure decreased, Chelation therapy, Convulsion, Dizziness, Eating disorder, Fluid replacement, Gastric disorder, Headache, Hyperbaric oxygen therapy, Loss of consciousness, Neurological symptom, Oxygen supplementation, Sinus disorder, Tremor, Weight decreased

Symptom Text: Information has been received from a kindergarten teacher concerning her husband's relative'S churchmember's daughter, a 14 year old girl who on an unspecified date was vaccinated with the third dose of GARDASIL. After getting all three doses of GARDASIL, the patient was treated by a holistic doctor for the following experiences attributed to the GARDASIL vaccine: headache, "stomach stays inflamed", blood pressure dropping extremely low causing dizziness and passing out, tremors and seizures. The patient had a sensation that she was going to pass out in bed one night. The next night, on 31-DEC-2008, it happened. Her mattress was moved to the floor for safety reasons. The family decided she cannot be left alone anymore. The patient would not be returning to school. The doctor said she would miss this semester. The school has set her up with online classes so she won't miss any of her credits. It was reported that "she doesn't feel good enough for any of that as yet, but she's moving in the right direction". She was sleeping in a hyperbolic chamber at night to help get oxygen into her body. That was helping. She was also on oxygen during the day for the same reason. She was receiving electrolyte drinks. She was to begin nutritional IV's to supply her body with nutrients. The chemicals in her body have built barriers and she is not receiving the nutrients from food that she needs. She has lost weight. She had quit eating for awhile but now the doctor has her eating every two hours. She had an appointment with a homeopathic neurologist scheduled. The family reported problems with the patient's veins. A nurse tried to put a shunt in and it infiltrated after 2 days. The nurse tried 5 times and couldn't get the IV back in. The doctor wanted a central line put in. The patient had "a little sinus thing going on" and couldn't get in the hyperbaric chamber for most of the last week. She realy began to have some bad days. She started having small seizures (19-JAN-2009). But her "sinus thing' got better so she could stand for

Other Meds: Unknown

Lab Data: plasma iron assay, extremely high

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **339713-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Feb-2009	06-Feb-2009	0	17-Feb-2009	19-Feb-2009	VA		19-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling hot, Immediate post-injection reaction, Loss of consciousness

Symptom Text: GARDASIL injection given in left deltoid at 4:15 pm, client stated she was dizzy and felt hot at that time. Client lost consciousness at 4:16 pm, was assisted to lie down. Client able to answer questions at 4:20 pm, BP 72/50, pulse 72. BP 88/50 at 4:35pm.

Other Meds:

Lab Data: None

History: Allergic to sulfa

Prex Illness:

Prex Vax Illns:

Vaers Id: **339718-1 (S)** **Related reports:** 339718-2; 339718-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Nov-2008	29-Nov-2008	26	17-Feb-2009	19-Feb-2009	IN		10-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2927AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0548X	0	Right arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Acute respiratory failure, Aphasia, Asthenia, Blood product transfusion, Chronic respiratory failure, Convulsion, Disseminated intravascular coagulation, Encephalitis, Encephalitis viral, Gait disturbance, Gastrointestinal tube insertion, Hypophagia, Hyporeflexia, Hypotension, Hypotonia, Intensive care, Mechanical ventilation, Mental status changes, Partial seizures, Pyrexia, Renal failure acute, Septic shock, Somnolence, Staphylococcal identification test positive, Tracheostomy, Transfusion, Unresponsive to stimuli

Symptom Text: Approx 3 weeks after getting 1st set of Gardasil, patient complained that she was weak and was having a hard time speaking. On 11/29/08 patient had 2 seizures. She was was taken to the ER. Since the first few days of her illness, she stopped being able to talk, walk and has been completely unresponsive. She is on a ventilator & has a feeding tube. She has neurological movements. All of the testing done shows that patient has encephalitis. The cause of the Encephalitis is a reaction to the Gardasil Vaccine. 2/18/09 Received hospital medical records of 12/1-12/4/2008. FINAL DX: meningoencephalitis w/significant mental changes & seizures Records reveal patient experienced seizure that progressed to loss of speech, sustained focal seizures, oral intake reduced, drowsiness, floppy. Developed fever in hospital. Neuro & ID consult done. Tx w/antiseizure meds, antivirals, antibiotics. Transferred to higher level of care peds neuro ICU. 3/9/09 Received ER records of 12/5/08. FINAL DX: Encephalitis/encephalopathy; seizure disorder; history of depression w/suicidal attempts Records reveal patient had been transferred from outlying hospital. Exam revealed drowsiness, not able to follow commands, PERRL, hypertonicity of all limbs, DTRs increased. No PICU bed available & held in ER. Neuro consult done. Tx w/antivirals & continued on antiseizure meds. 3/9/09 Received hospital medical records of 2/10-currently inpatient FINAL DX: recent viral encephalitis(presumed HSV) & subsequent neurologic devastation presented w/MSSA septic shock, DIC, acute on chronic respiratory failure, acute renal failure, s/p tracheostomy Records reveal patient had been d/c from PICU w/HSV encephalitis 10/2008 w/resulting severe neurological damage. Now w/fever, hypotension & decreased mental status. Transferred from outlying ER w/platelets of 17. Tx w/IV antibiotics, plts/FFP/PRBC transfusions, pressors. Patient trach to vent w/large amount yellow sputum.

Other Meds: N/A

Lab Data: MRI,Spinal Tap,CT scan, EEG, Echo gram, EKG and multiple other tests. She has been hospitalized. LABS: CBC & CMP WNL. ESR 63(H). CT & MRI head WNL. EEG abnormal. CSF: WBC 84(H), lymphs 94%(H), protein & CSF WNL.

History: None PMH: Family hx: epilepsy

Prex Illness: None

Prex Vax Illns: Encephalitis~HPV (Gardasil)~1~14~Patient

Vaers Id: **339718-2 (S)** **Related reports:** 339718-1; 339718-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-Nov-2008	29-Nov-2008	24	10-Mar-2009	12-Mar-2009	--		13-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abasia, Asthenia, Confusional state, Convulsion, Dizziness, Headache, Intensive care, Malaise, Mechanical ventilation, Tracheostomy, Unresponsive to stimuli

Symptom Text: Pt went to her pediatrician for her physical. Prior to getting her first dose of GARDASIL on 11/5/08, Pt was a perfectly healthy 13yr old. Pt was a straight A student. On 11/28/08, Pt complained that she was feeling dizzy and had a headache. After resting that night, she awoke the next day not feeling better. On 11/29 after she rested during the day, she complained that she was feeling weak. That afternoon, Pt had 2 seizures. She was taken to the emergency room. Pt was very confused and had a difficult time talking. After being transferred to a hospital that had a neurologist on staff. Pt's condition only got worse and within 3 days, she wasn't able to talk, walk, eat, sit up, or respond. She was air lifted to Hospital. She has been struggling ever since. She is unresponsive, on a ventilator, has a tracheostomy tube. She has had countless test that show negative results. She is still in the Intensive Care Unit in Hospital.

Other Meds:

Lab Data: Since her illness, Pt has had countless testing done. Those include but are not limited to, CT scan, MRI, EEG, EKG, blood work, X rays. She has been in several hospitals as a result of her illness.

History: No Known conditions.

Prex Illness:

Prex Vax Illns:

Vaers Id: **339718-3 (S)** **Related reports:** 339718-1; 339718-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Nov-2008	29-Nov-2008	26	29-Apr-2009	30-Apr-2009	--	WAES0903USA05055	30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Right arm	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Aphasia, Asthenia, Brain oedema, Computerised tomogram, Convulsion, Echocardiogram, Electrocardiogram, Electroencephalogram, Encephalitis, Gastrointestinal tube insertion, Intensive care, Laboratory test, Lumbar puncture, Mechanical ventilation, Nuclear magnetic resonance imaging, Unresponsive to stimuli

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Act. A 13 year old female who on 03-NOV-2008 was vaccinated with GARDASIL (lot number, route and site not reported) into her right arm. Approximately 3 weeks after getting 1st set of GARDASIL, on approximately 24-NOV-2008 the patient complained that she was weak and was having a hard time speaking. On 29-NOV-2008 the patient had 2 seizures. She was taken to the emergency room (ER). Since the first few days of her illness, she stopped being able to talk, walk and has been completely unresponsive. She was on a ventilator & had a feeding tube. She had neurological movements. All of the testing done showed that the patient had encephalitis. The cause of the encephalitis movements. All of the testing done showed that the patient had encephalitis. The cause of the encephalitis was a reaction to the GARDASIL vaccine. Magnetic resonance imaging (MRI), Spinal Tap, Computed tomography (CT) scan, electroencephalogram (EEG), Echo gram, Electrocardiography (EKG) and multiple other tests were performed with no results reported. The patient required an emergency room visit and hospitalisation and the reporter considered the events as serious. No further information is available. Abasia, aphasia, asthenia, convulsion, encephalitis, gait disturbance, gastrointestinal tube insertion, mechanical ventilation and unresponsive to stimuli were considered to be disabling and immediately life-threatening. The original reporting source was not provided. The VAERS ID# is 339718. The original reporting source was not provided. The VAERS ID# is 339718. Follow-up information has been received from a nurse practitioner who received an email concerning a 13 year old female who was vaccinated with a dose of GARDASIL and experienced a serious adverse reaction. The email stated that the patient spent 4 months in the intensive care unit in a hospital due to brain infection and swelling. It also stated that the patient has no muscle control, was

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339723-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	10-Feb-2009	10-Feb-2009	0	17-Feb-2009	19-Feb-2009	IN		19-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest discomfort, Hypoaesthesia

Symptom Text: Mom states that 4 hours after immunization that Hannah complained of "butt & thighs are numb & chest feels jittery". Did not call physician and symptoms were gone in the morning. Mother refuses future HPV.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339757-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	05-Jan-2009	07-Jan-2009	2	18-Feb-2009	20-Feb-2009	CA		13-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0573X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Balance disorder, Condition aggravated, Confusional state, Depressed mood, Disturbance in attention, Dizziness, Dysthymic disorder, Fatigue, Hyperreflexia, Nausea, Personality disorder, Psychomotor skills impaired, Tachyphrenia

Symptom Text: Weakness, nausea, tiredness, confusion, off balance AM & PM, racing thoughts and actions in the AM. 2/25/09 MR received. HPV vax 12/2/08 and 1/5/08. Pt to be seen for cognitive eval on 1/23/09, but pt was 45 minutes late. Pt c/o dizziness, weakness and difficulty concentrating. Referred to ER for physical complaints. Not seen in ER. Consult (+) for hyperreflexia of R upper extremity. Sent for MRI. 3/9/09 Additional records received. Psych consult states pt has hx of depressive sx since 2003. Recently d/c antidepressant. Started on another recently. Exam with some psychomotor slowing and depressed mood. DX: Dysthymia. Cluster B personality features. Arthralgia of knees. Anemia-on iron. Later eval reports sx may be r/t Lupus dx since MRI (-)

Other Meds: None at the time

Lab Data: Labs and diagnostics: MRI brain (-). X-ray spine (+) for dextroscoliosis. Knee X-ray (+) for ? quadreiceps tendinosis. ESR 27.

History: Depression. PMH: Lupus. Mild cognitive impairment. Tinnitus. Headache. PTSD. Major depression recurrent. R knee arthralgia

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339760-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Jan-2009	15-Jan-2009	0	18-Feb-2009	19-Feb-2009	MN		19-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pallor

Symptom Text: Pt given GARDASIL vaccine about 15 minutes later. Pt had light headiness and dizzy, pale and nausea.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339768-1 (S)** **Related reports:** 339768-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	16-Jan-2009	25-Jan-2009	9	18-Feb-2009	20-Feb-2009	KY		09-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	2	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Deep vein thrombosis, Liver function test abnormal, Pain in extremity, Viral infection

Symptom Text: 1/6/09 - Vaccine administered. 1/19/09 - Developed severe viral symptoms. 1/25/09 - Dx with DVT and hospitalized; put on Heparin. 1/27/09 - D/C on Lovanox inj and Coumadin. 2/26/09-records received-for DOS 1/26-1/27/09-DC DX: Left lower extremity deep vein thrombosis in left mid superficial femoral vein to popliteal vein. Possible infectious mononucleosis versus cytomegalovirus (acute). Elevated liver function tests. Presented with 3 day history of left lower extremity pain

Other Meds: Yaz (1st pack)

Lab Data: Ultrasound; numerous blood tests. Doppler ultrasound demonstrated 2/26/09-records received-Left lower extremity deep vein thrombosis in left mid superficial femoral vein to popliteal vein. Anemia with hematocrit of 33.3. Elevated LFTs.

History: 2/26/09-records received- Recently started oral contraception use Yaz 3 weeks prior to onset of symptoms.

Prex Illness: 2/26/09-Last week C/O sore throat, cervical lymphadenopathy, excessive fatigue with increased sleeping, hepatic tenderness and e

Prex Vax Illns:

Vaers Id: **339768-2 (S)** **Related reports:** 339768-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	10-Jul-2008	10-Jul-2008	0	18-Feb-2009	19-Feb-2009	KY	WAES0902USA01484	20-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Dysstasia, Gait disturbance, Inappropriate schedule of drug administration, Pain in extremity, Pyrexia, Thrombosis

Symptom Text: Information has been received from an office manager who is the mother of a 23 year old female with a medical history of broken hand and wrist injury which required plate on hand and knee injury (ruptured bursa), who on 22-APR-2008 was vaccinated with the first dose of GARDASIL IM 0.5 mL. On 10-JUL-2008, the patient was vaccinated with the second dose of GARDASIL IM 0.5 mL and on 16-JAN-2009, the patient was vaccinated with the third dose of GARDASIL (Lot number 0947X) 0.5 mL IM in the left deltoid. Concomitant therapy included YAZ. On 19-JAN-2009, the patient developed a fever. The patient had positive markers for mononucleosis but had a series of pending tests. On 23-JAN-2009, the patient experienced left leg pain. The pain continued for the next couple of days and on 25-JAN-2009 she went to the emergency room where she was diagnosed with a blood clot. She was transferred to another hospital because there were no beds and was hospitalized for 3 days. An ultrasound was performed which was positive for blood clot. The patient was treated with heparin for the clots. On 27-JAN-2009, the patient was discharged with LOVENOX and COUMADIN. The patient will be on the blood thinner for a minimum of 3-6 months. Currently, the patient was not able to walk long distances or stand for long periods of time. The patient was not able to play her usual sports because of being on blood thinners. As of 09-FEB-2009, the patient was recovering. The blood clots was considered to be immediately life-threatening and disabling by the office manager. This is an amended report. The GARDASIL dose given closest to the earliest AE onset date was changed from the third dose given on 16-JAN-2009 to the second dose given on 10-JUL-2008. Additional information has been requested.

Other Meds: YAZ

Lab Data: ultrasound, 01/??/09, positive for blood clot; diagnostic laboratory, 01/??/09, positive mononucleosis markers

History: Hand fracture; Wrist injury; Knee injury; Hand operation; Bursa disorder

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339771-1 (D)** **Related reports:** 339771-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-Apr-2008	26-Oct-2008	181	18-Feb-2009	19-Feb-2009	IL		08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Cardiac arrest, Cardiomegaly, Cough, Pulmonary embolism, Upper respiratory tract congestion

Symptom Text: She developed a pulmonary embolism after having 3 rounds of vaccine GARDASIL. She was a healthy, active teenager. 2/23/09-autopsy report received immediate cause:Massive pulmonary embolism. Mild cardiomegaly. Last several days C/O cough and congestion. 3/9/09-ED records received for DOS 10/26/08-presented in full cardiac arrest after suffering a full and prolonged cardiac arrest, aystole. Expired.

Other Meds:

Lab Data: 3/9/09-records received-WBC 17.3.

History: 5/7/09-records received-5/7/09-records received-office visit 4/21/00-evaluation for dehydration, vomiting, sore throat and febrile. Impression strep pharyngitis. 9/2/05-routine physical. Assessment:overweight. Office visit 1/4/08-C/O lump in neck noticed in 9/07. Intermittently hurts. Assessment:mild lymphadenopathy.

Prex Illness:

Prex Vax Illns: Bloodclot~HPV (Gardasil)~3~13~Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339771-2 (D)** **Related reports:** 339771-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-Apr-2008	26-Oct-2008	181	09-Apr-2009	10-Apr-2009	--	WAES0903USA05057	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Autopsy, Cardiac arrest, Cardiomegaly, Cough, Death, Pulmonary embolism, Respiratory tract congestion

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 13 year old female with blood clot on 28-APR-2008 was vaccinated with the third dose of GARDASIL (lot # reported as 659964/1978U), vaccination route and site not reported). The patient was a healthy, active teenager. On 26-OCT-2008, the patient developed a pulmonary embolism after having 3 rounds of GARDASIL. The patient complained of cough and congestion which lasted several days. Emergency department records for the date of surgery on 26-OCT-2008 was received on 09-MAR-2009, which reported that the patient presented in full cardiac arrest after suffering a full and prolonged cardiac arrest, asystole. The patient expired. Autopsy report was received on 23-FEB-2009 which revealed that immediate cause of death: massive pulmonary embolism, mild cardiomegaly. The original reporting source was not provided. The VAERS ID # is 339771. A standard lot check investigation was performed. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center and was released. No further information is available.

Other Meds: Unknown

Lab Data: WBC count, 10/26/08, 17.3

History:

Prex Illness: Clot blood

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339778-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	12-Jan-2009	12-Jan-2009	0	18-Feb-2009	20-Feb-2009	HI		20-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Palpitations

Symptom Text: Patient vacant 15 minutes after the shot. After 15 minutes when she get up + walk she fell little bit dizzy + palpitation few minutes. Notified provider + provider said it's OK.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339790-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	30-Dec-2008	30-Dec-2008	0	18-Feb-2009	20-Feb-2009	WV		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Pt called office and c/o L upper arm still being sore 2 weeks after injection. Received GARDASIL 12/30/08- Called office 1/14/09.

Other Meds: YAZ ? antibiotic for URI

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: 339798-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	10-Jul-2008	10-Jul-2008	0	18-Feb-2009	19-Feb-2009	KY	WAES0902USA01484	19-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Dysstasia, Gait disturbance, Inappropriate schedule of drug administration, Pain in extremity, Pyrexia, Thrombosis

Symptom Text: Information has been received from an office manager who is the mother of a 23 year old female with a medical history of broken hand and wrist injury which required plate on hand and knee injury (ruptured bursa), who on 22-APR-2008 was vaccinated with the first dose of GARDASIL IM 0.5 mL. On 10-JUL-2008, the patient was vaccinated with the second dose of GARDASIL IM 0.5 mL and on 16-JAN-2009, the patient was vaccinated with the third dose of GARDASIL (Lot number 0947X) 0.5 mL IM in the left deltoid. Concomitant therapy included YAZ. On 19-JAN-2009, the patient developed a fever. The patient had positive markers for mononucleosis but had a series of pending tests. On 23-JAN-2009, the patient experienced left leg pain. The pain continued for the next couple of days and on 25-JAN-2009 she went to the emergency room where she was diagnosed with a blood clot. She was transferred to another hospital because there were no beds and was hospitalized for 3 days. An ultrasound was performed which was positive for blood clot. The patient was treated with heparin for the clots. On 27-JAN-2009, the patient was discharged with LOVENOX and COUMADIN. The patient will be on the blood thinner for a minimum of 3-6 months. Currently, the patient was not able to walk long distances or stand for long periods of time. The patient was not able to play her usual sports because of being on blood thinners. As of 09-FEB-2009, the patient was recovering. The blood clots was considered to be immediately life-threatening and disabling by the office manager. This is an amended report. The GARDASIL dose given closest to the earliest AE onset date was changed from the third dose given on 16-JAN-2009 to the second dose given on 10-JUL-2008. Additional information has been requested.

Other Meds: YAZ

Lab Data: ultrasound, 01/??/09, positive for blood clot; diagnostic laboratory, 01/??/09, positive mononucleosis markers

History: Hand fracture; Wrist injury; Knee injury; Hand operation; Bursa disorder

Prex Illness:

Prex Vax Illns:

Vaers Id: **339799-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Jan-2009	08-Feb-2009	24	18-Feb-2009	19-Feb-2009	FR	WAES0902USA01846	19-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Dyspnoea, Muscle twitching, Tremor

Symptom Text: Information has been received from a retired physician concerning her 15 year old granddaughter who was vaccinated with a third dose of GARDASIL (lot# and route not reported) into the upper arm mid of January 2009. On 08-FEB-2009 the patient developed weakness, trembling and twitching of arms and legs and difficult breathing during holidays. The patient was hospitalized on the same day. The patient has not recovered at the time of reporting. The first and second dose of GARDASIL (both lot# not reported) administered in May 2008 and July 2008 were well tolerated. Other business partner numbers include: E2009-01115. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **339802-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Dec-2008	12-Feb-2009	73	18-Feb-2009	19-Feb-2009	IL	WAES0902USA02190	18-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1423X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Dizziness, Gaze palsy, Grand mal convulsion, Loss of consciousness, Moaning, Nausea, No reaction on previous exposure to drug, Syncope, Tinnitus

Symptom Text: Information has been received from a physician concerning a 22 year old female who was vaccinated with the second 0.5 ml dose of GARDASIL (lot# 1423X) 2 months ago (approximately December 2008). On 12-FEB-2009 the patient experienced a seizure. The patient was sent to the emergency room. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested. 3/9/09 Received GYN medical records of 10/08-2/12/2009 along w/note that no lot #s are available. FINAL DX: Records reveal patient experienced condyloma & had cryo tx 11/20/08, 12/8/08, 12/18/08, 1/8/09, 1/22/09, 2/12/09. HPV #1 given LA on 12/8/08, HPV #2 given 2/12/09 LA. On 2/12 had syncopal episode then tonic-clonic seizure x approx 1 min w/eyes deviation upwards, groaning but no loss of sphincter control. Sent to ER for observation & w/u. 3/16/09 Received ER medical records of 2/12/2008. FINAL DX: seizure activity likely secondary to vasovagal syncope Records reveal patient experienced witnessed seizure in GYN office s/p HPV shot. Episode preceded by dizzness, ringing in ears & then blacked out. When came too had dizziness, confusion & nausea.

Other Meds: Unknown

Lab Data: Unknown LABS:CBC & CMP WNL. CT head reported as WNL, no report available.

History: Unknown PMH: irregular menses, dysmenorrhea, genital HPV (+).

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339816-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-Feb-2009	09-Feb-2009	0	18-Feb-2009	20-Feb-2009	PA		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB257AA	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0571X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness, Myoclonus

Symptom Text: Administered HEP A into R deltoid. Then administered GARDASIL into R deltoid. 10-15 seconds later, patient lost consciousness + fell backwards from sitting position onto exam table. About 5 seconds later, pt began to have myoclonus movements on extremities, lasting < 7 seconds.

Other Meds:

Lab Data: None

History: NKDA

Prex Illness:

Prex Vax Illns:

Vaers Id: **339820-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
49.0	F	28-Nov-2008	30-Nov-2008	2	18-Feb-2009	19-Feb-2009	FR	WAES0902AUS00019	19-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0353U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Oropharyngeal pain, Radiotherapy, Tonsillar neoplasm

Symptom Text: Information has been received from a health professional, via CSL as part of a business agreement (manufacturer control No. 2009 02 10 LS1), concerning a 49 year old female who on 28-NOV-2008 was vaccinated with her second dose of GARDASIL (Lot # 0353U, Batch # NH00870, Expiry date 22-FEB-2010). This was inappropriate schedule of drug administration due to the patient's age of 49 years. On 30-NOV-2008, 2-3 days after the second vaccination with GARDASIL, the patient experienced a sore throat and two weeks later, a tonsillar tumour was diagnosed. Subsequently the tonsillar tumour was removed and at the time of reporting on 10-FEB-2009, the patient was undergoing radiation treatment. Upon internal medical review, tonsillar tumour was considered an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339825-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Oct-2008	20-Oct-2008	7	18-Feb-2009	20-Feb-2009	PA		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash macular

Symptom Text: Extensive macular rash extending medial upper arm down to antecubital fossa

Other Meds:

Lab Data: Referred to Dermatology

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339836-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-May-2008	16-May-2008	0	18-Feb-2009	20-Feb-2009	GA		12-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	1	Unknown	Unknown	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Dizziness, Headache, Immediate post-injection reaction, Loss of consciousness, Orthostatic hypotension, Syncope, Syncope vasovagal, Vision blurred, Visual impairment

Symptom Text: Within 10 minutes of receiving GARDASIL, patient passed out, regained consciousness. Since that time - 2 episodes of similar symptoms with loss of vision for a few seconds and feels dizzy. 3/9/09 Received PCP medical records of 12/30/08. FINAL DX: syncope Records reveal patient experienced back pain, knot at left hip, fleeting dizziness, dimming vision beginning w/HPV vaccine & had since had episodes of passing out. Examination revealed orthostatic blood pressure & referred to cardio for tilt table test. Also referred MRI of left hip. 3/9/09 Received Cardiology records of 1/16/2009. FINAL DX: neurocardiogenic syncope Records reveal patient experienced daily episodes of blacking out, seeing stars, HA & blurred vision x 9 mo. Instructed to increase fluid intake, add salt to diet & exercise to strengthen legs & augment venous return to heart.

Other Meds:

Lab Data: Cardiology consult LABS: EKG WNL. Tilt table test.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **339838-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Jan-2009	12-Jan-2009	0	18-Feb-2009	19-Feb-2009	AL	AL0902	19-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1311X	1	Right arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB520AA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB239AA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Eye oedema, Pruritus, Rash erythematous

Symptom Text: Approx. 30 minutes after injections began ruritic episode with erythematous rash on inner arms, One area on chest with slight edema of eyes. Sent to M.D., M.D. sent to E.R.

Other Meds: Novalog Insulin 70/30 mix 48 units 9AM- Metaformin 100mg at HS Reg. insulin per sliding scale

Lab Data: Pt. with type II diabetes.

History: Diabetes type II, PinsinHips 2003

Prex Illness: Anxious, no illness

Prex Vax Illns:

Vaers Id: **339842-1** **Related reports:** 339842-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		18-Feb-2009	19-Feb-2009	MI		19-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Feeling hot, Immediate post-injection reaction, Musculoskeletal stiffness, Myalgia, Oedema peripheral

Symptom Text: Received HPV Vaccine dose #3. Did fine in office. Fifteen minutes after leaving (while still in car) patient noticed that her hand was quite swollen and red. No difficulty breathing, lip swelling or other swelling noted. Patient "felt warm". Swelling persisted for about an hour that night and swelled again the next day mainly after basketball practice. Deltoid pain noted since shot. No fever. Stated "hard to turn neck at basketball practice". Attendance at school not affected.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339842-2** **Related reports:** 339842-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	04-Feb-2009	04-Feb-2009	0	25-Feb-2009	04-Mar-2009	MI		04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal stiffness, Oedema peripheral, Skin warm

Symptom Text: 15 min after injection, (R) hand swollen. No resp sx, no hives, felt "warm". Swelling decreases and increases through SAT AM. Neck muscle felt stiff during Basketball Practice but was able to play/go to school.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **339848-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Feb-2009	18-Feb-2009	0	18-Feb-2009	19-Feb-2009	NM		19-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2683AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Pain in extremity

Symptom Text: VACCINE GIVEN AT 0915 LD IM WAITED 20 MIN IN THE LOBBY WITHOUT REACTIONS. LEFT AND WENT BACK TO SCHOOL AT 1120 SHE COMPLAINED OF LEFT ARM PAIN AND DIZZINESS MOTHER WAS NOTIFIED TO PICK UP DAUGHTER AT SCHOOL. PATIENT ARRIVED AT 1215 AT OUR CLINIC VITALS T 98.0, BP 118/72, P 105 R 20, PATIENT STATES SHE FEELS DIZZY. PATIENT SEEN BY DR. AT 1300 VITALS T 97.5, P 82 BP 114/80 R 20 MOTHER STATES PATIENT IS FEELING BETTER. NO OTHER COMPLAINTS VOICED.

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **339854-1 (S)** **Related reports:** 339854-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	24-Jul-2008	10-Sep-2008	48	18-Feb-2009	23-Feb-2009	GA		01-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	2	Left arm	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Angioedema, Anxiety, Choking, Dehydration, Dermatitis allergic, Dyskinesia, Dyspnoea, Eyelid oedema, Hypersensitivity, Idiopathic urticaria, Nasal congestion, Oedema peripheral, Pain, Rash, Throat tightness, Tremor, Urticaria

Symptom Text: 3rd in the series of Guardasil on 7/24/2008. On 9/10/2008, patient went to emergency room in ambulance due to rash and difficulty breathing, assumed allergic reaction to something. On 9/20/2008, patient had 2nd reaction with severe hives, shaking, jerking spasms and dehydration, assumed allergic reaction. Both times treatment was IV benedryl and prednazone pack. Allergist consultation visit the following day resulting in his prescribing use of over the counter allergy meds; Claritin in the AM, Pepsid mid day, Zyrtec at bedtime, benedryl as needed. 9/25/2008 patient was asleep and woke up choking with extreme breathing difficulties, resulting in another ambulance ride and a 3rd emergency room visit. Treatment was IV benedryl and Prednazone pack. Over the next 5 months several (5-7) cases of mild to moderate hives during which patient took over the counter benedryl and hives went away. On 2/09/2008, patient had severe abdominal pain, began having difficulty breathing and noted hives. This resulted in 3rd ambulance ride to emergency room. For 5 months, patient has taken over the counter allergy meds regularly as described above. Up to this point in her life she has had no known allergies, no anaphylaxis and has been in very good health, active in sports. During this 5 months, she has been to the emergency room 4 times, 3 of those with severe breathing difficulties. Symptoms include hives, abdominal pain, swelling of hands and fingers, difficulty breathing all occurring rapidly. This is considered to be a life threatening situation. It appears that this response could have been caused by Guardasil injection from 7/24/2008. 3/17/09-received office records for date of vaccine. Well visit. krk 4/6/09-records received-ED visit 9/O itching and diffuse swelling, facel feels swollen. PE:eyelids slightly swollen. DX:acute allergic reacion. acute allergic rash. ED visit 9/20/08-C/O allergic reaction, ithcy urticarial rash suddenly with some shortness of breath. Previous episodes of urtic

Other Meds:

Lab Data: allergist has performed general bloodwork 4/13/09-records received-Skin testing positive.

History: none 4/13/09-records received- PMH:seasonal allergies.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **339854-2 (S)** **Related reports:** 339854-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	24-Jul-2008	24-Sep-2008	62	26-Mar-2009	27-Mar-2009	GA	WAES0903USA01599	27-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Anaphylactic reaction, Convulsion

Symptom Text: Information has been received from a physician concerning a 20 year old female patient with no pertinent medical history and eye redness who on 04-JAN-2008 was vaccinated with the first dose of GARDASIL (Lot # 659437/1266U) intramuscularly. On 20-MAR-2008 the patient was vaccinated with the second dose of GARDASIL (Lot # 660387/1967U) intramuscularly and on 24-JUL-2008 the patient received the third dose of GARDASIL (Lot # 660620/0571X) intramuscularly. It was reported that approximately two months after receiving the third dose of GARDASIL the patient experienced a delayed anaphylactic allergic reaction. The reaction was described as being severe but there were no specific symptoms provided. It was reported that the anaphylactic reaction has been concurrent. The number of recurrent anaphylactic episodes was unspecified. The patient was seen at the emergency room following each episode and received intravenous fluids and epinephrine. The reporting physician considered the delayed anaphylactic allergic reaction to be other important medical event, life threatening and significantly disabling. A standard lot check investigation was performed for the Lot # 660387/1967U. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center for Biologics Evaluation and Research and was released. A standard lot check investigation was performed for the Lot # 660620/0571X. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center for Biologics Evaluation and Research and was released. A standard lot check investigation was performed for the Lot # 659437/1266U. All in-process quality checks for the lot number in qu

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Eye redness

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339881-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Jan-2009	02-Feb-2009	26	18-Feb-2009	20-Feb-2009	MD		27-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Goitre, Neck mass

Symptom Text: Given 1st GARDASIL 1/7/09 at routine health assessment Patient seen in the office on 2/5/09. Developed lump in her neck on 2/2/09. Diagnosed with goiter. Thyroid testing - T4, T3, TSH normal. Thyroglobulin Ab - negative Has euthyroid goiter.

Other Meds:

Lab Data: Free T4, 1.04; T3, 109.8; TSH, 2.16; Thyroglobulin Ab, neg; Thyroperoxidase AB, neg;

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339885-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jan-2009	03-Jan-2009	1	18-Feb-2009	20-Feb-2009	IL		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Rash, Vomiting

Symptom Text: Vaccine given 1/2/09 symptoms began 01/03/09 included: dizziness, lasted 2 hrs. rash lasted 2 days n with vomiting 1 X. Per the patient mother BENADRYL was given. No other side effects post 2' days.

Other Meds:

Lab Data:

History: Ceclor Med.

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339902-1** **Related reports:** 339902-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Feb-2009	13-Feb-2009	0	18-Feb-2009	20-Feb-2009	CA		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Gaze palsy

Symptom Text: Patient was given vaccine. Approximately 5-7 minutes after patient's eyes rolled back. Upper body began to jerk. Called 911.

Other Meds: AMOX

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **339902-2** **Related reports:** 339902-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Feb-2009	13-Feb-2009	0	23-Feb-2009	24-Feb-2009	CA	WAES0902USA02664	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse concerning a 17 year old female patient who on 13-FEB-2009 was vaccinated with the first dose of GARDASIL, within five minutes post vaccination the patient had a seizure. The nurse reported that the patient was taken and admitted to the hospital. The nurse reported that the patient had been released from the hospital but did not know how long time the patient was in the hospital, and the physician wanted to run some tests to make sure that nothing else was going on with the patient. At the time of the report the patient was recovering. Upon internal review seizures was considered to be as an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339930-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-Jan-2009	20-Jan-2009	1	18-Feb-2009	20-Feb-2009	OH		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash generalised, Urticaria

Symptom Text: Urticarial rash - generalized RX - BENADRYL & PREDNISONE

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339931-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.9	F	15-Jan-2009	15-Jan-2009	0	18-Feb-2009	20-Feb-2009	SC		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	06504	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Myalgia, Nausea

Symptom Text: Approx 5 hours after injection, pt c/o extreme muscle pain in legs arms, back and abdomen. -No local reaction noted @ injection site. Pt also c/o H/A and nausea no V/D no fever. Symptoms lasted until 1-16-09 @ noon. : per mom report.

Other Meds: None

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 339941-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	28-Dec-2007	02-Jan-2008	5	18-Feb-2009	20-Feb-2009	PA		10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abasia, Arthralgia, Arthritis, Aspiration joint, Genital herpes, Impetigo, Joint effusion, Joint swelling, Musculoskeletal stiffness, Oral herpes, Polyarthritis, Rheumatoid arthritis, Synovitis, Tendon pain, Tendonitis

Symptom Text: Developed Rheumatoid Arthritis-- Pain began within 5 days of last dose of GARDASIL vaccination. Severe joint pain--unable to walk. 2/26/09 Received PCP vaccine records & medical records of 1/2-8/29/2008. FINAL DX: Rheumatoid arthritis Records reveal patient had known right knee, left hip & low back pain. By 2/08 had diffuse joint swelling while at college & seen in student health where CRP & RA factor both (+). Referred to Rheum. Tx w/steroids, plaquenil, methotrexate & humira. Right knee synovial fluid drained 6/08. RTC 7/08 w/right heel pain x 1 mo. Dx w/right Achilles tendonitis. Referred to ortho but did not go. RTC 8/08 w/probably genital herpes & oral cold sores. Tx w/antivirals. Symptoms did not resolve, seen in student health & dx w/impetigo. 3/4/09 Received Rheum medical records of 2/08-12/08. FINAL DX: intensely inflammatory additive symmetrical polyarthritis w/flagrant synovitis while on steroids Records reveal patient experienced joint pain, swelling & stiffness beginning 12/07. Exam revealed multiple sites of synovitis, right knee warmth & effusion. Tx w/additional meds of hydroxychloroquine & methotrexate. Humira added later as s/s persisted.

Other Meds: At time- None

Lab Data: 2/18/08 Anachoice screen; Ferritin; Rheumatoid Factor; Creactive protein; CBC; PIT; Differential; Chest x-ray. LABS: WBC 13.9(H). Herpes simplex virus (-). MRI of right knee done 12/2006 abnormal. Noted to have CRP increase & R

History: None PMH: Family hx: juvenile idiopathic polyarthritis.

Prex Illness: None- Healthy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339946-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	03-Nov-2008	Unknown		18-Feb-2009	19-Feb-2009	CA		04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	NOVARTIS VACCINES AND DIAGNOSTICS	88645		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0575X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Migraine

Symptom Text: Chronic Headache (Migraine)

Other Meds: FLONASE nasal

Lab Data:

History: allergic rhinitis

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339947-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Jan-2009	21-Jan-2009	1	18-Feb-2009	23-Feb-2009	NH		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1012X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0575X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Induration, Rash erythematous, Urticaria

Symptom Text: 1/21/09 woke in AM with redness size of baseball then increased to size of softball per dad. 1/23/09 seen in office induration centrally with 16x11 erythematous urticarial Rx.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339952-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-Jan-2009	30-Jan-2009	10	18-Feb-2009	20-Feb-2009	WI		20-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Rash

Symptom Text: The phone call from Pt's mother stating Pt has little red bumps/rash on chest and both arms. Instructed mother to take her to MD for diagnosis. Mother stated she would probably just wait for them to go away.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339956-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
40.0	F	16-Dec-2008	13-Jan-2009	28	18-Feb-2009	20-Feb-2009	TX		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Rash

Symptom Text: Pt c/o rash 3 weeks after injection.

Other Meds: EFLEXOR XR; VALTREX, SEASONIQUE

Lab Data:

History: Allergies - Benzol Peroxide

Prex Illness:

Prex Vax Illns:

Vaers Id: **339960-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	20-Jan-2009	20-Jan-2009	0	18-Feb-2009	20-Feb-2009	OR		20-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Headache, Injection site pain, Insomnia, Myalgia, Pain, Pyrexia, Sluggishness, Somnolence

Symptom Text: One day after receiving injection patient had localized pain at site, aches, drowsy, muscle soreness especially in back down to middle lower back. C/o fever, some headaches, trouble sleeping and hard time getting going in the am.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339966-1** **Related reports:** 339966-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jan-2009	16-Jan-2009	0	18-Feb-2009	20-Feb-2009	AZ		06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3028AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1311X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope 3/3/09-records received-brief syncopal episode after immunizations, resolved without treatment. Seen on 1/19/09 for PPD reading.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **339966-2** **Related reports:** 339966-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jan-2009	Unknown		18-Feb-2009	26-Feb-2009	AZ	WAES0901USA03827	27-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3028AA	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	1311X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 18 year old female patient (weight 113 pounds, height 61.10 inches) who on the morning of 16-JAN-2009 was vaccinated with a first dose of GARDASIL, intramuscularly, lot # 661531/1311X. Concomitant therapy included a first dose of ADACEL, intramuscularly, lot # C3028AA the same day. It was reported that the patient experienced syncope. Patient recovered. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339967-1** **Related reports:** 339967-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Jan-2009	21-Jan-2009	0	18-Feb-2009	20-Feb-2009	AZ		03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	B289CB	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncope

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **339967-2** **Related reports:** 339967-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Jan-2009	21-Jan-2009	0	18-Feb-2009	26-Feb-2009	AZ	WAES0901USA03264	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	B289CB	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1311X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a 12 year old female patient who on 21-JAN-2009 was vaccinated intramuscularly with GARDASIL vaccine (Lot#661531/1311X). Concomitant therapy included HAVRIX. On the same day, the patient experienced syncope after receiving a dose of GARDASIL vaccine. The patient recovered shortly. The reporter did not know if this was her first, second or third dose of GARDASIL vaccine. The patient was seen by a nurse. Follow up information received on 27-JAN-2009. It was reported that the 12 year old female patient, on 21-JAN-2009 was vaccinated intramuscularly into the left arm with the first dose of GARDASIL vaccine (Lot# 661531/1311X). Concomitant vaccination included a first dose of HAVRIX administered intramuscularly into the right deltoid. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **339995-1** **Related reports:** 339995-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	14-Aug-2008	14-Aug-2008	0	18-Feb-2009	20-Feb-2009	MO		20-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2638AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1740U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pain in extremity

Symptom Text: Shortly after vaccination c/o being light headed, dizzy, feeling like she was going to pass out. Slept 2-3 hours, R arm hurt, did not seek medical attention.

Other Meds: None

Lab Data: None

History: Seasonal allergies; Morphine

Prex Illness: None

Prex Vax Illns:

Vaers Id: **339995-2** **Related reports:** 339995-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	14-Aug-2008	14-Aug-2008	0	16-Mar-2009	31-Mar-2009	--	WAES0902USA02431	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Injection site pain, Pain in extremity

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female with drug hypersensitivity to MORPHINE who on 14-AUG-2008 was vaccinated IM with the first dose of GARDASIL 0.5ml (LOT # 659962/1740U). Concomitant therapy included MENACTRA. After receiving her first dose of GARDASIL, the patient experienced dizziness and lightheadedness, and slept for a few hours. The patient also experienced pain in her arm at the injection site. Subsequently, the patient recovered from adverse events (date unspecified). It was reported that the patient sought medical attention: phone call. Additional information has been requested.

Other Meds: MENACTRA

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **339999-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Aug-2008	19-Aug-2008	14	18-Feb-2009	20-Feb-2009	OK		11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	3	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site anaesthesia, Injection site paraesthesia, Paraesthesia, Refusal of treatment by patient

Symptom Text: On 8/5/08 pt rec'd HPV-4. On 1/12/09 when nurse in contact with pt again. Pt reports injection site tingling for 2 weeks then site went numb approx 2" diameter around injection site. I informed I would check with our vaccine advisor at city health dept who advised VAERS and to give 2nd HPV. Our physician notified and documentation out in chart. Pt is refusing further HPV.

Other Meds:

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340000-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	04-Feb-2009	04-Feb-2009	0	18-Feb-2009	23-Feb-2009	OK		25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0847X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Hypoaesthesia, Injection site pain, Pain in extremity, Paraesthesia

Symptom Text: c/o pain numbness going down L arm with injection (in left arm). Numbness, tingling severe within 15 min-Startes within 3 hours numbness @ L foot. Next day bilat fee. Went to ED- told she was having allergic reaction-gave BENADRYL. 2/9/09 to clinic- Neuro/vasc assesment WNL. Went to MD 2/10 -> EMG WNL. 2/11-decreasing numbness lingering.

Other Meds:

Lab Data: EMG-WNL

History: None

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340020-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Jan-2009	28-Jan-2009	0	19-Feb-2009	20-Feb-2009	CA		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2617AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0650X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Nervousness, Pallor

Symptom Text: Gave vaccines, pt. was nervous, I left the room so pt. could get dressed. MOP said pt. got up to change and pt. fell back. Pt. was pale. We laid her down in the bed, gave her water and checked vitals. Was checked by physician after and was cleared to go home. Ok.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340032-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	21-Jan-2009	22-Jan-2009	1	18-Feb-2009	20-Feb-2009	ME		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	MERCK & CO. INC.	1039X	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0570X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2841BA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3031AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nuclear magnetic resonance imaging normal, Ophthalmological examination abnormal, Optic neuritis, Vision blurred

Symptom Text: Developed blurry vision within 24 hrs of above vaccinations seen by optho- optic neuritis, MRI was negative for mass, treated with oral steroids. Was c/o blurry vision & pressure.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340034-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	04-Sep-2008	05-Sep-2008	1	19-Feb-2009	20-Feb-2009	MO		20-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Reported rash on (R) side of face and on arm. Last for 3 days.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340043-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Jan-2009	27-Jan-2009	0	19-Feb-2009	20-Feb-2009	WV		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	2	Gluteous maxima	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope

Symptom Text: Pt had brief near syncopal episode when she got up from exam table, less than 2 minutes after injection. Completely resolved in 10 minutes. Did not completely lose consciousness.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340065-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	15-Jan-2009	15-Jan-2009	0	19-Feb-2009	20-Feb-2009	PA		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1183X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0650X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Palpitations

Symptom Text: Light headed, heart racing, palpitations.

Other Meds: ADDERALL XR 20mg; TQD

Lab Data:

History: ADHD

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340079-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Jan-2009	08-Jan-2009	0	19-Feb-2009	20-Feb-2009	CA		03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	0	Left arm	Unknown	
	DTAP	SANOFI PASTEUR	UT2798BA	5	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Syncope, Unresponsive to stimuli

Symptom Text: Pt had syncope within 3 min, fell to floor, hit head. Unresponsive for several minutes. VS were stable. Went to ER for eval. Recovered, sent home.

Other Meds: None

Lab Data: CMP; CBC; UA; CT of head

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **340093-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Feb-2009	03-Feb-2009	0	19-Feb-2009	20-Feb-2009	FR	WAES0902USA02479	20-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1316U	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Pyrexia, Rash generalised, Thrombocytopenia, Vomiting

Symptom Text: Information has been received from a gynaecologist that a 15 year old female patient was vaccinated with a second dose of GARDASIL (batch # NH45640, lot # 1316U, injection route not reported) into the left upper arm on 03-FEB-2009. In the night p.v. the patient developed vomiting. Subsequently, exact date not reported she complained about fever lasting for 2 days and diarrhea for half a day. The patient was monitored in a hospital for 6 hours, but not hospitalized. She recovered from these events. On 06-FEB-2009, the patient developed generalised exanthema and thrombocytopenia. Blood count on 06-FEB-2009: leukocytes 11000 and thrombocytes 100000. On 09-FEB-2009: thrombocytes 130000, lymphocytosis 55% (not otherwise specified). The patient was recovering from thrombocytopenia at the time of reporting. Outcome for exanthema was not reported. The first dose of GARDASIL (batch # NH38400, lot # 1400U) administered on 31-OCT-2008 was well tolerated. Other business partner numbers include E200901198.

Other Meds: Unknown

Lab Data: WBC count, 06Feb09, 11000; platelet count, 06Feb09, 100000; atypical lymphocyte, 09Feb09, 55%; platelet count, 09Feb09, 130000

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340095-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		19-Feb-2009	20-Feb-2009	FR	WAES0902USA02339	20-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Affect lability, Hypoaesthesia, Multiple sclerosis, Muscular weakness, Pyrexia

Symptom Text: Case received from a health care professional on 13-FEB-2009 and transmitted by a distributor under reference number CM9024. A 16 year old female patient with no relevant medical history reported received the second dose of GARDASIL (IM, batch number not reported) on an unspecified date. 4 days later the patient experienced atypical numbness. 20 days after the vaccination the patient visited a neurologist in his private practice while presenting with symptoms of left side hypoaesthesia, lability and mild muscle weakness. In addition the patient had mild fever at 37.3 degree. A brain MRI scan was performed (unspecified date) and revealed multiple cerebral foci with increased gandolinum uptake in T2 sequences. A possible diagnosis of multiple sclerosis was given. The patient was in good health and was not hospitalized nor received any treatment. The patient had a free medical history and no concomitant treatment. The reporting physician did not associate those adverse events to the vaccination with GARDASIL. Further information is expected. Multiple sclerosis like syndrome and fever were considered to be an other important medical event by the health care professional. Other business partner numbers include E2009-01355.

Other Meds: None

Lab Data: magnetic resonance imaging, brain MRI: revealed multiple cerebral foci with increased gandolinum uptake in T2 sequences; body temp, 37.3 degree

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340096-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		19-Feb-2009	20-Feb-2009	FR	WAES0902USA02476	20-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from a gynecologist concerning a female, age and age group not reported, who was vaccinated with GARDASIL. The physician was told from a customer that the female suffered from multiple sclerosis-like symptoms and was treated in a hospital. No relevant department in this hospital knew about such a case. Multiple sclerosis-like symptoms was reported as an other important medical event. No further details available so far, the case is closed. Other business partner numbers include E2009-01322.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340097-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	19-Nov-2008	20-Nov-2008	1	19-Feb-2009	20-Feb-2009	FR	WAES0902USA02475	20-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash generalised

Symptom Text: Information has been received from a Health Authority (reference number #ES-AGEMED-920696241) concerning a 14 year old female who on 19-NOV-2008 was vaccinated with a dose of GARDASIL (batch number not reported) by intramuscularly route. It was reported that on the day after vaccine administration, 20-NOV-2008 the patient presented with a generalised escarlet-like exanthema and pruritus. XAZAL was prescribed to treat adverse events from the 27-NOV-2008, one tablet per day. The patient was feeling much better. The patient recovered from the generalised exanthema (stop date reported as 19-NOV-2008), pruritus was still ongoing. Case reported as serious by the HA with other medically important condition as criteria. Other business partner number included: E2009-01338. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340112-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	U	31-Dec-2008	15-Jan-2009	15	19-Feb-2009	20-Feb-2009	CO		11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	1	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Depression, Dysarthria, Gastrointestinal disorder, Headache, Hypoaesthesia, Meningitis aseptic, Musculoskeletal stiffness, Nausea, Neck pain, Neurological symptom, Obsessive-compulsive disorder, Oxygen saturation decreased, Paraesthesia, Phonophobia, Photophobia, Speech disorder, Visual impairment, Vomiting

Symptom Text: Nausea, headaches, frequent illness including viral spinal menengitis, numbness and tingling in different areas of the body. First shot 10/31/08, second shot 12/31/08. Symptoms began 1/15/09. No physician is interrested in determining if this is related to Gardasil. 3/6/09 MR received for DOS 2/9-10/2009 with D/C DX: Hx of Aseptic meningitis and Headache. Pt initially presented to local hospital with c/o H/A, neck stiffness and pain, phono/photophobia, GI distress, nausea and vomiting. Pt was DX with aseptic meningitis and admitted x week. Pt currently presnting with transient neuro deficits including L & R sided paresthesias, dysarhtria, and difficulty speaking the last half of words. Pt c/o visual obstruction (like TV snow) during episodes. BP 86/58. O2 sat 90% RA. PE (+) for mild facial asymmetry-? chronic. Started on Lexapro for depression and OCD traits and possibly developing migraines.

Other Meds: Yaz

Lab Data: Labs and diagnostics: LP with WBCs 122-100% monos, CSF protein 109, glucose 57. HSV PCR (-). EEG abnormal-temporal slowing.

History: none. PMH: OCs

Prex Illness: none

Prex Vax Illns:

Vaers Id: **340119-1 (S)** **Related reports:** 340119-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Nov-2008	24-Nov-2008	5	19-Feb-2009	23-Feb-2009	OH		27-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB246AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1448U	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2620AA	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Right arm	Intramuscular	
MMR	MERCK & CO. INC.	0266X	0	Right arm	Subcutaneously	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Asthma, Chest pain, Diarrhoea, Dyspnoea, Haematochezia, Headache, Intensive care, Musculoskeletal chest pain, Pulmonary embolism

Symptom Text: Two weeks before Thanksgiving, mother says patient had cold symptoms, coughing and nasal congestion. The week of Thanksgiving, Nov. 24, 2008, patient c/o difficulty breathing, chest pains and a headache. To hospital emergency room. Patient was admitted and hospitalized two days in ICU and three days on the hematology unit according to mother. Diagnosis, Pulmonary Embolism. Another emergency visit to hospital on Feb. 13, 2009 for symptoms of diarrhea and bloody stools. 2/25/09-records received for DOS 11/24-11/28/08-DC DX: Pulmonary embolism. Presented with increasing shortness of breath, worsening cough anc chest wall pain for 2 weeks. Seen in Ed 1 week prior with shortness of breath and CXR determined to be asthma.

Other Meds: Levenox, two injections daily for three weeks then discontinued, Coumadin daily, Seroquel 100 mg. one daily

Lab Data: Chest X-ray, venous blood draws, CAT Scan, Nuclear contrast test, and many other tests but mother can not remember. 2/25/09-records received- On admission CXR revealed incrased perihilar markings and CT chest angiogram showed decreased att

History: Hx. of anxiety and four years ago diagnosed having Thrombophilia per mother. 2/25/09-records received-PMH: MTHFR mutation.

Prex Illness: Mother says two weeks before Thanksgiving, patient had cold symptoms, coughing and nasal congestion.

Prex Vax Illns:

Vaers Id: **340119-2 (S)** **Related reports:** 340119-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Nov-2008	24-Nov-2008	5	15-Apr-2009	16-Apr-2009	--	WAES0903USA05087	16-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1448U	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2620AA	0	Left arm	Intramuscular	
MMR	MERCK & CO. INC.	0266X	0	Right arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB246AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Asthma, Chest pain, Cough, Diarrhoea, Dyspnoea, Haematochezia, Headache, Intensive care, Musculoskeletal chest pain, Nasal congestion, Nasopharyngitis, Pulmonary embolism

Symptom Text: Information has been received from an agency concerning an 16 year old female patient with a history of anxiety and four years ago was diagnosed as having thrombophilia per mother, and patient medical history showed methylenetetrahydrofolate reductase (MTHFR) mutation, who on 19-NOV-2008, was vaccinated with the first dose of GARDASIL (lot # 659653/1448U) IM into left arm; first dose of MMR II (Lot # 659706/0266X) subcutaneously into the right arm; first dose of MENACTRA (Lot # U2620AA) IM into left arm; first dose of HAVRIX (Lot # AHAVB246AA) IM into right arm; and first dose of BOOSTRIX (Lot # AC52B030AA) IM into the right arm. Concomitant therapy included LOVENOX, SEROQUEL and COUMADIN. The patient had cold symptoms, coughing and nasal congestion. On 24-NOV-2008, the patient complaint of difficulty breathing, chest pains and headache. The patient went to hospital emergency room. The patient was admitted and hospitalized two days in ICU and three days on the hematology unit according to mother. Diagnosis pulmonary embolism. Another emergency visit to hospital on 13-FEB-2009, for symptoms of diarrhea and bloody stools. 25-FEB-2009, records received for date of service 24-NOV-2008 to 28-NOV-2008, diagnosed pulmonary embolism. Patient presented with increasing shortness of breath, worsening cough and chest wall pain for two weeks. Seen in ED 1 week prior with shortness of breath and Chest X-ray determined to be asthma. Chest X-ray, venous blood draw, CAT scan, Nuclear contrast test, and many other test but mother can not remember. Laboratories reported: On admission Chest X-ray revealed increased perihilar marking and CT chest angiogram showed decreased att. The VAERS ID # is 340119. A standard lot check was performed. All in-process quality checks for the lot number 659653/1448U Were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements for the Center and was released. No furthe

Other Meds: LOVENOX; SEROQUEL; COUMADIN

Lab Data: chest X-ray, increased perihilar markings; computed axial, chest angiogram showed decreased att

History: Anxiety

Prex Illness: Thrombophilia; Gene mutation

Prex Vax Illns:

Vaers Id: **340161-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	08-Oct-2008	14-Oct-2008	6	20-Feb-2009	23-Feb-2009	FR	WAES0902USA02481	23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Epilepsy

Symptom Text: Information has been received from a health care professional concerning a 14 year old female patient who on 08-OCT-2008 was vaccinated with the second dose of GARDASIL (batch number, route and site of administration not reported). On 14-OCT-2008 the patient developed convulsions and was sent to emergency unit. After this occasion she had several minor incidences of convulsions and on 13-NOV-2008 she was admitted to hospital for investigation, where she underwent EEG among other tests. She was diagnosed with epilepsy. The outcome is not recovered. The patient was vaccinated with the first dose of vaccine on 08-AUG-2008 with no adverse reaction. Other business partner numbers include: E2009-01165. No further information is available. Case is closed.

Other Meds: Unknown

Lab Data: electroencephalography, 13?Nov08, was diagnosed with epilepsy

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340162-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	16-Jan-2009	18-Jan-2009	2	20-Feb-2009	23-Feb-2009	FR	WAES0902USA02490	23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1647U	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bronchospasm, Dyspnoea, No reaction on previous exposure to drug, Oropharyngeal pain, Pyrexia, Rhinorrhoea

Symptom Text: Information has been received from the patient's mother concerning her daughter (a 20 year old female) who on 16-JAN-2009 was vaccinated with the third dose of GARDASIL (lot# 1647U, batch# NH52670, route and site not reported). Secondary suspect therapy included TERBASMIN given on 24-JAN-2009. On 18-JAN-2009, 2 days after vaccine administration, the patient presented with fever and throat pain. During the following days the fever dropped, nose mucus secretion appears. On 23-JAN-2009 the patient visited the doctor due to difficulty breathing. She is referred to the emergency room with a bronchoconstriction. URBASON and VENTOLIN along with SERETIDE and TERBASMIN are administered to treat adverse event. The patient is hospital admitted due to bronchoconstriction on the 24-JAN-2009, she remains hospitalized for 4 days. Prior doses were well tolerated. Other business partner numbers include: E2009-01347. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340164-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		20-Feb-2009	23-Feb-2009	NM	WAES0902USA02440	23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was intramuscularly vaccinated with the second dose of GARDASIL. Three weeks later the patient developed two seizures. The patient was given anti-seizure medications. At the time of reporting, the patient recovered from seizures. Upon internal review, seizures were considered to be other important medical events. Follow-up information was received from an office manager concerning the 19 years old patient who did not receive GARDASIL in the physician's office and is no longer seen by the physician. The patient's mother mentioned the adverse event to the doctor when she brought the patient's younger sibling for a visit. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 340165-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Oct-2008	07-Oct-2008	6	20-Feb-2009	23-Feb-2009	FR	WAES0902USA02782	23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Demyelination, Encephalitis post immunisation, Vision blurred

Symptom Text: Information has been received from a Health Authority (reference number ES-AGEMED-308185236) concerning a 17 year old female with a history of fall with blow to left occipital region of head 15 days before the hospital admission (01-OCT-2008); systemic herpes zoster infection in 1996; herpes zoster in first and second branches of left trigeminal nerve, disseminated without complications who in October 2008, was vaccinated with GARDASIL intramuscularly. It was reported that the patient presented a post vaccination encephalitis and demyelinating disease, from 07-OCT-2008 recovering on 14-JAN-2009. It was reported that the patient was vaccinated with the second dose of GARDASIL 2 months ago, beginning of October 2008, exact date not reported. The patient was hospital admitted on 15-OCT-2008. A week before hospital admission, the patient began to notice problems when reading the computer screen, unable to read properly the ending of words accompanied with a blurry vision sensation. No cephalgia. Since problem with vision persisted during the next few days, the patient visited the ophthalmologist on 13-OCT-2008, who during the examination saw in the campimetry a right homonymy hemianopsy with macular conservation. The patient was sent to the emergency room for further exploration and a neuroimaging test. After performing a computed tomography (CAT) scan, that showed hypodense images of left parietoccipital. The patient is orientated and conscious in time and space. Her language is normal, articulated with no disphasic elements. Conserved memory. No rigidity of the neck nor meningeal signs. Both carotids beat symmetrically, no murmurs, cranial pairs with right homonym hemianopsy, rest of pairs are among normal values, muscular strength is well conserved symmetrical V/V, sensitivity conserved symmetrically. ROT: 2-3/5 symmetric, RCP: bilateral flex. NO tremors, no dismetries, or axial distonia. No signs of vestibular or extrapyramidal pathology. Conserved vesicular with no added noise. Rest of exploration is normal. The

Other Meds: Unknown

Lab Data: visual field test, 13Oct08, right homonym with macular conservation, no cephalgia; Magnetic resonance imaging, 17Oct08, abnormal; Magnetic resonance imaging, 24Oct08, no significant findings; Visual evoked potential, 27Oct08, normal; Head c

History: Fall; Systemic herpes zoster infection; Herpes zoster disseminated

Prex Illness:

Prex Vax Illns:

Vaers Id: **340166-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	08-Jan-2009	08-Jan-2009	0	20-Feb-2009	23-Feb-2009	FR	WAES0902USA02779	23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea, Pulse abnormal, Tachycardia

Symptom Text: Information has been received from a health care professional concerning a 16 year old female with a medical history of asthma who on 08-JAN-2009 was vaccinated intramuscularly with a second dose of GARDASIL (batch # not reported). Concomitant therapy included VENTILAN. On the same day the patient experienced tachycardia with filiform beat, with dyspnoea and fainting sensation. She had recovered on the same day. The reporter mentioned that adrenaline and a subcutaneous corticosteroid had been administered to the patient. The patient's events were considered to be other important medical events because there's the risk of anaphylactic shock. Other business partner numbers included E2009-01390. Additional information has been requested.

Other Meds: VENTILAN, Dec08 - Unk

Lab Data: Unknown

History: Asthma

Prex Illness:

Prex Vax Illns:

Vaers Id: **340168-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	05-Feb-2009	05-Feb-2009	0	20-Feb-2009	23-Feb-2009	AR	AR0903	06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	MSD0651X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Dysphagia, Muscular weakness, Pain, Paralysis

Symptom Text: Paralysis - entire body - breathing on her own, difficulty swallowing, weakness arm and legs at 2200 then progressed this AM. 2/27/09-records received-for DOS 2/5-2/8/09-DC DX: weakness. Presented with whole body weakness status post Gardasil and Depo provera shot. Initial C/O all over body aches and joint pain. Weakness began in arms.

Other Meds: Depo Provera

Lab Data: UA -trace bacteria; WBC, 16.9; Hgb, 15.5; Drug screen (+) Cannabis. See attached - labs 2/27/09-records received-ESR and CRP normal.

History: NKDA; Hx of abdominal gun shot at age 9. 2/27/09-records received-PMH: GSW to abdomen and left malleolar fracture. Premature birth at 27 weeks.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340172-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	19-Feb-2009	19-Feb-2009	0	20-Feb-2009	23-Feb-2009	FL		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Myalgia, Pyrexia

Symptom Text: Fever, chills, muscle aches.

Other Meds: ORTHO EVRA Patch

Lab Data: UPT - neg

History: NKDA

Prex Illness: None reported

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340239-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Feb-2009	17-Feb-2009	1	20-Feb-2009	23-Feb-2009	VA		23-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1543X	0	Right arm	Subcutaneously	
FLU	SANOFI PASTEUR	U2795BA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB329BA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Dizziness, Erythema, Oedema peripheral, Pain in extremity, Pruritus, Somnolence, Vomiting

Symptom Text: the day after the vaccine was given the patient noticed, redness, swelling, itching and pain of her right arm. Dizziness and sleepiness notices as well., vomited x 2, on day 2 the area increased in erythema, elbow was painful., directed to take Motrin, Benadryl and apple cool compresses

Other Meds:

Lab Data: None

History: Penicillin allergies

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340240-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Feb-2009	11-Feb-2009	0	20-Feb-2009	23-Feb-2009	IN		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB320AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1311X	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B033BA	6	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pain, Vomiting

Symptom Text: Vomiting, headache and achy, a few hours after receiving vaccines.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340242-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Feb-2009	17-Feb-2009	0	20-Feb-2009	23-Feb-2009	IL		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2774AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1737X	1	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2580AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site inflammation, Injection site pain

Symptom Text: Patient was given 4 vaccines on 2/17/09 afternoon (menactra, varivax, gardasil, adacel). Late that evening note redness and soreness to the back of her left arm. Mom treated with cold compress, but soreness and redness did not resolve. Seen her on 2/19/09; teen has circumscribed area of pink inflammation to back of left upper arm. Approximately the size of 1/2 dollar coin. No induration or fluctuance. This site is consistent with where varivax vaccine was given, both per record and per LPN who gave vaccine. Due to teen's hx of eczema and cannot absolutlely r/o secondary infection, was placed on Amoxicillin.

Other Meds:

Lab Data:

History: Hx Eczema

Prex Illness:

Prex Vax Illns:

Vaers Id: **340244-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Feb-2009	19-Feb-2009	0	20-Feb-2009	23-Feb-2009	CO		20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB 3290A	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0070X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Allergy to vaccine, Anxiety, Chills, Dysarthria, Feeling hot, Grip strength decreased, Headache, Hypoaesthesia, Injection site erythema, Injection site pain, Injection site reaction, Injection site swelling, Injection site warmth, Joint range of motion decreased, Musculoskeletal pain, Myalgia, Oropharyngeal pain, Paraesthesia, Swollen tongue

Symptom Text: Patient C/O of headache, swelling resulting in left arm numbness, swollen tongue and slurred speech. Patient seen in ER and treated with Prednisone, Benedryl, and pain medication (dosages unknown)Patient releasedto mother and reports doing better the next morning 3/18/09 Received ER medical records for 2/19 & 2/21/2009. FINAL DX: Allergic reaction to Gardasil, left arm injection site reaction allergic Records reveal patient experienced tongue swelling, slurred speech, reddened & swollen left arm injection site from elbow to neck w/decreased left hand grip strength on 2/19. Returned to ER on 2/21 due to increased left deltoid/shoulder pain w/numbness & tingling of arm, subjective fever, chills, sore throat, anxiety since HPV shot. Exam revealed soft tissue tenderness swelling w/decreased ROM of left shoulder. Tx w/pain meds, improved & d/c to home on continued pain meds, steroids & antihistamine.

Other Meds: none

Lab Data: none

History: none PMH: ear ache & tonsillitis.

Prex Illness: none

Prex Vax Illns: Arm pain~HPV (Gardasil)~2~16~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340247-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Feb-2009	19-Feb-2009	2	20-Feb-2009	23-Feb-2009	CA		23-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: Local swelling and erythema 2 days after injection with Tdap (ADACEL) and HPV4 at same site.

Other Meds: none

Lab Data:

History: none

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340251-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	21-Nov-2008	23-Nov-2008	2	20-Feb-2009	23-Feb-2009	NY		22-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0752X	1	Unknown	Unknown	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Balance disorder, Blindness unilateral, Condition aggravated, Diplopia, Dizziness, Injection site mass, Migraine, Nausea, Thrombocythaemia, Thrombosis, Transient ischaemic attack, Vision blurred

Symptom Text: Loss of balance, double vision, dizziness, nausea, abnormally high blood platelet count. 3/12/09 Received ER medical records of 11/28/2008. FINAL DX: migraine HA; dizziness Records reveal patient experienced dizziness & blurred vision right eye, nausea x 3 days. Seen by neuro, dx w/migraine & scheduled for ophtho eval all as outpatient. PCP requested CT scan. Remained stable in ER & d/c to home w/PCP & neuro f/u. 4/16/09 Received vaccine & PCP medical records of 6/21/07-3/12/09. FINAL DX: likely TIA due to thrombocytosis Records reveal patient experienced good general health on 9/19/07 for HPV #1 & tol well. RTC 11/20 only for HPV #2. RTC 12/11/08 for Heme consult & dx w/thrombocytosis & on baby ASA; had lump left arm x 1 mo. RTC 12/30 w/ double vision. Neuro consult done 1/8/09 reveals pt w/dizziness & double vision & seen in ER. Previous optometry exam revealed stroke/clot right eye. Now w/double vision intermittently. Tx w/meds. RTC 3/12/09 meds changed. RTC 3/19/09 states 2 days s/p HPV#2, lost balance, lost vision right eye x 3 days & nauseated.

Other Meds:

Lab Data: Brain CT scan, brain MRI, Factor 5 blood test, FISH blood test, lyme disease, CBC, Evoked potential test. LABS: PAP smear neg. CBC, BMP & CT of brain WNL.MRI brain & evoked potentials WNL. Chromosome tests WNL. Antithrombin III & anti

History: none PMH: migraine HA x 3 yrs. Factor V Leiden WNL. Family hx: endometrial ca, CVA. 9/19/08 HPV#1, no lot # available.

Prex Illness: none

Prex Vax Illns:

Vaers Id: 340261-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Feb-2008	19-Feb-2008	0	20-Feb-2009	23-Feb-2009	PA		23-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1331X	0	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B033BA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1548X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Balance disorder, Dizziness, Feeling abnormal, Gaze palsy, Hypotonia, Paraesthesia oral

Symptom Text: After giving Varicella vaccine, Tdap, then HPV, child's eyes rolled back, body slumped to right side, b/l arms and legs waved/flapped side to side. No jerking motions. No rigidity of child's body noted. No pallor or cyanosis. Immediately requested mother to notify MD. Layed child down flat on exam table. Within seconds, child opened her eyes and asked what was the matter. I asked her if she remembered what happened. She remembered feeling light-headed. Then felt like she "had a dream". Child A,A,Ox3. Child c/o tingling feeling in arms and lips. BP done (refer to vitals section). Dr Winters responded first then DR Ferran. Had child lay flat until feeling of dizziness passed. Water given. Had child sit with feet dangling. Then had child stand. When initially stood up, child c/o unsteady feeling. Sat child in chair for 15-20min. Child reported that she felt fine, was able to walk steadily, no feeling of dizziness. Dr Ferran okayed that child go home. Left with mother and sibling. Father was driving family home.

Other Meds:

Lab Data:

History: none

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340308-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		18-Feb-2009	24-Feb-2009	VA	WAES0902USA00407	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia

Symptom Text: Information has been received from a physician concerning a teenager patient who was vaccinated with three doses of GARDASIL on unspecified dates. Subsequently the patient experienced weakness and went to see the doctor. The doctor did not think this was related to GARDASIL. The outcome was not provided at the time of reporting. This is one of several reports received from the same source. Additional information had been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340309-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		18-Feb-2009	24-Feb-2009	--	WAES0902USA00406	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a nurse practitioner concerning 2 patients at the practice who were vaccinated with a dose of GARDASIL on unspecified dates. Subsequently, they experienced extended loss of consciousness after getting GARDASIL. This is one of several reports received from the same source. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340310-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		18-Feb-2009	24-Feb-2009	VA	WAES0902USA00083	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia

Symptom Text: Information has been received from a physician concerning a teenager patient who was vaccinated with three doses of GARDASIL on unspecified dates. Subsequently the patient experienced weakness and went to see the doctor. The doctor did not think this was related to GARDASIL vaccine. The outcome was not provided at time of reporting. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340311-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	24-Feb-2009	--	WAES0902USA00068	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaccination complication

Symptom Text: Information hs been received from a registered nurse concerning a female with sulfanomide allergy who was vaccinated with a dose of GARDASIL on an unspecified date. Subsequently the patient had a "reaction" after receiving GARDASIL. No other detail information was provided. The outcome was unknown at time of reporting. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340312-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	28-Jan-2009	28-Jan-2009	0	18-Feb-2009	24-Feb-2009	WA	WAES0902USA00031	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injection site pain

Symptom Text: Information has been received from a receptionist in a physician's office concerning her daughter who on 28-JAN-2009 was vaccinated with the fourth dose of GARDASIL (lot # unspecified). In addition, the patient's arm is sore at the injection site. The outcome is unknown. It was reported that the patient was vaccinated with the first, second and third dose of GARDASIL on 18-AUG-2007, 04-JAN-2008 and 14-MAY-2008 respectively. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness: unknown

Prex Vax Illns:

Vaers Id: **340313-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Jan-2009	28-Jan-2009	0	18-Feb-2009	24-Feb-2009	--	WAES0902USA00020	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a nurse practitioner and the mother concerning a 16 year old female with no medical history and drug allergies who on 28-JAN-2009 11:45 was vaccinated with the first 0.5 ml dose of GARDASIL (lot # 661703/0651X) IM in the left arm. On the same day the patient was also vaccinated with a dose of HAVRIX into the right arm. There was no other concomitant medication. About an hour later after the patient went to school she blanked out in class. This was after 12:30. The teacher thought the patient was sleeping because her head was down and he called her name. The kids in class shook her and she woke up. She lost consciousness for about 5 minutes. The patient said that she did not hear any of the lessons. The patient was recovered after she was shaken on the same day. The patient sought unspecified medical attention. This is one of several reports received from the same source. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340314-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jan-2009	01-Jan-2009	0	18-Feb-2009	27-Feb-2009	--	WAES0901USA04442	27-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from an office staff member concerning a female patient who in approximately January 2009 was vaccinated with the first dose of GARDASIL (lot # not available). The patient became lightheaded and went to the emergency room after receiving the vaccine (approximately January 2009). The patient becoming lightheaded was considered another important medical event by the reporter because the patient went to the emergency room. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340315-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Jul-2008	01-Jul-2008	0	18-Feb-2009	24-Feb-2009	CA	WAES0902USA04426	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Acrochordon, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning an 11 year old female patient who in July 2008 "6 months ago" was vaccinated with the first dose of GARDASIL (lot # not reported). It was reported that the patient developed skin tags under each of her arms a few days after receiving her first dose of GARDASIL. It was reported that the number of skin tags increased after receiving her second dose. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340316-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	25-Nov-2008	25-Nov-2008	0	18-Feb-2009	24-Feb-2009	MD	WAES0901USA04422	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia oral, Rash pruritic, Similar reaction on previous exposure to drug

Symptom Text: Information has been received from a physician concerning an 11 year old female patient with asthma who on 25-NOV-2008 was vaccinated intramuscularly with a 0.5 ml dose of GARDASIL (Lot # 660016/0570X). Concomitant therapy included MSD, ALBUTEROL (unspecified) and influenza virus vaccine (unspecified). The patient developed a pruritic rash after administration of her first dose of GARDASIL. On 26-JAN-2009 the patient received her second dose GARDASIL (Lot # 661841/0653X). Concomitant therapy included MENACTRA. It was reported that the patient developed a pruritic rash and tingling in her tongue. She was treated with BENADRYL. At the time of reporting the patient had not recovered. Additional information has been requested.

Other Meds: ALBUTEROL; SINGULAIR

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340317-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	24-Feb-2009	--	WAES0901USA04407	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a medical assistant concerning 3 female patients who fainted after receiving the first dose of GARDASIL. Medical attention was sought. The patients recovered attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340318-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Sep-2008	01-Nov-2008	61	18-Feb-2009	24-Feb-2009	--	WAES0901USA04393	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema nodosum

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who on an unspecified date received the first dose of GARDASIL. In September 2008, the patient was vaccinated with the second dose of GARDASIL (lot # was not available). In November 2008, the patient developed erythema nodosum on her two legs. The patient's erythema nodosum on her two legs persisted. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340319-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	24-Feb-2009	IN	WAES0901USA04391	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL and her hair started falling out. The patient's mother called the clinic. At the time of reporting, the outcome was unspecified. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340320-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		18-Feb-2009	24-Feb-2009	--	WAES0901USA04385	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has been received from a physician concerning a patient who was vaccinated with a dose of GARDASIL (Lot # not reported). After patient received the vaccine experienced an unspecified side effect. The physician who reported the adverse experience did not administer the vaccine. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340321-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	27-Jan-2009	27-Jan-2009	0	18-Feb-2009	24-Feb-2009	NJ	WAES0901USA04376	23-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1423X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Chills, Diarrhoea, Dyspnoea, Fatigue, Guillain-Barre syndrome, Influenza like illness, Pain, Paraesthesia

Symptom Text: Information has been received from a registered nurse concerning a 26 year old female with polycystic ovarian syndrome, a history of thoracic sympathectomy for excessive sweating, and not known drug allergies, who on 27-JAN-2009 was vaccinated with a 0.5 mL first dose of GARDASIL (lot # 1423X), intramuscularly. Concomitant therapy included MIRCETTE and prenatal vitamins (unspecified). That evening the patient had episodes of diarrhea, flu like feeling, fatigue, achiness and chills. The symptoms persisted and the patient stated that she started to develop tingling in her lower legs and feet on 29-JAN-2009. The registered nurse requested that the patient took her temperature and it was 98.4 degrees F. The patient sought medical attention through a phone call. At the time of this report the patient had not recovered. Additional information has been requested.4/8/09records received-presented in ED on 2/2/09 with C/O pins and needles in legs and hands s/p gardasil vaccine. Paresthesia and weakness lower extremities. Mild shortness of breath. PE RLE 4/5 LUE 4/5. No actual motor weakness. DX: Mild Guillain Barre secondary to vaccination.

Other Meds: MIRCETTE; vitamins (unspecified)

Lab Data: temperature measurement, 98.4 degrees F 4/9/09-records received-CBC WNL.

History: Excessive sweating 4/8/09-records received-PMH: T2-T4 sympathectomy with chronic sweating/chills.

Prex Illness: Polycystic ovarian syndrome

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340322-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Jul-2008	14-Jul-2008	0	18-Feb-2009	24-Feb-2009	CT	WAES0901USA04368	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypersensitivity

Symptom Text: Information has been received from a physician concerning a 15 year old patient who on 13-MAY-2008 was vaccinated with first dose of GARDASIL (Lot # not reported). On 14-JUL-2008 patient received second dose of GARDASIL (Lot # not reported) 0.5ml. After the second dose of vaccine patient developed allergic reaction. Patient received third dose of GARDASIL (Lot # not reported) on 18-NOV-2008. On approximately 18-NOV-2008. The adverse event disappeared after got third dose of vaccine. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340323-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	30-Dec-2008	04-Jan-2009	5	18-Feb-2009	24-Feb-2009	MA	WAES0901USA04367	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Burning sensation, Pruritus, Urticaria

Symptom Text: Information has been received from a physician concerning an 18 year old female with no medical history who on 30-DEC-2008 was vaccinated with the third 0.5 ml dose of GARDASIL (lot# unspecified). There was no concomitant medication. On 04-JAN-2009 the patient experienced hives all over the body, itching and burning. The patient recovered on 13-JAN-2009. The first dose was administered on 19-JUN-2008 and second dose on 19-AUG-2009. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340324-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		18-Feb-2009	24-Feb-2009	IL	WAES0901USA04253	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Information has been received from a physician concerning an unknown number of patients who were vaccinated with a dose of GARDASIL and experienced pain after vaccination. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. Follow information received on 30-JAN-2009 stated that the reporter didn't had more information to provide. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340325-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	08-Feb-2008	Unknown		18-Feb-2009	24-Feb-2009	CO	WAES0901USA04188	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injected limb mobility decreased, Pain in extremity

Symptom Text: Information has been received from a Certified Medical Assistant concerning a 21 year old female with a history of dysmenorrhea and pelvic pain as well as no known drug allergies who was 08-FEB-2008 vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot# 655327/1287U). There was no concomitant medication or lab diagnostics. On an unspecified date the patient experienced pain in the same arm she received her first dose of GARDASIL. The patient was not able to lift her arm. At the time of reporting the patient was recovered. The patient sought medical attention by visiting the physician's office. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Dysmenorrhea: Pelvic pain

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340326-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Jan-2009	01-Jan-2009	0	18-Feb-2009	24-Feb-2009	NC	WAES0901USA04169	25-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
VARCEL	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning an approximately 14 year old female who was vaccinated with the first 0.5 ml dose of GARDASIL, VARIVAX (Merck) and hepatitis A vaccine (manufacturer unknown) a few weeks ago. She was told to wait in the lobby for 15 minutes before she was supposed to leave. While walking to the lobby the patient fainted. No injuries occurred. No lot number was provided. The patient was recovered few weeks ago. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340327-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	24-Feb-2009	--	WAES0901USA04124	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (lot number, injection site and route not reported). Subsequently the patient experienced persistent headache. The patient contacted the physician regarding the persistent headache. The outcome of the patient's experience was unknown.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 340329-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-May-2007	01-Oct-2008	496	18-Feb-2009	26-Feb-2009	--	WAES0901USA03986	10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1447F	2	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Arthralgia, Bronchitis, Chest pain, Cough, Dizziness, Dyspnoea, Fall, Fatigue, Headache, Influenza like illness, Middle ear effusion, Muscular weakness, Myalgia, Nausea, Oropharyngeal pain, Pain in extremity, Pyrexia, Tendonitis

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female patient who in November 2006, was vaccinated with GARDASIL IM for her first dose. The patient experienced flu like reactions after the first dose such as headache, fever, nausea and dizziness. The patient received the second dose of GARDASIL IM on 09-JAN-2007 and experienced sore arm (unspecified which arm). The patient received the third dose of GARDASIL IM on 24-MAY-2007. The patient was having unusual joint pain (all over but mostly in the knees), excessive fatigue, moments of shortness of breath, lots of muscle weakness, period of stomach aches, dizziness (may have been related to fluid in the ears), and chest pain on exercising. It was unspecified the time period all these symptoms occurred. The patient remembered having stomach problems but not sure as to the timing of the onset of the problem in relation to the third dose. The patient was last seen in the office on 22-JAN-2009 and was not doing any better. The patient had also sought medical attention by phone calls and office visits. Additional information has been requested. 3/6/09 Received PCP medical records of 4/12/2008-1/27/2009. FINAL DX: polyarthralgia Records reveal patient experienced feeling feverish, sore throat, fall from horse w/o LOC or injury then developed frontal HAs, LUQ pain after meals, fatigue. RTC 10/08 w/left hip pain, dx w/greater trochanter tendinitis w/early ileatal band syndrome. RTC 12/08 w/dry nonproductive cough x 2 wks, dx bronchitis & tx w/oral antibiotics. RTC 1/09 w/recurrent cough, difficulty breathing, fatigue, muscle aches, HA & dizziness. Dx w/recurrent bronchitis. RTC 1/14 w/persisting HA, resolved dizziness & persistent muscle/joint aching. RTC 1/27/09 & reports having flu-like s/s after initial HPV vaccine. Referred to Neuro when CT head neg but no record available.

Other Meds: Unknown

Lab Data: head computed axial, negative; diagnostic laboratory, metabolic panel, negative; complete blood cell, negative; Lyme disease assay, negative; Epstein-Barr virus, negative LABS: rapid strep (-). CT head, CXR WNL. ANA 9(H). CBC & CMP WN

History: Unknown PMH: reflux.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340330-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-May-2008	12-May-2008	0	23-Feb-2009	24-Feb-2009	IL	WAES0901USA03717	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Drug exposure during pregnancy, Eclampsia, Hypertension

Symptom Text: Information has been received from a registered nurse, for the Pregnancy Registry for GARDASIL, concerning a 17 year old female patient with attention deficit/hyperactivity disorder and penicillin allergy who on 27-NOV-2007 was vaccinated with the first dose of GARDASIL (lot# 659437/1266U) 0.5 ml intramuscularly. On 31-JAN-2008, the patient received the second dose of GARDASIL (lot# 659055/1522U) 0.5 ml intramuscularly. The patient received the third dose of GARDASIL (lot# 659182/1757U) 0.5 ml intramuscularly on 12-MAY-2008. Concomitant therapy included methylphenidate hydrochloride. The patient was pregnant after receiving the three doses of GARDASIL. No adverse effect was reported. The patient sought unspecified medical attention. Estimated last menstrual period: 19-MAY-2008, Estimated delivery date: 23-FEB-2008. Follow up information has been received from the physician, who reported that on 26-JAN-2009, the female patient delivered a normal and healthy male baby weighing 3062g and apgar score 7/9. There were no congenital anomalies and complications or abnormalities. No complications during the labor/delivery and diagnostic tests during pregnancy were not performed. No infections or illnesses during the pregnancy. The patient had hypertension, eclampsia and seizure during her pregnancy. The patient did not have prenatal care. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Concerta

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 5/19/2008); Penicillin allergy; Attention deficit/hyperactivity disorder

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340331-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	08-Dec-2008	08-Dec-2008	0	18-Feb-2009	24-Feb-2009	--	WAES0901USA03895	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vomiting

Symptom Text: Information has been received from Merck Pregnancy Registry for GARDASIL vaccine from a Nurse practitioner concerning an 18 year old female with AUGMENTIN allergy and no pertinent medical history who on 06-OCT-2-008 was vaccinated with first dose of GARDASIL vaccine (Lot # not reported). Concomitant therapy included ZOFRAN. On 08-DEC-2008 she received second dose of GARDASIL (Lot # not reported). When she received second dose of vaccine she was pregnant. Patient had last menstrual period on 13-NOV-2008. Estimated date of delivery was 29-AUG-2009. The patient received out patient IV therapy for hyperemesis. Ultrasound was performed to confirm pregnancy. Additional information has been requested.

Other Meds: ZOFRAN

Lab Data: ultrasound - To confirm pregnancy

History:

Prex Illness: Pregnancy NOS (LMP = 11/13/2008) Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **340332-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-May-2008	27-May-2008	0	18-Feb-2009	27-Feb-2009	CT	WAES0901USA03981	20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who on 25-MAR-2008 was vaccinated with first dose of GARDASIL (Lot # not reported). On 27-MAY-2008 she received second dose of GARDASIL (Lot # not reported) 0.5ml. After the second dose of vaccine she developed serious allergic reaction. She received third dose of GARDASIL (Lot # not reported) on 28-SEP-2008. The adverse event disappeared after got third dose of vaccine. The patient sought unspecified medical attention. This is one of two reports from the same source. Upon internal review, serious allergic reaction was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340333-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Apr-2008	Unknown		23-Feb-2009	24-Feb-2009	--	WAES0902USA02626	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Alopecia, Arthralgia, Back pain, Convulsion, Cyanosis, Fatigue, Gingival bleeding, Headache, Immediate post-injection reaction, Respiratory arrest, Visual impairment

Symptom Text: Information was viewed on the Internet concerning a 19 year old patient who in approximately April 2008 (10 months ago), was vaccinated with the first dose of GARDASIL. Second dose was administered (unspecified date). The mother of the patient reported that prior to first shot, the patient was healthy and active. After the vaccination the patient's back started hurting immediately and about three weeks after the first dose of GARDASIL the patient had her first seizure. After the second dose of GARDASIL the seizures, increased, as did severe stomach pain experienced, fatigue, headache, joint pain, vision problems, hair loss and bleeding gums. The mother reported that the patient has been hospitalized four times, there has been multiple ambulance calls daily seizures, several incidents of cluster seizures where she stopped breathing and turned blue. The mother reported that patient seemed to be improving as time goes by. Therapy with GARDASIL was discontinued. Attempts to verify the existence of an identifiable patient have been unsuccessful. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 340334-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	16-Sep-2008	04-Nov-2008	49	23-Feb-2009	24-Feb-2009	FL	WAES0902USA02661	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Chest pain, Cough, Deep vein thrombosis, Hypercoagulation

Symptom Text: Information has been received from a physician concerning a 20 year old female with respiratory allergies who on 21-FEB-2008, 24-APR-2008 and 16-SEP-2008 was vaccinated with the first, second and third dose of GARDASIL respectively (first and second dose lot # unspecified, lot # third dose 660612/0229X). Concomitant therapy included MENACTRA (administered on 21-FEB-2008), ZYRTEC and ALLEGRA. On 04-NOV-2008 the patient went to the physician's office with chest pain and coughing. On 07-NOV-2008 and 14-NOV-2008 the patient came back to the physician's office because the symptoms were still persisting. On 14-NOV-2008 the physician suggested to the patient to go to the hospital. The patient was hospitalized on 15-NOV-2008, a lot of different unspecified tests were done, and the patient was diagnosed with hypercoagulable state and deep venous thrombosis. On an unspecified date the patient was released from the hospital, but the physician did not mention how long the patient was in the hospital for. The physician stated he feels that hypercoaguable state and DVT are life threatening, he was unsure if GARDASIL caused the experience. The patient is still recovering. Additional information has been requested.

Other Meds: Zyrtec; Allegra

Lab Data: diagnostic laboratory, 11/15/08, unspecified lab tests

History:

Prex Illness: Allergic respiratory symptom

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340336-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		23-Feb-2009	24-Feb-2009	CA	WAES0902USA02666	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with on unspecified date with a dose of GARDASIL. Within 1 week of vaccination the patient developed Bell's palsy. The patient sought medical attention by contacted office. Upon internal review Bell's palsy was considered to be as an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340337-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Aug-2007	Unknown		23-Feb-2009	24-Feb-2009	--	WAES0902USA02698	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Alopecia, Autonomic nervous system imbalance, Dizziness, Immune system disorder, Loss of consciousness, Migraine, Nausea, Orthostatic intolerance, Panic attack, Staphylococcal infection, Vision blurred

Symptom Text: Information has been received from a consumer via the Internet concerning her daughter who in August 2007, was vaccinated with GARDASIL. Subsequently the patient had been sick ever since. The patient had several hospital stays, saw a neurologist on a reg basis, and had been diagnosed with dysautonomia with orthostatic intolerance. The patient experienced blackouts, chronic dizziness and took massive anxiety medicines. She also experienced loose clumps of her hair, blurred vision, migraine headaches, nausea and panic attacks. The patient's immune system had been so compromised that she had gotten MRSA (resistant staff) two times and was hospitalized for that. The patient was also an honor student (straight A's) with a very bright future. Her grades had dramatically dropped. The reporter stated that they had to put her on a plan at school so that her attendance can not be held against her, and her teachers had to reduce her work load because she did not know from one day to the next whether she would be able to get out of bed. At the time of reporting, the outcome was unknown. Attempts are being made to verify the existence of an identifiable patient and reporter. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340338-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-Dec-2008	19-Dec-2008	0	23-Feb-2009	24-Feb-2009	FR	WAES0902USA02783	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0467U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Vertigo

Symptom Text: Information has been received from the health agency (documentation # 29795). A 12 year old female patient (no medical history reported) was vaccinated with the second dose of GARDASIL (batch # NG14300, lot # 0467U, route: intramuscular, site not reported) on 19-DEC-2008. 15 to 20 minutes after vaccination the female patient developed headache and vertigo. Blood pressure RR: 105/72. The duration of reaction was about 6 hours. It was reported that the female patient has recovered. This case was classified by the reporter as medically significant. The case is closed. Other business partner numbers include E200901337.

Other Meds: Unknown

Lab Data: blood pressure measurement, 105/72

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340339-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	28-Jan-2009	28-Jan-2009	0	23-Feb-2009	24-Feb-2009	FR	WAES0902USA02995	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0747X		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Anaphylactic shock, Hyperventilation, Malaise, Urticaria

Symptom Text: Information has been received from a health agency (HA reference # DK-DKMA-20090229). It was reported that a 12 year old female patient was vaccinated with a dose of GARDASIL (IM, batch # NJ38950, lot # 0747X, site of administration not reported) on 28-JAN-2009. Approximately five minutes after the vaccination on 28-JAN-2009, the patient had an anaphylactic shock and experienced hyperventilation, malaise and developed a rash which was presumably urticarial. Her pulse was reported to have been 150 and her blood pressure 140/80 mmHg. The patient was injected with 0.5 milliliter epinephrine (manufacturer unknown, concentration not reported) IM in the right arm. The GP tried to place a drip in the patient but failed. The patient was injected with 2 milliliter TAVEGYL IM (manufacturer unknown, concentration and site of administration not reported) to which she responded well and was thereafter sent acute to the emergency room. At arrival to the emergency room the patient experienced rash again and was administered SOLU-MEDROL IV (manufacturer unknown, concentration and site of administration not reported). The patient was admitted to the hospital's children ward for observation for 24 hours with SOLU-MEDROL injection every 6th hour. The patient recovered (time not further specified) and was released from the hospital with stable blood pressure and feeling well. Other business partner numbers include E200901463.

Other Meds: Unknown

Lab Data: Blood pressure measurement, 140/80 mmHg; Total heartbeat count, 150

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340340-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	01-Nov-2008		23-Feb-2009	24-Feb-2009	FR	WAES0902USA03009	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Bronchitis, Cardiomyopathy, Dyspnoea exertional, Left atrial dilatation, Mitral valve incompetence, Oedema peripheral, Pulmonary hypertension, Ventricular hypokinesia

Symptom Text: Information was received from the health authorities under the local reference numbers NY20090035 and NY0919105 concerning an 18 year old smoking female patient with medical history of psoriasis who on an unspecified date received a dose of GARDASIL. Secondary suspected therapy included the chemotherapy course with intravenous dose of doxorubicine hydrochloride since May 2008 for right leg synovial sarcoma. On 01-SEP-2008 and 02-SEP-2008 a sixth course of chemotherapy was performed in good conditions, with a good tolerance. Before or after this course (precise date not reported), the patient received a dose of GARDASIL. On 03-SEP-2008, the patient was seen to perform an isotopic ventriculography. The left ventricular ejection fraction was measured at 67% i.e. no modification since the examination date 05-MAY-2008. On 15-DEC-2008, the patient was seen for asthenia, dyspnoea on effort, lower limb oedema since the beginning of November 2008 and episode of bronchitis. On 16-DEC-2008, biological tests revealed pro brain natriuretic peptide (BNP) at 2651 pg/L, urea at 0.21 g/L and creatininaemia at 8.8 mg/L. Cardiac work-up performed on 18-DEC-2008 evidenced a cardiomyopathy severely hypo kinetic with left ventricular impairment, left ventricular ejection fraction at 20%, without left cavitary dilatation, non-significant mitral insufficiency, dilatation of the left atrium, dilatation of the lower vein with loss of respiratory sensitivity, pulmonary hypertension with pulmonary artery pressure (PAP) at 50 mmHg and a slight pericardial side. The patient was hospitalized on 19-DEC-2008 in a specialized unit. On 24-DEC-2008, pro BNP was 984, urea was 0.46 and creatininaemia was 9.6. The evolution was on-going. The health authorities assessed the causal relationship between the reported reactions and vaccination as "doubtful" and they assessed the causal relationship between the reported reactions and chemotherapy as "possible" according to the foreign method of assessment. Other business partner numbers included E2009-01393

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 18Dec08, cardiomyopathy severely hypo kinetic with left ventricular impairment; echocardiography, 18Dec08, dilatation of the left atrium, dilatation of the lower vein with loss of respiratory sensitivity; diagnos

History: Psoriasis

Prex Illness: Smoker

Prex Vax Illns:

Vaers Id: **340347-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	23-Jan-2009	24-Jan-2009	1	18-Feb-2009	24-Feb-2009	TX	WAES0901USA03962	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Information has been received from a physician concerning a 22 year old female who on 23-Jan-2009 was vaccinated in arm with the second dose of GARDASIL vaccine. On 24-JAN-2009, the patient developed a rash all over her body. It was reported that the patient does not plan on receiving a third dose. Lot number was not available. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340348-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Nov-2008	06-Dec-2008	18	23-Feb-2009	24-Feb-2009	FR	WAES0902USA03257	10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Information has been received from a health authority (HA ref. DK-DKMA-20090206), concerning a 14 year old female who on 18-NOV-2008 was vaccinated with the first dose of GARDASIL (lot number, batch number and site of administration not reported), intramuscularly. Approximately 14 days later the patient experienced what might have been paralysis in the left side of the face. The patient was unable to fully close her left eye and had fewer wrinkles around left eye than around her right eye when she squeezed her eye tightly together. The patient's smile was crooked and she could feel a difference in the area around her mouth and eyes that was not normal. The patient was having her teeth in the upper mouth regulated with permanent braces and this was at first thought to be the reason for the adverse event. The patient was therefore seen by a dental specialist on 11-DEC-2008 who thought it to be paralysis in a facial nerve and referred the patient to her GP. The patient was seen by her GP on 12-DEC-2008 who thought the facial paralysis was due to a previous infection (no infection reported in patient history). The GP referred the patient to an ear/nose/throat specialist who did an ear pressure test, hearing test and neuro test (not further specified, date not reported) and concurred that the adverse event was probably due to an infection in the past. Eight days later on 25-DEC-2008 the patient was recovered. The patient's mother thought there might be a connection between GARDASIL vaccination and the facial paralysis. Upon internal review facial paralysis was considered a medically significant event. The case was closed. Other business partner number included: E2009-01274. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340351-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		23-Feb-2009	24-Feb-2009	FR	WAES0902USA02753	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Thrombocytopenic purpura

Symptom Text: Information has been received from a health care professional concerning a 19 year old female patient with no relevant medical history who was vaccinated with the third dose of GARDASIL (batch number not reported) on an unspecified date. On an unreported date after the vaccination the patient experienced a purpura thrombocytopenic. She was treated with corticotherapy (unspecified date). At time of reporting the outcome was not specified. The patient had no concomitant treatment. Purpura thrombocytopenic was determined to be an other important medical event. Other business partner numbers include: E2009-01915. No further information is available.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340352-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-Oct-2008	25-Nov-2008	47	23-Feb-2009	24-Feb-2009	FR	WAES0902USA02996	24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Blood test, Dizziness, Lumbar puncture, Myalgia, Neuralgia, Neuropathy peripheral, Nuclear magnetic resonance imaging, Sensory disturbance, Visual impairment

Symptom Text: Information has been received from an agency under reference number DK-DKMA-20090211 concerning a 14 year old female who on 09-OCT-2008 was intramuscularly vaccinated with a first dose of GARDASIL. The patient was not receiving any concomitant medication. On 25-NOV-2008, the patient developed neuropathy possibly Guillain-Barre syndrome. The patient showed signs of immunologic reaction with neuropathic pain, sensory aberrations, myalgia, arthralgia, dizziness and visual disturbances. On an unspecified date, the patient was hospitalized and had blood samples taken (not further specified, no results reported). The patient also had a lumbar puncture and a magnetic resonance imaging (MRI) scan was performed (not further specified, no result reported). At the time of reporting the patient was not recovered. Other business partner numbers included E2009-01443. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340353-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	23-Jan-2009	23-Jan-2008	-366	18-Feb-2009	24-Feb-2009	--	WAES0901USA03954	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a 22 year old female patient with yeast hypersensitivity, no drug/reactions allergies who on 23-JAN-2009 was vaccinated with a 0.5 mL dose of GARDASIL vaccine. Concomitant therapy included hormonal contraceptives (unspecified). "Eight hours after receiving the GARDASIL vaccine", the patient experienced a rash on her legs. The patient sought unspecified medical attention. There were no laboratory or diagnostic tests performed. At the time of reporting, the patient was recovering. Additional information has been requested.

Other Meds: HORMONAL CONTRACEPTIVES

Lab Data: None

History:

Prex Illness: Hypersensitivity

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vaers Id: **340354-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		18-Feb-2009	24-Feb-2009	IL	WAES0901USA03943	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Similar reaction on previous exposure to drug

Symptom Text: Information has been received from a physician concerning a 17 year old female with drug hypersensitivity and allergic reaction to AMOXICILLIN and CODEINE who on 31-OCT-2008 was vaccinated with a first dose of GARDASIL vaccine. The patient received a second dose of GARDASIL vaccine (Lot #661046/0546X). There was no concomitant medication. 4 days after vaccination with the second dose of GARDASIL vaccine the patient developed persisting injection site pain lasting more than 5 days, the patient was vaccinated in the deltoid with a 1 inch needle. The patient was treated with hot compresses and anti inflammatory medication. After the first dose of GARDASIL vaccine she had pain, but it resolved in a few days. No laboratory studies performed. The patient sought medical attention through an office visit. At the time of this report the patient had not recovered. Follow up information received on 30-JAN-2009 stated that the patient had called back the physician with injection site pain 10 days after the GARDASIL vaccine was administered. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Drug hypersensitivity; Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **340355-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	21-Nov-2008	Unknown		18-Feb-2009	24-Feb-2009	--	WAES0901USA03940	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Furuncle, Injection site pustule, Purulence

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female patient with no pertinent medical history and no known drug allergies, who on 21-NOV-2008 was vaccinated with the first dose of GARDASIL vaccine (lot # 661530/0575X) 0.5 ml intramuscularly. There was no concomitant medication. The patient experienced puss-filled boils around the site of injection (2008). The boils "come and go" for the last eight weeks. She had had a total of 8-10 boils so far. The patient had a tattoo on her left arm (around the deltoid area) which she had had for years prior to receiving the vaccine. The patient's puss-filled boils around the site of injection persisted. The patient sought medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vaers Id: **340356-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	Unknown	25-Jan-2009		23-Feb-2009	02-Mar-2009	MN		17-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Activities of daily living impaired, Anorexia, Depression, Dyskinesia, Headache, Muscle twitching, Restless legs syndrome, Rheumatic fever, Streptococcal identification test negative

Symptom Text: My daughter started to get restless in the legs and had many headaches. She was twitching and couldn't stop from jerking movements in head and legs. We thought maybe she got a hold of some kind of drug. The doctors said she has rheumatic fever. This is triggered by strep throat. The only problem she tested negative for that. Now she can't even walk. She has no hunger and is very depressed. 10 years old and making drugs that take healthy kids and turn them into this. I didn't like the idea of my child taking this drug and my wife only did because the doctor said he highly recommended it. Well now that this has happened I have found out that they have had 21 deaths in 2 years. Thanks for telling us that in the side effects. I don't see anything mentioned about this. My daughter got only one dose and was set to get her second when this happened. This drug needs to be taking off the market. I don't want to see another family go through what we are going through. She has missed 3 weeks of school and I don't see her recovering anytime soon. 1 death is too many and I know that there are many out there that will be permanently disabled over this drug. PLEASE TAKE THIS DRUG OFF THE MARKET. I will continue to spread the word out to Family & Friends in hope that they won't put their child in the hands of this drug maker. GARDASIL needs to be stopped.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 340357-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Jan-2009	22-Jan-2009	6	23-Feb-2009	27-Feb-2009	FL		25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Bronchitis, Dizziness, Influenza like illness, Loss of consciousness, Malaise, Mouth injury, Mydriasis, Nausea, Pain, Pallor, Pyrexia, Suture insertion, Syncope, Tooth injury

Symptom Text: Patient received her 1st GARDASIL shot on 1-16-09. She received no other shots and was on no medication. On 1-20-09, patient woke up with flu-like symptoms fever, upper respiratory congestion, body aches, and weakness. On 1-22-09, patient was treated at urgent care for her flu-like symptoms and bronchitis. She was given a 1st dose of Azithromycin, PREDNISONE and MUCINEX mid-morning. After sleeping for 2 1/2-3hours, patient got up, sat down to eat felt ill, got up, and passed out, hitting her two front teeth and severing them. She went by ambulance to hospital ER, although she regained consciousness right away, her skin was a strange white color and her pupils were dilated. She has had no other problems since her ER treatment, but her two front teeth had to be replaced with crowns. 3/16/09-ED records received for DOS 1/22/08-presented with C/O lightheadness, syncope, nausea, felt faint, brief loss of consciousness. Abrasions on inner lips, oral laceration, suturing required. Dental injury. Impression: syncope.

Other Meds: not at time of vaccination

Lab Data: EKG, normal; Chest X-ray, showed bronchitis 3/16/09-records received-WBC 3.2, Hgb 14.9, neutrophils elevated 77.8, lymphocytes decreased 15.4, glucose 110. Chest x-ray normal.

History: allergic to Amoxicillin

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340359-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	27-Jan-2009		23-Feb-2009	24-Feb-2009	--		25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypersensitivity, Rash, Rash pruritic

Symptom Text: I was given the GARDASIL shot. A week after being injected I had a serious allergic reaction and broke out in a very itchy rash all over my fingers and between fingers, and also spots on my face. The rash consisted of little bumps, and was spreadable.

Other Meds:

Lab Data:

History: I've never had an allergic reaction to any medicine in previous situations.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340360-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	06-Nov-2008	25-Dec-2008	49	23-Feb-2009	24-Feb-2009	--		13-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	1	Unknown	Unknown	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthropod bite, Chest pain, Contusion, Dysgeusia, Erythema, Hypoaesthesia, Lymphadenopathy, Pharyngitis streptococcal, Pruritus, Purpura, Tenderness, Upper respiratory tract infection, Urticaria

Symptom Text: My daughter had the vaccine GARDASIL and now her arm is bruising up looks really nasty and she saying she's got numbness of the arm and Dr. don't think it's the GARDASIL I'm very worried, she does allergies but Dr. did say shot was ok for her. 3/18/09 Received vac records & PCP medical records of FINAL DX: purpuric rash LUE; allergies; urticaria Records reveal patient experienced good health on day of #1 & #2 HPV vaccines. RTC 1/15/09 w/rash, redness, itching & bruising LUE which had started in wrist area & moved up arm. Dx w/insect bite (spider) LUE. Tx w/IV antibiotic & antihistamine. RTC 2/2/09 w/URI & pain left arm. Dx w/strep throat & URI. Tx w/antibiotics. Seen in ER 2/3/09 for probable insect bite LUE & enlarged bilateral axillary lymph nodes. Tx w/continued antibiotics & antihistamines. RTC 2/19 w/purpuric rash left arm & 2/24 w/bruising & tenderness of both arms, chest pain & taste alteration. Dx w/allergies & urticaria. Tx w/antihistamines.

Other Meds:

Lab Data: LABS: Blood c/s, CRP, PT/PTT all WNL.

History: She does have allergies PMH: asthma, seasonal allergies.

Prex Illness:

Prex Vax Illns:

Vaers Id: **340362-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	07-Feb-2009	07-Feb-2009	0	23-Feb-2009	24-Feb-2009	OR	OR200905	24-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB262AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	1311X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	12874AA	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	ACS2B020AA	5	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1753X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Feeling abnormal, Immediate post-injection reaction, Mydriasis

Symptom Text: pt c/o "fuzziness". Slumped in chair post immz given pupil dilated. Assisted to cot when appropriate. Applied cool rag. Given snack & juice when recovered. Total time 10 minutes.

Other Meds:

Lab Data: None

History: denied

Prex Illness: none stated

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340376-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Feb-2009	05-Feb-2009	1	23-Feb-2009	24-Feb-2009	AL		25-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1101U		Right arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B021AA		Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1425F		Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site swelling

Symptom Text: Pt received varicella vaccine RA SQ on 2-4-09 and returned to office 2-16-09 with red/swollen (15 mm) in area around injection site and reported area itches instructions given per VIS and to return if area worsens or gets larger.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340377-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	21-Oct-2008	Unknown		23-Feb-2009	24-Feb-2009	AZ		25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Pt learned she was pregnant 2 months after receiving GARDASIL vaccine. Pt miscarried at 2 1/2- 3 mos pregnant.

Other Meds: BC (OCP)

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340379-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Feb-2009	16-Feb-2009	0	23-Feb-2009	24-Feb-2009	MN		24-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2822AA	0	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	0653X	0	Unknown	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B027AA	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Head injury, Immediate post-injection reaction, Loss of consciousness, Muscle twitching

Symptom Text: Gave 3 immunizations, about 3-4 min later fell to the right off chair, hit head on floor. I helped her up. She was twitching. Felt dizzy, blacked out. Layed her on table, took blood pressure (normal) gave juice. Felt fine afterwards (time 5 min)

Other Meds:

Lab Data:

History:

Prex Illness: None Known

Prex Vax Illns:

Vaers Id: **340384-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	11-Feb-2009	11-Feb-2009	0	23-Feb-2009	24-Feb-2009	PA		25-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB247AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0575X	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	62733AA	0	Left arm	Intramuscular	
FLU	SANOFI PASTEUR	U2769AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Headache - post immunization evening - continuing at time/date of call on 02/12/09. Given MOTRIN by mother - Mother related - Some relief - but once MOTRIN dose wore off - teen c/o headache again.

Other Meds:

Lab Data:

History: None Known or indicated on IMZ record

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340389-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Feb-2009	11-Feb-2009	0	23-Feb-2009	24-Feb-2009	OH		25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	1063U	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	U2423AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Dizziness, Immediate post-injection reaction, Nausea, Pain in extremity, Syncope

Symptom Text: Pt with initial syncope, nausea, lasting several minutes post injection. Was monitored for 20 min and was normal. 1 week later developed chest pain, arm and leg pain with dizziness. Normal exam. Mom concerned RE clot. CT done, NEG for embolus.

Other Meds: None

Lab Data: CT chest, neg for P. E.

History: Benign Murmur

Prex Illness: No

Prex Vax Illns:

Vaers Id: **340400-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	--	WAES0901USA03934	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site, Injection site pain, Malaise, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered nurse concerning a 28 year old female patient with asthma, allergies an allergies to penicillin, CECLOR, and CIPRO who was vaccinated on an unspecified date with the first and second doses of GARDASIL. Concomitant therapy included BACTRIM, Albuterol , and allergy immunotherapy and allergy medication. The patient was given GARDASIL in the gluteal area for both doses. The patient developed pain at injection site after receiving each dose and pain had not resolved. The patient also experienced fever and malaise fro several days after both doses. Malaise and fever had resolved.

Other Meds: Albuterol; BACTRIM

Lab Data: None

History:

Prex Illness: Asthma; hypersensitivity; penicillin allergy; allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340401-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	VA	WAES0901USA03906	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Influenza like illness

Symptom Text: Information has been received from a RN concerning a 16 year old female who was vaccinated with her first dose of GARDASIL on an unspecified date (injection). The patient developed "flu-like" symptoms and diarrhea the next day after receiving the first dose of GARDASIL. Lot # is not available. The patient sought medical attention by visiting the nurse's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340402-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	12-Dec-2008	18-Dec-2008	6	23-Feb-2009	02-Mar-2009	CT	WAES0902USA03903	02-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Information has been received from a certified nurse midwife concerning a 24 year old female patient with asthma, epilepsy and migraine headaches, no drug reactions/allergies, who on 12-DEC-2008 was vaccinated intramuscularly into the left deltoid with the first 0.5 mL dose of GARDASIL (Lot # 661044/0548X). Concomitant therapy included SYNTHROID, TOPAMAX and asthma inhaler (unspecified). On 18-DEC-2008 the patient experienced dizziness and waves of nausea for four days, the patient stated that, was able to continue A.O.L.. Symptoms decreased after 22-DEC-2008, then went away. The patient had recovered. The patient called to the office on 22-DEC-2008. There were no laboratory or diagnostic tests performed. Additional information is not expected.

Other Meds: SYNTHROID; TOPAMAX

Lab Data: None

History:

Prex Illness: Asthma; Epilepsy; Migraine

Prex Vax Illns:

Vaers Id: **340403-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Jan-2009	09-Jan-2009	0	18-Feb-2009	26-Feb-2009	OH	WAES0901USA03830	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hepatitis, Infectious mononucleosis, Malaise

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female student with a slight temperature at the time of vaccination (99.9 degrees) (weight 110 pounds, height 60.5 inches) who on the morning of 09-JAN-2009 was vaccinated in the arm with a first dose of GARDASIL. Concomitant therapy included DORYX, DIFFERIN and FEMCON. It was reported that the patient after receiving GARDASIL began feeling ill later that evening. The nurse stated that the patient went to pediatric physician twice and was diagnosed with mononucleosis and mononucleosis caused hepatitis. The nurse indicated that the patient's mother believes GARDASIL caused or worsened the condition. Patient not recovered. Additional information is not expected.

Other Meds: DIFFERIN; DORYX; FEMCON FE

Lab Data: Body temp, 99.9 F

History: Unknown

Prex Illness: Fever

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340405-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Feb-2009	20-Feb-2009	0	23-Feb-2009	24-Feb-2009	AZ		24-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2827CA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3032AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Confusional state, Dizziness, Immediate post-injection reaction, Loss of consciousness, Nausea, Syncope

Symptom Text: PATIENT FAINTED IMMEDIATELY AFTER INJECTION OF GARDASIL. 5 SEC. OF COMPLETE UNCONSCIOUSNESS FOLLOWED BY CONFUSION, DIZZINESS AND NAUSEA UPON AWAKING. PATIENT MONITORED FOR ADDITIONAL 15MIN AFTER INJECTIONS WITH VITAL SIGNS AND COMFORT MEASURES.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340421-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Feb-2009	02-Feb-2009	0	23-Feb-2009	24-Feb-2009	OH		24-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0575X	2	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB262AA	1	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1907U	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Nausea, Pallor

Symptom Text: Client became pale and complained of being nauseated and light-headed. RN assisted client in putting her in a supine position with legs elevated. This releaved the light-headedness but client continued to be pale and nauseated. These symptoms began immediately after injection and continued for 20 minutes at which time the client stated she felt okay, skin color had returned to normal and she was sent home with her mother.

Other Meds: none

Lab Data:

History: PCN

Prex Illness: no

Prex Vax Illns: same~HPV (Gardasil)~2~15~In Patient

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340440-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	21-Jan-2009	30-Jan-2009	9	23-Feb-2009	24-Feb-2009	MO		04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0630X	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Pt received GARDASIL injection 1/21/09. Pt reported being pregnant 1/20/09.

Other Meds: NUVARING

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **340443-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	26-Jan-2009	26-Jan-2009	0	18-Feb-2009	26-Feb-2009	MO	WAES0901USA03709	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site erythema, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: Information has been received from a respiratory therapist concerning a 11 year old female patient with no pertinent medical history and no known drug allergies, who on 26-JAN-2009 was vaccinated with the first dose of GARDASIL (lot# 661703/0651X) 0.5 ml intramuscularly. Concomitant therapy included CLARITIN. On 26-JAN-2009, four minutes after receiving the injection, the patient experienced pain, swelling and redness at the injection site, and the area was hot to the touch. The patient applied ice to the area. Additional information has been requested.

Other Meds: CLARITIN

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340444-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
48.0	F	Unknown	26-Jan-2009		18-Feb-2009	26-Feb-2009	MO	WAES0901USA03695	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Accidental exposure, Eye irritation, Lacrimation increased

Symptom Text: Information has been received from a physician concerning a 48 year old female licensed nurse practitioner with sulfanomide allergy who was administering GARDASIL when the needle broke and some of the vaccine splashed into her left eye. The left eye was watering a little and a tiny bit of burning. The eye was being irrigated. The needle used was not from a pre filled syringe. The patient sought medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Sulfonamide allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **340445-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	VA	WAES0901USA03688	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Joint swelling

Symptom Text: Information has been received from a nurse concerning a 26 year old female who was vaccinated with a first dose of GARDASIL, lot number not reported. The nurse stated that one of the patient's ankles swelled after receiving the GARDASIL vaccine. The patient sought unspecified medical attention. Her outcome is unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340446-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	--	WAES0901USA03572	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician assistant concerning a female patient who "experienced a severe headache after her first dose of GARDASIL (lot # not provided). She recovered by experienced a severe headache again after receiving her second dose of GARDASIL (lot # not provided). Patient sought unspecified medical attention and dose not plan on receiving a third dose. At the time of this report patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340447-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Oct-2008	01-Oct-2008	0	18-Feb-2009	26-Feb-2009	TX	WAES0901USA03670	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amenorrhoea, No reaction on previous exposure to drug

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with attention deficit disorder and depression who on 24-JUN-2008 was vaccinated with the first dose of GARDASIL vaccine (no lot# provided). In October 2008 the patient was vaccinated with the second dose of GARDASIL vaccine (no lot# provided) 0.5 ml and has not got her menstrual cycle. Patient sought unspecified medical attention. At the time of the report the patient had not yet recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Attention deficit disorder; Depression

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340448-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	04-Sep-2008	04-Sep-2008	0	18-Feb-2009	26-Feb-2009	--	WAES0901USA03669	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site rash, No reaction on previous exposure to drug, Rash, Rash erythematous

Symptom Text: Information has been received from a registered nurse concerning an 18 year old female patient who on 05-APR-2007 was vaccinated with the first dose of GARDASIL (Lot # 654535/0960F) intramuscularly. On 08-APR-2008 the patient was vaccinated with the second dose of GARDASIL vaccine (Lot # 658222/0927U), and on 04-SEP-2008 the patient received the third dose of GARDASIL (Lot # 660555/0279X). There was no concomitant medication. It was reported that on 05-SEP-2008 the patient experienced a "reddened rash" on her right arm, at the injection site, and the right side of her face. The rash resolved in three days without requiring treatment. It was reported that the patient was administered with the first and second doses without adverse symptoms. The patient called health department. This is one of several cases from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340449-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Jun-2008	26-Jun-2008	1	18-Feb-2009	26-Feb-2009	--	WAES0901USA03655	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Myalgia, Pyrexia, Rash

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female patient with no pertinent medical history and no known drug allergies/drug reactions who on 25-JUN-2008 was vaccinated with the first 0.5 ml dose of GARDASIL (Lot # 659962/1740U) intramuscularly. There was no concomitant medication. It was reported that on 26-JUN-2008 the patient experienced a fever and muscle aches and the symptoms resolved on approximately 30-JUN-2008. On 27-AUG-2008 the patient was vaccinated with the second dose of GARDASIL (Lot # 660555/0279X). On 28-AGU-2008 the patient developed a rash on her trunk. It was reported that the rash resolved on 30-AUG-2008. The patient called health department. This is one of several cases from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340450-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	--	WAES0901USA03654	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from nurse practitioner concerning a "high school age" female patient who on unspecified date was vaccinated with two doses of GARDASIL vaccine. It was reported that the patient fainted after receiving her second dose of GARDASIL vaccine. I was reported that the patient recovered shortly after fainting. The patient sought medical attention. This is one of several cases from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340451-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Apr-2008	Unknown		18-Feb-2009	26-Feb-2009	NM	WAES0901USA03641	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Dizziness, Headache, Learning disorder, Similar reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from a consumer concerning her daughter who on 18-Apr-2008 was vaccinated with the first 0.5ml dose of GARDASIL. After getting the first dose the patient experienced joint pain in back, hip and knees. On 16-Jul-2008 received the second dose of HPV vaccine and experienced fainting, dizziness, headache, trouble comprehending in school and joint pains. At the time of reporting the mother's patient stated that daughter still had headaches and dizziness. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340452-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	26-Nov-2008	26-Nov-2008	0	18-Feb-2009	26-Feb-2009	--	WAES0901USA03640	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT HIV test positive

Symptom Text: Information has been received from a nurse practitioner concerning an 18 year old female patient who on 26-NOV-2008 was vaccinated intramuscularly with a 0.5 ml dose of GARDASIL. It was reported that a HIV test performed on 26-NOV-2008 showed she was IgA positive. A western blot test had an indeterminate result. On 05-DEC-2008 the viral load was 0. On 07-JAN-2009 another HIV EIA ELISA showed she was IgA positive and the Western Blot result was indeterminate. The nurse stated that the results were the same for both dates. Additional information has been requested.

Other Meds: Unknown

Lab Data: Serum tissue, 01/26/08, positive; Serum tissue, 01/07/09, positive; Western blot HIV-1, 01/07/09, indeterminate; Western Blot HIV-1, 01/26/08, indeterminate; Plasma HIV RNA, 12/05/08, 0.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340453-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Oct-2008	16-Oct-2008	0	18-Feb-2009	26-Feb-2009	--	WAES0901USA03550	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cardiac disorder

Symptom Text: Information has been received from a consumer concerning her 14 year old female daughter who on 16-OCT-2008 was vaccinated with the first dose of GARDASIL vaccine. On 16-OCT-2008, the patient had heart problems. It is unknown if the patient sought medical attention. At the time of reporting the patient had not recovered. Therapy with human papillomavirus vaccine was discontinued. This is one of two reports from the same source. The patient's sibling experienced severe breathing problems after vaccination with GARDASIL vaccine (MSD WAES 0901USA03777). No further information is available. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340454-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	PA	WAES0901USA03543	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who on unspecified dates was vaccinated with the first dose and the second dose of GARDASIL vaccine. Concomitant therapy included hepatitis A Vaccine (inactive) (manufacturer unknown) when the patient received the first dose of GARDASIL vaccine. Subsequently, the patient developed 2 nodes on her neck and her "glands" were swollen within 24 hours after receiving the first dose of GARDASIL vaccine. Subsequently, the patient recovered. The physician also noted that the patient experienced the same symptoms after receiving the second dose of GARDASIL vaccine. The patient was seen by the physician. Subsequently, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340455-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	--	WAES0901USA03541	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injected limb mobility decreased

Symptom Text: Information has been received from a physician. The physician reported that "she heard from a friend that the female patient, who was not the physician's patient, on an unspecified date was vaccinated with a dose of GARDASIL. Subsequently the patient was unable to move the arm the injection was given. The physician also reported that the patient had to go to physical therapy". At the time of reporting, the patient's outcome is unknown. Attempts to verify the existence of an identifiable patient (and/or reporter, as appropriate) have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340456-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Jan-2009	23-Jan-2009	0	18-Feb-2009	26-Feb-2009	MA	WAES0901USA03523	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	1398X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Joint swelling

Symptom Text: Information has been received from a Registered Nurse concerning a 14 year old female patient with Flu vaccine allergy and gastroesophageal reflux disease who on 23-JAN-2009 was vaccinated with first dose of GARDASIL vaccine (Lot # 659964/1978U) 0.5ml, intramuscularly and first dose VARIVAX vaccine (Oka/Merck) (Lot#662184/1398Xs). There were no concomitants medications. On 23-Jan-2009 approximately 20 minutes after the patient received vaccines she experienced red and swollen knee. There were no Laboratory diagnostics studies Performed. At the time of the report on 23-Jan-2009 the patient was not recovered. Patient sought medical attention was saw by a nurse. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Allergy to vaccine; Gastroesophageal reflux disease

Prex Vax Illns:

Vaers Id: **340457-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Jun-2008	01-Jun-2008	0	18-Feb-2009	26-Feb-2009	MO	WAES0901USA03516	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lethargy, Pyrexia

Symptom Text: Information has been received from a clerk in a physician's office concerning her 19 year old daughter who in approximately June 2008 "Summer 2008", was vaccinated with first dose of GARDASIL (Lot # not reported). Approximately 24 hours after she became lethargic and developed a fever. The symptoms resolved after 3-4 days. The patient has since had the second and third dose of GARDASIL (Lot # not reported) without any problems or adverse reactions. Patient sought unspecified medical attention. Additional information has been request.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340458-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	22-Jan-2009	23-Jan-2009	1	18-Feb-2009	26-Feb-2009	PA	WAES0901USA03509	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Pain, Tremor

Symptom Text: Information has been received from a nurse concerning a 23 year old female patient who on unspecified dates was vaccinated with the first and the second of GARDASIL. On 22-JAN-2009 the patient was vaccinated with 0.5 ml of the third dose of GARDASIL (Lot not reported). There was no concomitant medication. On 23-JAN-2009 the patient experienced achiness and shaky. As of 23-JAN-2009 the patient outcome was unknown. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340459-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	VA	WAES0901USA03506	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dyspnoea, Injection site reaction, Mass, Myalgia, Nausea, Pyrexia

Symptom Text: Information has been received from a physician concerning a female patient who on unspecified date was vaccinated with her second dose of GARDASIL (Lot not reported). After vaccination the patient developed injection site reaction, fever, nausea, shortness of breath, muscle aches, weakness and lump in her back. On unspecified date the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340460-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	16-Jan-2008	02-Jun-2008	138	18-Feb-2009	26-Feb-2009	FL	WAES0901USA03501	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Herpes simplex

Symptom Text: Information has been received from a office manager concerning a 19 year old female patient with no known drug allergies/drug reactions who on 16-JAN-2008 was vaccinated with the first 0.5 ml dose of GARDASIL intramuscularly. On 12-MAR-2008 the patient received the second dose of GARDASIL (Lot # 659182/1757U). There was no concomitant therapy. It was reported that the patient experienced outbreak of herpes simplex type 1 on 02-JUN-2008. It was reported that the patient was prescribed VALTREX, KEFLEX, and BACTROBAN ointment and subsequently recovered. On 15-JUL-2008, the patient was vaccinated with the third dose of GARDASIL. It was reported that the patient had a pa smear on 14-JAN-2009 which revealed high-risk HPV. The patient sought medical attention with an office visit. This is one of several cases from the same source. Additional information has been requested.

Other Meds: None

Lab Data: Cervical smear, 01/14/09, high risk HPV.

History: None

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340461-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-Oct-2006	Unknown		18-Feb-2009	26-Feb-2009	--	WAES0901USA03498	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0637F	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Information has been received from a registered nurse concerning her 18 year old daughter who on 27-OCT-2006 was vaccinated with the first dose of GARDASIL vaccine (Lot#653937/0637F). Concomitant vaccination included VARIVAX (unspecified). It was reported that patient experienced arm tingling 1 1/2-2 years after receiving her first dose of GARDASIL vaccine. It was reported that the patient did not receive the second or third doses. The patient had recovered on an unspecified date. The patient sought medical attention. Additional has been requested.

Other Meds: INFLUENZA VIRUS VACCINE

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340462-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	23-Jan-2009	23-Jan-2009	0	18-Feb-2009	26-Feb-2009	OH	WAES0901USA03494	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness

Symptom Text: Information has been received from a physician concerning a 13 year old female patient with a history of passing out every time she received an injection, who on 23-JAN-2009 was vaccination with the first dose of GARDASIL vaccine. Concomitant suspect therapy included VARIVAX vaccine (Oka/Merck) (duration and dose not reported). Other concomitant therapy included FLUMIST and HAVRIX. It was reported that the patient passed out after receiving GARDASIL vaccine. The patient passed out after receiving GARDASIL vaccine. The patient had recovered on 23-JAN-2009. The patient sought medical attention. No further information is available.

Other Meds: HAVRIX, FLUMIST

Lab Data: Unknown

History: Passed out

Prex Illness:

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340464-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	31-Dec-2008	14-Jan-2009	14	18-Feb-2009	26-Feb-2009	FL	WAES0901USA03441	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, No reaction on previous exposure to drug

Symptom Text: Information has been received from a nurse at physician's office concerning a female patient who on 31-DEC-2008, was vaccinated with the third dose of GARDASIL, intramuscularly. The nurse reported that on approximately 14-JAN-2009, the patient experienced redness and swelling around injection site about two and half weeks post vaccination. The nurse reported that the patient did not have any reaction after the first or second dose of GARDASIL. No lot number was provided. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340465-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Dec-2008	Unknown		18-Feb-2009	26-Feb-2009	OH	WAES0901USA03440	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a physician who on 01-DEC-2008 was vaccinated with a dose of GARDASIL vaccine. The patient had an abnormal pap. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340466-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	22-Jan-2009	22-Jan-2009	0	18-Feb-2009	26-Feb-2009	KY	WAES0901USA03437	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Insomnia, Pain, Pyrexia

Symptom Text: Information has been received from a physician concerning his 12 year old daughter with no known medical history and drug allergies, who on 22-JAN-2009 was vaccinated with a third dose of HPV vaccine at 15:00. Concomitant therapy included PREVACID. On 22-JAN-2009 the patient had a hard time falling sleep and woke up with a 102 degree fever and her legs were achy. The physician had given his daughter ADVIL liquid gels 400 mg for her symptoms. No laboratory studies were performed. The patient sought medical attention with her father. At the time of this report the patient had not recovered. Additional information has been requested.

Other Meds: PREVACID

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340467-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	23-Jul-2008	23-Jul-2008	0	18-Feb-2009	26-Feb-2009	OH	WAES0901USA03348	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Metrorrhagia, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning a 13 year old female with no drug reactions or allergies who on 23-JUL-2008 was vaccinated with a first dose of GARDASIL 0.5 ml, IM. The patient received the second dose of GARDASIL 0.5 ml, IM on 02-JAN-2009. The nurse reported that the patient experienced "spotting" after each dose. The patient had not previously had a period prior to receiving GARDASIL, so the spotting was unexpected. At time of reporting, the patient had recovered on an unspecified date. There were no lab diagnostic studies performed. The patient sought medical attention at the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340468-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-Jan-2009	21-Jan-2009	1	18-Feb-2009	26-Feb-2009	CA	WAES0901USA03315	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pyrexia, Skin warm, Stomach discomfort

Symptom Text: Information has been received from a consumer concerning his 15 year old daughter with acne, no known allergies and no pertinent medical history, who received her first dose of GARDASIL vaccine in 2008 (lot not reported) On 20-JAN-2009 the patient was vaccinated with 0.5 ml of the second dose of GARDASIL vaccine (yeast) (Lot not reported) intramuscularly. There was no concomitant medication. On the night of 21-JAN-2009 the patient developed upset stomach, headache and a fever (the reporter stated that the patient felt hot to touch). The father stated it could be viral since his daughter was a teenager and was in high school. As of 22-JAN-2009 the patient has not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Acne

Prex Vax Illns:

Vaers Id: **340469-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jan-2009	16-Jan-2009	0	18-Feb-2009	26-Feb-2009	AZ	WAES0901USA03292	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	1311	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning an 18 year old female patient who on 16-JAN-2009 was vaccinated intramuscularly with the first dose of GARDASIL vaccine (Lot# 661531/1311X). Concomitant therapy included ADACEL and tuberculin purified protein derivative (unspecified). On the same day, the patient experienced syncope after receiving her first dose of GARDASIL vaccine. The patient was seen by a nurse. There were no laboratory or diagnostic tests performed. The ptient recovered shortly. Additional information has been requested.

Other Meds:

Lab Data: Tuberculin purified protein.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340470-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	01-Jul-2008		18-Feb-2009	26-Feb-2009	KS	WAES0901USA03289	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a consumer concerning her 14 year old female daughter with no pertinent medical history, no drug reactions/allergies, who in April 2008 was vaccinated with the first dose of GARDASIL vaccine and on an unspecified date was vaccinated with the second dose of GARDASIL vaccine. There was no concomitant medication. In July 2008, the patient noticed that her hair began to thin out and within 2 months she lost all her hair. The reporter took her daughter to the dermatologist. The consumer specified they took test but did not provided what type of test. The consumer stated that "the patient had had wigs and shampoos, name of shampoo unspecified, to help hair grow back, but non of that was working." The dermatologist as well as the family doctor indicated this was due to GARDASIL vaccine. Therapy with human papilloma virus vaccine was discontinued. At the time of reporting, the patient had not recovered. This is one of two reports received from the same source. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory - specified they took test but did not provide what type of test

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340471-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	15-Aug-2008	15-Aug-2008	0	18-Feb-2009	25-Feb-2009	CA	WAES0901USA03288	26-Feb-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	
MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning a female patient who on 15-AUG-2008 was vaccinated with the first 0.5 mL dose of GARDASIL. Concomitant therapy included MENACTRA and hepatitis A virus vaccine (manufacturer unknown). On the same day, the patient experienced dizziness. Subsequently, the patient recovered. The patient sought unspecified medical attention. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340473-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	TN	WAES0901USA03159	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who was vaccinated IM with the first dose of GARDASIL (lot number not provided). Subsequently the patient experienced fainting in the waiting room of the physician's office. At the time of this report, the patient recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340475-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	12-Jan-2009	12-Jan-2009	0	18-Feb-2009	26-Feb-2009	--	WAES0901USA03127	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contusion, Drug administered at inappropriate site

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female with no known drug reaction/allergies and a history of exercise induced asthma who on 02-JUL-2008 was vaccinated with the first dose of GARDASIL vaccine, 0.5ml, intramuscularly. On 05-AUG-2008 was vaccinated with the second dose of GARDASIL vaccine, 0.5ml, intramuscularly and on 12-JAN-2009 was vaccinated with the third dose of GARDASIL vaccine 0.5ml, intramuscularly. The nurse practitioner reported that on 12-JAN-2009, the patient experienced bruising after receiving her third dose of GARDASIL. The nurse also reported that the patient received the third dose as an intramuscular injection that was administered below the deltoid region of the arm. The lot numbers for the vaccines were not available. The patient recovered on an unspecified date. The patient sought medical attention calling to nurse's practice. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **340476-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	20-Jan-2009	20-Jan-2009	0	18-Feb-2009	26-Feb-2009	NJ	WAES0901USA03113	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Incorrect dose administered, No adverse event

Symptom Text: Information has been received from a physician concerning a patient who on 20-JAN-2009 was vaccinated with third dose of GARDASIL (Lot # not reported) Intramuscularly. The patient received less than half her third dose because the patient jerked her arm away during administration of the vaccine. No adverse effect was reported.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340477-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	PA	WAES0901USA03100	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Urticaria

Symptom Text: Information has been received from a nurse concerning a 18 year old female patient who was vaccinated with first dose of GARDASIL (Lot # not reported). After the patient received the vaccine she developed hives and rashes on her face. The patient sought medical attention with the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340478-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	MA	WAES0901USA03098	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who was vaccinated with two doses GARDASIL. Subsequently the patient may be experiencing irregular menstrual cycles. At the time of this report, the outcome was unknown. The patient sought medical attention via telephone. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340479-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	--	WAES0901USA03097	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a Nurse Practitioner concerning a female who was vaccinated with a first dose of GARDASIL vaccine, and developed hives on her chest and neck. The patient sought nurse practitioner for medical attention. At the time of reporting, the patient's outcome was unspecified. Additional information has been requested

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340480-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Oct-2008	Unknown		18-Feb-2009	26-Feb-2009	FL	WAES0901USA03093	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Inappropriate schedule of drug administration, Psoriasis

Symptom Text: Information has been received from a physician concerning a 17 year old female patient who on 27-JUN-2008 was vaccinated with first dose of GARDASIL (Lot # 660555/0279X) and on 13-OCT-2008 she received second dose of GARDASIL (Lot # 660555/0279X). At an unspecified interval after her second dose she developed "allergies". The patient went to an immunologist and allergist for these "allergies". Both specialists diagnosed her with "psoriasis due GARDASIL". Patient was currently beginning treatment for this condition but no specifics known. At the time on the report on 21-JAN-2009 patient was not recovered. Patient sought medical attention at the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340481-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	20-Jan-2009	20-Jan-2009	0	18-Feb-2009	26-Feb-2009	--	WAES0901USA03077	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Fatigue, Syncope

Symptom Text: Information has been received from a practice manager concerning a 21 year old female with no pertinent medical history, drug reactions or allergies who on 20-JAN-2009 was vaccinated intramuscularly with a first 0.5 ml dose of GARDASIL (Lot#660616/0570X). Concomitant therapy included YAZ. On 20-JAN-2009, "within 30seconds of receiving her first dose of GARDASIL vaccine", the patient fainted. she revived after a few minutes her fainted again "15 minutes later". It was reported that the patient revived and was given juice and crackers, and left the office in stable condition. A follow-up phone call was placed to the patient on 21-JAN-2009 and the patient stated that she felt "tired and weak". No lab diagnostic studies were performed. At time of the report, 21-JAN-2009, the patient had not recovered. Additional information has been requested.

Other Meds: YAZ

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340482-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	31-Dec-2008	31-Dec-2008	0	18-Feb-2009	26-Feb-2009	FL	WAES0901USA03066	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	00663X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site mass, Injection site pain, Injection site swelling

Symptom Text: Information has been received from an office manager (also reported as an emergency medical technician concerning a 23 year old female patient with graves' disease, no drug reactions / allergies, who on 11-Oct-2007 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL. Concomitant therapy included ethinyl estradiol Seasonale and LEXAPRO. On 31-Dec-2008 the patient was vaccinated intramuscularly with the third 0.5ml dose of GARDASIL (lot#660391/0063X). On 19-Jan-2009 the patient developed a painful, swollen lump at the injection site. The patient was examined in the office on 21-Jan-2009 and was prescribed warm compresses and ibuprofen. There were no laboratory or diagnostic test performed. At the time of reporting, the patient had not recovered. Additional information has been requested.

Other Meds: Lexa pro ; Seasonale

Lab Data: None

History:

Prex Illness: Graves disease

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340483-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-Jan-2009	19-Jan-2009	0	18-Feb-2009	26-Feb-2009	OH	WAES0901USA03059	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Rash

Symptom Text: Information has been received from a registered nurse concerning a 12 year old female patient who on 11-OCT-2008 was vaccinated with the first dose of GARDASIL (Lot # 660393/0067X) and on 19-JAN-2009 received the second dose of GARDASIL (Lot # 661046/0381X). After receiving her second dose of GARDASIL the patient developed a rash on her chest. She was prescribed BENADRYL for the treatment of her symptoms. It was reported that there was no adverse event after the first dose of GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340484-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jan-2009	01-Jan-2009	0	18-Feb-2009	26-Feb-2009	--	WAES0901USA03056	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a 14 year old female who "sometime this month" was vaccinated with the first dose of GARDASIL vaccine. Subsequently the patient fainted. At time of the report the patient was recovered. The patient sought medical attention: the patient was in the clinic when AE occurred. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340485-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	CA	WAES0901USA03051	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning several females who on unknown date were vaccinated with GARDASIL vaccine. On unspecified date the patients experienced mild nausea and vomiting. At the time of reporting, the outcome was not reported. Attempts were made to obtain additional identifying information to distinguish the individual patients mentioned in this report. The reporter did not know how many girls or their names. This is one of the several reports from the same source. No further information was available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340486-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	AL	WAES0901USA02938	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information has been received from physician concerning a 14 year old female who was vaccinated the first dose of with GARDASIL on an unspecified date. Subsequently the patient experienced abnormal wart growth on the inside of her thigh. She was not given any further doses or medication to treat the wart. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340487-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	03-Dec-2008	03-Dec-2008	0	18-Feb-2009	26-Feb-2009	--	WAES0901USA02772	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Diarrhoea, Dizziness, Headache, Influenza like illness, Nausea, Pain

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female who on 03-DEC-2008 was vaccinated with the first dose of GARDASIL (lot # 0947X), IM, 0.5 ml. There was no concomitant medication. On the same day the patient experienced flu like symptoms including nausea, dizziness, headache, body ache and diarrhea. The patient did not perform any lab diagnostics study. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340488-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	19-Dec-2008	19-Dec-2008	0	18-Feb-2009	26-Feb-2009	MA	WAES0901USA02752	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Oedema peripheral

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female who on 12-MAY-2008 was vaccinated intramuscularly in the left arm with a first dose of GARDASIL (lot # 660387/1967U) 0.5 mL and on 19-DEC-2008 was vaccinated with a second dose of GARDASIL (lot # 660585/0297X). On 20-DEC-2008 the patient experienced swelling of her entire left arm and hand. On unspecified date, the patient recovered. This AE was mentioned to the physician by the patient's mother during an office visit with sibling of the patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340489-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	01-Oct-2008	01-Oct-2008	0	18-Feb-2009	26-Feb-2009	TN	WAES0901USA02751	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, No reaction on previous exposure to drug

Symptom Text: Information has been received from a pharmacist concerning her 9 year old daughter who in August 2008, was vaccinated with a first dose of GARDASIL and in October 2008, was vaccinated with a second dose of GARDASIL. There was no concomitant medication. In approximately October 2008 (some time after Dose 2), the patient experienced hair shedding and hair loss. The patient did not seek medical attention. At the time of reporting, the patient's hair shedding and hair loss persisted. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340490-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	09-Jan-2009	09-Jan-2009	0	18-Feb-2009	26-Feb-2009	CO	WAES0901USA02738	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect route of drug administration, Injection site haematoma

Symptom Text: Information has been received from a nurse concerning a 25 year old female with no drug allergy who on 09-JAN-2009 was vaccinated with the first dose of GARDASIL (661531/1311X), 0.5 ml. Concomitant therapy included DEPO-PROVERA. The nurse indicated that the GARDASIL may have been administered as a subcutaneous injection. Subsequently the patient experienced bruising at the site of GARDASIL administered. The patient did not perform lab diagnostics study. At time of the report the patient was recovered. The patient called the practice. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340491-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	01-Jan-2008		18-Feb-2009	26-Feb-2009	--	WAES0901USA02737	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Breast cyst

Symptom Text: Information has been received from a nurse practitioner concerning a female who was vaccinated with the first dose of GARDASIL. "Few months ago" the patient found a hard round cyst in left breast after receiving GARDASIL. The patient performed breast exam. At the time of the report the patient was not recovered. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340492-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Jan-2009	19-Jan-2009	0	18-Feb-2009	26-Feb-2009	CA	WAES0901USA02713	09-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	2	Left arm	Intramuscular	HPV4

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Bradycardia, Nausea, Syncope, Syncope vasovagal, Vomiting

Symptom Text: Information has been received from a physician concerning a female who on was vaccinated in the deltoid with the first and second dose of GARDASIL on unspecified date and experienced nausea. On 19-JAN-2009 she was vaccinated in the deltoid with a third dose of GARDASIL. On 19-JAN-2009, the patient experienced severe vomiting, nausea and low heart rate and became weak. The patient had electrocardiogram performed and the result was not reported. The patient sought unspecified medical attention. On the same day shortly afterwards, the patient recovered. Follow-up information was received from the physician's nurse via phone call. The patient also experienced nausea after the first and second dose of GARDASIL. This is one of the several reports from the same source. Additional information has been requested. 3/3/09 Received vaccine records & medical records from PCP. FINAL DX: vasovagal attack Records reveal patient was in good health on 9/11/06 for HPV #1. RTC 8/27/07 for HPV #2 w/dysmenorrhea & tender lymph node on neck. Started BCP. RTC 5/1/08 w/depression. Tx w/meds & referred for counseling. RTC 9/29/08 w/strep throat. RTC 1/19/09 for HPV #3 then fainted, vomited, nauseated, bradycardia.

Other Meds: Unknown

Lab Data: Unknown LABS: EKG WNL.

History: Unknown PMH: cholelithiasis, wheezing, UTI. Allergy: several drugs. Contraception patch. Menometrorrhagia, dysmenorrhea, strep throat, depression, whiplash injury, ADHD, cardiac arrhythmia, lymphadenopathy, chronic bronchitis, conjunctivitis, allergic rhinitis.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340493-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Jan-2009	16-Jan-2009	0	18-Feb-2009	26-Feb-2009	--	WAES0901USA02707	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a healthcare worker concerning a 14 year old female with penicillin allergy and drug hypersensitivity of DARVOCET-N who on 16-JAN-2009 was vaccinated intramuscularly with a first dose of GARDASIL (lot # 661766/0652X) 0.5 mL. There was no concomitant medication. Within a few hours of receiving GARDASIL the patient experienced a rash on her neck and chest. The patient called the practice. On unspecified date, the patient recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Penicillin allergy; Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340494-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jan-2008	01-Jan-2008	0	18-Feb-2009	26-Feb-2009	KY	WAES0901USA02700	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Cough, Dizziness

Symptom Text: Information has been received from a physician concerning a female with eczema who about 1 year ago, was vaccinated with the first dose of GARDASIL, 0.5 mL, intramuscularly (lot number not reported). It was reported that the patient developed a persistent dry cough immediately after receiving the GARDASIL. The cough is worse at night but does not wake the patient. She experienced dizziness and weakness immediately after administration of the vaccine but the symptoms were resolved in 2 days without treatment. The patient did not return to the office to complete the vaccine series. They physician has scheduled the patient for an office evaluation. The physician did not think that the vaccine caused the persistent dry cough, and the patient will be worked up for allergies. Patient not recovered from persistent drug. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 340500-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	02-Oct-2007		24-Feb-2009	25-Feb-2009	DE	WAES0711USA01322	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Back pain, Drug exposure during pregnancy, Induced labour, Nausea, Uterine contractions during pregnancy, Vomiting

Symptom Text: Initial and follow-up information has been received through the Merck pregnancy registry through a 23 year old female consumer who was vaccinated with her first dose of GARDASIL (date not specified). On an unspecified date, the patient was vaccinated with her second dose of GARDASIL. On 19-OCT-2007, the patient was vaccinated with her third dose of GARDASIL. There was no concomitant medication. Subsequently, the patient found out she was 5 weeks pregnant (LMP approximately 02-OCT-2007). In follow-up information, the patient reported that on 02-JUL-2008, she had her baby boy. Follow up information has been received from the consumer and a completed questionnaire on 16-FEB-2009. The consumer reported that her son was now 7 months old and was healthy and well. He weighed 7lbs 14 oz, and was 21" long at birth. She stated she was told the baby is physically and developmentally at a 1 year old level, doing very well. The consumer said she had some minor complications during the pregnancy, starting with nausea and vomiting for the first five months, and at 25 weeks had a lot of premature contractions but only dilated to 1 cm. She was advised to increase her rest based on the number of contractions she was having. She never had any further cervical changes, and never had a diagnosis of preterm labor, just preterm contractions. Her labor was induced at 39 weeks (reason not provided) and had a normal vaginal delivery. It was reported on the questionnaire that the patient with no infections or illnesses during pregnancy, no concurrent medical conditions, on an unspecified date experienced low back pain during pregnancy. Other medications used during this pregnancy included REGLAN, ZOFRAN and prenatal vitamins (unspecified). The patient had a negative "CF" profile and 1st trimester ultrasound screening within range. On 02-JUL-2008 at 37 weeks from LMP, the patient delivered with no complications, a normal male liveborn infant with no congenital anomalies or other complications or abnormalities. He weighed 7lbs 14 oz, and was

Other Meds: REGLAN; ZOFRAN; vitamins (unspecified)

Lab Data: diagnostic laboratory, CF profile negative; diagnostic laboratory, 1st trimester us screening within range

History:

Prex Illness: Pregnancy NOS (LMP = 10/2/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340501-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		24-Feb-2009	25-Feb-2009	--	WAES0902USA01674	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial palsy, Headache

Symptom Text: Information has been received from a Registered Nurse (R.N.) concerning a patient who was vaccinated with the second dose of GARDASIL. The patient experienced paralysis on the right side of her face 10 days after receiving the second dose of vaccine provided during a clinical trial. The patient also noted that she has experienced headaches since receiving the second dose. Upon internal review, paralysis on the right side of the face was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340502-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Sep-2008	01-Sep-2008	0	24-Feb-2009	25-Feb-2009	WA	WAES0902USA03098	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypoaesthesia

Symptom Text: Information has been received from a physician concerning a 19 year old female who in early September 2008, was vaccinated with the first dose of GARDASIL (lot # not reported). The physician stated that the patient received the first dose of GARDASIL and then she started to have numbness all throughout her body. The physician does not know if the numbness started at the injection site or not, but the numbness started to get progressively worse. The patient had a test done for multiple sclerosis and lyme disease with negative results. The physician indicated that the patient still has the numbness throughout her body. The physician considered the event to be disabling. Additional information has been requested.

Other Meds: Unknown

Lab Data: clinical immunology, multiple sclerosis negative; Lyme disease assay, negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340503-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		24-Feb-2009	25-Feb-2009	--	WAES0902USA02699	25-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Eating disorder, Gastrointestinal disorder, Hypoaesthesia, Pain

Symptom Text: Information was viewed on the internet concerning a 14-year-old female patient, who on an unspecified date was vaccinated with a dose (s) of GARDASIL. It was reported that the patient has been "suffering since September 2008, she is now in her third hospital". It was also reported that she "has nearly died from this vaccine. She can not eat anything, her digestive system and intestines have shut down, she had the numbness in her legs and the horrible pain. She has nearly lost her entire freshman year of high school, her mother has not been able to work since September". No further information is expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340510-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	09-Feb-2009	09-Feb-2009	0	24-Feb-2009	26-Feb-2009	OK		26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1311X	0	Left arm	Unknown	
	VARCEL	MERCK & CO. INC.	1548X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site pruritus, Injection site swelling

Symptom Text: Left arm was swollen from shoulder down to elbow, golf ball sized, red, hard knot at injection site + itching.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340523-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	18-Feb-2009	18-Feb-2009	0	24-Feb-2009	26-Feb-2009	OR		17-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Anorexia, Anxiety, Asthenia, Chills, Dizziness, Dyspnoea, Gait disturbance, Headache, Heart rate irregular, Mobility decreased, Nausea, Palpitations, Peptic ulcer, Sinus tachycardia, Visual impairment

Symptom Text: < 1 hr post vaccine admin. Pt c/o lightheaded, loss of appetite, nausea, cold chills, unable to move feet. C/o vision change. 1 hour later pt c/o headache & stomach pain. C/o weakness. Difficulty ambulating. & irregular heartbeat & palpitations. 3/16/09 Received PCP medical records of 1/28-2/19/2009. FINAL DX: anxiety, sinus tachycardia resolved. Records reveal patient experienced epigastric pain c/w PUD. Tx w/meds. RTC 2/18 & epigastric pain had resolved until day prior when returned but much milder. To continued meds x 2 mo than return for recheck. Seen in ER on 2/19 for SOB, tachycardia. Exam at that time was WNL & d/c to home.

Other Meds: TRINESA; OMEPRAZOLE

Lab Data: LABS: EKG WNL. H.pylori (-).

History: None

Prex Illness: Possible stomach ulcer

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340524-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Feb-2009	17-Feb-2009	0	24-Feb-2009	26-Feb-2009	MT		26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash

Symptom Text: TC from pt one hour after recurring second shot of GARDASIL. Pt self report "3 white spots, on my face" noticed after she left the clinic. "a little itchy" advised to go to Urgent care- denied sob, facial swelling no other hives or itchiness. Pt did not go to Urgent care she called her mom who told her to call her primary care doctor who advised her to take po BENADRYL which she did. Attempt to call pt to see if symptoms resolved- pt did not call back yet.

Other Meds: NUVARING

Lab Data:

History: Allergy: Chocolate

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340529-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Feb-2009	18-Feb-2009	1	24-Feb-2009	25-Feb-2009	OR		26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1017X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0575X	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2965AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2030AA	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB260AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye irritation, Feeling hot, Headache, Loss of consciousness, Rash

Symptom Text: C/O feeling hot, HA, eyes burning then blacked out. Woke up on floor. Also w/ rash on abdomen and thigh.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340539-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Feb-2009	Unknown		24-Feb-2009	26-Feb-2009	KY		26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	14464	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle spasms, Skin hyperpigmentation

Symptom Text: Hyperpigmentation on (L) arm (Linear appearance), non-raised, even distribution, cramping in hands (B) on occasions

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340553-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	16-Jun-2008	Unknown		24-Feb-2009	26-Feb-2009	NY		26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: pt states after she received 2nd vaccine of gardasil she continues with a rash on her body.Saw PCP doctor was then referred to dermatologist were contact dermitis was discussed with pt.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340584-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	11-Feb-2009	13-Feb-2009	2	24-Feb-2009	26-Feb-2009	NC		27-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Chills, Decreased appetite, Diarrhoea, Fatigue, Feeling abnormal, Headache, Hyperacusis, Lymphadenopathy, Malaise, Nausea, Pain, Photophobia, Vision blurred

Symptom Text: Patient calls VHC x 3 in past week. "Just don't feel like myself; very tired, achy, constant HA, nodes on side of neck and under chin are enlarged." Reports chills, general malaise, ongoing, constant frontal HA with changes in vision- not as sharp with glasses on and blurry with glasses off, photophobia, some noise sensitivity, slight nausea (negative prior hx migraines), decreased appetite, loose stools s/p GARDASIL #1 on 02-11-09. Seen by PCP on 02-20-09, who Dx'd as "Acute Cervical Lymphadenitis." Bloodwork: CBC with DIFF, CMP, ESR, HIV-1 AB, RPR, Reticulocytes, TSH sensitive ALL WNL with exception of slightly decreased Hgb of 11.7 - patient states she was at the end of her menstrual cycle when the labs were drawn. HIV-1 AB and RPR results pending-advised patient to call PCP for results. Patient is very anxious because her cousin was recently dx'd with HIV. Patient is currently not sexually active- her husband, AD military spouse, is deployed at present.

Other Meds: Ibuprofen 800 mg po tid with food; EXCEDRIN prn for HA's; OTC Super B-Complex

Lab Data: CBC with Diff; ESR; TSH-sensitive; CMP; HIV-1 AB; RPR

History: NKDA. Patient had recent (10FEB09) Allergy work-up, which was negative for environmental allergens per skin testing. Normal Pulmonary Function testing. Dx was vasomotor rhinnitis.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340594-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Feb-2009	24-Feb-2009	0	24-Feb-2009	26-Feb-2009	MD		26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1423X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: 3rd dose of GARDASIL administered on 2/24/09. Pt experienced syncope, pt recovered well. Waited 15 mins. Stated she felt better exited office.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **340596-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	--	WAES0901USA02699	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Muscular weakness, Paraesthesia

Symptom Text: Information has been received from a registered pharmacist concerning three female patients who on unknown dates were vaccinated with GARDASIL, lot # not reported. The pharmacist stated that she heard of three patients who experienced immediately "electric feeling" pain at injection site when GARDASIL vaccine was administered. The pain extended down to the finger tips from the injection site of upper arm. The pain resolved without treatment within a few hours but the "arm felt weak for a couple of days". All three patients recovered fully. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340597-1** **Related reports:** 340597-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	15-Apr-2008	01-Sep-2008	139	18-Feb-2009	26-Feb-2009	PA	WAES0901USA02690	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Anaemia

Symptom Text: Information has been received from a consumer concerning her 18 year old daughter with asthma who in the summer of 2008, was vaccinated with the first dose of GARDASIL (lot # was not reported). Concomitant therapy included ADVAIR. The patient's mother stated her daughter had 2 doses of the vaccine and reported that around the first week of September 2008 the patient's hair started to fall out. The consumer stated that her daughter's hair started to fall out in clumps and within months all of her fell out. The patient was seen by a rheumatologist, her primary care physician, and a dermatologist; numerous amounts of blood work were done for all auto immune disorders, vitamin deficiency, Lyme disease and many others. The only thing that the blood work has shown is that she was slightly anemic. They still can not find anything that would cause her hair to fall out. The consumer stated that she did not let her daughter get the third dose and stated that she did research that the vaccine can cause alopecia and she can not figure anything else but the vaccine that could cause this. This is one of several reports received from the same source. Additional information has been requested. 4/3/09 Office note received for DOS 2/26/09 with DX: Alopecia areata, approaching universalis. Pt presented with c/o progressive, extensive hair loss involving scalp, eyebrows, eyelashes and body hair since 9/2008. PE confirms c/o. Tx: steroids.

Other Meds: ADVAIR

Lab Data: hematology, for auto immune disorder, vitamin deficiency, Lyme disease

History: PMH: asthma, Hep C

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **340597-2 (S)** **Related reports:** 340597-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Apr-2008	01-Nov-2008	200	24-Mar-2009	25-Mar-2009	PA		25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	17574	1	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Alopecia areata, Alopecia effluvium, Alopecia universalis, Menstruation irregular, Stress, Weight increased

Symptom Text: Pt seen 12/1/08 for hair loss started "past several weeks" mother concerned pt may have "alopecia areata" about 5-6 yrs ago mom had seen some "bald spots" went away. Receding hairline "few weeks ago", also wt gain 12 lb in 10 month, irregular menses; history of increase stressors at that time includ. applying to college, nervous about acceptance, and living in dorm - sharing bathroom, fear exposure to germs, father lost job, filing bankruptcy. PE showed diffuse hair thinning. Dx: telogen effluvium alopecia--> refer to Derm; Labs drawn. Rx topical triamcinolone oint 0.1% TID x 2-3 wk. Pt transferred records to another doctor 12/26/08. Now parents state diagnosed with alopecia universalis. They feel is from her GARDASIL vaccine.

Other Meds: ADVAIR 250/50; WESTCORT Cream 0.2% topically; ZYRTEC D; RHINOCORT nasal spray.

Lab Data: By my office: 12/4/08 CBC, comp. metabolic profile; ESR; TSH; free T4 - within normal limits

History: Allergic rhinitis; asthma; eczema

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340598-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Nov-2008	01-Nov-2008	0	18-Feb-2009	26-Feb-2009	--	WAES0901USA02575	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Allergy to vaccine, Swelling face, Urticaria

Symptom Text: Information has been received from a consumer concerning her approximately 20 year old daughter with no pertinent medical history, who in November or December 2008 was vaccinated with the second dose of GARDASIL (no lot # provided) and broke out in hives on her face with swelling on her face. There was no concomitant medication. Patient sought medical attention by going to the allergist and was allergy tested which determined she is allergic to GARDASIL which will not be reintroduced. At the time of this report, the patient had not yet recovered. Additional information has been requested.

Other Meds: None

Lab Data: Allergy test

History:

Prex Illness: Allergy to vaccine

Prex Vax Illns:

Vaers Id: **340599-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jun-2008	Unknown		18-Feb-2009	26-Feb-2009	--	WAES0901USA02567	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal distension, Drug exposure during pregnancy, Vomiting in pregnancy

Symptom Text: Information has been received from a consumer for the pregnancy registry of GARDASIL vaccine concerning his fiancee who has has two doses of GARDASIL vaccine beginning in June 2008. It was reported that the patient had the symptoms of pregnancy such as morning sickness and bloating. At the time of the report the patient had no pregnancy test done. The patient did not seek medical attention. No further information is available.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340600-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
1.3	M	Unknown	Unknown		18-Feb-2009	26-Feb-2009	WV	WAES0901USA02535	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	MMR	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Wrong drug administered

Symptom Text: Information has been received from a medical assistant and a registered nurse concerning a 15 month old patient who vaccinated with a dose of GARDASIL due to nursing error. No adverse effect reported. Follow up information was received on 27-Jan-2009: The healthcare worker reported that the patient was supposed to received Enders-Edmonston + Jeryl-Lynn + Wistar RA 27/3 but the nurse grabbed GARDASIL instead. It was reported that the patient experienced a rash on his trunk and neck. It was reported that the patient was given Benadryl and the symptoms improved. It was reported that the patient has not received Enders-Edmonston + Jeryl-Lynn + Wistar RA 27/3 MSD. Follow-up information received from a registered nurse on 30-Jan-2009 who reported that the rash that the patient developed faded the next day and was gone by 2 days. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340601-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	14-Jan-2009	24-Jan-2009	10	18-Feb-2009	26-Feb-2009	TX	WAES0901USA02502	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Burning sensation, Incorrect route of drug administration, Pain in extremity

Symptom Text: Information has been received from a medical assistant concerning a female patient who on 14-JAN-2009 was vaccinated subcutaneously with the third dose of GARDASIL vaccine instead of intramuscularly. The reporter stated that the patient reported a "burning feeling" down her arm when the GARDASIL vaccine was given, and she did not have this "burning feeling" after the first two doses but only with this last dose. The patient currently had some soreness in the lower triceps of her arm. The patient sought unspecified medical attention. At the time of reporting, the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340602-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Jan-2009	03-Jan-2009	0	18-Feb-2009	26-Feb-2009	NY	WAES0901USA02494	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oligomenorrhoea, Urticaria

Symptom Text: Information has been received from a patient's mother concerning her 12 year old daughter with no pertinent medical history and no known drug allergies/drug reactions who on 03-JAN-2009 was vaccinated with the third dose of GARDASIL. There was no concomitant medication. It was reported that the patient's menstrual cycle was going on 10 days and had hives. At the time of the report the patient had not laboratory diagnostics studies performed. At the time of the report the patient had not recovered. The patient did not seek medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340603-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Jan-2009	15-Jan-2009	0	18-Feb-2009	26-Feb-2009	--	WAES0901USA02463	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a 13 year old female patient who on 15-JAN-2009 was vaccinated intramuscularly with the second dose of GARDASIL vaccine into the upper deltoid. Concomitant therapy included INFLUENZA VIRUS vaccine (unspecified) in the opposite arm. Within a few moments of receiving the second dose of GARDASIL vaccine, the patient fainted. The patient sought unspecified medical attention. Subsequently, the patient recovered. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vaers Id: 340604-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	22-Dec-2008	Unknown		18-Feb-2009	26-Feb-2009	--	WAES0901USA02390	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site mass, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female patient with AZITHROMYCIN allergy and a history of seizures and a strong family history of cancer, who on 22-DEC-2008 was vaccinated with a dose of GARDASIL vaccine. Concomitant therapy included YASMIN. On an unknown date the patient developed a painful lump. It was reported that there is still a "knot" in the arm, tenderness and swelling. The patient was seen for an office visit. Additional information has been requested.

Other Meds: YASMIN

Lab Data: Ultrasound - subcutaneous small bruise / post inflammatory change

History: Convulsion; Family history of cancer

Prex Illness: Drug hypersensitivity

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340605-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	--	WAES0901USA02385	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a Nurse Practitioner concerning a female patient who completed GARDASIL vaccine (lot # not provided) series. The patient was sexually active and she was positive for the HPV Test. This is one of two reports from the same source. Additional information has been requested.

Other Meds:

Lab Data: Cervix HPV DNA assay, Positive

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340606-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	--	WAES0901USA02384	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a doctor of pharmacy who spoke with a nurse in her facility and stated that on an unspecified date another patient was vaccinated with the GARDASIL series. It was reported that the patient has experienced loss of menses after starting the GARDASIL series. This is one of several cases from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340607-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Oct-2008	20-Nov-2008	50	18-Feb-2009	26-Feb-2009	--	WAES0901USA02133	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Drug exposure during pregnancy, Nausea

Symptom Text: Information has bee received from a 19 year old female patient for GARDASIL, concerning herself with no pertinent medical history and no known drug allergies who on 01-OCT-2008 was vaccinated with the first dose of GARDASIL (lot # not provided). There was no concomitant medication. In December 2008 the patient became pregnant. LMP was 20-NOV-2008, and EDD was 27-AUG-2009. In December 2008, the patient experienced pregnancy symptoms like dizziness and nausea. Home urine pregnancy test was performed (no result provided). At the time of this report, the adverse events were ongoing. The patient sought medical attention via contacting physician. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP=11/20/2008)

Prex Vax Illns:

Vaers Id: **340608-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	OK	WAES0901USA02114	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea

Symptom Text: Information has been received from physician concerning a female patient who was vaccinated with a 0.5 ml dose of GARDASIL vaccine. The patient experienced shortness of breath 24 hours after receiving GARDASIL vaccine. At the time of reporting the patient was recovered. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vaers Id: **340609-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Jan-2009	15-Jan-2009	0	18-Feb-2009	26-Feb-2009	OK	WAES0901USA02093	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle spasms, Pain, Tenderness

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 15-JAN-2009 was vaccinated with a 0.5 ml dose of GARDASIL vaccine. Subsequently (on 15-JAN-2009) the patient experienced severe muscle spasms in right flank above hip into back, and pain and tenderness to touch. Symptoms started 15 to 20 minutes after leaving the office. At the time of the report, 15-JAN-2009, the patient was reportedly recovering. No further information was provided. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340610-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Jan-2008	15-Jan-2009	380	18-Feb-2009	26-Feb-2009	--	WAES0901USA02043	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a 19 year old female with no drug allergy who in January 2008 was vaccinated with the first dose of GARDASIL. She stated she had all 3 doses. On 15-JAN-2009 the patient was told she had papilloma viral infection. No medical attention was sought. At the time of reporting, the patient's HPV infection persisted. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340611-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	RI	WAES0901USA02042	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pelvic pain

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a third dose of GARDASIL vaccine and experienced pelvic pain. Unspecified medical attention was sought. At the time of reporting, the patient's outcome was unspecified.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340612-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	09-Oct-2008	16-Oct-2008	7	18-Feb-2009	26-Feb-2009	--	WAES0901USA02018	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a registered nurse concerning a 20 year old female who on 09-OCT-2008 was vaccinated with the first 0.5 ml dose of GARDASIL vaccine (lot#661764?0650X). There was no concomitant medication. One week later after getting GARDASIL vaccine the patient developed alopecia, she would not be taking any more doses of GARDASIL vaccine. At the time of reporting, the outcome was unknown. No additional information was provided. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340613-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	03-Feb-2008	27-Jun-2008	145	18-Feb-2009	26-Feb-2009	GA	WAES0901USA02008	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse concerning a 19 year old female patient for the pregnancy registry for GARDASIL. With allergy to BENADRYL, who on 03-Feb-2008 was vaccinated with the first dose of GARDASIL. On an unspecified date the patient received the second dose GARDASIL. Concomitant therapy included prenatal vitamins. She was determined to be pregnant. Last menstrual period: 27-Jun-2008. Estimated delivery date: 03-Apr-2009. In October 2008, she tested positive for HIV ELTSA test and negative for HIV western blot test. In December 2008 she tested undetermined for HIV western blot

Other Meds: Vitamins

Lab Data: Diagnostic Laboratory - Syphilis negative; Diagnostic Laboratory - prenatal screen ; Serum HIV-1 and/ or 2 10/08 - positive; Serum HIV-2 western blot 10/08 - negative; Serum HIV-2 western blot 12/08 - undetermined; Serum hepatitis B AB - n

History:

Prex Illness: Pregnancy NOS (LMP=6/27/2008) Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340614-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Oct-2007	01-Oct-2007	0	18-Feb-2009	26-Feb-2009	--	WAES0901USA01986	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Amenorrhoea, Skin discolouration, Weight increased

Symptom Text: Information has been received from a doctor of pharmacy concerning her daughter who in October 2007 was vaccinated with the first dose of GARDASIL. In December 2007 the patient received her second dose of GARDASIL and in July 2008 the patient was vaccinated with the third dose of GARDASIL. It was reported by the pharmacist that since her daughter was given the GARDASIL she has not had a menstrual cycle. Her daughter also had dark spots on her hands, has had an increase in weight gain and hair loss since she started the GARDASIL series. The patient had not recovered at the time of the report. Follow up information was received on 16-JAN-2009: the doctor of pharmacy stated that her daughter was not pregnant. She stated her daughter was an otherwise healthy 14 year old. It was reported that the patient was amenorrheic for almost one year. It was reported that the patient was no taking any other concomitant medication. The pharmacist was concerned regarding the possibility of future fertility problems for her daughter in the near future. The doctor of pharmacy had a full medical evaluation scheduled for her daughter in the near future. This is one of several cases from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 340615-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	28-Oct-2008		18-Feb-2009	26-Feb-2009	NC	WAES0901USA01979	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hypoaesthesia, Muscular weakness, Paraesthesia, Throat tightness, Urticaria, Vision blurred

Symptom Text: Information has been received from a physician and her assistant concerning 23 year old female who on an unknown date was vaccinated with a first dose of GARDASIL vaccine and a second dose of GARDASIL vaccine on 12-JAN-2009, lot number 661766/0652X. It was reported that the patient experienced dizziness and blurry vision after receiving the first dose of GARDASIL vaccine. On 12-JAN-2009 the patient felt like her throat was closing and took BENADRYL. On 14-JAN-2009 the patient called the office and reported her left leg and arm were numb, right hand was tingling and she was still experiencing intermittent blurry vision. The physician prescribed ZYRTEC for the next week to treat what she feels may be an allergic reaction to the vaccine. Her outcome is unknown. Follow-up information received from physician's assistant indicated that the patient was vaccinated with the first dose of GARDASIL vaccine on 28-OCT-2008, lot number 661530/0575X. Concomitant medication include FENCOM for birth control. It was reported that the patient called the office on 15-JAN-2008 to report that she was experiencing hives. Follow up information was received from the physician who noted that the patient has a long-standing "histrionic personality" and an anxiety disorder for which she takes KLONOPIN as needed. She claims to have experienced some throat tightness after dose 1, but did not report this to her physician until after his occurred with dose 2. She has had multiple symptoms of numbness, tingling and weakness of the extremities (of note, the injection was given in the right arm but complaining have been on the left side initially, then bilaterally); however, she has been able to go to work as a hairdresser. Since the development of hives, the patient has not been seen in the office and has not responded to phone messages from the physician's office. No further doses of GARDASIL are planned, given the concern about hypersensitivity. Follow-up information received from her physician indicated that the patient called the office on 1

Other Meds: KLONOPIN; FEMCON FE

Lab Data: Unknown

History:

Prex Illness: Contraception; Anxiety disorder; Histrionic personality

Prex Vax Illns:

Vaers Id: **340616-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	30-Nov-2007	01-Dec-2008	367	18-Feb-2009	26-Feb-2009	--	WAES0901USA01978	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a Nurse Practitioner concerning a 22 year old female virgin patient with no pertinent medical history no drug reactions or allergy who on 07-JUN-2007 was vaccinated with first dose of GARDASIL vaccine (lot # not reported) 0.5ml, intramuscularly. On 09-AUG-2007 patient received second dose of GARDASIL vaccine (lot # not reported) 0.5ml, intramuscularly and on 30-NOV-2007 she received third dose of GARDASIL vaccine (lot # 659439/1267U) 0.5ml, intramuscularly. Concomitant therapy included hormonal contraceptives (unspecified). Patient was virgin prior GARDASIL vaccination. In December 2008 the patient had an abnormal pap and DNA test was positive for high risk HPV. Patient sought medical attention was seen in the office. This is one of two reports from the same source. Additional information has been requested.

Other Meds: HORMONAL CONTRACEPTIVES

Lab Data: Pap test, 12/??/08, - Abnormal; Cervix HPV DNA assay, 12/??/08, - was positive for high risk HPV

History: None

Prex Illness:

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340617-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	--	WAES0901USA01971	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass, Injection site pain

Symptom Text: Information has been received from a registered nurse concerning a female, who was vaccinated with the second dose of GARDASIL, IM in upper deltoid, single dose vial. Subsequently the patient experienced an injection site reaction which included a lump and soreness about 4-5 days after receiving the vaccine. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340618-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Jan-2009	15-Jan-2009	1	18-Feb-2009	03-Mar-2009	PA	WAES0901USA01963	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Rash

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female patient with penicillin allergy, who on 14-JAN-2009 was vaccinated with the first 0.5 mL dose of GARDASIL (Lot # 661530/0575X). On 15-JAN-2009 the patient experienced a rash on her wrist and up her arm. The patient sought unspecified medical attention. There were no laboratory or diagnostic tests performed. The patient recovered on 16-JAN-2009. Follow up information received from the medical assistant on 26-JAN-2009. It was reported that the 16 year old female patient with penicillin allergy that caused rash, on 14-JAN-2009 was vaccinated into the left deltoid with the first 0.5 mL dose of GARDASIL. On 15-JAN-2009, the patient experienced a mild rash to hands and lower forearm areas bilaterally, slight erythema that had pruritis. The symptoms started to resolved and then returned after shower. The patient denied any changes to medication, powders, soaps, lotions and/or detergents. The patient did not require treatment. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: Rash

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340619-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Aug-2008	26-Aug-2008	0	18-Feb-2009	26-Feb-2009	--	WAES0901USA01947	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from a consumer concerning her 15 year old female daughter with no pertinent medical history and no drug reactions/allergies, who on 20-MAR-2008 was vaccinated with the first 0.5mL dose of GARDASIL. There was no concomitant medication. On 26-AUG-2008 her daughter fainted after getting second dose of GARDASIL and on the same day patient recovered. The reported stated that her daughter did not experience any adverse event after getting first dose of GARDASIL. The patient sought unspecified medical attention. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340620-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		18-Feb-2009	04-Mar-2009	--	WAES0901USA01860	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning "almost every single patient" (approximately 237) who was vaccinated with GARDASIL. Subsequently the patients complained of injection site pain after the first, second and third doses of GARDASIL. It was unknown if the patients sought medical attention. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340621-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	08-Jan-2009	12-Jan-2009	4	18-Feb-2009	04-Mar-2009	NJ	WAES0901USA01832	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site haematoma, Injection site pain, Injection site swelling, No reaction on previous exposure to drug

Symptom Text: Information has been received from a medical assistant concerning a 17 year old female with no pertinent medical history who on 30-OCT-2008 was vaccinated with the first dose of GARDASIL, on 8-JAN-2009 was vaccinated with the second dose of GARDASIL (LOT# 0947X) IM into the left deltoid. There was no concomitant medication. On 12-JAN-2009, the patient had an injection site reaction including swelling, pain and bruising after vaccination with her 2nd dose of GARDASIL. The patient's injection site reaction including swelling, pain and bruising persisted. The patient did not have an AE after her first dose. it was reported that the patient sought medical attention: phone call. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340622-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	26-Feb-2009	--	WAES0901USA01823	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a female who was vaccinated with a dose of GARDASIL (lot # not reported). Subsequently the patient fainted. The outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340623-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Dec-2008	01-Dec-2008	0	18-Feb-2009	04-Mar-2009	TX	WAES0901USA01820	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a Certified Medical Assistant concerning an approximately 14-year-old female with no known drug allergies who was vaccinated intramuscularly with her first 0.5 ml dose of GARDASIL vaccine (655604/0052X) abut three weeks ago (approximately December 2008). The patient experienced pain at the injection site during administration of GARDASIL vaccine. The patient was recovered. This is the second of two patients for reporter. The patient sought medical attention. Addition information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340624-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Oct-2008	01-Oct-2008	0	18-Feb-2009	26-Feb-2009	--	WAES0901USA01813	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse practitioner concerning her daughter who in October 2008, was vaccinated the first dose of GARDASIL. Concomitant therapy included meningococcal vaccine. In October 2008 after she received the dose , the patient experienced fainted. Subsequently the patient recovered. It is unknown if the patient sought medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340625-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		18-Feb-2009	04-Mar-2009	KY	WAES0901USA01810	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Sensation of heaviness

Symptom Text: Information has been received from a physician concerning a 15 year old female who was vaccinated with a 0.5ml dose of GARDASIL (lot number not provided) on an unspecified date. After receiving GARDASIL she experienced a "heavy arm". It was unknown which arm was affected. The outcome was unknown at the time of reporting. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340626-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	13-Jan-2009	13-Jan-2009	0	18-Feb-2009	04-Mar-2009	--	WAES0901USA01808	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Vision blurred

Symptom Text: Information has been received from a registered nurse concerning her 26 year old daughter who on 13-JAN-2000 was vaccinated with a second dose of GARDASIL 0.5 ml. There was no concomitant medication. After a couple of hours the patient experienced dizziness, horrible headache and blurry vision. At the night of 13-JAN-2009 ("last night") the patient recovered. The patient sought medical attention of the nurse is also her mother. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340627-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	12-Jan-2009	14-Jan-2009	2	18-Feb-2009	04-Mar-2009	CA	WAES0901USA01796	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Musculoskeletal stiffness, Neck pain, Pain in extremity

Symptom Text: Information has been received from a nurse concerning a 14 year old female student patient who on 12-JAN-2009 was vaccinated with the third dose of GARDASIL (LOT # 661841/0653X). Concomitant therapy included CIPRODEX. It was reported that the patient woke up on 14-JAN-2008 with a pain in her arm that goes up to her neck making her have a stiff neck. She also head pain, "but is not a headache". The nurse also reported that the patient did not have any swollen glands and did not have a fever, but the patient had taken TYLENOL and went to school. The nurse also stated that the patient did not have any problems after receiving the first and second dose of GARDASIL. Additional information has been requested.

Other Meds: CIPRODEX tablets

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340628-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	26-Aug-2008	26-Aug-2008	0	18-Feb-2009	04-Mar-2009	MA	WAES0901USA01793	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0067X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female patient with CODEINE allergy who on 19-JUN-2008 was vaccinated intramuscularly with the first dose of GARDASIL vaccine (Lot#660393/0067X) and with the second dose on 26-AUG-2008. Concomitant therapy included MENACTRA. The nurse reported that on 26-AUG-2008 the patient fainted twice after receiving the vaccine. The patient first fainted 4 hours after the vaccination. After the patient fainted for the second time, she was taken to an emergency room and discharged after receiving intravenous fluid. The patient had not yet received the third dose. The patient recovered on 26-AUG-2008. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340629-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	05-Jan-2009	Unknown		18-Feb-2009	04-Mar-2009	NC	WAES0901USA01766	10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a dose of GARDASIL (Lot # was not available) experienced severe headaches after receiving the vaccine. The patient went to emergency room because of these headaches but it was not known if she was admitted to the hospital. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340630-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	07-Jan-2009	07-Jan-2009	0	18-Feb-2009	04-Mar-2009	VA	WAES0901USA01758	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vomiting

Symptom Text: Information has been received from a nurse concerning a 25 year old female patient with no known drug reactions/allergies and medical history who on 07-JAN-2009 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL (Lot #661530/0575X). Concomitant therapy included LEVORA. The nurse reported that the patient began vomiting 2.5 to 3 hours after administration the vaccine. The patient vomited through that night and the next day. The physician prescribed PHENERGAN for the patient which were effective in treating the symptom. The patient sought medical attention by phone. The patient recovered on 09-JAN-2009. Additional information has been requested.

Other Meds: LEVORA

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340631-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	04-Mar-2009	--	WAES0901USA01741	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Pallor, Vomiting

Symptom Text: Information has been received from a female patient, with no known drug reactions/allergies and no pertinent medical history, who was vaccinated with three doses of GARDASIL. There was no concomitant medication. The consumer stated she is seeing a new doctor and the doctor provided her with a fourth dose of GARDASIL. She also mentioned she vomited and turned pale white taking the doses of GARDASIL. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340632-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Aug-2008	Unknown		18-Feb-2009	04-Mar-2009	VA	WAES0901USA01731	10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Tachycardia

Symptom Text: Information has been received from a licensed practical nurse concerning a 19 year old female patient with no known medical history; who on 20-AUG-2008 was vaccinated with a 0.5 ml second dose of GARDASIL vaccine, intramuscularly. There was no concomitant medication. The patient developed tachycardia after she received the GARDASIL vaccine. The patient sought medical attention through a cardiologist visit. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340633-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	08-Jan-2009	08-Jan-2009	0	18-Feb-2009	04-Mar-2009	--	WAES0901USA01652	03-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	UNKNOWN MANUFACTURER	NULL	0	Unknown	Unknown	
HPV4	MERCK & CO. INC.	66176/0652X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Discomfort, Dysuria, Escherichia infection, Hypoaesthesia, Paraesthesia, Urinary hesitation, Urinary tract infection

Symptom Text: Information has been received from a nurse practitioner concerning a 19 year old female who on 08-Jan-2009 was vaccinated with the first dose of GARDASIL lot number 661766 /0652X, 0.5ml, intramuscularly into the right deltoid. The patient also received her second dose of Hepatitis A virus vaccine. Other concomitant therapy included YAZ. It was reported that on 08-Jan-2009 in the evening, the patient developed numbness and tingling in her legs from the knees down. The patient stated to the nurse practitioner that the discomfort has gotten worse every day and when she laid down she developed numbness and discomfort starting at her sacrum and continuing down her legs. The nurse practitioner also mentioned that the patient was having difficulty urinating. The nurse practitioner reported that the patient had not sustained any injury. At the time of the report, the patient had not recovered. On 13-Jan-2008, the patient was seen in the office. Additional information has been requested. 3/3/09 Received vaccine record & GYN records of 1/8-1/13/2009. FINAL DX: none provided. Records reveal patent in good health on 1/8. RTC 1/13 w/dysuria & hesitancy x 3 days and legs tingling/numbness since 1/8. Referred to PCP. Calls to patient after 1/13 not returned. 3/24/09 Received additional GYN records of 2/26/09. Patient returned to clinic for hormon implantation birth control.

Other Meds: YAZ

Lab Data: LABS: Pap smeal 6/08 WNL. UA neg for pregnancy, c/s(+) e. coli.

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340634-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	05-Mar-2009	AL	WAES0901USA01631	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a female patient who on vaccinated with the three doses of GARDASIL. Shortly after the third dose she developed an abnormal pap smear. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: biopsy

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340635-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Oct-2008	Unknown		18-Feb-2009	05-Mar-2009	IL	WAES0901USA01626	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a dose of GARDASIL last fall and said the vaccine hurt so much. This is one of three reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340636-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Sep-2008	15-Sep-2008	0	18-Feb-2009	26-Feb-2009	NY	WAES0901USA01623	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0053X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site discolouration, Vaccine positive rechallenge

Symptom Text: Information has been received from a licensed practical nurse concerning an 18 year old female patient with no known medical history and drugs allergies, who on 15-Sep-2008 was vaccinated with a first dose of GARDASIL , (lot # 0053X), intramuscularly. On 17-Nov-2008 the patient received a second dose of GARDASIL (lot#0702X),Intramuscularly. There was no concomitant medication. After both doses the patient developed a "white flat halo " around the injection site. The first halo was not noticed until the patient noticed until the second halo. At the time of this report the patient had not recovered. The patient sought medical attention through an office visit. Additional information has been requested

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340637-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	05-Mar-2009	--	WAES0901USA01616	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, No reaction on previous exposure to drug

Symptom Text: Information has been received from a nurse Concerning a female who was vaccinated with the third dose of GARDASIL vaccine. The nurse reported that "the patient received the third dose of GARDASIL and then 24 hours later the patient's mom called the nurse and told her the patient had a headache". The nurse stated that she advised the patient's mother to speak to the patient's physician. The patient did not seek medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340638-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Dec-2007	01-Jan-2009	397	18-Feb-2009	05-Mar-2009	NY	WAES0901USA01610	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Neuropathy peripheral

Symptom Text: Information has been received from a physician concerning a female patient with unspecified psychiatric problems and restless legs syndrome who in December 2007 was vaccinated with a dose of GARDASIL vaccine (Lot not reported). Recently the patient was diagnosed with peripheral neuropathy. The patient sought medical attention at the office. As of 13-JAN-2009 the outcome of the patient was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Psychiatric disorder NOS; Restless legs syndrome

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340639-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	13-Nov-2008		18-Feb-2009	05-Mar-2009	--	WAES0901USA01588	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Pain in extremity, Urticaria

Symptom Text: Information has been received from a nurse practitioner concerning a 25 year year old female patient with no pertinent medical history, not known drug reactions/allergies who on 01-JUL-2008 was vaccinated intramuscularly with the first GARDASIL vaccine, on 02-SEP-2008 was vaccinated intramuscularly with the second 0.5 mL dose of GARASIL vaccine. The patient did not have any adverse effects after the first or the second dose. On an unspecified date, in approximately 2008 the patient was vaccinated intramuscularly with the third 0.5 mL dose of GARDASIL vaccine. Subsequently the patient developed "achiness" in the injection arm 24 hours after her third dose of GARDASIL vaccine. The nurse practitioner mentioned that patient had not sustained any injury. The patient was sent to see an allergist since she had developed hives on approximately 13-NOV-2008, "2 months ago". The patient's hives were treated with ZYRTEC. While seeing the allergist the patient mentioned the "achiness" to her arm. The allergist recommended that the patient saw her primary care provider since he felt it was "a drug reaction". The patient was seen on 12-JAN-2009 and the nurse practitioner stated she was able to reproduce the discomfort by "pressing down inside elbow and the patient experienced tingling in three of her fingers". The nurse practitioner mentioned "I did not believe that this is caused by GARDASIL vaccine and there was something else going on". At the time of reporting, the patient had not recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340640-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		18-Feb-2009	05-Mar-2009	CA	WAES0901USA01517	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Panic attack, Respiratory rate increased, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician assistant concerning a 15 or 16 year old female patient who on unknown dates was vaccinated with a first and second dose of GARDASIL, lot number not specified. Approximately 2 weeks after the dose was given the patient experienced "panic attack", where she felt pain in her chest and rapid breathing, it happened after both doses of GARDASIL. The assistant stated that the Dr. advised not to get the 3rd dose of GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340641-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	05-Mar-2009	AR	WAES0901USA01508	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Skin haemorrhage

Symptom Text: Information has been received from a registered nurse concerning her daughter who was vaccinated with the third dose of GARDASIL. Four days after the third dose the patient experienced bleed in her arm. It did not happen with the previous dose. At the time of reporting, the outcome was unknown. It is unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340642-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	05-Mar-2009	NJ	WAES0901USA01340	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Information has been received from a physician concerning a female who on unspecified date was vaccinated with a first dose of GARDASIL and had syncope. The physician did not specify if the patient fully fainted. After the second dose of GARDASIL on unspecified date, the patient felt dizzy. The physician reported that the patient then received the third dose of GARDASIL on unspecified date but they had her lay down to receive the vaccine and no experience was reported. The patient sought medical attention to the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 340643-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	01-Nov-2008		18-Feb-2009	05-Mar-2009	TX	WAES0901USA01321	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from a physician concerning a 13 year old female patient, who on unspecified dates, was vaccinated with the second dose of GARDASIL, 0.5ml. The patient had a rash on stomach from insect bite at the time of vaccination. The physician reported that in November 2008, the patient experienced syncope after receiving the second dose of GARDASIL. The patient recovered the same day. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Insect bite NOS

Prex Illness: Rash

Prex Vax Illns:

Vaers Id: **340644-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	05-Mar-2009	NY	WAES0901USA01318	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Joint swelling, Oedema peripheral, Pruritus, Urticaria

Symptom Text: Information has been received from a nurse concerning a female who was vaccinated with a first dose of GARDASIL. The patient called the nurse 4 to 5 weeks ago (approximately December 2008) and reported that she experienced swelling of her wrist and palm of her hands, the sole of her feet were very itchy, and had welt or hives on her hips and one breast. No additional information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340645-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	08-Jan-2009	08-Jan-2009	0	18-Feb-2009	05-Mar-2009	--	WAES0901USA01310	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a Nurse concerning a 20 year old female patient with no pertinent medical history and no drug reactions or allergies who on 08-Jan-2009 was vaccinated with first dose of GARDASIL vaccine (Lot #66016/0570X). Concomitant therapy included LO/OVRAL. On 08-JAN-2009 after she received vaccine she fainted. There were no Laboratory Diagnostics Studies performed. On 08-JAN-2009 patient was recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: LO/OVRAL

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vaers Id: **340646-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	24-Dec-2008	24-Dec-2008	0	18-Feb-2009	05-Mar-2009	MI	WAES0901USA01304	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Depressed level of consciousness, Dizziness, Hypoventilation, Immediate post-injection reaction, Unresponsive to stimuli

Symptom Text: Information has been received from a registered nurse concerning a 23 year old female patient with no pertinent medical history and no known drug allergies who on 24-DEC-2008 was vaccinated with the first IM dose of GARDASIL vaccine (lot# 0947X). Concomitant therapy included calcium (unspecified), vitamins (unspecified) and DESOGEN. On 24-DEC-2008 the patient experienced felt dizzy 3 minutes and lay down. The patient became frail and unresponsive for 20-30 seconds. her pupils were equal, dilated and reactive to light. Her blood pressure was 100/50, pulse was 52, and had shallow breathing. About 2-3 minutes after being responsive, the patient fell back into a state of unresponsiveness and was difficult to arouse, This lasted for a few minutes and then she became fully alert. The emergency medical services were called and the patient was given juice boxes and bagel. EKG was normal and blood sugar after the food intake was 112. On 24-DEC-2008 the patient recovered from the adverse events. Additional information has been requested.

Other Meds: Calcium (unspecified); DESOGEN; vitamins (unspecified)

Lab Data: Blood pressure, 12/24/08, 100/5; Electrocardiogram, 12/24/08, normal. Laboratory results - Blood glucose, 12/24/08, 112; Total heartbeat count, 12/24/08, 52.

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340647-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
43.0	F	Unknown	Unknown		18-Feb-2009	05-Mar-2009	PA	WAES0901USA01294	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Papilloma viral infection

Symptom Text: Information has been received from a nurse in the physician's office concerning a 43 year old female who was vaccinated with three doses of GARDASIL and was diagnosed with papilloma viral infection shortly afterward. PAP smear was performed (result not reported). At the time of reporting the patient's outcome was unspecified. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340648-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	08-Jan-2009	08-Jan-2009	0	18-Feb-2009	05-Mar-2009	NE	WAES0901USA01258	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from a physician's assistant concerning a 15 year old white female, 75.9 kg and 157cm in height, who on unspecified dates was vaccinated with the first and the second doses of GARDASIL vaccine, intramuscularly, and on 08-JAN-2009 at approximately 11:30 AM, was vaccinated with the third dose of GARDASIL, intramuscularly (Lot # 661044/0548X). The patient had sinusitis and laryngitis at the time of vaccination. The physician's assistant reported that on 08-JAN-2009, the patient experienced syncope within 1-2 minutes after receiving immunization. She reported that it was followed by full and complete recovery on 08-JAN-2009. The patient was observed in clinic by parent, medical and nursing staff and left after appropriate interval on foot. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness: Laryngitis; Sinusitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340649-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	01-Jan-2009		18-Feb-2009	05-Mar-2009	--	WAES0901USA01227	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rectal discharge

Symptom Text: Information has been received from a consumer concerning her daughter who was vaccinated with the third dose of GARDASIL. In January 2009 ("a couple of days ago"), the patient experienced an oily discharge that appeared to be green in color leaking from her rectum. At the time of this report, the outcome was unknown. The patient did not seek medical attention and the reporter stated that she would be contacting her daughter's doctor. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340650-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-May-2008	22-May-2008	21	18-Feb-2009	05-Mar-2009	FL	WAES0901USA01221	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pericardial effusion

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 01-MAY-2008 was vaccinated with the third dose of GARDASIL (lot # 0152X) and 3 weeks later (approximately 22-may-2008) was diagnosed with pericardial effusion. At the time of reporting the patient was not recovered. Lab diagnostics studies performed included echocardiogram.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340652-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	08-Jan-2009	08-Jan-2009	0	18-Feb-2009	05-Mar-2009	--	WAES0901USA01181	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Sinusitis

Symptom Text: Information has been received from a physician's assistant concerning a 13-15 year old female who on 08-JAN-2009 was vaccinated with the third dose of GARDASIL, and lost consciousness. It was also reported that the patient had a sinus infection. The patient sought unspecified medical attention. On the same day, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340653-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	30-Dec-2008		18-Feb-2009	05-Mar-2009	--	WAES0901USA01176	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Human papilloma virus test positive

Symptom Text: Information has been received from a 21 year old female with attention deficit disorder and no medical history who was vaccinated with three doses of GARDASIL on unspecified dates. Concomitant therapy included YAZ for birth control and Concerta for attention deficit disorder. On 30-DEC-2008 the patient administered a pap smear test which came back positive for HPV. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: YAZ; CONCERTA

Lab Data: Cervical smear, 12/30/08, positive

History:

Prex Illness: Attention deficit disorder

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340654-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Jan-2009	07-Jan-2009	2	18-Feb-2009	05-Mar-2009	NY	WAES0901USA01148	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Hypersensitivity, Pruritus, Urticaria

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter with a history of drug hypersensitivity to MYNOCYCLINE who on 05-JAN-2009 was vaccinated with a first dose of GARDASIL. Concomitant therapy included YASMIN 3 mg everyday and BENADRYL. On 07-JAN-2009 the patient experienced allergic reaction including itching, redness and welts and hives. At the time of reporting, the patient's allergic reaction persisted. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: BENADRYL; YASMIN

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **340661-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Jan-2009	28-Jan-2009	0	25-Feb-2009	26-Feb-2009	FR	WAES0902USA03631	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fall, Grand mal convulsion, Headache, Heart rate increased, Hyperventilation, Hypoaesthesia, Leukocytosis, Loss of consciousness, Ocular hyperaemia, Pallor

Symptom Text: Information has been received from local health authority (reference # ES-AGEMED-589239339) regarding a 17-year-old female patient with no known relevant medical history, who on 28-JAN-2009 was vaccinated with a dose of GARDASIL (lot number and injection site unknown) via intramuscular route. On the same day, seconds after vaccination, the patient felt dizziness and fell to the floor unconsciously, after a few seconds she began with tonic-clonic convulsions for 5 to 10 seconds. The patient stopped seizing for 30 seconds and then began with convulsive movements again for another 5 to 10 seconds. Approximately one minute afterwards, the patient slowly recovered consciously, but lost consciousness again in 2 or 3 more occasions. The patient complained for having a numbness sensation in hands. The patient was pale and her systolic arterial pressure was 80 mmHg (diastolic was not noticed). Laboratory tests on 28-JAN-2009 also showed: glucose 107 mg/dL, electroencephalogram normal, arterial oxygen saturation 97%, leukocytosis with left deviation. Her pulse was quick and initially imperceptible and filiform later on. The patient was hyperventilating (40 breaths per minute) and eyes were red. Pulmonary auscultation was normal. The patient did not present with allergic reaction signals (bronchospasm, laryngeal oedema, erythema). The episode lasted for about 10 minutes, after which the patient recovered. 100 cc's of physiological serum and 40 mg of intravenous URBASON were administered to the patient in order to treat adverse event. After the episode, laboratory tests showed: mean arterial pressure 115/70, heart rate 90 bpm, respiration rate 18 rpm. On the next day the patient presented with cephalgia in the occipital region that ceased with paracetamol. It is reported that the patient had recovered from these events, exact date not reported. The events were considered serious by health authority as other important medical events. Other business partner numbers included: E200901371.

Other Meds: Unknown

Lab Data: Blood pressure measurement, 28Jan09, 80 mmHg, systolic blood pressure registered; Electroencephalography, 28Jan09, normal; Diagnostic laboratory test, 28Jan09, leukocytosis with left deviation; Diagnostic laboratory test, 28Jan09, 115/70, m

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340662-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	06-Jan-2009	26-Jan-2009	20	25-Feb-2009	26-Feb-2009	FR	WAES0902HKG00001	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a health professional (clinic nurse) concerning a 26 year old female with a history of induced abortion 6 years ago who on 06-JAN-2009 was vaccinated with second dose of GARDASIL (with the first dose received on 25-OCT-2008). There was no concomitant medication. After vaccination with the second dose, the patient was found to be pregnant and subsequently, the patient experienced accidental miscarriage on approximately 26th January 2009 when she traveled outside foreign country. The doctor felt that this was an individual case and was not related to administration of GARDASIL. Accidental miscarriage is considered to be an other important medical event. Since the patient was not followed up by the doctor, no further information is available.

Other Meds: None

Lab Data: None

History: Abortion induced

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340668-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Aug-2007	01-Dec-2007	107	25-Feb-2009	26-Feb-2009	NY		12-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0181U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain lower, Crohns disease, Diarrhoea, Dysmenorrhoea, Gastrointestinal sounds abnormal, Malaise

Symptom Text: Abdominal pain, diahrrea, general ill feeling 12/07. Again 8/08 - Diagnosed Crohn's disease 10/08. 3/9/09 Received PCP vaccine records & medical records of 8/16/07-2/19/2009. FINAL DX: none provided Records reveal patient experienced good health on 8/16/07. Received HPV #1 & also started on BCP for dysmenorrhea. RTC 12/10/07 w/abdominal pain x 4-5 days, diarrhea. Exam revealed decreased bowel sounds & LLQ tenderness. Dx w/possible colitis.

Other Meds:

Lab Data:

History: None HPV #2 given 10/17/07, LA, 0469U; HPV #3 given 2/20/08, LA, 1287U PMH: environmental allergies.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340677-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	25-Feb-2009	25-Feb-2009	0	25-Feb-2009	26-Feb-2009	SC		26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3032AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2687AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0843X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Nausea

Symptom Text: mild nausea immediately following Gardasil #1 injection. Sxs resolved spontaneously over course of next 30 minutes while being seen in clinic.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340678-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	25-Feb-2009	25-Feb-2009	0	25-Feb-2009	26-Feb-2009	FL		26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Immediate post-injection reaction, Nausea, Syncope

Symptom Text: Fainted shortly after administration of Gardisil. Out for 3-4 seconds. Observed for 45 minutes before going home. At home and still reports nausea and dizziness.

Other Meds:

Lab Data:

History: n/a

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340679-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	Unknown		25-Feb-2009	26-Feb-2009	GA		26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1297X	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1782X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: Mom calling office c/o site where varicella given had a hard knot, warm to touch, whole back of arm swollen, painful to the point that it kept patient up at night. Told mom to do cold compresses and motrin call if symptoms worsen.

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340687-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Feb-2009	25-Feb-2009	0	25-Feb-2009	26-Feb-2009	MO		26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Paraesthesia

Symptom Text: Patient was administered the Merck HPV vaccine - third dose, patient reported left hand tingling. Physician evaluated - patient returned home. Physician called patient at home at 3:00pm - patient reported that tingling is resolved

Other Meds:

Lab Data: none

History: sulfa allergy

Prex Illness: none noted

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340696-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		25-Feb-2009	26-Feb-2009	CA	WAES0902USA02176	26-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, No reaction on previous exposure to drug

Symptom Text: Information has been received from a physician concerning an 18 or 19 year old female with a history of seizure "in the past during an IV administration on an unknown date" who was vaccinated IM with a 0.5 ml third dose of GARDASIL (date of administration and lot # were not known). Subsequently the patient experienced a seizure following the third vaccination. Unspecified medical attention was sought. Lab tests were performed, all of following were normal: MRI, CT scan and EEG. The patient did not experience postictal symptoms. The patient recovered from seizure on an unknown date. The seizure was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Magnetic resonance, normal; computed axial, normal; electroencephalography, normal

History: Convulsion

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340700-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Aug-2007	10-Aug-2007	7	25-Feb-2009	27-Feb-2009	NM		30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	AC52B015AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0960F	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Asthma, Blood pressure abnormal, Chest pain, Costochondritis, Diarrhoea, Dizziness, Dyspnoea, Headache, Heart rate increased, Loss of consciousness, Nausea, Pain, Syncope

Symptom Text: About 1 wk after 1st GARDASIL, my daughter began having headaches, nausea and began passing out. Began having trouble breathing. Pediatrician referred her to cardiologist. Tilt table test were done. BP problems were noted. She has been on medications since. 3/3/09-records received presented with C/O fainting spells 2-3 times per day no LOC. Assessment:chronic fainting spells, chronic dizziness. 7/16/08 C/O abdominal pain watery diarrhea. Positive ill contact. 8/22/08-C/O SOB. History of episodic SOB at school day of visit. C/O body aches. Bronchial asthma. 10/17/08 chest pain with tenderness center or chest. Assessment costochondritis. 1/22/09-persistent headache. 3/9/09-consultant records received for DOS 5/14/08-seen for C/O dizziness and fainting for one month. All occur with position changes. C/O fatigue. Heart rate mildy accelerated prior to fainting and feels dizzy and wobbly. Impression:mostly likely secondary to neurocardigenic syndrome. Office visit 6/4/08-Continues to faint on daily basis and having difficulty breathing when running. Impression strong vasodilatory component. Neurocardiogenic syncope. Recommend volume loading and salt in diet. Office visit 8/27/08-continues to have dyspnea mostly during PE at school, feels like she cannot breathe, loses breath,loses balance and nearly faints. C/O shortness of breath rather than syncope.

Other Meds: None at time of vaccine

Lab Data: 3/9/09-records received-Electrocardiogram normal. 2D echo with color flow and Doppler normal with trace tricuspid insufficiency with low estimated RV pressure. Holter examination normal. Title table exam multiple episodes of fainting.Pulmon

History: None 3/9/09-records received-PMH:bronchitis and whooping cough.

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340701-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	24-Feb-2009	24-Feb-2009	0	25-Feb-2009	04-Mar-2009	IL		04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2720AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0843X		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cold sweat, Hyperhidrosis, Syncope

Symptom Text: Pt had an episode of syncope, sweating and clammy

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **340717-1** **Related reports:** 340717-2; 340717-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	20-Oct-2008	21-Oct-2008	1	25-Feb-2009	04-Mar-2009	IN		10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0802U	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2824AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Anxiety, Asthenia, Blindness, Bone pain, Chest pain, Dizziness, Fall, Flank pain, Headache, Hyperaesthesia, Hyperventilation, Hypoaesthesia, Incoherent, Musculoskeletal pain, Myalgia, Pain, Pain in extremity, Panic attack, Paraesthesia, Syncope

Symptom Text: Information received from patient's mother by phone. Per mother Pt. began having body pain at 2:00AM on 10-21-08, unresolved by TYLENOL. No fever. At 6:00 AM on 10-21-08 Pt. arrived at mother's house, fell on floor complaining of severe pain in flesh, bones and muscles. Also complained of headache, dizziness, "unable to move". Mother reports patient was sensitive to touch, was assisted to bed. Mother reports patient had pain, weakness X 6 days, was unable to attend school and stayed in bed and slept for 6 days taking TYLENOL every 6 hours while awake. (M) reports patient was able to ambulate to bathroom and kitchen to eat. Mother reports symptoms improved on 10-26-08 but did not completely resolve. Mother reports approximately 11-2-08 patient had worsening pin for 1-2 days in (L) shoulder, left sided chest pain, pain in abdomen and legs. Pain improved but continues to "come and go". Mother reports that on 1-22-09 patient was sitting in class and suddenly lost eyesight and reported dizziness and being unable to move. Was reported by witnesses to be mumbling and incoherent and was taken to hospital by ambulance. Mother reports patient had left sided pain, numbness and a "prickly sensation" all over but mostly in upper body. Patient had numerous tests including CAT Scan, EKG, blood tests and IV fluids/medication (potassium, ATIVAN). Mother reports all test came back "negative". Patient had appointment with MD on 1-23-09 and had more testing for "artery inflammation" and Lupus among others. Mother reports a.u tests "negative". Patient to have follow up with Neurologist. 3/3/09 Received vaccine records & ER medical records of 1/22/2009. FINAL DX: hyperventilation syndrome; panic attack; numbness. Records reveal patient experienced anxiety, syncope, hyperventilation while in class. Tx w/IVF. Improved & d/c to home.

Other Meds: None

Lab Data: All "negative" per Mother. 1-22-09 EKG; CAT Scan; multiple blood tests; Urine tests. 1-23-09 Testing for Lupus; "artery inflammation", among others per mother's report LABS: WBC 12.9(H), H/H 15.1/43.5(H). potassium 3.3(L), anion gap 15

History: Allergies: Brazil nuts (Anaphylaxis in 1987); Pecans, Walnuts; Pollen; Dust mites. "Mild verbal tick"

Prex Illness: None

Prex Vax Illns:

Vaers Id: **340717-2** **Related reports:** 340717-1; 340717-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	20-Oct-2008	21-Oct-2008	1	03-Mar-2009	04-Mar-2009	IN	200900749	04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	NULL	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blindness, Dysarthria, Headache, Hypersomnia, Pain, Pain in extremity, Paraesthesia

Symptom Text: Initial report received on 25 February 2009 from the patient's parent. A 24-year-old female patient had received two vaccines on 20 October 2008. She had received a first dose of ADACEL and a dose of GARDASIL (manufacturer Merck). The lot numbers, routes and sites of administration for both vaccines were unknown. At the time of vaccinations, the patient had no concurrent illnesses, or use of other medications, but had medical history of severe allergy to Brazil nuts and allergy to other nuts. Within 24 hours after vaccination (02:00am on 21 October 2008), the patient had pain in her arm (unknown which arm), body aches, tingling all over, and headache. Per the reporter, the patient slept for six days. On 21 January 2009 (93 days post-vaccination), the patient "lost vision" and had garbled speech. She was taken to the emergency room where several diagnostic tests were completed. The diagnostic tests included CAT scan, EKG, drug toxicity test, and other blood test. The results of the tests were not provided. As of 25 February 2009, the patient continues to have intermittent body aches and tingling. At the time of this report, the recovery status of the patient was unknown. Documents held by sender: None.

Other Meds:

Lab Data: CAT scan; EKG; Drug toxicity test and other blood tests - results not provided.

History: At the time of vaccination on 20 October 2008, the patient had no concurrent illnesses; but did have a history of severe allergy to Brazil nuts and allergy to other nuts. The patient was not taking any concomitant medications at that time; and had not experienced any adverse events with prior vaccinations. The patient had not received any other vaccinations within four weeks of 20

Prex Illness:

Prex Vax Illns:

Vaers Id: **340717-3 (S)** **Related reports:** 340717-1; 340717-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Oct-2008	01-Oct-2008	0	04-Mar-2009	05-Mar-2009	--	WAES0902USA04039	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	TTOX	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Blindness, Bone pain, Dizziness, Headache, Hypersomnia, Hypoaesthesia, Incoherent, Myalgia, Pain, Vision blurred

Symptom Text: Information has been received from a consumer concerning her daughter, a 24 year old female with allergy to nuts who in the afternoon October 2008 (also reported as in December 2008) was vaccinated with the first dose of GARDASIL, IM, 0.5ml. Concomitant therapy included tetanus toxoid. At 02:00 the patient complained of body pain that got worse and worse. The very next morning the patient came to the house at 6:00AM and collapsed on her floor, complaining of severe pain in her joints, flesh and bones. The patient stated "this is the worse pain ever." The patient could not stand to be touched or moved without having severe pain. The patient also had muscle pain and bone pain. The patient was a nursing student and did not go to class that day. The patient slept for 7 days before recovering. During that time, if the patient was awake, she complained of lots of pain, including a headache. The patient was given TYLENOL for the headache. The patient also experienced dizziness and lightheadedness. Since that time, there had been progressive problems in her condition. A few days ago (on approximately 20-FEB-2009) while the patient was in her nursing class she lost her vision, her vision then became blurry, developed left side pain and numbness and a pain attack. The patient was speaking incoherently. (The following day the patient she was in her head saying "help me out of the class, something is wrong" but the other students told her that they were not able to understand her.) The patient was taken to the hospital (emergency room), she was not admitted. She had undergone multiple diagnostic tests. All results had come back negative. The patient continued to complain of pain that came on and then faded, and then came on again and then faded. Sometimes the whole body was in pain, including thoracic area, chest, arm, leg, sometimes it was just left-sided pain. The patient was told not to receive any additional doses of GARDASIL by her physician. The patient's events were considered to be disabling. A

Other Meds:

Lab Data: Diagnostic laboratory, 02/??/09, normal; Computed axial, 02/??/09, normal

History:

Prex Illness: Allergy to nuts

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340719-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	08-Jan-2009	Unknown		18-Feb-2009	05-Mar-2009	AZ	WAES0901USA01143	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Rash, Urticaria

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a first dose of GARDASIL without any reactions and on 08-JAN-2009 was vaccinated with second dose of GARDASIL. Concomitant therapy included Plan B which was given on 07-JAN-2009. Subsequently the patient experienced hives and rash. The patient was seen at the physician's office. At the time of reporting, the patient's hives and rash persisted. Additional information has been requested.

Other Meds: Plan B

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340720-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	U	10-Nov-2008	Unknown		18-Feb-2009	05-Mar-2009	TN	WAES0901USA01142	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus

Symptom Text: Information has been received from a registered nurse concerning a 21 year old patient who on 10-NOV-2008 was vaccinated with a first dose of GARDASIL. Subsequently the patient experienced itching and redness at the injection site. On unknown date, the patient recovered from redness at the injection site. At the time of reporting, the patient's itching at the injection site persisted. The patient sought medical attention by contacting office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340721-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	05-Jan-2009	08-Jan-2009	3	18-Feb-2009	05-Mar-2009	IL	WAES0901USA01138	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised, Rash pruritic

Symptom Text: Information has been received from a 19 year old female with no known drug allergies who on 05-JAN-2009 was vaccinated with the third dose of GARDASIL vaccine. There was no concomitant medication. On 08-JAN-2009 the patient experienced a rash that originally appeared on one arm and then the other arm and was all over her body in small patches at time of the report. She stated the rash was extremely itchy. The patient did not perform any lab diagnostics studies. At time of the report the patient was not recovered. The patient sought medical attention via telephone. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vaers Id: **340722-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Jul-2008	11-Jul-2008	0	18-Feb-2009	05-Mar-2009	--	WAES0901USA01134	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Drug administered at inappropriate site, Pain, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning a 16 year old female with no medical history of drug allergy who on 11-JUL-2008 was vaccinated with the first dose of GARDASIL (lot # 660557/0072X). 0.5ml, IM in her arm. Concomitant therapy included hormonal contraceptives (unspecified). On 11-JUL-2008 the patient experienced pain. The patient was a gymnast and the pain interfered with her performance at a competition the following day. The second dose was administered on 12-SEP-2008 in her gluteal muscle at the patient's request. The patient did not perform any lab diagnostics studies. At time of report the patient recovered. The patient did not seek medical attention. Follow-up information has been received from a nurse concerning the patient who received the third dose of GARDASIL in the arm on 15-JAN-2009. Subsequently the patient experienced soreness. At time of the report the outcome of the patient was unknown. The patient sought unspecified medical attention. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340723-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Jul-2008	01-Dec-2008	151	18-Feb-2009	05-Mar-2009	--	WAES0901USA01128	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner, for GARDASIL, a Pregnancy Registry product, concerning a 17 year old female who on 03-JUL-2008 was vaccinated with the first dose of GARDASIL. The patient has only been given the first dose of GARDASIL. The patient was 5 weeks pregnant but has already started the GARDASIL vaccine series. The patient had an abnormal PAP smear when she reported being pregnant but she already started the GARDASIL series. The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Pregnancy NOS (LMP = 12/5/2008)

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340724-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	05-Mar-2009	AZ	WAES0901USA01027	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a medical assistant concerning her daughter who was vaccinated with the first dose of GARDASIL on an unspecified date. Subsequently the patient experienced extreme dizziness. No further information provided. The outcome was unknown at time of reporting. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340725-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	05-Mar-2009	MO	WAES0901USA01024	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with three doses of GARDASIL vaccine (no lot number was provided). Subsequently the patient had been diagnosed with cervical dysplasia. At the time of this report, the outcome was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340726-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-May-2008	01-Jun-2008	4	18-Feb-2009	05-Mar-2009	--	WAES0901USA01020	10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Vomiting

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year female who in May 2008, was vaccinated with the first 0.5ml dose of GARDASIL lot#655327/1287U. Concomitant medication included YASMIN. Up to 4 months after receiving GARDASIL (Sep-2008), the patient experienced vomiting and a headache. It is unknown whether patient will continue with the series however she has yet to receive the second dose. At the time of reporting (08-Jan-2009) the patient was recovered. The patient sought medical attention. Additional information has been requested. with the series however she has yet to receive the second dose. At the time of reporting (08-Jan-2009) the patient was recovered. The patient was recovered. The patient sought medical attention. Additional information has been requested.

Other Meds: YASMIN

Lab Data: Unknown

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340727-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jul-2008	01-Dec-2008	153	18-Feb-2009	05-Mar-2009	FL	WAES0901USA01008	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Vaginal discharge

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter with no medical history and drug allergies, who in July 2008 was intramuscularly vaccinated with the third 0.5 ml dose of GARDASIL. There was no concomitant medication. Several weeks ago the patient experienced vaginal discharge and it was not itchy, painful or "smell". The patient's vaginal discharge came and went. At the time of reporting, the patient did not recover. The patient did not seek medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340728-1** **Related reports:** 340728-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Sep-2008	04-Sep-2008	1	18-Feb-2009	05-Mar-2009	--	WAES0901USA01005	11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	19680	0	Unknown	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Injection site mass, Screaming

Symptom Text: Information has been received from a nurse practitioner concerning an 18 year old female who was vaccinated with the second dose of GARDASIL intramuscularly 0.5mL in approximately September 2008 ("about 4 months ago"). There is no concomitant medication. In approximately September 2008 ("within 24 hours of administration), the patient experienced severe headaches and had a large lump at the injection site. She was found by her mother in bed holding her head, hollering and thrashing. She was taken to the emergency room and had a scan of her head taken. The test came back benign. The headache lasted for about 5 days. The patient recovered 5 days later after onset. Additional information has been requested.

Other Meds: None

Lab Data: Head computed axial

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340728-2** **Related reports:** 340728-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	05-Mar-2009	--	WAES0901USA00374	11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Injection site nodule

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who was vaccinated with the second dose of GARDASIL. Subsequently the patient experienced headache and granuloma at injection site. It lasted for 5 days and then the patient went to the emergency room. At the time of this report, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340729-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-May-2008	Unknown		18-Feb-2009	05-Mar-2009	--	WAES0901USA00984	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Information has been received from a nurse practitioner concerning a 17 year old female who on 06-MAY-2008 was vaccinated with GARDASIL intramuscularly 0.5 mL. Subsequently the patient developed intermittent "aching" to her hips, knees and right ankle after vaccination. The patient visited the office. At the time of reporting, the patient's intermittent "aching" to her hips, knees and right ankle after vaccination persisted. No further information was available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340730-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
45.0	F	Unknown	Unknown		18-Feb-2009	05-Mar-2009	--	WAES0901USA00872	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse reaction, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a 45 year old female patient who was vaccinated with two doses of GARDASIL vaccine (no lot number was provided). Subsequently the patient experienced unspecified problems. At the time of this report, the outcome is unknown. It is unspecified if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vaers Id: **340731-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	24-Nov-2008	24-Nov-2008	0	18-Feb-2009	05-Mar-2009	CO	WAES0901USA00856	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site mass, Injection site pain, No reaction on previous exposure to drug

Symptom Text: Information has been received from a registered nurse concerning a 22 year old female who on unspecified dates was vaccinated with the first and the second dose of GARDASIL vaccine. Patient did not experience any problems. On 24-NOV-2008, the patient was vaccinated with the third dose of GARDASIL vaccine (lot number 661764/0650X)0.5 ml IM and experienced a lump in the injection site area shortly after on the same day. The lump was painful to touch. The patient sought medical attention, called office. The location of the lump was unspecified. The lump resolved on its own couple of weeks after received the third dose. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340732-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Jul-2008	16-Jul-2008	0	18-Feb-2009	05-Mar-2009	NM	WAES0901USA00808	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Dizziness, Pyrexia, Vision blurred

Symptom Text: Information has been received from a medical assistant concerning a 13 year old female patient with no pertinent medical history and with allergic reaction to ERYTHROMYCIN who on 18-APR-2008 was vaccinated with the first 0.5 ml dose of GARDASIL intramuscularly. There was no concomitant medication. On 16-JUL-2008 the patient was vaccinated with the second 0.5 ml dose of GARDASIL (Lot # 659439/1267U) intramuscularly. It was reported that the patient has been having symptoms after receiving GARDASIL. It was reported that the patient experienced dizziness and blurry vision in the office after receiving the second dose of GARDASIL. The patient went home after the recovery. It was reported that the patient has been having occasional fever and back pain since receiving the second dose of GARDASIL. The patient was seen by the physician. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Allergic reaction to antibiotics.

Prex Vax Illns:

Vaers Id: **340733-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Oct-2008	Unknown		18-Feb-2009	05-Mar-2009	--	WAES0901USA00803	27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Basilar migraine, Condition aggravated, Dizziness, Dysarthria, Headache, Hypoaesthesia, Loss of consciousness, Pallor, Paraesthesia, Vision blurred, Visual impairment

Symptom Text: Information has been received from a doctor of pharmacist concerning a 17 year old female patient with no pertinent medical history and no known drug allergies/drug reactions, who completed her GARDASIL vaccine series "sometime" last year. Concomitant therapy included hormonal contraceptives (unspecified) and vitamins (unspecified). It was reported that about a month after completion of the series the patient began to develop "stabbing left hemisphere head pain and numbness to the left arm and leg. It was reported that the patient has continued to have biweekly "attacks" since the beginning of symptoms. At the time of reporting the patient had a blood work, head computed axial tomography and an magnetic resonance imaging of head done. All results were negative. At the time of the report the patient had not recovered. The patient sought medical attention with the neurologist. Additional information has been requested. 3/16/09 Received Neuro medical records of 1/8-2/18/2009. FINAL DX: probable basilar migraine Records reveal patient experienced four spells of unconsciousness, pallor, slurred speech over several weeks preceded by blurred vision & seeing spots. Has had frequent dizziness, right parietal pain, contralateral arm & leg tingling. Referred for MRI & tx w/meds. RTC 2/18 w/good response to meds.

Other Meds: hormonal contraceptives, vitamins (unspecified)

Lab Data: diagnostic laboratory - negative; head computed axial - negative; magnetic resonance - negative LABS: Echocardiogram, EKG, EEG done 11yo all WNL.

History: None PMH: Overweight, appendectomy & cholecystectomy, 12yo. LOC w/possible seizure, 11yo. Family hx: migraines

Prex Illness:

Prex Vax Illns: No Relevant Data~ ()~~0~Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340734-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	29-Dec-2008	29-Dec-2008	0	18-Feb-2009	05-Mar-2009	OH	WAES0901USA00802	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a registered nurse concerning a 10 year old female patient who on 15-MAY-2008 was vaccinated with the first dose of GARDASIL. On 29-DEC-2008 the patient was vaccinated with the third dose of GARDASIL (Lot # 660620/0571X). It was reported that the patient developed a rash 6 hours after the third dose of GARDASIL was given. The patient was recovered. It was reported that patient's mother called physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340735-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-May-2008	25-May-2008	5	18-Feb-2009	05-Mar-2009	IN	WAES0901USA00796	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Herpes zoster, Pain, Pruritus, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 20-MAY-2008 was vaccinated with the first dose of GARDASIL vaccine (lot no. 659180/1758U) 0.5 ml, IM. On 29-JUL-2008 was vaccinated with the second dose of GARDASIL vaccine (lot no. 660387/1967U) 0.5 ml, IM and on 24-NOV-2008 with the third dose of GARDASIL vaccine (lot no. 655604/0052X) 0.5 ml, IM. The physician reported that the patient developed Zoster 7 to 10 days after administration of her first and second dose of GARDASIL vaccine. The physician reported that the first outbreak of Zoster was below her breast bone at the end of her sternum. It was 3 inches wide. The patient had severe pain and some itchiness. The physician did not know the location of her second outbreak because the physician did not examine the patient but rather treated her over the phone. The patient was treated with VALTREX and ADVIL both times. The second outbreak required to be treated with a second course of VALTREX. Cultured cessions from the first outbreak confirmed Varicella Zoster virus. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic microbiology, 05/??/08. Culture lesion confirmed Varicella Zoster virus

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340736-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Oct-2007	12-Mar-2008	149	18-Feb-2009	05-Mar-2009	OH	WAES0901USA00457	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix normal

Symptom Text: Information has been received from a consumer concerning her 19 year old daughter who on 09-APR-2007 was vaccinated with the first dose of GARDASIL. On 08-JUN-2007, the patient was vaccinated with the second dose of GARDASIL and on 15-OCT-2007 with the third dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified) and ALDACTONE tablets. On 12-MAR-2008, was performed a papanicolau test with abnormal results. On 16-SEP-2008, was performed her last PAP test with normal results. This is one of several reports provided by the same source. Additional information has been requested.

Other Meds: Hormonal contraceptives; ALDACTONE tablets

Lab Data: Pat test, 03/12/08, abnormal; Pap test, 09/16/08, normal.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340737-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Sep-2008	06-Dec-2008	96	18-Feb-2009	27-Feb-2009	--	WAES0901USA00375	27-Feb-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Headache, Nausea

Symptom Text: Information has been received from a 24 year old female patient, for GARDASIL vaccine, a Pregnancy Registry product concerning herself with no pertinent medical history and no known drug allergy who in September 2008, was vaccinated with the second dose of GARDASIL vaccine. Concomitant therapy included INFLUENZA VIRUS vaccine (unspecified). In approximately 06-DEC-2008 ("a month ago"), the patient was pregnant. LMP was approximately 06-DEC-2008 and estimated delivery date was 12-Sep-2009. The patient also experienced feeling nauseous and headache. Therapy with GARDASIL vaccine was discontinued. No lab diagnostics studies were performed. The patient did not seek medical attention. At the time of reporting, the patient did not recover yet. No further information is available.

Other Meds:

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 12/6/2008)

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vaers Id: **340740-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Jan-2009	05-Jan-2009	0	18-Feb-2009	05-Mar-2009	UT	WAES0901USA00366	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0544X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site erythema, Injection site rash, Injection site reaction, Rash macular

Symptom Text: Information has been received from a physician concerning a 16 year old female with no medical history or drug allergy who on 05-JAN-2009 was vaccinated with the third dose of GARDASIL (lot # 0544X), 0.5ml. IM. There was no concomitant medication. The patient developed a rash in the area of the injection site almost immediately after receiving her third dose of GARDASIL vaccine on 05-JAN-2009. The rash, which was red and blotchy, extended from the deltoid area to the elbow but it was not known whether right or left arm involved. The patient was given BENADRYL and the rash resolved by 06-JAN-2009. The patient sought attention by office visit. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340741-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Dec-2008	30-Dec-2008	0	18-Feb-2009	05-Mar-2009	MA	WAES0901USA00365	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from 2 nurses concerning a 17 year old female with a history of fainting who on 30-DEC-2008 was vaccinated with the first dose of GARDASIL. The patient fainted within an hour after receiving the vaccine. The patient fainted 3 times. The patient recovered that same day and went home. Lot# was not available. The patient sought medical attention by visiting the nurse and physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Syncope

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340742-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	30-Dec-2008		18-Feb-2009	05-Mar-2009	--	WAES0901USA00353	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Urticaria

Symptom Text: Information has been received from a physician assistant concerning an 18 year old female with reactions to vaccines who was vaccinated with a dose of GARDASIL (lot# 660557/0072X). On 30-DEC-2008 the patient broke out in hives on the face, "abs", arms, and torso. The patient was given BENADRYL in the office and within 15 minutes, the hives were gone. The patient was sent home with a Prednisone prescription. The patient recovered on 30-DEC-2008. It was unspecified which dose the patient had a reaction from therefore it is unknown which dose is the lot number provided. The patient sought medical attention at the physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Vaccination adverse reaction

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340743-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Dec-2008	Unknown		18-Feb-2009	05-Mar-2009	CA	WAES0901USA00352	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vomiting in pregnancy

Symptom Text: Information has been received from a 24 year old female medical assistant who in December 2008, was vaccinated with a second dose of GARDASIL, 0.5ml. At the time of reporting the patient was pregnant. Follow-up information has been received from the patient concerning herself whose LMP was sometime in November 2008 and due date was sometimes in the beginning of September 2009. This was her third pregnancy and she has 2 living children. The patient said everything felt fine so far, except for the morning sickness. The patient saw a new OB, who told her everything was fine. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 11/1/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340744-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Jan-2009	02-Jan-2009	0	18-Feb-2009	05-Mar-2009	IL	WAES0901USA00349	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Rash, Vomiting

Symptom Text: Information has been received from a physician concerning an 17 year old female who on 02-JAN-2009 was vaccinated with the first dose of GARDASIL. Within a couple of hours the patient became dizzy. Eight hours later she experienced nausea and vomiting. She also had a rash that lasted 2 to 3 days. At the time of reporting, the patient recovered from the events. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340745-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Jul-2007	22-Dec-2008	525	18-Feb-2009	05-Mar-2009	LA	WAES0901USA00342	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0243U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse, for the Pregnancy Registry for GARDASIL, concerning an 18 year old female with urinary frequency, obesity and hypertension, a history of tonsillitis and no drug allergies who was intramuscularly vaccinated with the first and second 0.5 ml doses of GARDASIL on 16-JUL-2007 and 22-DEC-2008 (1st lot # 656372/0243U, 2nd lot # 651044/0548X), respectively. Concomitant therapy included YASMIN. On 22-DEC-2008 the patient had a negative early pregnancy test and on 29-DEC-2008 it was positive. It was also reported that the urine analysis positive for protein, and a complete blood cell count was performed. No other adverse effects were reported. The patient was seen for medical attention. Additional information has been requested.

Other Meds: YASMIN

Lab Data: urinalysis - positive for protein; urine beta-human 12/22/08 - negative; urine beta-human 12/29/08 - positive

History: Tonsillitis

Prex Illness: Pregnancy NOS (LMP = Unknown) Urinary frequency; Obesity; Hypertension

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340746-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Aug-2007	01-Aug-2007	0	18-Feb-2009	05-Mar-2009	VA	WAES0901USA00341	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician concerning an 11 year old female who in August 2007, was vaccinated with the first dose of GARDASIL. "The same day of the vaccination", after receiving the vaccination, the patient passed out in the office. On unspecified date, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340747-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	05-Mar-2009	MA	WAES0901USA00318	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cellulitis, Pyrexia

Symptom Text: Information has been received from a registered nurse, concerning a female patient, who on an unspecified date was vaccinated with GARDASIL. The registered nurse mentioned the patient developed a fever and Cellulitis like reaction after receiving her first of HPV vaccine. The patient sought medical attention and was seen at the physician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340748-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	05-Mar-2009	IL	WAES0901USA00315	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chills, Hot flush, Paraesthesia

Symptom Text: Information has been received from a registered nurse, concerning a female patient, who on an unspecified date was vaccinated with GARDASIL ,0.5ml intra muscularly. The registered nurse reported that the patient developed tingling in both her hands, chills and hot flashes after receiving the vaccine. It was not specified by the registered nurse when the symptoms developed or how many doses of the vaccine the patient had received. The registered nurse mentioned that "the patient may have been coming down with the flu at this time." The patient sought medical attention through a telephone call. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness: Flu

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340749-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jan-2008	01-Jan-2008	0	18-Feb-2009	05-Mar-2009	--	WAES0901USA00309	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Information has been received from an educator concerning a 7th to 9th grade female student, who "within the last 12 months" was vaccinated intramuscularly with a 0.5 mL dose of GARDASIL. The patient may have been vaccinated in combination with other vaccines that was needed to go back into middle school. "Within the last 12 months", when she got vaccinated, the patient felt "excruciating" pain. Subsequently, the patient had recovered at the time of vaccination. The reporter did not know if the patient experienced the adverse event with their 1st, 2nd or 3rd dose. The patient sought unspecified medical attention. This is one of several cases from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340750-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jan-2008	01-Jan-2008	0	18-Feb-2009	05-Mar-2009	--	WAES0901USA00308	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Presyncope

Symptom Text: Information has been received from an educator concerning a 7th to 9th grade female student, who "within the last 12 months" was vaccinated intramuscularly with a 0.5 mL dose of GARDASIL. The patient may have been vaccinated in combination with other vaccines that was needed to go back into middle school. "Within the last 12 months", when vaccinated, the patient almost fainted. Subsequently, the patient had recovered at the time of vaccination. The reporter did not know if the patient experienced the adverse event with their 1st, 2nd or 3rd dose. The patient sought unspecified medical attention. This is one of several cases from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340751-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	05-Mar-2009	--	WAES0901USA00307	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from an educator concerning a 7th to 9th grade female student, who "within the last 12 months" was vaccinated intramuscularly with a 0.5 mL dose of GARDASIL. The patient may have been vaccinated in combination with other vaccines that was needed to go back into middle school. "Within the last 12 months", when vaccinated, the patient fully fainted. Subsequently, the patient had recovered at the time of vaccination. The reporter did not know if the patient experienced the adverse event with their 1st, 2nd or 3rd dose. The patient sought unspecified medical attention. This is one of several cases from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340752-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	05-Mar-2009	OH	WAES0901USA00289	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a female with allergy to latex who was vaccinated with GARDASIL. Concomitant therapy included penicillin (unspecified). 4 to 6 hours later the patient broke out in hives. The reporter was uncertain if hives were related to the GARDASIL. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: penicillin (unspecified)

Lab Data: Unknown

History:

Prex Illness: Latex allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340753-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	08-Oct-2008	Unknown		18-Feb-2009	05-Mar-2009	--	WAES0901USA00200	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Inappropriate schedule of drug administration, Pyrexia

Symptom Text: Information has been received from a 27 year old female patient who on 08-OCT-2008 was vaccinated with a first dose of GARDASIL, when she was already 27 years old; the patient experienced headache and some fever. The caller cannot get the second and the third dose of GARDASIL because her insurance will not cover it because of her age. The patient did not seek medical attention. The patient recovered on an unspecified date. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340758-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	10-Jun-2008	10-Jun-2008	0	18-Feb-2009	05-Mar-2009	AZ	WAES0901USA00188	31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Back pain, Depression, Mood swings, Myalgia, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a consumer concerning her 12 year old daughter with no known medical history and allergies, who on 10-JUN-2008 was vaccinated with a first dose of GARDASIL. On 10-JUN-2008 the patient experienced fever of 102 for three to four days. She also started getting depressed, and she begun having mood swings, memory loss, achy back and muscle pain. After she received the second dose of GARDASIL, she came down with a fever of 103 and the symptoms continued and had not improved. There were no laboratory diagnostics performed. The patient did not seek medical attention. At the time of this report the patient had not recovered. Follow up information received on 19-JAN-2009 stated that a phone call was received from the reporter, she mentioned that a physician did not administered the GARDASIL vaccine, a nurse did. Additional information has been requested. 3/2/09 Per reporter/parent pt has not sought tx for fear of being prescribed psychiatric meds. Case closed.

Other Meds: None

Lab Data: body temp 06/10/08 - 102 body temp - 103

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340759-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	Unknown		18-Feb-2009	05-Mar-2009	VA	WAES0901USA00173	09-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Information has been received from a physician concerning a 12 year old female patient who on an unknown date was vaccinated with the first dose of GARDASIL 0.5 mL. After received the first dose of GARDASIL, the patient experienced pain in her whole arm. The patient was sent to the emergency room. On an unspecified date, the patient recovered from pain in her whole arm. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340760-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Aug-2008	02-Sep-2008	2	18-Feb-2009	05-Mar-2009	PA	WAES0901USA00154	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vaccine positive rechallenge

Symptom Text: Information has been received from a Registered Nurse concerning a 17 year old female patient with no pertinent medical history and no drug reactions or allergies who in July 2008, was vaccinated with first dose of GARDASIL (Lot # not provided) 0.5 ml, intramuscularly and at the end of August 2008 the patient received second dose of GARDASIL (Lot # not provided) 0.5ml, intramuscularly. There was no concomitant medication. After 2 days the patient received first dose of GARDASIL she experienced mild nausea. The nausea resolved within 2 days without treatment. The patient experienced moderately severe nausea starting 2 days after receiving her second dose. The nausea lasted 4-5 days and resolved without requiring treatment. The patient did not experience vomiting. There were no Laboratory Diagnostic performed. The patient sought medical attention by phone. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340761-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	10-Oct-2007	20-Oct-2007	10	18-Feb-2009	05-Mar-2009	OH	WAES0901USA00061	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Fungal infection, Lymphadenopathy

Symptom Text: Information has been received from a consumer concerning her 21 year old daughter with no previous medical history reported who on 06-APR-2007 was vaccinated with the first dose of GARDASIL. On 07-JUN-2007, the patient was vaccinated with the second dose of GARDASIL and on 10-OCT-2007 with the third dose of GARDASIL. Concomitant therapy included birth control (unspecified). She had her papanicolaou test on 20-OCT-2007 and on 21-MAY-2008 and both came back ASCUS, and her last papanicolaou test on 03-DEC-2008 came back normal. In December 2007 and April 2008, the patient experienced yeast infections. In November 2008, the patient experienced swollen gland in her groin. Subsequently, the patient recovered. The patient sought unspecified medical attention. This is one of several reports provided by the same source. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Pap test, 10/20/07, ASCUS; Pap test, 05/21/08, ASCUS; Pap test, 23/03/08, normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340762-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	08-Oct-2008	13-Oct-2008	5	18-Feb-2009	06-Mar-2009	PA	WAES0901USA00052	06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Colposcopy, Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed practical nurse for the Pregnancy Registry for GARDASIL, concerning a 26 year old female patient with a history of papilloma viral infection, who on 10-APR-2008 was vaccinated with the first dose of GARDASIL (Lot number 659964/1978U) 0.5 mL IM. On 11-JUN-2008, the patient was vaccinated with the second dose of GARDASIL (660393/0067X) 0.5 mL IM and on 08-OCT-2008 was vaccinated with the third dose of GARDASIL (Lot number 660557/0072X) 0.5 mL IM. There was no concomitant medication. The nurse reported that the patient who received all three doses of GARDASIL was pregnant. A urine pregnancy test done on 08-OCT-2008 at the office was negative. The last menstrual period was on 14-OCT-2008 and the estimated delivery date will be on 21-JUL-2009. Follow up information was received from the LPN who reported that the patient with asthma (status post), had a 3 previous pregnancies (2 full term deliveries (39 weeks both) and 1 elective termination at 4 weeks). The patient did not had any birth defects or infant complications in any previous pregnancy. On 29-DEC-2008, the patient was placed on prenatal vitamins. On 13-0CT-2008 a PAP was performed, positive result for ASCUS and HRHPV. On 12-DEC-2008, a colposcopy was performed (results not provided). Additional information has been requested.

Other Meds:

Lab Data: beta-human chorionic, 10/08/08, urine pregnancy test: negative; Pap test, 10/13/08, ASCUS: positive, HRHPV

History: Pregnancy; Delivery; Pregnancy termination

Prex Illness: Pregnancy NOS (LMP = 10/14/2008); Asthma

Prex Vax Illns:

Vaers Id: **340763-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Dec-2008	16-Dec-2008	7	18-Feb-2009	05-Mar-2009	--	WAES0901USA00041	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Infectious mononucleosis

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with no drug reactions or allergies who on 09-Dec-2008 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. The mother reported that 7 to 10 days after vaccination, approximately on 16-Dec-2008, the patient experienced severe joint pains. Mother also stated the patient was brought to the emergency room but was not admitted in the hospital. Mother also reported that after some blood test done, the patient was diagnosed of "mononucleosis" Blood test was done 2 weeks after the patient received GARDASIL, approximately on 23-Dec-2008. The patient recovered at the end of December. Additional information is not expected.

Other Meds: None

Lab Data: Diagnostic Laboratory 12/23/08 - Mononucleosis

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340764-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	30-Oct-2008	18-Nov-2008	19	18-Feb-2009	06-Mar-2009	MN	WAES0812USA04853	06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse concerning a 16 year old female with no medical history and allergies and 0 previous pregnancies, who on 30-OCT-2008 was vaccinated with a 0.5 mL first dose of GARDASIL vaccine (lot #661530/0575X), intramuscularly. Concomitant therapy included ALESSE. On 30-OCT-2008 the patient discovered that she was pregnant, the nurse mentioned that the LMP was 18-NOV-2008, but the patient had an abnormal cycle and the LMP may had been a month earlier. Laboratory diagnostics studies performed include a urine pregnancy test on 18-DEC-2008 at the office, a pre-natal blood work drawn on 23-DEC-2008 (results pending) and a prenatal ultrasound scheduled for next week. Clonazepam (dates taken 20-OCT-2008 for 2 days), PREDNISONE (dates taken 22-NOV-2008 for 3 days) and chlorpromazine (dates taken 20-OCT-2008 for 2 days) were taken by the patient. No adverse effects reported. The patient sought medical attention through an office visit. follow up information received on 27-JAN-2009 from an initial pregnancy questionnaire stated that the patient had recurrent hiccups. Concomitant therapy included MENACTRA. CHLORPROMAZINE (25-NOV-2008 to 28-NOV-2008, 25 mg 3/day). PREDNISONE (22-NOV-2008 to 25-NOV-2008, 20 mg x 2 daily) and CLONAZEPAM (20-NOV-2008 to 22-NOV-2008, 0.25 mg 0.5 mg 2 x day) were taken by the patient for hiccup syndrome. On 07-JAN-2009 the patient had an ultrasound performed for dating, the fetal heart rate was 135; 1 weeks 0 days. The estimated delivery date was 26-AUG-2009 (previously reported 25-AUG-2009). Additional information has been requested.

Other Meds: ALESSE, INFLUENZA VIRUS vaccine, MENACTRA

Lab Data: diagnostic laboratory, 12/23/08, -; ultrasound, 01/07/09, - FHR 135; 1 weeks 0 days; urine beta-human, 12/18/08

History:

Prex Illness: Pregnancy NOS (LMP = 11/18/2008) Hiccups

Prex Vax Illns: No Relevant Data~ ()~~0~In Patient

Vaers Id: **340765-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	15-Aug-2008	15-Aug-2008	0	18-Feb-2009	05-Mar-2009	--	WAES0811USA02352	06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depression, Drug exposure during pregnancy

Symptom Text: Information has been received from a certified nurse midwife for the Pregnancy Registry for GARDASIL vaccine, concerning a 19 year old female who on 15-AUG-2008 was vaccinated intramuscularly with a first 0.5ml of GARDASIL vaccine. The patient sought medical attention at the practice. The patient's LMP was 05-AUG-2008. No adverse event. Follow-up information was received on 08-DEC-2008. It was reported that this was the patient's second Pregnancy, and she had one previous full term delivery. There is no birth defect and no infant complications in previous pregnancy. On 15-OCT-2008 the ultrasound showed intrauterine pregnancy 9 weeks and on 04-DEC-2008 MSAFP was performed. Medication taken during pregnancy included WELLBUTRIN, SR100 mg. BID, started on 06-NOV-2008 for depression. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP=8/5/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340766-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	04-Nov-2008	Unknown		18-Feb-2009	06-Mar-2009	IL	WAES0811USA02127	06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cyst rupture, Drug exposure during pregnancy, Pelvic pain

Symptom Text: Information has been received from a Registered Nurse regarding the Pregnancy registry for HPV concerning a 24 year-old female with penicillin and dyes allergy and a history of abnormal pap smear, who on 01-MAY-2008 was vaccinated with the first dose of GARDASIL, on 01-JUL-2008 was vaccinated with the second dose of GARDASIL, and on 04-NOV-2008 was vaccinated with the third dose of GARDASIL (lot # 659962/1740U) 0.5 ml via intramuscular. There was no concomitant therapy. The patient saw the nurse. Urine pregnancy test was performed. The patient became pregnant after receiving GARDASIL and her last menstrual period was on 09-OCT-2008 and EDC is on 16-JUL-2009. Follow-up information has been received from a completed questionnaire on 14-JAN-2009 which reported: A female patient on 01-MAY-2008, 01-JUL-2008 and 04-NOV-2008 was vaccinated with three doses of GARDASIL (lot # 659962/1740U) respectively. The third dose of GARDASIL was also reported as WP-M902. The patient had one previous full term pregnancy, with no complications. It was confirmed that the patient's LMP was 09-OCT-2008 and the EDC was 16-JUL-2008. On 24-NOV-2008, the patient underwent an ultrasound due to pelvic pain. The result indicated Intrauterine Pregnancy at 6 weeks and 2 days and a ruptured corpus luteal cyst. Follow-up information has been received from the Registered Nurse on 16-Jan-2009 which reported: The patient remained pregnant and as of 05-DEC-2008, the ruptured corpus luteal cyst had completely resolved. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, 11/24/08, IUP at 6w 2d, pelvic pain, ruptured corpus luteal cyst

History: Papanicolaou smear abnormal

Prex Illness: Pregnancy NOS (LMP = 10/9/2008); Penicillin allergy; Hypersensitivity

Prex Vax Illns:

Vaers Id: **340767-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	12-Dec-2007	26-Feb-2008	76	18-Feb-2009	06-Mar-2009	--	WAES0810USA02628	06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia of pregnancy, Drug exposure during pregnancy, Polyhydramnios, Pregnancy induced hypertension, Retained placenta or membranes

Symptom Text: Information has been received from a Registered Nurse, for the Pregnancy Registry for GARDASIL vaccine concerning a 24 year female with of asthma and drug allergic to penicillin, in AUG-2007 motor vehicle accident resulting in multiple fractures, left arm, left leg, right arm; liver and kidney damage; a splenectomy at the time of vaccination, discontinued all medications related to MVA prior to 12 weeks pregnant (PREVACID, NEXIUM), AMBIEN, SEROQUEL, CELEBREX, PROZAC), who on 22-OCT-2007 was vaccinated with the first dose of GARDASIL vaccine (lot# 655154/12100), 0.5ml intramuscular right deltoid, on 12-DEC-2007 was vaccinated the second dose of GARDASIL vaccine (lot#655327/1287U), 0.5ml intramuscular right deltoid. Concomitant therapy included VENTOLIN, fluticasone propionate (+) ADVAIR; prenatal vitamins (unspecified) daily. On 28-FEB-2008 the patient experienced the last menstrual period, and the estimated delivery date was on05-DEC-2008. On 01-APR-2008, the patient serum beta human chorionic gonadotropin test (B HCG; was positive. The patient was reported as a gravida 1, paro 0 (no pregnancies). On 07-APR-2008, the patient underwent an untrasound due to bleeding. The results revealed a single live intrauterine pregnancy (SLIUP) at 5 weeks, 4 days. EDC 04-DEC-2008). On 27-MAY-2008, the patient's 1st trimester screen revealed normal nuchal translucency, at 12 weeks, 6 days. Additional follow-up information had been received from a completed pregnancy questionnaire on 05-JAN-2009: This report concerned a female patient with depression-anxiety and asthma. ETC was 04-DEC-2008. Concomitant therapy included PROZAC, ADAVIR, VENTOLIN, AMBIEN, and iron. During pregnancy, the patient experienced polyhydramnioe and PIH (pregnancy induced hypertension). The patient underwent multiple ultrasounds, non stress testing and PIH labs. PIH labs were normal. In April 1 2009 ADVAIR was discontinued. During delivery, the patient retained placenta-which required manual extraction and O+E. On 17-NOV-2008, 37 3/? weeks from LMP, a nor

Other Meds: VENTOLIN (ALBUTEROL); PROZAC; ADVAIR; iron (unspecified); ZOLOFT; vitamins (unspecified); AMBIEN.

Lab Data: Ultrasound, 04/07/2008, SLIUP SN 4d. US due to bleeding/EDC 04-DEC-2008; Diagnostic laboratory, 05/27/08, 12w 6d, normal nuchal translucency/first trimester screen; Serum beta-human, 04/01/08, positive.

History: Motor vehicle accident; Arm fracture; Renal injury; Splenectomy; Hepatic damage.

Prex Illness: Pregnancy NOS (LMP=2/28/2008); Asthma; Penicillin allergy; Anxiety-depresion

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340768-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	28-Jan-2008	11-Feb-2008	14	18-Feb-2009	05-Mar-2009	--	WAES0810USA00870	06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1287U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner for the pregnancy registry for GARDASIL vaccine concerning a 27 year old female with a history of 5 pregnancies and 4 live births and no pertinent medical history and no allergies who on 28-JAN-2008 was vaccinated with a first dose of GARDASIL vaccine 0.5 ml (lot # 655327/1287U). Other medication used during pregnancy included pre-natal vitamins, ZOFRAN ODT 8mg PRN for nausea (previously reported as vomiting), FERROUS SULFATE 325 mg daily for anemia and MACROBID 100 mg BID for UTI. There were no birth defects and no infant complications in previous pregnancies. The patient became pregnant after vaccination "34 weeks" ago. The date of last menstrual period was 11-FEB-2008. The estimated due date is 17-NOV-2008. The patient sought medical attention seen at the practice. The routine pregnancy work up was performed. On 31-MAR-2008 the ultrasound was performed. On 02-JUN-2008 MSAFF was performed with normal limits. Follow-up information was received from pregnancy questionnaire. On 10-MAR-2008 the routine pregnancy labs were performed within normal limits. On 29-JUL-2008 the glucose test was performed within normal limits. On 29-JUL-2008 the whole blood hematocrit ad blood hemoglobin test were performed with the results of mild anemia. On 14-OCT-2008 the vaginal Streptococcus group B culture test was performed with negative results. On 02-NOV-2008 the patient with 1 spontaneous abortion (incomplete abortion D&C done) delivered a male health baby weighing 7 pounds 6 ounces with apgar score 9/10 at 38 weeks. There was no congenital anomalies or other complication or abnormalities. There was no complication during pregnancy and delivery. Additional information is not expected.

Other Meds:

Lab Data: diagnostic laboratory, 03/10/08, - routine pregnancy work up; ultrasound, 03/31/08, - 1st trimester routine within normal limits; serum alpha-fetoprotein, 06/02/08, - within normal limits; serum glucose, 07/29/08, - within normal limits; he

History:

Prex Illness: Pregnancy NOS (LMP = 2/11/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340769-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		18-Feb-2009	06-Mar-2009	--	WAES0806USA02226	06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Gestational diabetes

Symptom Text: Initial and follow up information has been received from a nurse, for the pregnancy for GARDASIL, concerning a black female with one previous pregnancy and one full term delivery with no birth defects who was vaccinated with a 1st dose of GARDASIL when she was 5 weeks pregnant (previously reported as 16 weeks gestation on 11-Jun-2008) with LMP of 04-Mar-2008 (previously reported as approximately 15-Feb-2008). Other therapies included prenatal vitamins (unspecified). No adverse events reported. On 14-May-2008 the patient had a routine ultrasound, results indicated that the dating was 9w6D and estimated delivery date was 11-Dec-2008. The patient outcome was not reported. Additional information has been requested. Follow up information has been received from a complete pregnancy questionnaire on 30-Dec-2008 for the pregnancy registry for GARDASIL, concerning a black female patient with one previous pregnancy, no pertinent medical history and no known allergies who on an unspecified date was vaccinated with a dose of GARDASIL when she was 5 weeks pregnant (LMP: 04-Mar-2008). On 14-May-2008 the patient had a routine ultrasound, results indicated the age of the fetus was 9 weeks and 6 days and on 19-Nov-2008 the patient delivered a normal infant. In the following up information received on 30-Dec-2008 contained the following adverse experiences: gestational diabetes mellitus which was treated with Metformin (500-750 mg daily). No further information is available.

Other Meds: None

Lab Data: Ultrasound 05/14/2008 - EDC 12/11/08; routine dating 9W6D

History:

Prex Illness: Pregnancy NCS (LMP = 3/4/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340770-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	22-Feb-2008	22-Feb-2008	0	18-Feb-2009	06-Mar-2009	HI	WAES0802USA06329	06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	655327/1287U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Nasopharyngitis, Respiratory tract congestion, Urinary tract infection

Symptom Text: Information has been received through the Merck pregnancy registry from a female consumer, nurse practitioner and physician concerning female with history of caesarian delivery and abnormal past papanicolaou test and none known drug reactions / allergies, who on 22-Feb-2008 (also reported as 22-June-2008 was vaccinated intramuscularly, into left deltoid, with her 0.5ml first dose of GARDASIL (lot # 655327/128U) and found out she was pregnant (LMP) 26-Jan-2008, (also reported as 28-June-2008) . On 29-Feb-2008, the patient took pregnancy test that tested positive. The urine test for pregnancy was confirmed during the physician's office visit on 03-Mar-2008. Unspecified medical attention was sought during an office visit. No adverse symptoms. No further information was provided. Follow up information was received via pregnancy questionnaire from a physician. The patient had a history of early tobacco and discontinued with pregnancy. She had one previous pregnancy which was full term delivery and the infant complication was macrosomia. There was no other significant past medical history and concurrent medical conditions. During this pregnancy she took MACROBID 100mg bid and Phenazopyridine hydrochloride 200mg tid to treat urinary tract infection and pseudo ephedrine HCL 300mg prn tid to treat cold / congestion. Concomitant medication included multivitamins. Diagnostic test during the pregnancy included : cystic fibrosis on 16-APR-2008 was negative, serum alpha-fetoprotein test on 16-May-2008 was negative, ultrasound on 12-Jun-2008 CWO normal anatomy, and glucose tolerance test on 16-Sep-2008 was 1/4 elevated. On 23-Oct-2008, she delivery a normal health male baby weighting 3129 grams, length 48cm, and Apgar score was 9/9 at 39 weeks from her LMP. Additional information is not expected.

Other Meds: Vitamins

Lab Data: Diagnostic Laboratory 04/16/08 - cystic fibrosis negative; Ultrasound 06/12/08 - CWO normal anatomy; Beta-human chorionic 02/29/08 - positive; Beta-human chronic 03/03/08 positive; Glucose tolerance test 09/16/08 - 1/4 elevated ; Serum alph

History: Cesarean section; Papanicolaou smear abnormal; Ex-tobaco user

Prex Illness:

Prex Vax Illns:

Vaers Id: **340771-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Oct-2007	09-Oct-2007	0	18-Feb-2009	05-Mar-2009	PA	WAES0802USA00364	06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Drug exposure during pregnancy, Haemorrhage, Muscle spasms

Symptom Text: Information has been received from Pregnancy Registry for GARDASIL vaccine from a Registered Nurse (R.N.) concerning a female patient who was vaccinated with a third dose of GARDASIL vaccine (lot # unknown). The nurse reported that the patient received her third injection when she was pregnant but did not know it. It was unknown if medical attention was sought by the patient. The data of last menstrual period and estimated date of delivery is unknown. The outcome was unknown. Follow up information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 17 year old Caucasian female patient with no previous pregnancy history and no pertinent medical history who on 09-OCT-2007 was vaccinated with the first dose of GARDASIL (lot # not provided). Subsequently the patient was pregnant (LMP was 13-NOV-2007 and EDD was 20-AUG-2008). On 10-DEC-2007 she received the second dose of GARDASIL (lot # not provided) when she did not realize she was pregnant (previously reported the third dose). Concomitant therapy included allergy injection every other week for treatment of allergies. Other medications used during pregnancy included prenatal vitamin qd taken for December 2007 to August 2008. In October 2007, the patient experienced anxiety and ZOLOFT 50 mg qd was started. On 14-JAN-2008 ultrasound was performed for bleeding and cramping with the result of within normal limits. On 24-MAR-2008 routine ultrasound was performed again with the result of within normal limits. On 06-AUG-2008 (from LMP 37 weeks 6 days) the patient delivered a normal, healthy male baby weighting 8 pounds 10 ounces with no congenital anomalies. The Apgar score was 8/9. There was not complication during pregnancy and labor/delivery, and not infections or illness during pregnancy for the patient. Additional information is not expected.

Other Meds: allergenic extract

Lab Data: ultrasound 01/14/08 - within normal limits; ultrasound 03/24/08 - within normal limits; Apgar score 8/9 -

History:

Prex Illness: Pregnancy NOS (LMP = 11/13/2007 Hypersensitivity

Prex Vax Illns:

Vaers Id: **340772-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	29-Nov-2007	29-Nov-2007	0	18-Feb-2009	05-Mar-2009	GA	WAES0712USA00292	06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Labour induction, Prolonged pregnancy

Symptom Text: Information has been received through the Merck pregnancy registry from a physician concerning a 25 year old female with a history of tonsillectomy who on 29-NOV-2007 was vaccinated with the third dose of GARDASIL. No information was provided concerning the first or second dose of GARDASIL. On 29-NOV-2007 the patient also had blood work taken "which had showed she was pregnant" (LMP=05-SEP-2007). The patient sought unspecified medical attention and reported that she was about "three weeks pregnant". No further information was provided. Follow-up information has been received from a physician concerning the patient who was induced on 12-AUG-2008 because she was 41 weeks gestation, and had a vaginal delivery of a normal baby with "good Apgars", "everything went well". The reporter indicated that the patient did well and was discharged home with the baby on the next day No further information is available.

Other Meds: None

Lab Data: diagnostic hematology 11/29/07 -

History: Tonsillectomy

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340783-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	24-Feb-2009	25-Feb-2009	1	26-Feb-2009	04-Mar-2009	WV		06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1183X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site oedema

Symptom Text: Erythema, edema around immunization site. Approximately 1 1/2 in. diameter.

Other Meds:

Lab Data: None

History: Allergic rhinitis; Mild intermittent asthma

Prex Illness: None

Prex Vax Illns:

Vaers Id: **340807-1 (S)** **Related reports:** 340807-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Nov-2008	12-Nov-2008	1	26-Feb-2009	03-Mar-2009	CO		17-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Alopecia, Amnesia, Apathy, Back pain, Chronic fatigue syndrome, Cough, Decreased appetite, Depression, Diarrhoea, Disturbance in attention, Dyspnoea, Dysstasia, Epstein-Barr virus infection, Fatigue, Gait disturbance, Headache, Hypoaesthesia, Increased upper airway secretion, Insomnia, Irritability, Lip swelling, Mood swings, Nausea, Neck pain, Neurological examination normal, Non-cardiac chest pain, Pain in extremity, Paraesthesia, Presyncope, Rhinorrhoea, Sensation of heaviness, Staring, Vomiting

Symptom Text: chronic debilitating headaches, chronic diahrrea, severe back & abdominal pain, tingling in hands and feet,numbness in hands & feet, stabbing pain in lower legs and feet, inability to stand, inability to walk, difficulty breathing, swollen lips, chest pain in conjunction with neck pain, loss of hair, chronic debilitating fatigue, nausea, vomiting, short term memory loss, inability to concentrate, stares off in the distance for long periods of time. These started right after the vaccination and continue to this day & have made her life as she knew it unmanageable. She can no longer attend school. Numerous trips to her pediatrician, blood tests, urine test, stool tests, emergency room visits, referred to neurologists, nutritionist. No one knows how to treat her. There is no treatment apparently. 3/16/09 Received consult records of 2/24/2009. FINAL DX: probable chronic fatigue syndrome, possibly exacerbated by recent EBV infection; reactive depression; likely vasovagal episodes; possible anxiety disorder. Records reveal patient experienced fatigue, nausea, numbness/tingling of hands/feet, HA, neck pain, intermittent diarrhea, chest pain w/SOB & heart pounding, intermittent difficulty walking, difficulty concentrating, decreased appetite, insomnia, apathy, moody, irritable. Approx 1 wk after initial HPV & Depoprovera injections, 11/12/08, developed waxing/waning fatigue which escalated to missing school in Dec & Jan. Suggested antidepressant & counseling. 3/9/09 Received PCP medical records of 2/2007-3/2/2009 included ER records of 2/9/2009. FINAL DX:none provided Records reveal patient experienced good health on 11/12, received depo-provera 1st dose along w/HPV #1. RTC 2/11 s/p ER visit 2/9 for chest pain, cough, runny nose, phlegm congestion. Parent reported back pain, hand tremors, leg pain, leg swelling, back pain, dizziness, joint stiffness, decreased concentration, fatigue, intermittent diarrhea, nausea since 11/08. Missed several days of school. Developed leg heaviness, gait disturbance,

Other Meds: none

Lab Data: ESR, ASO, FT4, TSH, ANA TITER, ANTI-DS-DNA, EBV AB PROFILE ACT WKST: FANA, STOOL, URINE, CARDIAC ENZYMES, EKG, CHEST X-RAY, CAT SCAN - NEURO TESTING IS NEXT WEEK. LABS 2/18/09: ASO 161(H). EBV IgG (+), nuclear antigen neg, IgM (+). ESR 3

History: none PMH: acute pharyngitis, HA, acute sinusitis, cough, acne vulgaris tx w/minocin, abdominal pain, diarrhea. Family hx: depression, suicide.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **340807-2 (S)** **Related reports:** 340807-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Nov-2008	12-Nov-2008	1	10-Apr-2009	13-Apr-2009	--	WAES0903USA05070	13-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Abdominal pain, Activities of daily living impaired, Alopecia, Amnesia, Antinuclear antibody, Back pain, Blood thyroid stimulating hormone, Cardiac enzymes, Chest X-ray, Chest pain, Computerised tomogram, Diarrhoea, Disturbance in attention, Dyspnoea, Dysstasia, Electrocardiogram, Epstein-Barr virus antibody, Fatigue, Free thyroxine index, Headache, Hypoaesthesia, Lip swelling, Nausea, Neck pain, Pain in extremity, Paraesthesia, Red blood cell sedimentation rate, Staring, Stool analysis, Streptococcal identification test, Urine analysis, Vomiting

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act, concerning a 16 year old female with no relevant medical history reported, who on 11-NOV-2008 was vaccinated with the first dose of GARDASIL, lot number 660616/0570X, intramuscularly, into the left arm. It was reported that the patient experienced chronic debilitating headaches, chronic diarrhea, severe back and abdominal pain, tingling in hands and feet, numbness in hands and feet, stabbing pain lower legs and feet, inability to stand, inability to walk, difficulty breathing, swollen lips, chest pain in conjunction with neck pain, loss of hair, chronic debilitating fatigue, nausea, vomiting, short term memory loss, inability to concentrate, stares off in the distance for long periods of time. It was reported that the patient started these right after the vaccination and continue to 12-NOV-2008 and had made patient's life as she knew it unmanageable. She could no longer attend school. Numerous trips to her pediatrician, blood test (erythrocyte sedimentation rate), Anti-streptolysin O, free thyroxin index, thyroid stimulating hormone, antinuclear titer, Anti-DS-DNA, EBV AB profile, fluorescent antinuclear antibody, urine tests, stool tests, cardiac enzymes, EKG, chest X-ray, CAT Scan (results not provided). There were a lot of emergency room visits, referred to neurologist and nutritionist. No one knew how to treat her. There was no treatment apparently. The neurological testing was scheduled for the next week. The listing indicated that one or more of the events was considered to be disabling, was considered to be immediately life-threatening. No further information is available. A standard lot check investigation was performed. All in-process quality checks for the lot number in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements o

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340830-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Feb-2009	19-Feb-2009	1	26-Feb-2009	04-Mar-2009	CO		24-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF452BA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Headache, Hyporeflexia, Vision blurred

Symptom Text: Pt c/o headaches, severe @times (6/10) lasting for 10 days post immunization. During 1st 24hrs post vaccine, also c/o lightheadedness / dizziness - resolved in 24hrs. 3/5/09 MR received from PCP. WCC 2/18/09 with vax given. TC from parent next day with c/o lightheadedness, dizziness, blurry vision and H/A. Not seen at this time. OV 2/25/09 for continued H/As, other sx resolving. Mom notes "not her usual perky self". PE (+) for DTRs 1+. Otherwise WNL. TC from parent 3/3/09-H/A are fine.

Other Meds: Concerta 54mg Motrin prn - headache

Lab Data: No adverse reactions after receiving HPV #1. PI for ADACEL states the study reports headache in some for 14 days after receiving vaccine

History: ADHD. PMH: premie-34 wks. RAD, T&A. Strep pharyngitis. ADD. obesity. Behavior changes 2008

Prex Illness: None

Prex Vax Illns:

Vaers Id: **340831-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Aug-2008	01-Aug-2008	0	27-Feb-2009	02-Mar-2009	--	WAES0810USA02517	02-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Anogenital warts, Caesarean section, Cervical dysplasia, Drug exposure during pregnancy, Failed trial of labour

Symptom Text: Information has been received from a Certified Nurse Midwife, for the Pregnancy Registry for GARDASIL, concerning a 19 year old female who in August 2008, was intramuscularly vaccinated with a dose of GARDASIL. It was reported that the patient was pregnant at the time of vaccination. The patient's LMP was 07-APR-2008 and the EDD was 12-JAN-2009. It was reported that this was the patient's first pregnancy. Pregnancy test was positive and ultrasound was performed on 10/14/2008. Follow up information was received from a certified nurse midwife who indicated the patient had positive atypical squamous cell of undetermined significance (ASCUS) HPV both in genital warts and in PAP test. The patient also had anemia during pregnancy. At 17 weeks gestation the patient performed ultrasound. On 29-JAN-2009, 41 weeks+ from her LMP, the patient delivered a health male baby weighing 9 pounds and 7 ounces. Apgar score was 7/9. The patient experienced low transverse cesarean section (LTCS) due to failure to progress (FTP). Upon internal review, low transverse cesarean section due to failure to progress was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: ultrasound, 10/14/08, 27 weeks gestation RCA; cervical smear, ASCUS HPV +; beta-human chorionic, 10/14/08, pregnancy test positive;

History:

Prex Illness: Pregnancy NOS (LMP = 4/7/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340832-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		27-Feb-2009	02-Mar-2009	VA	WAES0902USA03537	02-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Injection site pain, Loss of consciousness, Tremor

Symptom Text: Information has been received from a physician concerning a 23 year old female who was vaccinated with a first dose of GARDASIL 0.5ml IM. Subsequently the patient experienced "seizure like reaction", the patient was shaking and passed out shortly after receiving the dose of GARDASIL 0.5ml IM. After receiving her vaccination the patient became responsive again within 1-2 minutes and noted that the injection was very painful. The patient was in the office when the event occurred. It was noted that the patient had since returned to receive the second dose of GARDASIL 0.5ml IM with no problems. Upon internal review seizures like reaction was determined to be an other medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340833-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		27-Feb-2009	02-Mar-2009	ME	WAES0902USA03735	02-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Back pain, Headache

Symptom Text: Information has been received from a physician concerning a 15 year old female with no medical history and drug allergies who, on an unspecified date, was vaccinated intramuscularly with her first 0.5 ml dose of GARDASIL. There was no concomitant medication. The patient had experienced hip pain, lower back pain and headache after receiving the first dose of GARDASIL. It was noted that she had experienced pain in both of her hips but the left side had more pain than the right. The pain in her hips had made it difficult for the patient to participate in her soccer games. The patient sought medical attention and was seen by physician. The lot numbers and dates of administration were unknown. At the time of reporting (20-FEB-2009) the patient was recovering. The reporter considered the adverse experiences to be disabling. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340834-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	Unknown	Unknown		27-Feb-2009	02-Mar-2009	--	WAES0902USA03764	02-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Influenza like illness, Malaise, Myalgia, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a nurse concerning her 26 year old daughter who was intramuscularly vaccinated with the first and second 0.5 ml doses of GARDASIL several months ago. Subsequently the patient developed flu-like symptoms after administration of the first and second dose of GARDASIL. She also experienced vomiting and muscle aches both times. She missed work because of the severity of her symptoms. Her symptoms were worse after the second dose of GARDASIL as compared to the first dose. She would not be administered a third dose of GARDASIL. The patient recovered on unspecified dates. Flu-like symptoms, vomiting and muscle aches (both occurrences) were considered to be disabling because the patient "was very, very ill". The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 340835-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Sep-2007	01-Dec-2007	68	27-Feb-2009	02-Mar-2009	TX	WAES0902USA03784	12-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2323AA	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B016BA	5	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0245U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Chronic sinusitis, Disturbance in attention, Dyskinesia, Erythema, Eye disorder, Fall, Grand mal convulsion, Head injury, Headache, Hypokalaemia, Loss of consciousness, Nervousness, Partial seizures, Petit mal epilepsy, Postictal state, Syncope, Tonic clonic movements, Tremor

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female patient with no pertinent medical history and no known drug allergies or reactions who on 24-SEP-2007 was vaccinated with the first 0.5 ml IM dose of GARDASIL. There was no concomitant medication. In December 2007, the patient experienced blackout episodes and petit mal seizures. On 06-DEC-2007 the patient was vaccinated with the second 0.5 ml IM dose of GARDASIL, and on 07-AUG-2008 the patient received the third GARDASIL. Some time in 2008, the patient experienced grand mal seizures and had been hospitalized multiple times (details of hospitalizations not provided). The patient had been subsequently evaluated by an unspecified neurologist who had prescribed an unspecified anti-seizure medication. Neurological tests were performed with normal results. At the time of this report, the patient's blackout episodes, petit mal seizures and grand mal seizures persisted. Blackout episodes, petit mal seizures and grand mal seizures were also considered to be disabling and immediately life-threatening. This is one of several reports received from the same source. Additional information has been requested. 3/9/09 Received hospital records for multiple ER & admits: 3/20/2008 FINAL DX: syncopal episode vs anxiety attack Records reveal patient experienced brief episode of syncope while getting ready to travel to hospital for eye surgery she was very nervous about. Exam in ER revealed chewing movement of mouth/lips, shaking of LUE but was awake & alert. Tx w/anti anxiety med, improved & d/c to home. 4/20/2008 FINAL DX: syncope r/o seizure Records reveal patient experienced sudden LOC & fell to ground striking head. Out for approx 5 min w/jerking/seizure activity for short time. Exam in ER was WNL. Remained stable, d/c to home & referred to Neuro. 10/9/2008 Final DX: postictal state, probable seizure PTA; hypokalemia Records reveal patient experienced HA, facial redness & passed out. Remained stable, d/c to home w/PCP f/u.

Other Meds: None

Lab Data: neurological, normal LABS: CBC, CMP, UA, BNP & urine drug screen all WNL. Prolactin28.27(H). Potassium 3.3 (L). CT head WNL except chronic sinusitis.

History: None HPV #2 given 12/6/07, Lot # 0928U, IM/RA; HPV #3 given 8/7/08, Lot # 1967U, IM/RA.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340836-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	19-Dec-2008	19-Dec-2008	0	27-Feb-2009	02-Mar-2009	FR	WAES0902USA03845	02-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0467U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea, Vertigo

Symptom Text: Information has been received from Health Authority (documentation number #29839) on 18-FEB-2009 concerning a 11 year old female who on 19-DEC-2008 was vaccinated with the second dose of GARDASIL (lot #0467U, batch # NG14300, route: intramuscular, site not reported). It was reported that 15 minutes post vaccination the female patient developed vertigo, headache and nausea. Blood pressure: RR: 119/72. A duration of 3.5 hours was reported. Treatment of adverse events: bed rest. The female patient had recovered. This case was classified as medically important from the reporter. Other business partner numbers include: E2009-01521. This case is closed.

Other Meds: Unknown

Lab Data: Blood pressure measurement, 119/72

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 340837-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Dec-2008	27-Dec-2008	4	27-Feb-2009	02-Mar-2009	FR	WAES0902USA03857	02-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal discomfort, Convulsion, Dizziness, Inappropriate schedule of drug administration, Loss of consciousness, Nausea, Nuchal rigidity

Symptom Text: This is a case of misuse (third dose of vaccine administered one month after the second dose). Initial information has been received from a Health Authority (reference number # ES-AGEMED-113070438) on 18-FEB-2009. On 19-FEB-2009 additional information was received from the Health Authority correcting the first information sent. Last information was received concerning a 16 year old female who was vaccinated with the second dose of GARDASIL (batch number not reported) by intramuscular route (site not reported) on 23-DEC-2008 (vaccine administered out of the official vaccination campaign). On 27-DEC-2008 the patient presented with dizziness and nausea. The patient was then administered DOGMATIL, TORECAN and PRIMPERAN to treat these events. The patient got worse at night, and decided to go to a hospital's emergency room where she presented a loss of consciousness and nuchal rigidity (hospital discharge report hadn't been received yet). The patient didn't present with fever. Convulsions hadn't been confirmed. Meningitis or Meniere's vertigo were suspected, thus patient was kept under observation. The patient was hospital discharged next day. Auditive-vestibular and ocular pathologies had been discarded. Electrocardiogram results, blood test and a scanner were pending. The patient was at home, but she continued presenting with unspecified discomfort (dizziness, gastric discomfort). The patient's primary care physician had prescribed her SERC to use in case of a new episode of dizziness. The physician considered that adverse events could be due to an allergic reaction to the medication administered the day the adverse events started. A few days before second dose vaccine administration, the patient experienced some episodes of dizziness. The patient didn't have any problems after receiving the first dose of GARDASIL (batch number, date, route and site not reported). The patient received the third dose of GARDASIL in January 2009 (exact date not reported, batch number and site not reported) by intramus

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340838-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Jan-2009	20-Jan-2009	4	27-Feb-2009	02-Mar-2009	FR	WAES0902USA03865	02-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1647U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blood culture, Diarrhoea, Influenza like illness, Pyrexia, Stool analysis, Vertigo, Vomiting

Symptom Text: Information has been received from foreign Health Authority (reference # ES-AGEMED-813067338) regarding a 17 year old female who was administered on 16-JAN-2009 the second dose of GARDASIL (batch # NH52670, lot # 1647U) by intramuscular route. It is reported that on 20-JAN-2009 the patient presented with vertigo. She attended a hospital's emergency room where she was treated with TORECAN and she improves. On 29-JAN-2009 the patient presented with diarrhea and vomiting, again she visited the emergency room where she was hospital admitted. The patient was treated with serum therapy, antibiotics, metoclopramide and paracetamol. On 01-FEB-2009 the patient was discharged, although febricula persisted. On 10-FEB-2009, she is admitted again with the same clinical picture, a stool test and hemoculture are performed (results pending). The patient was discharged on 13-FEB-2009, kept under observation. The reporter informed that upon information obtained on 16-FEB-2009, according to the doctor the patient presented an intercurrent viral clinical picture with symptoms compatible with a pseudo-flu syndrome. The medical evaluation regarding this case has been that the events are not related with vaccine administration according to reporter's criteria. Further information is expected. Other business partner numbers include E200901560.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340839-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		27-Feb-2009	02-Mar-2009	IN	WAES0902USA04026	02-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse in a physician's office concerning a female who was vaccinated with a dose of GARDASIL (lot # not reported). Subsequently the patient experienced a seizure after the vaccination. The patient was air lifted to an unspecified hospital and was admitted as an inpatient for unspecified amount of time. At the time of the report (23-FEB-2009), the patient was recovering. It was reported that the patient was not given the vaccine at this physician's office. The nurse learned of this adverse event through the grandmother of the patient. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340840-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	14-Nov-2008	Unknown		27-Feb-2009	02-Mar-2009	IL	WAES0902USA04035	02-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Myelitis transverse

Symptom Text: Information has been received from a physician concerning a 21 year old female who on 05-SEP-2008 was vaccinated with a first dose of GARDASIL and on 14-NOV-2008 was vaccinated with a second dose of GARDASIL. Then the patient was diagnosed with transverse myelitis, which the physician stated it mimics multiple sclerosis. The patient saw a neurologist. At the time of reporting, the outcome was unknown. Upon internal review, transverse myelitis was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340845-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	27-Nov-2008	27-Nov-2008	0	27-Feb-2009	02-Mar-2009	FR	WAES0902USA03855	02-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Paraesthesia, Tachycardia, Tremor

Symptom Text: Information has been received from a Health Authority (reference number # ES-AGEMED-830750340) concerning an adolescent female (age not reported) with no medical history who on 27-NOV-2008 was vaccinated with a dose of GARDASIL (batch number not reported) by intramuscular route. It was reported that on the same date of vaccine administration, 27-NOV-2008 the patient experienced tremor, paresthesia in lower limbs, nausea and tachycardia. The patient was given adrenaline to treat adverse events. The patient recovered on the same date. No further information had been reported. Case reported as serious by the HA with other medically important condition as criteria. Other business partner numbers include: E2009-01549. Case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340849-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	24-Feb-2009	24-Feb-2009	0	27-Feb-2009	04-Mar-2009	CO		04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB329DA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Discomfort, Immediate post-injection reaction, Loss of consciousness

Symptom Text: Pt with extreme discomfort following inj. LOC after standing up- approx 10-15 min to fully recover- pt symptoms Hx of LOC with vaccine, but mother has similar Hx.

Other Meds: No

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **340853-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Feb-2009	12-Feb-2009	1	27-Feb-2009	04-Mar-2009	AZ		04-Mar-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MEN	UNKNOWN MANUFACTURER	U2662AA	0	Left arm	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B024AA	0	Right arm	Unknown	
VARCEL	MERCK & CO. INC.	0970X	1	Right arm	Unknown	
HPV4	MERCK & CO. INC.	0570X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Antibiotic therapy, Erythema, Induration, Pain, Pyrexia, Skin warm, Swelling

Symptom Text: Day after vaccinations, Pt developed severe swelling, pain, redness and the area became hard. She initially had a fever, but it went away. The area(back of right arm) remained very hot. E.R. and clinic doctors couldn't tell if it was an allergic reaction or an infection - Prescribed BENADRYL and Anti-biotic. Started to go away approx 5 days later.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 340876-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	14-Dec-2007	14-Jan-2008	31	27-Feb-2009	04-Mar-2009	CT		23-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	2	Left arm	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Alopecia, Cardiac ablation, Chest discomfort, Chest pain, Dizziness, Heart rate increased, Loss of consciousness, Oral contraception, Palpitations, Supraventricular tachycardia

Symptom Text: Was given the Gardasil shot in December 2007. In January 2008, diagnosed with Supraventricular Tachycardia (SVT): Blacked out/lost consciousness in the shower, woke up with a heart rate of 250bpm. Stayed for 45 minutes until given a shot of Adenosine. Required an Ablation (April 2008). Happened twice more after the first ablation (1 time requiring a double dose of the Adenosine shot). Will be having a second Ablation March 12, 2009. Also losing hair in clumps, chest pains similar to being stabbed 2-3 times a day (around the heart, but all over the chest area.) 3/13/09-records received-office visit 3/3/07 and first vaccine provided lot#0388U , vac #2 given on 8/14/07 lot#1060U and 3rd received 12/14/07 lot#1266U. Office visit 5/8/08-seen for gyn check up regular menses. ablation 4/08 for SVT. Taking oral contraceptives. 4/8/09-records received for DOS 4/17-4/18/08-DC DX: orthodoronic AV re-entry SVT. Recurrent drug resistant narrow complex tachycardia referred for electrophysiologic evaluation and successful ablation. First epidsode on 1/19/08 with sudden onset of lightheadedness with rapid palpitations and chest discomfort.Remote history of syncope that sounds vasovagal in nature.

Other Meds: Ortho Tri-Cyclin Lo

Lab Data: None Atypical chest pain with tranthoracic echocardiogram unremarkable.

History: Allergy-Minocyclin; Exercise Induced Asthma; Lyme Disease 3/13/09-records received- PMH:lyme's disease, Allergy to minocylin. 4/10/09-records received-Allergies:Monocyclin, hives. Recent diagnosis of Lyme's disease.

Prex Illness: None

Prex Vax Illns: None~ ()~~0~Patient|None~ ()~~0~Sibling

Vaers Id: **340882-1 (S)** **Related reports:** 340882-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Mar-2007	13-Mar-2007	0	28-Feb-2009	04-Mar-2009	NV		20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0263U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal distension, Abdominal pain upper, Agitation, Alopecia, Amenorrhoea, Arthralgia, Asthenia, Asthma exercise induced, Cardiovascular insufficiency, Constipation, Cyanosis, Dizziness, Dyspepsia, Epstein-Barr virus infection, Fatigue, Feeling cold, Gait disturbance, Gastrointestinal disorder, Headache, Irritability, Mobility decreased, Muscle spasms, Muscular weakness, Nausea, Oxygen saturation decreased, Pain in extremity, Pallor, Skin discolouration, Swelling face, Tinnitus

Symptom Text: AFTER FIRST GARDASIL VACCINE (administered 9/13/06): experienced dizziness, light-headed, nauseous, headaches, leg cramps, and shooting leg pain. AFTER SECOND GARDASIL VACCINE (administered 11/13/06): experienced same symptoms after first dose plus hair loss, abdominal bloating, menstrual cycle stopped, weakness, poor circulation. AFTER THIRD GARDASIL VACCINE (administered 3/13/07): experienced all symptoms listed above plus excessive hair loss, pale/purple skin, always cold, loud ringing in ears, extreme digestive problems, stomach pain, gastrointestinal discomfort, chronic constipation, joint pain, facial swelling, chronic fatigue, irritability, easily agitated, extreme weakness and all-over muscle fatigue (with difficulty in walking, talking, moving, etc.). TREATMENT: had to seek alternative medicine doctors to receive nutritional supplementation because other doctors could do nothing for me. Recently have been referred to a clinic. (scheduled appt. for 3/30/09). 3/18/09-records received for DOS 5/18-5/20/08-DC DX: Chronic constipation. Exercise induced asthma. Cyanosis. Pancytopenia. Presented to ED with increased generalized weakness and constipation since 2/08.Taking a Chinese herbal formula for chronic fatigue astra lsatis. Possibility of viral syndrome secondary to hepatitis C. PE: differential in pulses bilaterally, cyanotic in extremities pulse ox O2 saturation 87% at exercise but increased at rest.

Other Meds: none

Lab Data: Diagnosed with: Thrombocytopenia, Pancytopenia, Ammenorrhea, Hypothyroidism, Anemia, low blood pressure, Autoimmune Disorder, partial organ failure, digestive disorder, Epstein Barre, Orthopnoea, hormonal imbalance, urinary tract infection,

History: none 3/18/09-records received-Recurrent sinusitis, status post rhinoseptoplasty. hepatitis C. Questionalbe history of Epstein-Barr virus infection. Gastroesophageal reflux disease.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **340882-2 (S)** **Related reports:** 340882-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	13-Mar-2007	13-Mar-2007	0	09-Apr-2009	10-Apr-2009	--	WAES0903USA05111	21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0263U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal distension, Abdominal pain upper, Agitation, Alopecia, Amenorrhoea, Anaemia, Arthralgia, Asthenia, Autoimmune disorder, Cardiovascular insufficiency, Constipation, Dizziness, Dyspepsia, Epstein-Barr virus infection, Fatigue, Feeling cold, Gait disturbance, Gastrointestinal disorder, Headache, Hormone level abnormal, Hypokinesia, Hypotension, Hypothyroidism, Irritability, Muscle fatigue, Muscle spasms, Muscular weakness, Nausea, Organ failure, Orthopnoea, Pain, Pain in extremity, Pallor, Pancytopenia, Similar reaction on previous exposure to drug, Skin discolouration, Speech disorder, Swelling face, Thrombocytopenia, Tinnitus, Urinary tract infection, Vaccine positive rechallenge

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act concerning a 17 year old female who on 13-MAR-2007 was vaccinated with a third dose of GARDASIL intramuscularly into the left arm. After the first dose of GARDASIL (administered on 13-SEP-2006) the patient experienced dizziness, light-headed, nauseous, headache, leg cramps and shooting leg pain. After the second dose of GARDASIL (administered on 13-NOV-2006) the patient experienced same symptoms after first dose plus hair loss, abdominal bloating, menstrual cycle stopped, weakness, poor circulation. After the third dose of GARDASIL the patient experienced all symptoms listed above plus excessive hair loss, pale/purple skin, always cold, loud ringing in ears, extreme digestive, stomach pain, gastrointestinal discomfort, chronic constipation, joint pain, facial swelling, chronic fatigue, irritability, easily agitated, extreme weakness and all-over muscle fatigue (with difficulty in walking, talking, moving, etc.) The patient was diagnosed with thrombocytopenia, pancytopenia, amenorrhea, hypothyroidism, anemia, low blood pressure, antoimmune disorder, partial organ failure, digestive disorder, Epstein Barre, orthopnoea, hormonal imbalance, urinary tract infection. The patient had to seek alternative medicine doctors to receive nutritional supplementation because other doctors could do nothing for her. Recently she has been referred to a clinic (Scheduled appointment for 30-Mar-2009). This was originally reported by a consumer. A standard lot check investigation was performed. All in-process quality checks for the lot number 0263U in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center and was released.

Other Meds: None

Lab Data: Diagnostic laboratory, thrombocytopenia, pancytopenia, amenorrhea, hypothyroidism, anemia, low blood pressure, antoimmune

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340900-1 (S)** **Related reports:** 340900-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-May-2008	Unknown		02-Mar-2009	03-Mar-2009	--	WAES0902USA03436	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Back pain, Bone pain, Confusional state, Cystitis, Dyspnoea, Fatigue, Gastrooesophageal reflux disease, General physical health deterioration, Hallucination, Headache, Heart rate decreased, Hypoaesthesia, Pain, Pyrexia, Screaming, Sleep disorder, Syncope, Thrombosis, Vomiting, Wheelchair user

Symptom Text: Information has been received from a physician via an email from a consumer concerning the consumer's 16 year old daughter who on 20-MAY-2008 was vaccinated with the third dose of GARDASIL (lot no. and route not reported). The consumer reported that in the summer of 2008, the patient started to complain of constant fatigue, had fainting spells and random bouts of aches and pains. On 11-SEP-2008, she was sent home from school with complaints of headache, spine pain, confusion and symptoms of bladder infection. She was given antibiotics by the gynecologist and was sent home. The consumer reported that the next day (12-SEP-2008) the patient woke up screaming for help as she couldn't feel her arms and legs, was gasping for air, vomiting, had severe back pain and fever. The mother reported that at the emergency room (ER) the patient was given antibiotics and sent home as she was told she "may have passed a kidney stone". It was reported that over the next two weeks her health was deteriorating and after her fourth visit to the ER she was finally hospitalized for the next ten days. Over the course of her stay the patient was seen by teams of doctors from Neurology, Rheumatology, Infectious disease, Endocrinology, Adolescent medicine, Urology, and Cardiology. The consumer reported that the patient endured two spinal taps, many MRI, CAT scan, sonograms, ultrasound and blood workups until "her body could no longer emit any blood". The patient was on morphine drip for severe headaches, liquids for rehydration, PERCOCET for allover pain and two and nausea medication for severe vomiting and acid reflux. The patient was checked for Lyme disease, meningitis, lupus, fibromyalgia chronic fatigue Hoshimoto's disease kidney disease and multiple sclerosis and everything showed up negative. The patient became so sleep deprived because her heart rate was in the 30 range that a monitor constantly kept her awake. The patient started hallucinate and was developing blood clot in her legs from lack of use. The mother stated that since the

Other Meds: Unknown

Lab Data: cardiac monitoring, heart rate is in the 30 range

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340900-2 (S)** **Related reports:** 340900-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-May-2008	11-Sep-2008	114	18-Mar-2009	19-Mar-2009	NY	WAES0903USA00751	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Abdominal pain, Arthralgia, Asthenia, Back pain, Balance disorder, Cystitis, Dyspnoea, Fatigue, Gait disturbance, Headache, Hyperhidrosis, Movement disorder, Myalgia, Nausea, Photophobia, Pyelonephritis, Pyrexia, Sensory loss, Syncope, Tenderness, Tremor, Urinary tract infection, Vomiting, Wheelchair user

Symptom Text: Information has been received from a nurse practitioner concerning 16 year old female who was intramuscularly vaccinated with 1st, 2nd and 3rd 0.5 ml doses of GARDASIL (1st lot #658560/1062U, 2nd lot#659439/1267U, 2nd lot#659439/1267U, 3rd lot#660553/0070X) on 24-SEP-2007, 19-NOV-2007 and 20-MAY-2008, respectively. Concomitant therapy included YAZ, MACROBID and "septim (ceptim)". On 11-SEP-2008 the patient experienced urinary tract infection. On 12-SEP-2008 she experienced fever, vomiting and severe back pain. She went to the ER. On 14-SEP-2008 she had headaches, couldn't move her head and was shaky. She was weak and couldn't walk up stairs. A CAT scan was negative. On 25-SEP-2009 she went to a medical center for leg weakness, severe headache, costal vertebral tenderness and photophobia. An MRI done was negative. The patient was treated with morphine drip for her headaches. She was suggested by someone that it could be fibromyalgia. Other lab diagnostics studies included: STD check, vaginal culture, "kidney test", "urinary tract infection (UTI) test" and "e-coli test". All tests done were negative except for the one for her UTI. It was unknown if the patient was ever admitted to a hospital for adverse events. The patient was recovering at the time of reporting. Follow up information was received from a physician who reported that the 16 year old female student with penicillin allergy and post concussion syndrome was intramuscularly vaccinated with 3 doses of GARDASIL (1st dose into right deltoid, 2nd and 3rd doses into the left deltoid). There was no illness at time of vaccination. On 11-SEP-2008, the patient presented in the physician's office with urinary tract infection (UTI), low back pain, blood and leukocytes in urine. She was prescribed MACROBID 100 mg, po, Bid 7. On 12-SEP-2008 she went to emergency room (ER) due to worse syndromes and suggested to perform CT scan. Pyelonephritis was treated with axid ceftin. Nausea, vomiting and fever were treated with pyridine. She also complained of joint pain, could n

Other Meds: YAZ; MACROBID

Lab Data: computed axial, 09/14/08, negative; magnetic resonance, 09/21/08, negative; diagnostic laboratory, STD negative; diagnostic laboratory, e-coli negative; spinal tap, 09/17/08, negative; diagnostic laboratory, vaginosis DNA probe negative; di

History: 4/1/09-records received-allergy:Penicillin

Prex Illness: Penicillin Allergy; Post concussion syndrome

Prex Vax Illns:

Vaers Id: **340901-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		02-Mar-2009	03-Mar-2009	--	WAES0902USA03722	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Back pain, Bone pain, Cystitis, Dehydration, Dyspnoea, Fatigue, Gastrooesophageal reflux disease, Hallucination, Headache, Hypoaesthesia, Immunisation reaction, Pain, Pyrexia, Sleep disorder, Syncope, Thrombosis, Urinary tract infection, Vomiting

Symptom Text: Information has been received from a physician via an email concerning a female who was vaccinated with a dose of GARDASIL. The consumer reported that a ER nurse stated that the patient was admitted to the hospital with the same symptoms as the consumer's daughter down to constant fatigue, inability to walk, severe back pain, spine pain, symptoms of bladder infection, fainting spells, gasping for air, acid reflux, hallucination, headache, sleep deprivation, not feeling of her arms and legs, bouts of aches and pain, fever, blood clots in her legs, vomiting, dehydration and all over pain. It was reported by the nurse that this patient was finally diagnosed with a severe reaction to GARDASIL. Attempts are being made to verify the existence of an identifiable patient and reporter. Additional information will be provided if available. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340902-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	03-Apr-2008	29-Apr-2008	26	02-Mar-2009	03-Mar-2009	FR	WAES0902AUS00049	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Balance disorder, Condition aggravated, Juvenile arthritis, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician via CSL as part of a business agreement (manufacturer control # 2009 02 25 KC1) concerning a 12 year old female with systemic juvenile arthritis who on 03-APR-2008 was vaccinated with the first dose of GARDASIL. On 29-APR-2008 the patient experienced flare of rheumatoid arthritis. Subsequently the patient recovered from the flare of rheumatoid arthritis. On 19-JUN-2008 she was vaccinated with the second dose of GARDASIL. On 25-JUN-2008 the patient experienced a second flare of rheumatoid arthritis which resulted in a 2 day hospital admission. Subsequently, the patient recovered from the second flare of rheumatoid arthritis. It was reported that the patient had been unstable throughout the course of vaccination but her arthritis has now been stabilised. the patient will be enrolled in a study of antibody response to GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Juvenile arthritis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340903-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	03-Jan-2008	04-Jan-2008	1	02-Mar-2009	03-Mar-2009	FR	WAES0902USA03424	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Headache, No reaction on previous exposure to drug, Performance status decreased

Symptom Text: Information has been received from a pediatrician concerning a 17 year old female patient with no pertinent medical history reported who on an unspecified date was vaccinated with the second dose of GARDASIL (Lot # not reported). It was reported that on an unspecified date the patient developed headache. It was reported that as symptoms became chronic the patient underwent multiple examinations and was even hospitalized for diagnostics on an unspecified date. No cause for the complaint was found, migraine was ruled out. It was reported that treatment with different analgesics (not specified) was not successful. It was reported that finally treatment was started with butterbur (herbal preparation) which lead to slight improvement. A causal relation with the vaccine was seen by the parents who surfed the web for information about GARDASIL. It was reported that the third dose will not be administered. A psychosomatic cause was evoked by the reporter. It was reported that the patient's parents refused according to psychological diagnostics/intervention. The patient had not recovered at time of reporting. Follow up information was received: it was reported that the patient was 16 years old (previously reported as 17 years old) at the time to onset. The first dose of GARDASIL was given into the left upper arm on 07-NOV-2007 and was well tolerated. The second dose of GARDASIL (Lot # and injection route not reported) was administered on 03-JAN-2008 into the left upper arm. It was reported that the next day, on 04-JAN-2008 (previous onset date not reported), she developed headache (becoming chronic in the further course) as well as loss of performance and strength. Neurological investigations were performed (results not reported). It was reported that despite therapy attempts with analgesics, acupuncture and herbal preparation (Petadolex), the patient has not recovered at the time of reporting. Other business partner numbers include E2009-01456. No further information is available.

Other Meds: Unknown

Lab Data: neurological examination, results not reported

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340904-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	16-Jan-2009	16-Jan-2009	0	02-Mar-2009	03-Mar-2009	FR	WAES0902USA04447	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1647U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Convulsion, Feeling hot, Gaze palsy, Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Information has been received from a health care professional concerning a 25 year old female who on 16-JAN-2009 was vaccinated with the first dose of GARDASIL (lot# 1647U, batch# NH52670) route and site not reported. It is reported that the patient presented with convulsions, immediately after vaccine administration, these convulsions started from the abdomen and went up. The patient experienced a loss of consciousness and eye deviation. These events lasted for a few seconds or a few minutes. The patient was placed with her legs up, her arterial pressure was measured and a glycemic test was performed. Arterial pressure was a little low. The patient sat. She felt general weakness during chat afternoon and a warm/hot sensation right after she was vaccinated. The patient recovered. No further information has been requested. Additional information obtained on 18-FEB-2009: When the reporter was asked for a more detail description of the adverse event, she clarified that it was not a real convulsion but a convulsive syncope that lasted seconds (less than 1 minute) and resolved spontaneously. The event was defined as non serious by the reporter. Upon internal review, "convulsive syncope" was determined to be an other important medical event. Other business partner numbers include: E2009-01408. No further information is available. The case is closed.

Other Meds: Unknown

Lab Data: blood pressure measurement, 16Jan09, Arterial pressure was a little low

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340909-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		02-Mar-2009	03-Mar-2009	FR	WAES0902TUR00012	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cystitis, Gastrointestinal disorder

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with GARDASIL. Subsequently the patient experienced cystitis and GI system symptoms and was hospitalized on the day of vaccination. The reporter felt that cystitis and GI system symptoms were not related to therapy with GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340918-1 (S)** **Related reports:** 340918-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Nov-2008	15-Nov-2008	0	02-Mar-2009	03-Mar-2009	FR	B0561857A	03-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NH46170		Unknown	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Fall, Skull fracture, Subarachnoid haemorrhage, Syncope

Symptom Text: This case was reported by a regulatory authority (2009-00650) and described the occurrence of syncope in a 13-year-old female subject who was vaccinated with ENGERIX B (GlaxoSmithKline), GARDASIL (non-GSK). On 15 November 2008, the subject received unspecified dose of ENGERIX B (intramuscular, unknown injection site, lot number not provided), unspecified dose of GARDASIL (intramuscular, unknown injection site). On 15 November 2008, 5 minutes after vaccination with ENGERIX B and GARDASIL, the subject experienced syncope with a convulsion; then she fell on the floor and experienced skull fracture with a slight subarachnoid hemorrhage. The subject was hospitalized for 1 week. During the hospitalization no diagnostic or therapy documented regarding epileptic events, so that the convulsion has to be seen in the context of the syncope. At the time of reporting the events were resolved. The regulatory authority reported that the events were possibly related to vaccination with ENGERIX B and GARDASIL. Due to close temporal connection between the two vaccine administrations and the occurrence of the adverse events, it was not possible to identify one of the two vaccines rather their injection as cause. A non-medicamentous cause seemed to be however improbable. This was all the information available from the Regulatory Authority. If they receive additional information, they will report it as soon as they get it. Therefore this case has been closed.

Other Meds:

Lab Data: UNK

History:

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **340918-2 (S)** **Related reports:** 340918-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Nov-2008	15-Nov-2008	0	09-Mar-2009	10-Mar-2009	FR	WAES0903USA00142	19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Fall, Head injury, Immediate post-injection reaction, Malaise, Skull fracture, Subarachnoid haemorrhage, Syncope

Symptom Text: Case received from foreign Health Authority on 26-FEB-2009 under reference 2009-00650. It was reported that a 13 years old female adolescent received on the 15-NOV-2008 one intramuscular dose of GARDASIL 0.5 mL (lot# 654792/0873F is valid for ROTATEQ, but not valid for GARDASIL, site of administration not reported) and one milliliter intramuscular of ENGERIX B 20, (batch # and site of administration not reported). Directly after the administration, the patient felt unwell, but she did not inform the medical personnel. After getting up (5 minutes after the vaccination) the patient experienced a syncope with a convulsive seizure. She crashed on the back of her head and further experienced a skull fracture with a mild subarachnoidal hemorrhage. The patient was hospitalized for one week in the hospital where she recovered without sequelae. Other business partner numbers include: E2009-01736.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340924-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Feb-2009	25-Feb-2009	1	02-Mar-2009	04-Mar-2009	IN		05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Costochondritis

Symptom Text: Costochondritis R side > 1wk.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **340930-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	20-Jan-2009	21-Feb-2009	32	27-Feb-2009	04-Mar-2009	AR		04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Pt experienced HA which was constant x2 wks after GARDASIL vaccine. Ordered DARVOCET & asked pt to be seen for evaluation and she did not come in.

Other Meds:

Lab Data: No

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: **340931-1** **Related reports:** 340931-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	11-Jul-2008	11-Jul-2008	0	27-Feb-2009	04-Mar-2009	NY		17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Abdominal tenderness, Acne, Activities of daily living impaired, Arthralgia, Balance disorder, Chills, Dizziness, Ear pain, Fatigue, Headache, Joint stiffness, Loss of consciousness, Malaise, Mononucleosis syndrome, Nausea, Night sweats, Oropharyngeal pain, Pallor, Pyrexia, Sinus congestion, Splenomegaly, Upper respiratory tract infection, Viral pharyngitis, Weight decreased

Symptom Text: Persistent LUQ pain, fatigue and weight loss since administration of first GARDASIL vaccination. Pt and pt's mom did not report these symptoms. Pt received second dose of GARDASIL on 10/10/08 - mom reports original sign and symptom much worse with severe abdominal pain. Symptoms reported 10/30/08. Monospot and pain/ fatigue persisted - referred to GI. 4/9/09 MR received from PCP. Well check 7/11/08. HPV#1 given (0279X). Returned for 2nd HPV shot 10/10/2008 with lot #U2687AP recorded (see vax rec). Returned 10/30/08 with c/o 3 wk hx of nausea, pallor, sore throat, H/A and LUQ pain. Feeling tired and dizzy. PE (+) for palpable ridge of spleen, LUQ tenderness. Sent for CT. Returned 11/6/08 with report of one episode of passing out. Out of school all week. Assessment: Mono. Seen 11/24/08 for Mono with viral pharyngitis. By 12/4 08 parent reporting pt still ill with viral URI, still fatigued. Recheck 12/25/08. Reporting more frequent dizzy spells. No LOC. PE (+) for LUQ tenderness. Seen 1/13/09 for sore throat, sinus congestion, and R ear pain x 2 weeks. Still with abdominal tenderness. Some good days some bad. Referred to GI. 4/14/09 GI consult received. Initially seen 2/209 with c/o 3 month hx of abdominal pain, tiredness, fatigability, chills, H/A fever, lightheadedness and LUQ discomfort. Now daily sx with ~ 10lb weight loss. ROS additionally (+) for malaise, night sweats, recurrent sinus congestion, joint pain and stiffness, balance issues, dizziness, and new onset acne. PE (+) for epigastric tenderness. Assess: LUQ pain-discomfort of ? etiology. S/P mononucleosis syndrome. F/U 3/12/09 with continued sx. Impression: Chronic LUQ pain and nausea ?? etiology.

Other Meds:

Lab Data: CT of abdomen (neg); CBC; CMP; amylase; lipase. Labs and Diagnostics: Monospot (+). CBC WNL. CMP, amylase and lipase WNL. Lipase later up to 242 (H) by 2/2/09. TC (-) for strep. CT abdomen WNL. BE WNL. Duodenal bx WNL. Helicobacter (-)

History: amoxicillin. PMH: Allergies to Pertussis, Amox. L ankle pinning.

Prex Illness:

Prex Vax Illns: 7/11/08~HPV (Gardasil)~1~13~Patient

Vaers Id: **340931-2 (S)** **Related reports:** 340931-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Jul-2008	01-Jul-2008	0	03-Apr-2009	06-Apr-2009	--	WAES0903USA05500	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Blood amylase increased, Gastrointestinal disorder, Infectious mononucleosis, Nausea, Oropharyngeal pain, Similar reaction on previous exposure to drug, Splenomegaly, Weight decreased

Symptom Text: Information has been received from a nurse practitioner concerning a 14 year old female with a history of high fever after receiving unspecified pertussis vaccine as an infant who in July 2008, was vaccinated with the first dose of GARDASIL. There was no concomitant medication. In approximately July 2008, "2 days after administration of her first dose", the patient experienced gastrointestinal problems. Her symptoms lasted for 1 week. In September 2008, the patient was vaccinated with the second dose of GARDASIL. In approximately September 2008, "one week after administration of her second dose", the patient developed severe abdominal pain, nausea and severe sore throat. Her symptoms did not improve. On 30-OCT-2008 the patient was diagnosed with mononucleosis and enlarged spleen. Her gastrointestinal problems continued despite a CAT scan confirming spleen was no longer enlarged. The patient experienced severe pain in left upper quadrant of abdominal area. She had lost a lot of weight and had elevated amylase levels. She had been examined by a GI specialist but no diagnosis was reached. She was currently being treated with ZANTAC, ACTIGALL, DONNATAL and pancreatic enzymes. At the time of this report, the patient had not recovered. The reporter considered the events to be disabling due to the patient was "missing school and unable to participate in sports". Additional information has been requested.

Other Meds: None

Lab Data: computed axial, spleen was no longer enlarged

History: Fever; Vaccination adverse reaction

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340952-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	09-Feb-2009		02-Mar-2009	05-Mar-2009	--		06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Fatigue, Headache, Pain in extremity, Scan brain, Vision blurred

Symptom Text: My daughter received her 3rd injection of GARDASIL vaccine on Feb. 9th 2009. She had severe headaches ever since. We took her to the emergency room on Feb 13th. They ran a series of tests which included a brain scan. Nothing abnormal showed but she never got rid of her headache. To this day she is fatigued, dizzy, has headaches, blurry vision and arm pain. These side effects were never mentioned yet when I looked on the web many people said they had the same side effects after the vaccine. I am taking her to her pediatrician tomorrow to have him evaluate her again and we will go from there.

Other Meds: Feb 13, 2009 emergency room treatment

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340953-3**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	04-Feb-2008	21-Feb-2008	17	04-Mar-2009	05-Mar-2009	NC	WAES0902USA04271	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Blood test, Headache, Nausea, Pyrexia, Vaccine positive rechallenge, X-ray

Symptom Text: Information has been received from a consumer concerning her daughter, a 13 year old female with no medical history or drug allergy who was vaccinated with the first, the second and the third dose (lot # 660393/0067X) of GARDASIL on 04-FEB-2008, 16-APR-2008 and 18-AUG-2008 respectively. There was no concomitant medication. On 21-FEB-2008 the patient started to experience nausea, headache and stomach pain. On 01-MAY-2008 the patient had the same symptoms. On 03-SEP-2008 the patient experienced nausea, stomach pain and fever and the patient never recovered from that time on because the same symptoms kept coming back and the stomach pain became very severe that now she was out of school. The patient was brought to the emergency room on 29-SEP-2008, but she was not admitted in the hospital. The patient was currently experiencing severe stomach pain. The physician had referred the patient to a neurologist but it would be 3 months before she could get an appointment. The patient performed X-rays and blood work. Nausea, headache, stomach pain and fever were considered to be disabling since they resulted in the patient being out of school. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340954-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	U	23-Feb-2009	23-Feb-2009	0	02-Mar-2009	04-Mar-2009	--		04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Pain, Paraesthesia, Stomach discomfort

Symptom Text: My daughter received GARDASIL vaccine from her doctor on 02/23/2009. Since having the injection she has had a severe headache, body aches, upset stomach, dizziness and tingling in her hands and feet.

Other Meds:

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **340964-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		03-Mar-2009	04-Mar-2009	FR	WAES0902AUS00036	04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Aphasia, Arthropathy, Cerebrovascular accident, Hypoaesthesia, Malaise, Vaccine positive rechallenge

Symptom Text: Information has been received via CSL as part of a business agreement. It was reported in a newspaper article that a female high school student, aged approximately 18 years and a talented touch football player, was vaccinated in 2008 with GARDASIL (manufacturer unknown) (exact dates and number of doses not reported). Subsequently, not long after vaccination with GARDASIL (manufacturer unknown), the patient "started getting sicker and sicker after each (vaccination)" until she suffered a "stroke without the bleed" and was in hospital for three months. The patient stated that she had to "learn to walk and talk again". It was reported that the patient's mother believed that her daughter's stroke was caused by her cervical cancer vaccinations. However, the patient stated that "the doctor's don't believe (stroke) had anything to do with it". At the time of reporting on 18-FEB-2009, the patient had recovered from stroke and had been back playing football but still had "parts of me that are numb down my left side". Information received on 18-FEB-2009 contained the following adverse experience: "bad knee" (2009) resulting in the patient probably not being able to play football for another two years. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340965-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Jun-2008	15-Jul-2008	15	03-Mar-2009	04-Mar-2009	--	WAES0902USA04059	04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Autoimmune disorder, Convulsion, Headache, Muscular weakness, Nervous system disorder

Symptom Text: Information has been received from a nurse practitioner, who was told by one of her own patients, concerning a 15 year old female patient who is not a patient in her office, in late June 2008 was vaccinated with the first dose of GARDASIL at a pediatrician office. In mid July 2008, the patient experienced severe headaches, muscle weakness, neurological disorders and autoimmune issues. The reporter stated that the patient had out patient neurological tests done and she was currently experienced seizures. The HPV vaccine was discontinued. As of 23-FEB-2008, the patient had not recovered. The patient sought medical attention with a physician. Upon internal review seizures was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340966-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Oct-2007	17-Nov-2007	31	03-Mar-2009	04-Mar-2009	FR	WAES0902USA04284	04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Condition aggravated, Osteonecrosis, Systemic lupus erythematosus

Symptom Text: Information has been received from a physician concerning a 15 year old female with systemic lupus erythematosus (diagnosed at 14 years old) maintained on chloroquine. The patient received seven weeks of steroids at the onset of her disease after which she passed into remission. In September 2007, the patient received her first dose of GARDASIL. On approximately 17-OCT-2007 was vaccinated with the second dose of GARDASIL via I.M. On 17-NOV-2007 the patient developed reactivation of her SLE disease with elevation of ESR, anticardiolipin antibodies (IgM) and bilateral avascular necrosis of femoral heads. As of 24-FEB-2009 the patient symptoms persisted. The patient's bilateral avascular necrosis of femoral heads persisted. The outcome of the patient's reactivation of the SLE was not reported. The avascular necrosis of the femoral heads was considered to be disabling and Other Important Medical Event by the physician. No further information is available.

Other Meds: chloroquine

Lab Data: Erythrocyte sedimentation rate, 17Nov07, increased; Cardiolipin antibody test, 17Nov07, increased

History: Steroid therapy

Prex Illness: Systemic lupus erythematosus

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340967-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-May-2008	01-May-2008	0	03-Mar-2009	04-Mar-2009	--	WAES0902USA04441	04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Chest pain, Dyspnoea, Fatigue, Infectious mononucleosis, Malaise

Symptom Text: Information has been received from a teenage female athlete (runner) via a news report who in May 2008, was vaccinated with GARDASIL. In May 2008, within days of getting the vaccine, the patient became mysteriously ill and was hospitalized. The patient said she couldn't breathe and was really fatigued. Her chest was beginning to hurt like she was having an allergy or asthma attack. In July 2008, doctors diagnosed the patient with mononucelosis. As of 19-FEB-2009, the patient had not recovered and was still too weak to run. The patient's family thinks GARDASIL was responsible, but the patient's physician's did not know if her condition was related to the vaccine or if it was a coincidence. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340968-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Dec-2008	05-Jan-2009	19	03-Mar-2009	04-Mar-2009	IL	WAES0902USA04580	04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Dehydration, Malaise, Oropharyngeal pain, Pyrexia

Symptom Text: Information has been received from a medical assistant concerning a 15 year old female with no previous medical history or drug allergies reported who on 17-DEC-2008 was vaccinated with the first dose of GARDASIL (Lot # 661044/0548X), 0.5 mL, I.M. On around 05-JAN-2009, the patient became really sick, had a fever of 104 F, a sore throat, and was dehydrated. The patient was awakened in the middle if the night but was not fully alert. Her mother, who spoke with her that night, said that she did not know where she was. On 05-JAN-2009, the patient was taken to the emergency room. She was given MOTRIN and IV fluids. The emergency room could not find a cause for her illness. On 17-FEB-2009, the symptoms were resolved. The patient was followed up on 21-FEB-2009 by her primary care. The symptoms were considered to be an other important medical events by the medical assistant. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **340969-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	29-Dec-2007	24-Jan-2008	26	03-Mar-2009	04-Mar-2009	OR	WAES0902USA04384	04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Pregnancy test

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for GARDASIL, concerning a 26 year old female who was vaccinated with first and second 0.5mL doses of GARDASIL on 29-JUN-2007 and 29-SEP-2007. The physician reported that they believed the patient was pregnant on 10-DEC-2007. On 29-DEC-2007, the patient was vaccinated with the dose of GARDASIL. On 24-JAN-2008 the patient experienced miscarriage. Lab test performed included unspecified pregnancy test. This is one of two reports concerning the same patient. Upon internal review miscarriage has been considered an other important medical event. Subsequently in June 2008 the patient became pregnant again and on August 2008 the patient had another miscarriage (WAES #0902USA04455). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **340970-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	29-Dec-2007	01-Jun-2008	155	03-Mar-2009	04-Mar-2009	OR	WAES0902USA04455	04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Pregnancy test

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for GARDASIL, concerning a 26 year old female who was vaccinated with first, second and third 0.5mL dose of GARDASIL on 29-JUN-2007, 29-SEP-2007 and 29-DEC-2007. On 24-JAN-2008, the patient had a miscarriage (MSD WAES # 0902USA04384). Subsequently in June 2008 the patient became pregnant again and on August 2008 the patient had another miscarriage. Lab tests performed included unspecified pregnancy test. This is one of two reports concerning the same patient. Upon internal review, miscarriage was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Miscarriage

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **340992-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	19-Feb-2009	24-Feb-2009	5	03-Mar-2009	04-Mar-2009	CA		04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema

Symptom Text: Redness-trial of ZYRTEC, and if worsening then antibiotics.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341011-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	26-Feb-2009	Unknown		03-Mar-2009	04-Mar-2009	NY		04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site pain, Injection site swelling

Symptom Text: Patient had pain and swelling at injection site. Was seen in the ED 3 days later

Other Meds:

Lab Data:

History: GERD

Prex Illness: vertigo

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 341013-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-May-2007	24-May-2007	2	03-Mar-2009	05-Mar-2009	MI		22-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1208F	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Dizziness, Feeling hot, Headache, Loss of consciousness, Presyncope, Syncope, Vaccine positive rechallenge, Vision blurred

Symptom Text: Within 2 days of injection client passed out at school and again at hiome, no other s/s of illness. Admitted to hosp. for tests, all neg. Has passed out 9 times since 1st injection. Has had headachs almost daily since inj. Has been unconsious up to 5 min. and transported to hosp. by ambulance x2, wakes up with C/O Headache and blurred vison. Mom denies history of siezures, has seen pediatric cardiologist, just completed tilt table test, no results as of yet. Has been hospitalized 2 days after 1st episode and 4 days at a later time. Client has had 2nd HPV 08/07/2007 along with Hep A, Var,and MCV4, has continued with faint, but not increase in incidence since 2nd HPV 4/15/2009 Received Cardio consult of 2/3-3/2/2009. FINAL DX: none provided Records reveal patient seen for dizziness, presyncope & syncopal episodes of the past year w/increased frequency over past few wks. Episodes preceded by dizziness, blurred vision, feeling of weakness & warmth followed by brief LOC & prompt recovery. Had been hospitalized end of Jan 09. RTC 3/2 for (+) tilt-table test & tx w/meds & fluid increase.

Other Meds: Starte Fludrocortisone 1mg QD

Lab Data: 3/2/09 tilt table test. Mother states all other tests neg., but unsure what tests done. LABS: ECG WNL. Echocardiogram WNL. Tilt table test (+).

History: None PMH: HA, appendectomy, asthma. Family hx: CAD, DM.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341014-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Mar-2009	03-Mar-2009	0	03-Mar-2009	04-Mar-2009	NY		04-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0971X	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	1311X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Fainting episode within 5 minutes of administering #3 Gardasil and Varivax #2

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341023-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Feb-2009	27-Feb-2009	1	03-Mar-2009	04-Mar-2009	PA		20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1496X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Aphasia, Blepharospasm, Depressed level of consciousness, Eye rolling, Syncope, Unresponsive to stimuli

Symptom Text: Patient experienced a syncope episode Friday 2/27/09. Transported to emergency room via ambulance. Labs and CT of head negative. Most recent health event was GARDASIL vaccine 2/26/09 administration. 3/18/09-records received for DOS 2/27/09-presented to ED with questionable passed out not responding. Eyes rolled back and not responding per witness. PE: doesn't speak but will sit up and open mouth when asked. Rolling eyes side to side, fluttering lids, DTRs 2/4. Impression resolved altered LOC. Probable anxiety.

Other Meds: ORTHOTRICYCLEN LO

Lab Data: 3/18/09-records received- EKG sinus tach otherwise normal. CT brain negative. Lymph % low 9.0, gran % increased 85.9.

History: Acne; History of depression 5/07

Prex Illness: None

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341030-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		04-Mar-2009	05-Mar-2009	FR	WAES0902CAN00119	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from an Agency concerning a 14 year old female who was vaccinated with GARDASIL, lot # not available. Subsequently the patient died. The cause of death was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341032-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Aug-2008	01-Feb-2009	184	04-Mar-2009	05-Mar-2009	TX	WAES0902USA04440	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Headache

Symptom Text: Information has been received from a physician concerning a female patient who in August 2008, was vaccinated with a dose of GARDASIL (Lot not reported). In approximately February 2009, the patient told her doctor she experienced seizure and headaches. At the time of reporting the outcome of the patient was unknown. Upon internal review, seizure was considered to be an Other Important Medical Event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341033-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	10-Feb-2009	22-Feb-2009	12	04-Mar-2009	05-Mar-2009	FR	WAES0902USA04475	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Headache, Hypoaesthesia, Muscular weakness, Neurological examination normal

Symptom Text: Information has been received from a health professional concerning a 17 year old female who was vaccinated with the first dose GARDASIL (batch # not reported) via intramuscular route on 10-FEB-2009. 12 days later the patient presented with symptoms of numbness of upper and lower extremities, muscle weakness and dizziness and headache. The patient was hospitalized on 23-FEB-2009. Brain MRI and neurological tests were performed and results showed no findings. The patient was discharged from hospital on 24-FEB-2009 as symptoms had been resolved and the patient was in good health. She had no concomitant treatment administered and no medical history. The reporter did not associate adverse events to the vaccination. Other business partner numbers include: E200901710. Additional information has been requested.

Other Meds: None

Lab Data: Magnetic resonance imaging, 23Feb09, brain: no findings

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **341034-1 (S)** **Related reports:** 341034-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Feb-2009	25-Feb-2009	9	04-Mar-2009	05-Mar-2009	MI	WAES0902USA04545	28-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Hypersensitivity, Lip swelling, Oedema peripheral, Urticaria

Symptom Text: Information has been received from a consumer concerning her 14 year old daughter with purple cornflower allergy and no pertinent medical history, who in August 2008, was vaccinated with 0.5 ml of the third dose of GARDASIL. Concomitant therapy included birth control (unspecified). On 25-FEB-2009 the patient experienced hives all over her body and swollen hands, feet and lips. She was taken to emergency room and given prednisone 10 mg and "hydroxydine" 25 mg. On 26-FEB-2009 she was taken back to the hospital where she was admitted over night and released on 27-FEB-2009. She still has not recovered completely and still had break outs. Additional information has been requested. 3/13/09-records received from PCP severe allergic reaction to gardasil vaccine, on 2/18/09 hives, 2/22/09 seen in ED and again on 2/23/09 for 24 observation . Follow-up 3/8/09-when antihistamine wears off spots occur mostly on arms hands feet and thighs, rash is less and less. 4/6/09-records received for ED visit 2/22/09-C/O skin rash 3 days ago, generalized, urticarial rash. Assessment:allergic reaction-acute secondary to vaccine. 4/8/09-records received for DOS 2/23/09-ED Observation, C/O generalized itching times 5 days. DX:acute allergic reaction.

Other Meds: Hormonal contraceptives

Lab Data: Hematology

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

Vaers Id: **341034-2 (S)** **Related reports:** 341034-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Feb-2009	18-Feb-2009	2	26-Mar-2009	30-Mar-2009	MI		30-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Lip swelling, Oedema peripheral, Urticaria

Symptom Text: Hives head to toe, swollen feet, hands, lips on 2/18/09 went to Dr/shot and prescription. 2/22/09 worse breakout took to ER, shot and meds 2/23/09. Dr sent to hospital 24 hr observation IV Breathing treatments and injections 2/27/09 Dr follow up 3/13/09.

Other Meds: MICROGESTIN FE 1.5 mg 30 day for extreme period

Lab Data: 2/23/09 Bloodwork

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **341035-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-Nov-2008	10-Nov-2008	6	04-Mar-2009	05-Mar-2009	--	WAES0902USA04564	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0702X	1	Unknown	Unknown	HPV4 MEN

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Arthralgia, Back pain, Chest pain, Cognitive disorder, Convulsion, Depressed level of consciousness, Dizziness, Dysmenorrhoea, Dysphasia, Dysphemia, Expressive language disorder, Fall, Fear, Feeling abnormal, Headache, Hyperreflexia, Hyporeflexia, Mental status changes, Migraine, Myalgia, Neck pain, Pain, Somnolence, Speech disorder, Tachycardia

Symptom Text: Information has been received from a physician assistant concerning a female patient who on an unknown date was vaccinated with the second dose of GARDASIL (Lot number was not available). Subsequently, the patient experienced a day long seizures and severe headaches after receiving her second dose of GARDASIL. The patient was currently seeing a neurologist but was not yet recovered. On an unspecified date, a magnetic resonance imaging (MRI) was performed (results was not provided). Additional information has been requested. 04/14/2009 Neurology records received for eval of dysphasia, dizziness, H/A from 11/14/08-3/23/09. Pt had recently presented to ER on 11/10/08 with c/o chest pain upon inspiration. Initially thought to be asthma by parent and tx with nebs. Pt developed tachycardia and became frightened. Dx with anxiety and tx with Ativan in ER and D/c. The next day pt was difficult to arouse and was feeling dizzy. Parent noted pt was having problems with speech, halting and with problems expressing self which continued throughout the day in addition pt very sleepy. On 11/12/08 pt developed H/A which has continued on/off until 11/14/08 appt. PE (+) for halting speech with stuttering quality. DTRs 1-2 in UEs and 3+ in LEs. DX: Dysphasia-etiology unclear. Sent for MRI. Started on Topamax 1/12/09. Pt presented again 1/6/09 with several episodes of fogginess, cognitive sluggishness, falling asleep and H/A. Reports increased menstrual cramps. DX: H/A and altered mental status. ? migraine variant. Started on Topamax 1/12/09. Parent reports pt falling during skating practice with H/A and later H/A, neck pain, back pain, muscle and joint pain. Tx with medrol dosepak. By 3/2009 having frequent H/A often preceeded by neck pain, back pain with fogginess. 2nd opinion neuro consult 3/18/09. PE WNL except (+) trigger point pain of trapezius. Etiology of sx unknown. ? seizure despite normal EEG.

Other Meds: Unknown

Lab Data: Unknown. Labs and Diagnostics: MRI (+) for increased signal on T2. EEG WNL. Echo WNL. MRI/MRA WNL. MCV and MCH (H). . free T4 low 0.81.

History: Unknown PMH: fx ankle. asthma

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341036-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-Jan-2009	05-Feb-2009	16	04-Mar-2009	05-Mar-2009	FR	WAES0902USA04647	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Infectious mononucleosis, Liver function test abnormal, Mononucleosis heterophile test

Symptom Text: Initial information has been received from a Health Authority (reference number ES-AGEMED-820446241) concerning a 14 year old female who on 20-JAN-2009 was vaccinated with a dose of GARDASIL (batch number not reported) by intramuscular route, site of administration not reported. On 05-FEB-2009, 17 days after vaccination, the patient experienced an infectious mononucleosis and abnormal results in liver function tests. It was reported that the patient tested positive for the Paul Bunnell test. The patient's serology tests for hepatitis came out negative. The case was reported as serious by the Health Authority with other medically important condition as criteria. Case is closed. Other business partner number included: E2009-01726. No further information is available.

Other Meds: Unknown

Lab Data: Epstein-Barr virus antibodies, positive; clinical serology test, for hepatitis: negative

History: None

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341037-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Oct-2008	03-Feb-2009	111	04-Mar-2009	05-Mar-2009	FR	WAES0902USA04649	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from foreign Health Authority (reference number ES-AGEMED-418546244) regarding a 14 year-old female who was administered on 15-DEC-2008 a dose of GARDASIL (Batch number not reported) by intramuscular route (site of administration not reported). On the 03-FEB-2009, 51 days after vaccination, the patient had a syncope (coded in the adverse event box of the HA's report). It is reported that the patient had a loss consciousness for a few minutes (this adverse event is included in the narrative of the case in the HA's report, but is not include in the adverse event box of the report), the patient had prodromes, no convulsions or sphynter relaxation. Blood test and electrocardiogram were performed, test results were normal. The patient was vaccinated with a dose of GARDASIL on the 15-OCT-2008 by intramuscular route with no reported adverse events. Relevant Test/Laboratory Data: Blood work: normal. Loss of consciousness was considered to be an other important medical event. THE CASE IS CLOSED. Other business partner numbers included: E2009-01687. No further information is available.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, ??Feb09, Normal; Electrocardiogram, ??Feb09, Normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **341038-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-Jan-2009	23-Jan-2009	3	04-Mar-2009	05-Mar-2009	FR	WAES0902USA04655	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Balance disorder, Dizziness, Fatigue, Hyperhidrosis, Hypotension, Loss of consciousness, Pallor

Symptom Text: Initial information was received by Health Authority (reference number ES-AGEMED-820758241) regarding a 14 year-old female who was administered on the 20-JAN-2009 with a dose of GARDASIL by intramuscular route. On 23-JAN-2009 the patient presented with dizziness, balance difficulty, hypotension, facial pallor, loss of consciousness, excessive perspiration and tiredness. The patient had an oxygen saturation of 97%, arterial pressure was 60/35 mmHg. On the second reading oxygen saturation was 100% and pressure was 88/43 mmHg. The patient was told to hydrate abundantly, medical control was advised. It is reported that the patient recovered on the 23-JAN-2009. No further information has been reported. Case is closed. Other business partner numbers include: E2009-01634.

Other Meds: Unknown

Lab Data: Blood pressure measurement, 23Jan09, 60/35 mmHg; Blood pressure measurement, 23Jan09, 88/43 mmHg; Pulse oximetry, 23Jan09, 97%; Pulse oximetry, 23Jan09, 100%

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341039-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	28-Sep-2008	16-Dec-2008	79	04-Mar-2009	05-Mar-2009	FR	WAES0902USA04656	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Confusional state, Convulsion, Loss of consciousness, No reaction on previous exposure to drug, Syncope

Symptom Text: Initial information was received on the 23-FEB-2009 by the foreign Health Authority (reference number ES-AGEMED-318545244) regarding a 14 year-old female who was administered on the 27-NOV-2008 the second dose of a GARDASIL vaccine by intramuscular route. According to the reporter the patient has presented with 3 syncope episodes with chronic convulsions and loss of consciousness. These episodes occurred on the 16-DEC-2008, 19-JAN-2009 and on the 06-FEB-2009, each episode lasted for 2 minutes approximately. The events began with prodromes and at the end of each crisis the patient was confused, no esphinter relaxation. After the second episode, in order to perform some test, the patient was hospital admitted during 1 week. Prior dose was administered on the 28-SEP-2008 and was well tolerated by the patient. Other business partner numbers include: E2009-01624. Upon internal review, clonic convulsion was determined to be an other important medical event. No further information has been reported.

Other Meds: Prior dose was administered on the 28-SEP-2008 and was well tolerated by the patient.

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **341052-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	04-Apr-2008	Unknown		04-Mar-2009	06-Mar-2009	MN		01-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB215AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1486U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Chills, Condition aggravated, Cyanosis, Electroencephalogram normal, Hyperhidrosis, Pallor, Syncope, Tachycardia

Symptom Text: 4-21 - 4-22-08 was in hospital for syncopal episode. She had normal EEG recording. Was referred for evaluation of a 2 months Hx of spells. First in 2/2/08 - Felt chills, hands & face turned white with corresponding perioral cyanosis. Tachycardic with sweaty palms. Episode free for 3 mo. 4/14/09-records received for DOS 4/21/08-referred for evaluation of 2 month history of spells beginning 2/08, C/O feeling chilled to face and hands turned white with corresponding perioral cyanosis, tachycardic, sweaty palms. Seen in ED with normal EKG, CBC, chemistires. Out of country travel and upon return increase in spells. Syncope.

Other Meds:

Lab Data: Child has exercise induced Asthma- Symptoms above noted prior to HPV inj 4/14/09-records received-Normal cranial CT. Video EEG no abnormalities and no chanages with symptoms more likely vasomotor etiology as their cause. 24 hour urine for

History: Syncopal Episodes

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341059-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Feb-2009	19-Feb-2009	1	04-Mar-2009	05-Mar-2009	UT		22-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0553X	0	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B028AA	2	Left arm	Intramuscular	
MEN	UNKNOWN MANUFACTURER	U2846AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Fall, Fatigue, Gait disturbance, Hypoaesthesia, Joint sprain, Muscular weakness, Paraesthesia, Patellofemoral pain syndrome, Physical examination normal

Symptom Text: Patient was vaccinated for meningitis, gardasil, and tetanus on 2/18/2009. On 2/19/2009 she could hardly walk her legs were numb and very weak and she could barely move. I took her back to the Dr on 2/20/2009 and they said she had Guillain Barre Syndrome.3/9/09-records received-office visit 2/18/09-seen for routine visit. Office visit 2/20/09-C/O legs numb possible reaction to immunizatons. C/O numbness and weakness of both legs from knees down. Fatigues. PE:normal. DX: Paresthesia. 4/21/09-records received-office visit 3/17/09-C/O could not walk after shots last ime states had guillain barre syndrome. Day after vaccine could not walk, could walk with knees locked. Remained this way for over 3 weeks then in past 5 days progessively improved and now back to normal. No weakness of ankle movements and not unstable, describes a numb feeling without anesthesia from knee down. Sprained writs 9 months ago and has knee pain with activiites that require knee bending. PE:retropatellar tenderness bilaterally. Moves all extremities 5/5, sensation intact. 2+ DTRS. DX: muscle weakness generalized. sprain/strain wrist. patellofemoral syndrome. DX is not GBS as merely weakness of knee joint. Office visit 4/14/09-C/O left wrist pain and knees hurt. Fell down stairs yesterday.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **341064-1** **Related reports:** 341064-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Mar-2009	03-Mar-2009	0	04-Mar-2009	05-Mar-2009	SC		17-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1423X	0	Left arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U29278A	0	Right arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amnesia, Dyskinesia, Grunting, Head injury, Immediate post-injection reaction, Loss of consciousness, Muscle rigidity, Muscle tightness, Musculoskeletal pain, Presyncope, Staring, Urinary incontinence

Symptom Text: She recived Gardisil in left arm then Menigitis vaccine in right arm. Within a mintue of reciveing the second shot she passed out, her body became rigid with her eyes open in a fixed stare, jaw clinched, arms tightened towarsd body, shoulders rolled in towards body, lightly urinated on self, making a low grunting/gurgling sound. This went on for sveral minutes. She does not remember anything after the second shot until she woke up on the floor with a fleet of doctors around her. 3/09/09-records received for DOS 3/4/09-After receiving vaccines had a vagal reaction fell to floor lost consciousness and hit forehead. Had some jerking movements of extremities. Now C/O shoulder pain.

Other Meds: Topamax 25 mg daily, Imitrex 50 mg as needed, Depo Prevera Injection every 3 months

Lab Data: EEG, CT Scan , x-rays all performed the same day to eveluate injuries from the fall. 3/9/09-records received-X-ray right shoulder negative. CT head negative. Assessment: shoulder strain, head inury. EEG pending.

History: Pineal Cyst, Venous Angioma 3/9/09-records received-PMH: Migraines, renal cyst vesus angioma.

Prex Illness: Left eaar infection

Prex Vax Illns:

Vaers Id: **341064-2** **Related reports:** 341064-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Mar-2009	03-Mar-2009	0	17-Mar-2009	18-Mar-2009	SC	WAES0903USA01472	18-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	62927AA		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Fall, Head injury, Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female with neurological disorder who on 03-MAR-2009 was vaccinated with a dose of GARDASIL vaccine in her left arm (LOT# 1432X, this lot is valid for another MSD product). Concomitant therapy included MENACTRA in her right arm (LOT# 62927AA). The onset of adverse event was immediate. The patient experienced as either convulsion, seizure or potential syncope episode. The patient passed out, leapt off the table and fell on floor, and hit her head on the floor. The patient has a history of neurological problems so they went immediately to a neurologist to do an EEG. The results were still outstanding at the time of the reporting. As far as long term effects there were none reported at the time of the report. The patient was still being monitored. The patient visited an urgent care facility because the mother felt the patient was still out of sorts. The outcome of adverse events was unknown. It was reported that the patient was still out of sorts. The outcome of adverse events were unknown. It was reported that the patient sought medical attention: visit an urgent care facility. Upon internal review convulsion, seizure was determined to be an other important medical event. Additional information has been requested

Other Meds:

Lab Data: Electroencephalography, 03/03/09, results are outstanding

History:

Prex Illness: Neurological disorder NOS

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341077-1** **Related reports:** 341077-2; 341077-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Feb-2009	16-Feb-2009	15	04-Mar-2009	05-Mar-2009	ID		25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cyanosis, Dizziness, Headache, Hyperacusis, Immediate post-injection reaction, Migraine, Nausea, Photophobia, Somnolence, Syncope

Symptom Text: Immediately following vaccination go light headed turned blue and fainted out for approximately 60 seconds immediately followed by a migrain headache and nausea that lead us to the emergencey room 5 days later.3/6/09-records received for DOS 2/21/09-presented to ED with C/O ongoing headache, suddenly felt lightheaded and drowsy and slowly consciousness after recieving Gardasil vaccine 5 days prior. After regaining consciousness C/O severe frontal headache which waxes and wanes, worsened with bright lights and loud noises. Nauseated, emesis. Diagnosis-Headache.

Other Meds: birth control oral

Lab Data: was administered compazine and benedryl by iv

History: None 3/6/09-records received-PMH:long history of migraine headaches similar in severity.

Prex Illness: NA

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341077-2** **Related reports:** 341077-1; 341077-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Feb-2009	17-Feb-2009	1	17-Mar-2009	20-Mar-2009	ID		30-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Condition aggravated, Migraine, Nausea, Syncope, Vomiting

Symptom Text: Fainted immediately after administrating vaccination. Severe migraine headaches - at least one episode everyday lasting at least 30 min. Headaches - non-stop for five days after the vaccination. Associated nausea also with the headaches. Some vomiting.

Other Meds:

Lab Data:

History: Hx migraines, but pt was headache - free for >1 yr.

Prex Illness: None

Prex Vax Illns:

Vaers Id: **341077-3** **Related reports:** 341077-1; 341077-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Feb-2009	16-Feb-2009	0	22-Apr-2009	08-May-2009	ID	WAES0903USA01110	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Migraine, Syncope

Symptom Text: Information has been received from a certified medical assistant concerning a 15 year old female with no drug reactions or allergies and history of migraine but under reasonable control with IMITREX therapy who on 3-JUL-2008 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot # 0250X). On 16-FEB-2009 the patient was vaccinated IM with the second 0.5 ml dose of GARDASIL (lot # 661046/0546X). Concomitant therapy included IMITREX and unspecified oral contraceptive. On 16-FEB-2009 the patient fainted after getting GARDASIL. The patient was caught by the nurse and did not have any head injury. She recovered and was sent home. That night the patient developed a severe headache. Either the night of 16-FEB-2009 or the following day the patient went to the emergency room because of migraine symptoms. There was information on the ER treatment or test. Mother of the patient reported that she averaged about 1 migraine every couple of months. Since GARDASIL, the patient had been getting at least 1 headache/migraine a day that lasted at least 30 minutes. The patient was referred to pediatric neurologist but the patient's mother refused a brain MRI fro the patient. On 19-FEB-2009 urine pregnancy test was done and the result was negative. It was reported that the patient had been having continuous headaches for 2 and 1/2 weeks. At the time of this report, the patient's symptoms persisted. Additional information has been requested.

Other Meds: IMITREX; hormonal contraceptives

Lab Data: urine beta-human, 2/19/09, negative

History: Migraine

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341090-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	02-Feb-2009	02-Feb-2009	0	04-Mar-2009	05-Mar-2009	FR	B0561851A	05-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TD	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Syncope

Symptom Text: This case was reported by a regulatory authority (# AGEMED-330827440) and described the occurrence of syncope in a 29-year-old female subject who was vaccinated with DITANRIX, GARDASIL. Previous to vaccination the subject referred fear and anguish to vaccines. On 2 February 2009 the subject received booster dose of DITANRIX adult (intramuscular), unspecified dose of GARDASIL (intramuscular). On 2 February 2009, less than one day after vaccination with DITANRIX adult and GARDASIL, the subject experienced syncope. The regulatory authority reported that the events was clinically significant (or requiring intervention). On 2 February 2009, she totally recovered without problem. The regulatory authority reported that the event was possibly related to vaccination with DITANRIX adult and GARDASIL. No further information was expected as this was all the information that regulatory authorities had. Therefore this case has been closed.

Other Meds:

Lab Data: UNK

History:

Prex Illness: Afraid; Anguish

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341109-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	03-Mar-2009	03-Mar-2009	0	04-Mar-2009	05-Mar-2009	MN		22-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2689AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0653X	1	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3028BA	4	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: None

Other Meds: none

Lab Data: None

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **341119-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Mar-2009	03-Mar-2009	0	04-Mar-2009	05-Mar-2009	MI		16-Mar-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C2773AA		Left arm	Subcutaneously	
FLU	SANOFI PASTEUR	U2839AA		Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB329AA		Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0575		Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	42826CA		Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0054Y		Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bruxism, Gaze palsy, Immediate post-injection reaction, Musculoskeletal stiffness, Pallor

Symptom Text: Child rcvd ADACEL, MENACTRA, FLUZONE, Hep A, VARIVAX, and GARDASIL - just after receiving GARDASIL she stiffened up and eyes rolled back, turned pale, teeth clenched according to mom; BP - 119/79 - HR -~70/min- area no urticaria, lungs CTA, No angioedema- episode lasted approx 5 mins - received O2 via IVC (2 liters).

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 341124-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	10-Sep-2007	11-Nov-2007	62	05-Mar-2009	06-Mar-2009	--	WAES0903USA00102	01-May-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1208F	0	Unknown	Unknown	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB206AB	0	Unknown	Unknown	
MNQ	SANOFI PASTEUR	U2402AA	0	Unknown	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52800AA	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Anxiety, Asthma, Conversion disorder, Convulsion, Dysuria, Gastritis, Hypoaesthesia, Incorrect dose administered, Insomnia, Muscular weakness, Neck pain, Pain in extremity, Sensory loss, Stress, Urinary incontinence, Viral infection

Symptom Text: Information has been received from the patient's sister concerning her sister with no pertinent medical history or drug reactions or allergies who on unspecified dates was vaccinated with three doses of GARDASIL. There was no concomitant medication. After the third dose of GARDASIL, the patient experienced numbness in both legs. The consumer reported that the patient could not walk so she was admitted to a hospital for one week. When the patient was in the hospital they did many tests (also reported as no lab tests were performed) but could not find anything wrong and the patient was told it was psychological. The consumer also reported that in 2009, "recently", the patient was just administered a fourth dose of GARDASIL, but no adverse event was involved. At the time of this report, the outcome was unknown. No further information is available. 4/23/09 MR received from PCP with vax rec. Multiple vax received 9/10/07. Admitted to hospital 11/11-14/2007 with D/C DX: Convulsion Disorder (no mention of convusions in MR-conversion d/o dx by psych). Anxiety, convulsion reaction and asthma. Pt presented with increasing weakness and numbness of arms and legs. Recent viral gastritis. Psych consult to deal with family related anxiety. Able to walk with crutches at d/c. HPV#2 given 11/15/07. No mention of hospitalization in record. MD unaware of admission. Viral syndrome 3/27/08. HPV#3 5/13/08. OV 6/24/08 to r/o UTI 2' to urinary incontinence x 10 with dysuria. Tx abx. Reporting leg pain and dizziness 10/24/08. Diarrhea reported 12/27/08. Stomach pain and diarrhea reported 2/3/09. Recieved 4th dose Gardasil 2/26/09 4/27/09 MR received for DOS 11/11-14/07 with DX as above. Conversion Disorder (not convulsion disorder mentioned by neuro consult). Admitted to r/o TM or GBS. Pt reports cannot feel legs, arms are weak, with neck pain 7/10. Pt reports recent virus. (+) Waddell's sign. Medical w/u has been (-), so physch consult requested.. Pt has had multiple stressors recently. (+) insomnia. DX: Conversion

Other Meds: None

Lab Data: Unknown. Labs and diagnostics: 11/11/07- MRI T-spine WNL. MRI brain (+) for CSF attenuation in L cerebellopontine angle-likely archnoid cyst.

History: None. PMH: obesity. scoliosis. folliculitis. mild SAR/RAR.

Prex Illness:

Prex Vax Illns:

Vaers Id: **341125-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Jan-2009	30-Jan-2009	0	05-Mar-2009	06-Mar-2009	FR	WAES0903USA00146	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	
	MNC	WYETH PHARMACEUTICALS, INC	NULL		Unknown	Intramuscular	
	TD	UNKNOWN MANUFACTURER	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received via a health authority concerning a 14 years-old female who was administered one dose of GARDASIL (batch number was not reported, by intramuscular route, site not reported), one dose of DIFTAVAX (batch number not reported, by intramuscular route, site not reported) and one dose of MENINGITEC (batch number not reported, by intramuscular route, site not reported) on the 30-JAN-2009. It was reported that some minutes after vaccination in the nurse consultation presented a generalized convulsion of 1 minute duration that remitted spontaneously. The patient doesn't have a relevant medical history. The patient was recovered on 30-JAN-2009. Upon internal review, generalized convulsion was determined to be an other important medical event. Case is closed. Additional information is not expected. Other business partner numbers include E2009-01757 and ES-AGEMED-915125333.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **341132-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Oct-2008	23-Oct-2008	0	05-Mar-2009	06-Mar-2009	FR	WAES0902USA03870	06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Joint hyperextension, Syncope

Symptom Text: Information has been received from the Health Authorities (reference number ES-AGEMED-730749340, reported by a health care professional from a special follow-up program) concerning a 15 year old female patient who on 23-OCT-2008 was vaccinated with a dose of GARDASIL (lot number and site not reported) by intramuscular route. It had been reported that a few minutes after the vaccination, the patient presented with syncope with hyperextension in the arms and legs. A few seconds later, the patient recovered. Syncope was reported as an other important medical event. Other business partner numbers included: E2009-01568. No further information is available. The case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341143-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Oct-2008	13-Oct-2008	12	05-Mar-2009	06-Mar-2009	--		10-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Pyrexia

Symptom Text: I had the 1st GARDASIL vaccination in Oct 2008 and ever since then I have been having high fevers, between to 102-103.0.

Other Meds:

Lab Data: The first GARDASIL injection was in OCT 2008, the 2nd was in Dec. 2008. I have not received the third vaccination because I believe GARDASIL is the cause for my persistent fevers.

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 341165-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	27-Apr-2007	11-Jul-2007	75	05-Mar-2009	06-Mar-2009	MI		13-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0962	0	Left arm	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Chest pain, Contraception, Dysmenorrhoea, Dyspnoea, Loop electrosurgical excision procedure, Palpitations, Papilloma viral infection, Smear cervix abnormal, Tachycardia

Symptom Text: I went in for the 1st of three Guardisil vaccinations. I had a recent previous pap smear that normal, no HPV, no abnormal cells, nothing. After another pap (after having the vaccine) it was found that I did in fact now have HPV and a lession that needed a LEEP procedure to be removed. My gyno was stunned at how quickly this lesion manifested and how dangerous it had become so very quickly. I was lucky to have it removed when I did as my gyno said one more week and more than likely it would have been cancerous. I now need pap tests every 6 months to make sure I don't get cervical cancer (from a shot that was meant to protect me from it). I now have HPV forever, and I never had it before I got the vaccine. Married, monogamous (as is spouse), how did I get it then? And is it a coincidence that it happened very shortly after the HPV vaccine was administered? I think not. 4/7/09 Received PCP vaccine record & medical records for 4/27/07. FINAL DX: none provided. Records reveal patient was new patient to practice & experienced menstrual cramps since 1/07 when out of BCPs. Exam was WNL. 4/7/09 Received additional PCP records of 8/23/07. FINAL DX: chest pain, tachycardia Records reveal patient experienced chest pain, heart racing, SOB x 1 day. Began right after starting new BCP. Exam in office WNL. Referred for echocardiogram & BCP d/c'd. No further medical records or echocardiogram report available.

Other Meds: none

Lab Data: echocardiogram

History: none PMH: smoker.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **341176-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Feb-2009	Unknown		05-Mar-2009	06-Mar-2009	GA		06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	MSD1311X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Mother called and reported that patient was pregnant when she received her third Gardisil.

Other Meds:

Lab Data:

History: unknown

Prex Illness: None reported

Prex Vax Illns:

Vaers Id: **341197-1** **Related reports:** 341197-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	08-Sep-2006	05-Jun-2008	636	05-Mar-2009	06-Mar-2009	CA		12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688F	0	Left arm	Unknown	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B004AB	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Agitation, Amnesia, Bronchitis, Cognitive disorder, Confusional state, Convulsion, Educational problem, Fall, Paraesthesia, Postictal state, Posture abnormal, Sleep disorder, Tonic convulsion

Symptom Text: Pt had seizure while sitting and eating, talking neck twisted and fell to the floor while @ grandmother's house lasted 2min. Multiple seizures since then. Had 3 in one day on 6-11-08 while at school. 3/11/09 MR received from PCP from 9/2007-2/2009. WCC 9/18/07 with normal exam, well adolecent, no problems on 9/18/07. Several visits for bronchitis 12/07 and 5/08. Seen in f/u of tonic seizure which occured 6/5/08. 3 seizures 6/9/08. Referred stat to neurologist. 5 seizures 10/2008. 5 seizures Jan-Feb 2009. Neuro consult dated 12/11/08. 1st seizure lasting 2-3" with post-ictal confusion, agitation and amnesia. More recently pt reports increased sleep, problems with processing, and paresthesias. Grades have recently declined. 3/26/09 Neuro consult received as above.

Other Meds: None

Lab Data: CT scan w/o contrast in ER; EKG, Labs in ER; MRI head w/o and with contrast referred to Neurologist. Labs and Diagnostics: EEG abnormal. Brain MRI abnormal, repeat WNL.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **341197-2** **Related reports:** 341197-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jul-2007	09-Jun-2008	344	10-Mar-2009	11-Mar-2009	--	WAES0903USA00779	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a 16 year old female who in September 2006, was vaccinated with the first 0.5 ml dose of GARDASIL (lot # 653735/0688F). Concomitant therapy included BOOSTRIX on the same day. On 22-JAN-2007, the patient was vaccinated with the second dose of GARDASIL (lot # 655165/1425F). In July 2007, the patient was vaccinated with the third dose of GARDASIL (lot # not provided). On 09-JUN-2008 the patient developed seizures after getting all three doses of GARDASIL. At the time of this report, the patient's seizures persisted. Unspecified medical attention was sought. Upon internal review, seizure was considered to be other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341203-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	03-Mar-2009	03-Mar-2009	0	05-Mar-2009	06-Mar-2009	FL		06-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1756X	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	05706	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Unevaluable event

Symptom Text: None stated

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341206-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Jun-2008	23-Jun-2008	12	06-Mar-2009	09-Mar-2009	FR	WAES0807USA03179	26-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Hydronephrosis, Induced labour, Missed labour

Symptom Text: Information has been received from a gynecologist, concerning a 18-year-old female patient on 11-JUN-2008 was vaccinated with the third dose of GARDASIL route IM into deltoid muscle. On 23-JUN-2008, the patient was found to be pregnant. The last menstrual period was on 01-MAY-2008. Estimated date of birth 05-FEB-2009. No adverse effect occurred up to the time of reporting. Additional information received from a gynaecologist on 25-FEB-2009. It was reported that the patient developed hydronephrosis during pregnancy (onset date unknown). Due to hydronephrosis a medical induction of labour was started. Because of missed labor, a cesarean section was performed and the patient gave birth to a sound baby on 30-JAN-2009. The postnatal examination of mother and child showed no pathologies. Upon medical review, hydronephrosis and cesarean section were considered to be other important medical events. Other business partner numbers include E2008-05899. The case is closed. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 01May08)

Prex Vax Illns:

Vaers Id: **341207-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Dec-2008	01-Dec-2008	0	06-Mar-2009	09-Mar-2009	FR	WAES0902ISR00023	09-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Monoplegia

Symptom Text: Information has been received from a physician concerning a 25 year old female who in December 2008, was vaccinated with GARDASIL first dose. In December 2008, the patient experienced arm paralysis for two weeks. Subsequently, the patient recovered from arm paralysis. The physician indicated that the consumer (the patient's mother) reported to her about the event approximately one and half month posts the event by phone call. The adverse event was termed by the consumer as an "arm paralysis" and "could not move her hand". The reporting consumer indicated that the patient did not refer to a physician for examination at the time of the event. The physician advised the patient to refer for examination however the patient was not examined by the time of this report. The physician felt that the relation of arm paralysis to therapy with GARDASIL first dose is unknown. The physician raised the possibility that the event was not paralysis per se but rather pain from the injection however since the patient was not examined the physician could not determined that. Upon internal review, monoplegia was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **341208-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	12-Dec-2008	01-Jan-2009	20	06-Mar-2009	09-Mar-2009	MO	WAES0902USA03994	09-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Vaginal haemorrhage

Symptom Text: Information has been received from a licensed practical nurse concerning a 26 year old female with no known medical history and drug allergies, who on 12-DEC-2008 was vaccinated with a first dose of GARDASIL (lot # 660620/0571X) on 12-FEB-2009. The patient received a 0.5 mL second dose of GARDASIL (lot # 661764/0650X), intramuscularly. There was no concomitant medication. It was reported that the patient was pregnant. It was noted that the patient had experienced vaginal spot bleeding that was bright red. It was also reported that the patient miscarried. She was in her first trimester and probably only a couple weeks pregnant. Beta levels were negative and she will not require a dilation and curettage procedure. The patient sought medical attention through a phone call to the practice. Upon internal review, miscarried was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Serum beta-human, negative

History:

Prex Illness: Pregnancy NOS (LMP = 1/18/2009)

Prex Vax Illns:

Vaers Id: **341209-1** **Related reports:** 341209-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	02-Dec-2008	31-Dec-2008	29	06-Mar-2009	09-Mar-2009	NY	WAES0902USA04266	09-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician assistant and a licensed practical nurse, for GARDASIL, a Pregnancy Registry product, concerning a 20 year old female patient with asthma and no known drug allergies or reactions who on 02-DEC-2008 (after a negative pregnancy test) was vaccinated with the first 0.5 ml IM dose of GARDASIL (lot #0152X). Concomitant therapy included albuterol. It was noted that the patient got pregnant around the end of December 2008. About 6-7 weeks ago, the patient was assumed to undergo a miscarriage. She experienced abdominal pain. On 04-JAN-2009 the patient was seen at a hospital. On 06-JAN-2009 the patient was seen at the emergency room, experiencing a threatening spontaneous abortion, with no evidence of gestation sack and no evidence of embryonic pole. She was given birth control after the miscarriage. It was reported that unspecified blood was drawn and testing was done. On 26-JAN-2009 the patient had a HCG quant level of 16, and on 03-FEB-2009 a quant level of 5. But the patient never got her period. On 16-FEB-2009 physician assistant spoke with the patient's physician's office to confirm her lack of pregnancy and gave her a pregnancy test with negative result. On 16-FEB-2009 the patient received the second 0.5 ml IM dose of GARDASIL (lot #01423X). The patient also had an adverse event after this second dose (WAES # 0903USA00527). Upon internal review, miscarriage was determined to be an other important medical event. Additional information has been requested.

Other Meds: Albuterol

Lab Data: urine beta-human, 02/16/09, negative; serum beta-human, 01/26/09, 16; serum beta-human, 02/03/09, <5; beta-human chorionic, 12/02/08, negative

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Asthma

Prex Vax Illns: Vaccine exposure during; Cramp~HPV (Gardasil)~1~20~In Patient

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341209-2** **Related reports:** 341209-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	02-Dec-2008	13-Jan-2009	42	19-Mar-2009	20-Mar-2009	NY	WAES0903USA00527	31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	01423X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Muscle spasms, Pregnancy

Symptom Text: Information has been received from a physician assistant and a licensed practical nurse, for GARDASIL, a Pregnancy Registry product, concerning a 20 year old female patient with asthma and a history of miscarriage and no known drug allergies or reactions who on 02-DEC-2008 was vaccinated with the first 0.5 ml IM dose of GARDASIL (lot #0152X). Concomitant therapy included ALBUTEROL. On 16-FEB-2009 the patient received the second 0.5 ml IM dose of GARDASIL (lot #01423X). On 24-FEB-2008 the patient's mother reported that the patient experienced cramping and was in the emergency room. An ultrasound was done and showed the patient was 6 weeks pregnant. The office did not receive ER hospital records, so this was unconfirmed. At the time of reporting, the outcome was unknown. The patient also had a adverse experience after the first dose of GARDASIL (WAES # 0902USA04266). Additional information has been requested.

Other Meds: ALBUTEROL

Lab Data: ultrasound 2/24/09 - 6 weeks pregnant

History: Miscarriage

Prex Illness: Pregnancy NOS (LMP = Unknown) Asthma

Prex Vax Illns: Abdominal pain, Miscarriage, Vaccine exposure during~HPV (Gardasil)~1~20~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341210-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		06-Mar-2009	09-Mar-2009	FR	WAES0903AUS00038	10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a physician via CSL as part of a business agreement (manufacturer control # CSL 2009 03 03 JV3) concerning a female who was vaccinated some time between conception to implantation with GARDASIL. Subsequently it was determined through a morphology scan at 17 weeks that the foetus in utero has a congenital anomaly of atrioventricular septal defect. Additional information has been requested.

Other Meds: Unknown

Lab Data: Uterine ultrasound, congenital anomaly - atrioventricular septal defect

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341211-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	14-Jan-2009	16-Jan-2009	2	06-Mar-2009	09-Mar-2009	FR	WAES0903USA00046	10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0779X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arrhythmia, Clonus, Convulsion, Feeling abnormal, Loss of consciousness, Trismus, Urinary incontinence

Symptom Text: Information has been received from a general practitioner concerning a 19 year old female patient who received the first dose of GARDASIL on 14-JAN-2009 (lot #0779X, batch# NJ32820) IM. About two years ago the patient was taken oral contraceptive with HARMONET, 0.015 mg and 0.06mg. On 16-JAN-2009, two days after vaccination, the patient experienced one episode of loss of consciousness and convulsion crisis with clonic movement, loss of urinary sphincter control (urination occurred) and trismus. The episode started with a "feeling something in the head" as the patient was standing next to the vehicle after lunch. The duration of the episode was unknown. The patient recovered spontaneously without hospitalization or any medical treatment. The reporting physician stated that she was only informed about the event on 21-JAN-2009. In order to find a possible etiology, several tests were performed by the general practitioner who followed the patient: CAT scan, blood test and echocardiogram without abnormal results. An electroencephogram showed a "slight slow dysrhythmia (theta band), without a clear zone Predominance". The electroencephalogram will be repeated in March 2009. More information is expected. To be noted that the patient had no personal or family history of pathology or similar events. The case was not considered as serious by the reporter, nevertheless it was upgraded according to the company policy and seizure was considered to be an other important medical event. Other business partner number included E200901807.

Other Meds: Harmonet

Lab Data: Computed axial tomography, without abnormal results; Diagnostic laboratory test, without abnormal results; Echocardiography, without abnormal results; Electroencephalography, slight slow dysrthytmia (theta band), without a clear zone predom

History:

Prex Illness: Oral Contraception

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341212-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Jun-2008	01-Sep-2008	66	06-Mar-2009	09-Mar-2009	NC	WAES0903USA00062	10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Fatigue, Feeling abnormal, Infectious mononucleosis

Symptom Text: Information has been received from a office manager concerning a 14 year old female patient who on 28-APR-2008 was vaccinated with the first dose of GARDASIL (Lot number 660387/1967U). On 27-JUN-2008, the patient was vaccinated with the second dose of GARDASIL (Lot number 660553/0070X) and on 24-NOV-2008 with the third dose of GARDASIL (Lot number 661764/0650X). In September 2008, the patient complained of tiredness. The patient was cultured and was positive for mononucleosis. In January 2009, the patient began to felt awful and really bad. The patient had some laboratories taken and her blood work came back as: WBC-2, platelet-150, and no leukemia. The patient was hospitalized for one week. She had since been released from the hospital. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory, 01/??/09, blood work: no leukemia; Diagnostic laboratory, 09/??/08, positive for mononucleosis; WBC count, 01/??/09, 2; Platelet count, 01/??/09, 150

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341213-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	24-Feb-2009	25-Feb-2009	1	06-Mar-2009	09-Mar-2009	--	WAES0903USA00104	26-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1423X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Epilepsy

Symptom Text: Information has been received from an advanced registered nurse practitioner concerning a 23 year old female diagnosed with epilepsy 2 years ago who on 24-FEB-2009 was vaccinated with the first dose of GARDASIL (lot # not available). Concomitant therapy included Lamictal. The next day after receiving the first dose of GARDASIL (on 25-FEB-2009) the patient experienced epileptic seizures. Subsequently, the patient recovered from epileptic seizures. The patient sought medical attention to the nurse practitioner. Upon internal review, epileptic seizures was determined to be an other important medical event. Additional information has been requested. 3/19/09-records received-office visit 12/23/08 C/O darker old bleeding with menses. Gyn exam and pap. Visit on 2/24/09-received 1st HPV4 vaccine left deltoid. On 2/26/09-parent called indicating had a full gran mal seizure day after receiving Gardasil.

Other Meds: Lamictal

Lab Data: Unknown

History: 3/19/09-records received-PMH: Epilespy on Lamictal.

Prex Illness: Epilepsy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341214-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	03-Oct-2008	27-Oct-2008	24	06-Mar-2009	09-Mar-2009	FR	WAES0903USA00141	26-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1049U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Grand mal convulsion, No reaction on previous exposure to drug

Symptom Text: Information has been received from the Health Care Authorities (ref # ES-AGEMED-418580347) concerning a 19 year old female patient who was administered the third dose of GARDASIL (batch # NG52730, lot # 1049U) on 03-OCT-2008 by intramuscular route (site not reported). Twenty four days after vaccination, on 27-OCT-2008, the patient was attended at the emergency room due to generalized tonic-clonic convulsion. It was reported that the patient had no related previous history and she was not receiving any concomitant treatment at the time of vaccination. CAT scan performed on the same day was normal. An EEG was performed (exact date not reported) and results were pending at the time of this report. Previous vaccinations were well tolerated. Other business partner numbers included E2009-01756. The case was closed. No further information is available.

Other Meds:

Lab Data: Computed axial tomography, normal; Electroencephalography, pending

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341215-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	25-Jun-2008	01-Dec-2008	159	06-Mar-2009	09-Mar-2009	FR	WAES0903USA00418	26-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1358F	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Extensor plantar response, Monoparesis, Paraesthesia, Scotoma, Visual impairment

Symptom Text: Information has been received from a healthcare professional concerning an 18 year old female patient who had received the third dose of GARDASIL (lot#1358F, batch#NG01510) via the intramuscular route on 25-JUN-2008 and in December 2008, she developed paresis of the lower limb, paraesthesia of the right arm and vision disorder with scotoma. Physical examination revealed BABINSKI's sign. An MRI showed left posterior parietal lacunar images. At the time of reporting, lumbar puncture had not been performed yet. The diagnosis of multiple sclerosis was not made. According to the reporter, relationship between reactions and vaccination was rather doubtful. The patient had received the two first doses of GARDASIL on 25-JAN-2008 and 11-APR-2008, and a dose of REVAXIS in March 2008. MS-like syndrome was determined to be an other important medical event. Other business partner numbers include: E2009-01738. No further information is available.

Other Meds: REVAXIS

Lab Data: Physical examination, ??Dec?08, revealed Babinski's sign; Magnetic resonance imaging, ??Dec?08, left posterior parietal lacunar images

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 341216-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	08-Aug-2008	01-Sep-2008	24	06-Mar-2009	09-Mar-2009	CO	WAES0903USA00467	27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0927U	0	Unknown	Unknown	HPV4

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Aggression, Agitation, Aphasia, Blood product transfusion, Chemotherapy, Confusional state, Delirium, Depressed level of consciousness, Encephalitis, Encephalopathy, Gastrointestinal tube insertion, Intensive care, Mental status changes, Oxygen saturation decreased, Perseveration, Plasmapheresis, Speech disorder, Thrombosis

Symptom Text: Information has been received from a physician concerning a female patient who in July or August of 2008, was vaccinated with her second dose of GARDASIL. In September 2008, the patient had NMDA antibody receptor and encephalitis. Drug treatment was required. The patient presented at the emergency room and was hospitalized for 2 months. At the time of reporting the patient was recovering from the NMDA antibody receptor encephalitis. The patient was told that she could have recurring episodes. It was unknown if there would be significant disability. Additional information has been requested. 4/24/09 Received hospital medical records of 9/29-11/25/2008. FINAL DX: NMDA receptor positive encephalopathy; delerium; g-tube placement; left brachiocephalic IVC clot associated w/PICC line placement; antiphospholipid antibodies. Records reveal patient symptoms noted in outlying ER in addition to aggression began approx 5 days prior. Course waxed & waned w/intermittent decreased alertness & delerium, decreased O2 sats & was in/out of PICU. Tx w/IVIG x 5 days, steroids, IV antibiotics/antivirals, plasmaphersis x 4 days, antineoplastics, feeding tube placement & anticoagulants. Neuro, Rheum & Psych consult done. Slowly improved & d/c to home w/PCP, Thrombophilia, Rheum, REhab & surgery clinic appts. 4/7/09 Received hospital medical records of 9/27-9/29/2008. FINAL DX: probable encephalitis Records reveal patient experienced acute confusion, mental status change, repetitive garbled speech then aphasia, excitable. In hospital had alternating periods of quiescence & agitation, speech garbled, perseverating, neologisms & frequently aphasic. ID & Neuro consults done. Transferred to higher level of care.

Other Meds: Unknown

Lab Data: Unknown LABS: EEG abnormal. MRI WNL. Repeat LP done 10/3: wbc 42(H), protein & glucose (N), c/s neg. Initial CSF: WBC 142(H), RBC 5, neutros 2, lymphs 92, monos 6, glucose 54, protein 34, c/s neg. CBC: WBC 6900, neutros 62, bands 1,

History: Unknown PMH: chronic sinusitis, strep throat, IBS, encopresis, ankle fx. Foreign travel 8/08.

Prex Illness:

Prex Vax Illns:

Vaers Id: **341217-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Jul-2008	01-Jul-2008	0	06-Mar-2009	09-Mar-2009	FR	WAES0903USA00475	26-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope, Syncope vasovagal

Symptom Text: Information has been received from a Health Authority (reference number ES-AGEMED-389255339), concerning a 21 year old female patient who in July 2008 (exact date not reported), was vaccinated with the first dose of GARDASIL (Batch number, route and site not reported). It was reported that after receiving the vaccine, the patient presented a vasovagal syncope with loss of consciousness, ten minutes afterwards the patient recovered. The patient received the second and third doses with no adverse events. Case reported as serious by the HA with other medically important condition as criteria. Syncope, syncope vasovagal and loss of consciousness were considered to be an other important medical event. Other business partner numbers (E2009-01832). No further information is available. Case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **341218-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Jan-2009	16-Jan-2009	1	06-Mar-2009	09-Mar-2009	FR	WAES0903USA00476	26-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Dizziness, Feeling cold, Listless, Loss of consciousness, Malaise, Pallor, Vomiting

Symptom Text: Information has been received from a Health Authority (reference number ES-AGEMED-220771341) concerning a 14 year old female who on 15-JAN-2009 was vaccinated with a second dose of GARDASIL by intramuscular route. On 16-JAN-2009, a day after vaccination, the patient began with general malaise, on 17-JAN-2009, the patient was taken to the emergency room where she lost consciousness after having experienced dizziness, pallor, cold sensation and vomiting. The patient was sent home with a diagnosis of possible vasovagal syndrome. The patient did not attend school during that week due to feeling dizzy and listless. Case reported as serious by the HA with other medically important condition as criteria. It is reported that the patient recovered by 23-JAN-2009. Case is closed. Other business partner numbers included E2009-01829. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 341219-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Sep-2008	28-Sep-2008	5	06-Mar-2009	09-Mar-2009	FR	WAES0903USA00494	10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Amnesia, Convulsion, Disorientation, Drooling, Loss of consciousness, Tonic clonic movements, Tremor

Symptom Text: Initial information received on the 26-FEB-2009 from the Health Authorities (Reference number ES-AGEMED-608197236) regarding a 14 year old female who on 23-SEP-2008 was vaccinated with the third dose of GARDASIL (batch number not reported) by intramuscular route (site not reported). It has been reported that on 28-FEB-2008 when she woke up, the patient had a tremor on her right arm, and when she stood-up she had a convulsive crisis with loss of consciousness, tonic-clonic movements and drooling. No sphincter incontinence or ocular reversion. The patient presented a postcritical state (disorientated and couldn't remember anything until she was at the scanner). The patient was moved by a medical home care service (arterial pressure: 72/47; heart rate: 107, disorientated). The patient was didn't have a medical history of convulsive crisis. The patient had a normal physical exploration. Neurological exploration: no meningeal signs, nor nuchal rigidity, nor petechiae, normal cranial pairs, strength, feeling and nociception conserved. Presented reflexes. On 29-SEP-2008 an electroencephalogram was performed, several interference's appear with a spike morphology also several acute waved in the temporal areas, specially in the left side, these were more active during hyperpnea. The patient was discharged and diagnosed as a first convulsive episode. EEG was repeated after 10 days, patient remained without any medical treatment until this test. The results for EEG were pending. Convulsive seizure was considered to be an other important medical event by the HA. Other business partner numbers include E2009-01808.

Other Meds: Unknown

Lab Data: Physical examination, 28Sep08, normal; Electroencephalography, 29Sep08, abnormal; Arterial blood PO(2), 28Sep08, 72/47 mmHg; Blood glucose, 29Sep08, 109 mg/dL

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 341220-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	10-Nov-2008	11-Nov-2008	1	06-Mar-2009	09-Mar-2009	FR	WAES0903USA00498	24-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blood product transfusion, Coagulopathy, Haematoma, Haemorrhage, Mouth haemorrhage, Petechiae, Pruritus, Tooth extraction, Vaccine positive rechallenge

Symptom Text: Information has been received via a health authority (case no. 95400, local case no. IT077/09) concerning a 11 year old female who was affected by cheilo-palatoschisis (cleft palate), congenital dislocation of the hip and severe scoliosis who on 10-NOV-2008 was vaccinated with the first dose of GARDASIL. The following day (11-NOV-2008) she presented with intense itching of the lower limbs and then of the abdomen, followed by the onset of a large hematoma on the left calf (not related to any apparent trauma). The mother initially thought that the itching was connected to a brace the child was wearing for the scoliosis, thus she used creams (NOS) that did not calm the symptoms. Also reported coagulation difficulty following a tooth extraction, the child bled for 2 days. On 15-JAN-2009 the patient was vaccinated with the second dose of GARDASIL (lot # 1864U, batch # NJ16970). Following the administration of the second dose on 15-JAN-2009, the itching became more and more intense with onset of several petechiae on the limbs and hematomas on the legs, petechiae reported also in the oral cavity. On 29-JAN-2009 the pediatrician prescribes a blood drawing and has the child admitted to the hospital because platelets 3000mm. Upon admission the child was in good general condition with diffused petechiae on the limbs and oral cavity and hematomas on the arms. She was treated with immunoglobulins IV without improvement and then from 09-FEB-2009 with PREDNISONE. She was discharged on 12-FEB-2009. Her condition had improved. No further information is available. The case is closed. Other business partner number included E200901740.

Other Meds: Unknown

Lab Data: Neurological examination, within limits; Platelet count, 31Jan09, 19000; Platelet count, 02Feb09, 22000; Platelet count, 04Feb09, 14000; Hemoglobin, 12Feb09, 13.3; Neutrophil count, 12Feb09, 11300; Platelet count, 12Feb09, 14800; Pla

History:

Prex Illness: Cleft palate; Scoliosis; Congenital hip dislocation

Prex Vax Illns:

Vaers Id: **341230-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Aug-2008	Unknown		06-Mar-2009	09-Mar-2009	FR	WAES0902ISR00024	23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Facial spasm, Lacrimation increased

Symptom Text: Information has been received from a physician concerning a female who in August 2008, was vaccinated with GARDASIL second dose. In August 2008, five or six days post vaccination, the patient experienced facialis. Therapy with GARDASIL was interrupted. The reporter indicated that the patient is improving but still cannot completely closed the eye and the eye is teary. The reporter indicated that the reporting attending physician felt that facialis was not related to therapy with GARDASIL second dose. The reporter felt that he cannot relate facialis to therapy with GARDASIL second dose. Upon medical internal review facialis was considered to be disabling and other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341231-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		06-Mar-2009	09-Mar-2009	FR	WAES0903CAN00014	23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness, Tremor

Symptom Text: Information has been received from a consumer concerning a patient who was vaccinated with GARDASIL, lot # not available. Subsequently the patient experienced trembling, blackouts and seizures. Upon internal review, seizures were considered to be an other important medical event. No further information is available. This is one of several reports received from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341234-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Feb-2009	09-Feb-2009	0	06-Mar-2009	09-Mar-2009	PA		12-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Dizziness, Headache, Nausea

Symptom Text: Pt described chest heaviness, nausea, headache after administration of vaccine presented next day with persistent complaint. 3/10/09 Received PCP medical records of 2/10/09. FINAL DX: ? reation to Gardasil Records reveal patient w/chest heaviness, lightheaded, within few minutes of shot. RTC 2/10 w/nausea, HA, lightheadedness, left shoulder w/full ROM, no redness or tenderness.

Other Meds: None

Lab Data: EKG; CBC; LMP; TSH LABS: EKG WNL. CBC, TSH, CMP no results available.

History: Bicuspid Aortic Valve

Prex Illness: None

Prex Vax Illns:

Vaers Id: **341242-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Jun-2007	Unknown		06-Mar-2009	09-Mar-2009	FL		20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	02474	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1447F	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Patients received HPV # 1 6-26-07. Patient returns 8/30/07 for HPV #2 and says that her legs were hurting - come back 10/23/07 still c/o leg pain labs were ordered all normal.

Other Meds:

Lab Data: CBC; RF; CPK; C3-C4; ANA; ESR All normal; X-ray of spine normal

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341243-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	13-Feb-2009	13-Feb-2009	0	06-Mar-2009	09-Mar-2009	PA		23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Chest discomfort, Headache, Neck pain

Symptom Text: 2/13/09 stabbing head pain, 2/14/09 chest pressure, 2/15/09 back and neck pain, 2/16/09 all of above. 2/18/09 diagnosed with costiocondritis.

Other Meds: KARIVA

Lab Data: Diagnosed by Dr.

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: 341245-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	26-Feb-2009	27-Feb-2009	1	06-Mar-2009	09-Mar-2009	OH		23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Rash generalised, Urticaria

Symptom Text: Mother stated generalized Rash in AM-denies SOB. Instructed Tx BENADRYL and/or MD or ER if worse. Called mother 3-2-09 AM-she stated went to ER last night. Rash-increased-more like hives-and had Temp increase 101. Tx Steroids and BENADRYL. If still present after steroids, will go to family MD.

Other Meds:

Lab Data: None known

History: Allergy, morphine

Prex Illness:

Prex Vax Illns:

Vaers Id: 341247-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Sep-2007	19-Sep-2007	0	06-Mar-2009	10-Mar-2009	CO		24-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Abscess, Activities of daily living impaired, Anger, Anxiety, Arthropod bite, Autonomic nervous system imbalance, Cellulitis, Chest pain, Condition aggravated, Depression, Dizziness, Fatigue, Headache, Menieres disease, Migraine, Oropharyngeal pain, Orthostatic intolerance, Pharyngitis, Presyncope, Red man syndrome, Staphylococcal infection, Tinnitus, Upper respiratory tract infection, Vertigo, Vestibular disorder, Viral infection

Symptom Text: Ongoing dizziness, dysautonomia, fatigue. Has been treated for possible Meniere's disease and for anxiety. Recurrent MRSA skin infections since 9/2008. 3/20/09 Received PCP medical records which included hospital medical records, Neuro, ENT & Cardio consults. FINAL DX: chronic migraines; chronic dizziness; depression; anxiety; orthostatic intolerance; peripheral vertigo; active Meniere's disease, cochleovestibular; tinnitus; possible vestibular migraine; paced vertiginous syndrome; partial dysautonomia probably post viral; orthostatic intolerance grade 1. Records reveal patient experienced episodes of dizziness 9/19/07, near blacking out w/position changes. Already seeing Neuro at that time for migraines. PO fluids encouraged. RTC 11/28/07 for BCP when minocycline d/c for acne. RTC 1/21/08 w/anxiety, depression, anger x 1 year. Tx w/antidepressants & referred for counseling. RTC 5/12/08 feeling better but still anxious; meds adjusted. RTC 9/24/08 w/insect bite left inner thigh & cough. Dx w/cellulitis left leg & URI. Tx w/oral antibiotics. RTC 9/25/08 w/worsening cellulitis, dizziness, dysautonomia. Tx w/IM antibiotics & given FluMist. RTC 9/26/08 w/worsened cellulitis/early abscess & admitted to hospital 9/26-9/29/08. Tx w/Vanco & developed red man's syndrome, chest pain. C/S (+) MRSA. Recurred 10/29 & again 1/5/09 & tx w/oral antibiotics. Missed several days of school due to autonomic instability symptoms. RTC 2/20/09 w/sore throat, HA, abdominal pain, dizziness. Dx w/abdominal pain, dizziness & pharyngitis. Neuro consult 11/12/07-12/22/08. FINAL DX: chronic migraines; chronic dizziness; dysautonomia; depression; anxiety; orthostatic intolerance. ENT consult 2/1-4/21/08. FINAL DX: peripheral vertigo; active Meniere's disease, cochleovestibular; tinnitus; possible vestibular migraine; dysautonomia. Cardio consult 4/11-5/15/2008 FINAL DX: paced vertiginous syndrome; partial dysautonomia probably post viral; orthostatic intolerance grade 1; anxiety

Other Meds: TOPAMAX

Lab Data: Normal CBC. T4 Potassium, BMP Negative mono screen. Mild intolerance to tilt table test. LABS: rapid strep neg. EKG WNL.

History: Amblyopia, Migraines, dizziness, patellofemoral syndrome PMH: acne on minocycline x 2 yr; left orbital rim fracture; amblyopia; high triglycerides; dysautonomia; MRSA cellulits/abscess left thigh 9/08; tonsillectomy; PE tubes. Family hx: asthma, allergies, migraines, SLE, melanoma, DM, HTN, enlarged heart, hypothyroidism.

Prex Illness: Dizziness

Prex Vax Illns:

Vaers Id: **341249-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Feb-2009	22-Feb-2009	2	06-Mar-2009	09-Mar-2009	NJ		20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Broke out in hives on 2/22/09. Worsened by office visit on 2/23/09. No known new products of foods treated with SOLUMEDROL dose pack and hydrocortisone cream.

Other Meds: Albuterol HFA

Lab Data: None

History: obesity, hypertension, high cholesterol

Prex Illness: Coughing, diarrhea

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341277-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-Mar-2009	06-Mar-2009	2	06-Mar-2009	10-Mar-2009	GA		10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB329BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0940X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2668AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site warmth

Symptom Text: RED WARM AREA TO RIGHT ARM WHERE MENACTRA WAS GIVEN(03/04/2009).PATIENT WAS SEEN BY DR.NAVE AND MOM WAS INSTRUCTED TO WATCH AREA FOR ANY CHANGE AND APPLY COOL COMPRESS,GIVE IBUPROFEN.RECHECK IF NOT BETTER.

Other Meds:

Lab Data:

History:

Prex Illness: NONE

Prex Vax Illns: SISTER~Meningococcal (Menactra)~1~11~In Sibling1

Vaers Id: 341283-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	27-Feb-2009	02-Mar-2009	3	06-Mar-2009	11-Mar-2009	OK		13-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	UNKNOWN		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Anaphylactic reaction, Chest pain, Dyspnoea, Hyperhidrosis, Pruritus, Rash generalised, Respiratory distress, Stridor, Tachypnoea, Urticaria, Vaccination complication

Symptom Text: Patient received Gardasil and Menactra vaccinations on Friday, Feb. 27th at about 2 pm. She also had completed a course of Zithromax, but had previously received 2 courses of this medication. Patient felt fine throughout the weekend, but on Monday around 130 pm developed itching and slight rash. Played golf from 4-5 pm and rash worsened with sweating. That evening her mother gave her diphenhydramine and Calamine lotion which helped the rash decrease in size and decreased pruritis associated with the rash. On Tuesday morning the rash was very light, but again worsened throughout the day and greatly increased in size after golf from 4-5 pm. Mother described rash as now spread throughout body including abdomen, breasts, back, neck, and palms of hands and soles of feet. Patient began having breathing difficulties and was brought to an urgent care facility around 7 pm. She received epinephrine and IV methylprednisolone and was discharged after the breathing improved and the rash decreased in size. At about 1230 am that night the patient again experienced breathing difficulites and worsened rash and presented to the ER. She was given another dose of epi, IV steroids, and antihistamines. Patient was sent home after improvement, but again presented Wed am, this time to the TEC. Patient was admitted and received 2 more rounds of epi, scheduled methylprednisolone (25 mg IV q6h), scheduled hydroxyzine (50 mg po q6h), and Pepcid (20 mg IV q12h). Patient weighed 54.2 kg. Patient was discharged on Friday March 6th with an epi pen, prn hydroxyzine, oral steroids, H2 antag, etc. Medical residents described rash as hives. Patient reported no changes to diet or unusual outdoor triggers. When looking at literature, it appeared the majority of documented cases with Menactra were within 24hrs, but when looking at a study of Australian teenage girls receiving Gardasil, it appeared several of the cases were delayed in nature (up to a several days). Please contact PharmD for literature links. We felt given history of

Other Meds: Zithromax (previously received 2 courses) and unknown antihistamine with multiple previous exposures.

Lab Data: 3/4 CBC (0100) WNL with slightly elevated neutro @ 7.6, segs of 88, lymphs of 12; BMP WNL beside glucose elevated at 245 (patient on methylpred) and CO2 of 13; 3/4 (1306) WBC increased from 8.6 (previous CBC) to 19.1, neutro increased to

History: No significant PMH PMH: seasonal allergies. NICU x 2 wks for resp distress as 34 wk preemie. Family hx: food allergies.

Prex Illness: Sinus infection (receiving Zithromax)

Prex Vax Illns:

Vaers Id: **341304-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	17-Feb-2009	17-Feb-2009	0	06-Mar-2009	10-Mar-2009	WA		23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus generalised

Symptom Text: Pt received #2 GARDASIL vaccine inj 2-17-09. 1st injection was given at another clinic. Pt called 2-25-09 & stated shortly after she got home felt an " all over itching sensation". Denied any rash on other sx. Pt stated the itching was mild, lasted one week & went away on its own.

Other Meds: WELLBUTRIN

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **341313-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Dec-2008	01-Dec-2008	0	09-Mar-2009	10-Mar-2009	FR	WAES0903CAN00012	10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness, Tremor

Symptom Text: Information has been received from a father concerning his 11 year old daughter who in December 2008, was vaccinated with the second dose of GARDASIL, lot # not available. In December 2008, the patient experienced trembling, blackouts and seizures. Upon internal review, seizures were considered to be an other important medical event. Additional information has been requested. This is one of several reports received from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341314-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		09-Mar-2009	10-Mar-2009	FR	WAES0903CAN00013	23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness, Tremor

Symptom Text: Information has been received from a consumer concerning a patient who was vaccinated with GARDASIL, lot # not available. Subsequently the patient experienced trembling, blackouts and seizures. Upon internal review, seizures were considered to be an other important medical event. No further information is available. This is one of several reports received from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 341315-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Mar-2008	06-Mar-2008	0	09-Mar-2009	10-Mar-2009	ID	WAES0803USA03327	23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MMR	MERCK & CO. INC.	NULL		Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0522U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a nurse, for the Pregnancy Registry for GARDASIL, concerning a 17 year old female who on 06-MAR-2008 was vaccinated IM, 0.5mL with a 1st dose of GARDASIL (lot# 657737/0522U). Secondary suspect therapy included MMRII (lot# and dose not reported). Other concomitant therapy included MENACTRA (lot# not reported). On an unspecified date the patient took a home pregnancy test. On 08-FEB-2008 the patient had an ultrasound and was positive for pregnancy (LMP approximately 29-SEP-2007, EDD 07-JUL-2008). The patient sought unspecified medical attention in the physician office. Additional information has been received from the nurse who stated that the patient's baby was fine. The baby originally spent three weeks in the NICU (neonatal intensive care unit) under bililights due to hereditary spherocytosis. The nurse stated that "this was not all due to the GARDASIL because it was a hereditary condition." Additional information has been requested.

Other Meds:

Lab Data: ultrasound, 02/08/08, posit; beta-human chorionic, posit

History:

Prex Illness: Pregnancy NOS (LMP = 9/29/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341316-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	09-Feb-2009	10-Feb-2009	1	09-Mar-2009	10-Mar-2009	FR	WAES0903USA00497	23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Malaise, Syncope

Symptom Text: Information has been received via a health authority concerning a 20 year old female who on 09-FEB-2009 was administered a dose of GARDASIL (batch number not reported) by intramuscular route (site not reported). It has been reported that on 10-FEB-2009 the patient presented with a syncope, general malaise and abdominal discomfort. The patient recovered from syncope on 10-FEB-2009 (the duration of the event has not been reported) and recovered from general malaise and abdominal discomfort on 11-FEB-2009. Patient recovered completely on 11-FEB-2009. Case reported as serious by the Health Authority with other medically important condition as criteria. No other information has been reported. Case is closed. Additional information is not expected. Other business partner numbers included E2009-01793 and ES-AGEMED-508747234.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341318-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Sep-2008	Unknown		09-Mar-2009	10-Mar-2009	AZ	WAES0903USA00423	23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a registered nurse, for the Pregnancy Registry for GARDASIL, concerning a 15 year old female who on 18-SEP-2008 was vaccinated IM with the first dose of GARDASIL 0.5 ml (Lot# 660557/0072X). There was no concomitant medication. After receiving the first dose of GARDASIL, the patient became pregnant and experienced a miscarriage. It was noted that the pregnancy was lost at 16-18 weeks gestation. Upon examination the fetus was found to have spinal bifida. The outcome of miscarriage was unknown. It was reported that the patient sought medical attention: seen by the practice. Upon internal review, the patient's miscarriage was considered an other important medical event. Spina Bifida is considered a congenital anomaly. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory, fetus had spinal bifida

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341319-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		09-Mar-2009	10-Mar-2009	FR	WAES0903USA00294	23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Demyelination

Symptom Text: Information has been received from a general practitioner concerning a female who on an unspecified date had received a dose of GARDASIL (route, site and lot number not reported). On an unspecified date the patient experienced demyelinating disorder for which she had been hospitalized on 27-MAY-2008. The neurologist was contacted but he did not find any patient corresponding to the reported information. At the time of reporting the outcome was not specified. To be noted the general practitioner did not want to further document the case. Demyelination was considered to be other important medical event. Other business partner numbers included: E2009-01758.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341334-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Feb-2009	09-Feb-2009	0	09-Mar-2009	10-Mar-2009	TN	TN09002	20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Body temperature increased, Injection site pain, Injection site swelling, Nausea, Neck pain

Symptom Text: Swelling at site of injection- Soreness at site L arm and up into L neck. Temperature elevation up to 102 degrees accompanied by some nausea.

Other Meds: ORTHOCYCLEN

Lab Data:

History: Febrile seizures as a child.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341342-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	26-Feb-2009	26-Feb-2009	0	09-Mar-2009	10-Mar-2009	OH		11-Mar-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0063X	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB258AA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2613AA	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2759AA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1398X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pallor, Somnolence, Syncope

Symptom Text: After 5th injection, pt. felt nauseated then proceeded to faint. Recovered after anonic inhalent used. Again c/o nausea, sleepiness. Was very pale and sleepy. Was able to walk to car approx 45 hours later.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341343-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	26-Feb-2009	26-Feb-2009	0	09-Mar-2009	10-Mar-2009	OH		13-Mar-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2613AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0063X	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2759AA	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB2J8AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Musculoskeletal stiffness, Pallor, Pulse pressure decreased, Staring, Syncope, Vomiting

Symptom Text: Immediately after 4th injection (HPV) Pt had stiffening of body, gluteral oral sound, fixed stare, then fainted. Vomited after recovery from faint. Was pale with faint pulse. After resting she recovered without incident.

Other Meds: None

Lab Data: None

History: Allergic :PCN "hives" per mom

Prex Illness: None

Prex Vax Illns: Syncope~HPV (no brand name)~1~11~In Sibling

Vaers Id: **341345-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Feb-2009	24-Feb-2009	1	09-Mar-2009	10-Mar-2009	CA		23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1537X		Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C3032AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0653X		Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2820AA		Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	U2837AA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Chest pain, Injection site erythema, Injection site swelling, Pain in extremity, Vomiting

Symptom Text: Left arm/chest area pain and redness and swelling at site of injection of VARIVAX. Vomited once yesterday morning. Today felt tightness in chest.

Other Meds:

Lab Data:

History: None

Prex Illness: No

Prex Vax Illns:

Vaers Id: **341366-1** **Related reports:** 341366-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Dec-2008	05-Feb-2009	50	09-Mar-2009	10-Mar-2009	FR	B0563425A	10-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	
	DT	GLAXOSMITHKLINE BIOLOGICALS	XC12B019C2		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Eosinophilia, Leukocytosis

Symptom Text: This case was reported by regulatory authority and described the occurrence of leukocytosis in a 14-year-old female patient who was vaccinated with DITANRIX adult (GlaxoSmithKline) and GARDASIL vaccine (non-GSK). On 17 December 2008 the patient received a single dose of DITANRIX adult (0.5 ml, unknown). From 14 January 2009 to 17 January 2009 the patient received IBUPROFEN for influenza symptoms. It was reported that on an unknown date "at the end of January" the patient experienced abdominal pain on the left iliac fossa and abdominal ultrasound revealed normal results. The patient was prescribed IBUPROFEN from 01 February 2009 to 04 February 2009. It was reported that "the family physician requested a test and changed the medication to BUSCAPINE". On 5 February 2009, approximately 50 days after vaccination with DITANRIX adult and GARDASIL, the patient experienced leukocytosis and eosinophilia. This case was assessed as medically serious by GSK. At the time of reporting the outcome of leukocytosis and eosinophilia were unknown. The outcome of abdominal pain was resolved. The regulatory authority considered the causal relationship between the events and the suspect drugs was "conditional".

Other Meds:

Lab Data: Eosinophils, 05Jan2009, 14000mm3; Eosinophils, 12Feb2009, 4000mm3; Lymphocyte count, 05Jan2009, 30900mm3; Lymphocyte count, 12Feb2009, 11000mm3; It was reported that on an unknown date at "the end of January" the patient experienced abdomin

History: The patient had no previous allergies or parasitosis.

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **341366-2** **Related reports:** 341366-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Dec-2008	31-Jan-2009	45	09-Mar-2009	10-Mar-2009	FR	WAES0903USA00484	19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	
	DT	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain

Symptom Text: Initial information received on the 26-FEB-2009 by the Health Authority (reference number ES-AGEMED-918560244) regarding a 14 year old female who was vaccinated with GARDASIL (batch number not reported) by intramuscular route (site of administration not reported), 0.5ml, on 17-DEC-2008. On the same date, the patient also received a dose of DITANRIX (route unknown, site not reported). It was also reported that the patient had taken oral Ibuprofen (manufacturer unknown) to treat flu-like symptoms, from the 14-JAN-2009 until the 17-JAN-2009. By the end of January, the patient presented with abdominal pain in the left iliac fossa, the patient was attended in the emergency room where an abdominal sonogram was performed. Ibuprofen was prescribed from the 01-FEB-2009 until the 04-FEB-2009. The patient's general practician ordered some blood test and treatment with Ibuprofen was replaced with Buscapina, treatment start and end dates not reported. Test results for blood-tests on the 05-JAN-2009 were: Leukocytes 30900; Eosinophiles 14000 (48%), the rest of the biochemistry lab results were normal (hepatic, renal, amylase), the rest of hematologic series were normal. Abdominal pain had disappeared (date not reported). On the 12-FEB-2009 blood-test showed: Leukocytes: 11000, Eosinophiles 4000. No previous records of allergies or parasitosis. Case reported as serious by the Health Authority with other medically important condition as criteria. No further information has been received. Other business partner numbers include E2009-01825.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 05Jan09, the rest of hematologic series were normal; WBC count, 05Jan09, 30900; blood chemistry, 05Jan09, normal: hepatic, renal, amylase; eosinophil count, 05Jan09, 14000, 48%; WBC count, 12Feb09, 11000; eosinop

History:

Prex Illness: Flu syndrome

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341380-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
30.0	F	02-Feb-2009	02-Feb-2009	0	09-Mar-2009	10-Mar-2009	FR	WAES0903USA00492	13-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	
	DT	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypotonic-hyporesponsive episode, Inappropriate schedule of drug administration

Symptom Text: Information has been received via a health authority concerning a 30 year old female who on 02-FEB-2009 was administered a dose of GARDASIL (batch number not reported) by intramuscular route (site not reported). The patient received concomitantly, a dose of DITANRIX (batch number not reported) by intramuscular route (site of administration not reported). It has been reported that on 02-FEB-2009, the same day of vaccination, the patient presented with a hypotonic-hypoactive reaction. The patient recovered on the same day, 02-FEB-2009 (the duration of the event has not been reported) without problems. The patient reported before vaccination that she was afraid of vaccines and presented anxiety about being vaccinated. Case reported as serious by the health authority with other medically important condition as criteria. No other information has been reported. Case is closed. Additional information is not expected. Other business partner numbers include E2009-01818 and ES-AGEMED-330827440.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Anxiety

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341400-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		10-Mar-2009	11-Mar-2009	--	WAES0903USA00787	26-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Syncope

Symptom Text: Information has been received from a certified nurse midwife concerning a female who was vaccinated with a dose of GARDASIL. On an unspecified date, after receiving GARDASIL, the patient developed seizures and fainted. On an unspecified date, the patient recovered from seizures and fainted. The patient sought unspecified medical attention. Upon internal review, seizures was determined to be an other important event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **341402-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	12-Jul-2007	01-Nov-2008	478	10-Mar-2009	11-Mar-2009	FR	WAES0903USA00496	26-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1339F	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT No reaction on previous exposure to drug, Thrombocytopenia

Symptom Text: Information has been received from a physician via a health authority under the reference number PEI2009003298 concerning a 19 year old female who on 12-JUL-2007 was vaccinated with the first dose of GARDASIL (lot # 1339F, batch # NF23310). On 14-SEP-2007 the patient was vaccinated with the second dose of GARDASIL (lot # 0233U, batch # NF46760). The first dose and the second dose were well tolerated. On 14-JAN-2008 the patient was vaccinated with the third dose of GARDASIL (lot # 0483U, batch # NG20170) into the left upper arm. In November 2008, thrombocytopenia was diagnosed. No information regarding the patient's history, symptoms and exact lab values was given. The event was considered as life-threatening by the reporter and the patient was admitted to hospital. At the time of reporting, the patient was not yet recovered. Lot checks have been requested. Other business partner number included E200901801.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **341403-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		10-Mar-2009	11-Mar-2009	FR	WAES0903USA00469	26-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rheumatoid arthritis

Symptom Text: Information has been received from a specialist concerning a 20 year old female with Crohn's disease treated with tumor necrosis factor inhibitors and methotrexate who was vaccinated with the first dose of GARDASIL (batch # not reported) on an unspecified date. On an unspecified timeframe the patient presented with polyarthritis rheumatoid. At the time of reporting the outcome was not mentioned. The patient's polyarthritis rheumatoid was considered to be an other important medical event. Other business partner numbers include E2009-01834. Additional information has been requested.

Other Meds: methotrexate

Lab Data: Unknown

History:

Prex Illness: CROHN's disease

Prex Vax Illns:

Vaers Id: **341419-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Aug-2008	Unknown		10-Mar-2009	12-Mar-2009	NH		24-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abasia, Disturbance in attention, Headache, Insomnia, Syncope, Vaccine positive rechallenge, Visual acuity reduced

Symptom Text: 8/1/08- 1st shot- fainting began, headaches. 10/2/08-2nd shot- fainting + headaches continue inability to sleep or concentrate, inability to see or have use of her legs during fainting, sensitive nerves.

Other Meds: None

Lab Data: MRI; EEG; Heart monitor; Blood work.

History: Asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341422-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-Mar-2009	04-Mar-2009	0	10-Mar-2009	12-Mar-2009	WV		27-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2688AA	0	Left arm	Unknown	
	TDAP	SANOFI PASTEUR	C2768BA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1311X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure increased, Dyskinesia, Immediate post-injection reaction, Loss of consciousness

Symptom Text: Within 5 minutes after vaccination child passed out, jerking motions of extremities were noted. B/P elevated to 158/98. Recovered quickly. Referred to her family physician.

Other Meds: unknown

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341424-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Oct-2008	19-Nov-2008	22	10-Mar-2009	12-Mar-2009	NC		31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	2	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Back pain, Condition aggravated, Dizziness, Dyskinesia, Hyperreflexia, Tic

Symptom Text: Pt has a history of tic disorder in January 2009-exacerbation of tics. Parent concerned - poss. R/T GARDASIL administration. Persistent exacerbation with ER visit - X 1 hosp. 3/25/09 MR received for o/n admission for eval of increased tics, weakness, back pain and dizziness x 2-3 months in a pt with known Tourette's syndrome. Pt had been able to control tics until ~ 2-3 months ago. Pt received 3rd Gardasil 3 months ago. PE (+) for jerking of trunk and upper extremity approx every 15-30 seconds. Upper extremity DTRs hyperreflexive. Neuro consult with non-focal exam. Will try Haldol tx as out pt.

Other Meds: LEXAPRO; NEXIUM

Lab Data: Labs: CBC WNL. Chem WNL. Drug screen (-).

History: PMH: Tourrette's syndrome. GERD. Depression. Allergy to Geodon

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341425-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Oct-2008	22-Oct-2008	0	10-Mar-2009	11-Mar-2009	CA		15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Vaccine positive rechallenge

Symptom Text: Dizzy episode after 1st GARDASIL 8/18/08. Dizzy episode after 2nd GARDASIL 10/22/08. See attached.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341431-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	02-Mar-2009	Unknown		10-Mar-2009	11-Mar-2009	OR		01-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2821AA	0	Unknown	Unknown	
	TDAP	SANOFI PASTEUR	UF452AA	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1311X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pain, Pruritus, Swelling

Symptom Text: Painful red and swollen x 4 days; better today but continues and now itchy. Used ice and Motrin.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341433-1** **Related reports:** 341433-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	29-Jan-2009	03-Mar-2009	33	10-Mar-2009	12-Mar-2009	--		24-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pityriasis rosea, Tinea infection

Symptom Text: Around February of this year my daughter came up with a few ringworm's on her stomach and thigh. I bought the over-the-counter medication and was applying it 3 times a day to no avail then approximately three weeks after the initial outbreak she started getting more all over her stomach back and legs the other areas originally infected were not healing at all. I took her to our doctor and he diagnosed her with pityriasis rosea and has since put her on a steroid dose pack.. when I learned what it was I started doing some research to try and figure out how she had contracted the virus...then I read that it is possibly caused by a papilloma virus and that got me wondering if this also could be a side effect to the GARDASIL shot...my daughter got the 3rd GARDASIL shot 1/29/09 and the first hearld patch appeared less that a week later however I did not attribute it to the shot until I started doing some research... Could someone please let me know if this is a possible side effect that has just not been listed yet... I find it odd that she gets this virus, one I have never heard of before shortly after the injection...thank you

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341433-2** **Related reports:** 341433-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	29-Jan-2009	05-Feb-2009	7	28-Apr-2009	06-May-2009	AL		06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pityriasis rosea

Symptom Text: Approximately 1 week after my daughter had her GARDASIL vaccination she broke out into what I though was ringworm- after weeks of battling the ringworm's with OTC meds. I took her back to her Doctor who diagnosed her with pityriasis rosea - They put her on a Medrol dos Pak they cleared up some but then came back worse they put her on Prednisone saw 3 months later she still has it.

Other Meds: None

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **341458-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Feb-2009	23-Feb-2009	0	10-Mar-2009	11-Mar-2009	PR	PR-09-04	11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2318AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Pallor

Symptom Text: PATIENT REFERS DIZZINESS, PERSPIRATION AND PALENESS.LASTED FOR 20 MINUTES. RECOVERED AFTER LAYING DOWN.

Other Meds: NONE

Lab Data: NONE

History:

Prex Illness: NONE

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341462-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Feb-2009	09-Feb-2009	-8	10-Mar-2009	11-Mar-2009	PA		02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3068AA	0	Right leg	Intramuscular	
	MNQ	SANOFI PASTEUR	U2668AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1129X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Diet refusal, Fatigue, Headache, Lip swelling, Muscle strain, Myalgia, Oedema mouth, Pruritus, Urticaria

Symptom Text: After getting the gardasil vaccine three weeks ago, my daughter has severe back pain, general muscle aches, fatigue and terrible headaches. She also had swelling of her mouth and lips. I am very concerned about her back problem because it is very unusual and the doctor really doesn't know what is wrong. These symptoms didn't occur until after her first dose of gardasil. SHE WILL NOT BE RECEIVING THE LAST TWO DOSES OF THE DRUG! 4/1/09-records received-office visit 2/2/09-C/O hives rash on body since 2/7/09, itchy and red-seen in ED started on prednisone. assessment:dermatitis secondary to PCN. 2/17/09 office visit C/O bad headaches every couple of days. Not eating for one week but drinking soda and caffeine. Fatigue. Assessment possible eating diorder possible cause of headaches suspect underlying mood disorder. Received Gardasil/Adacel Menactra. Referred to eating disorder clinic. Office visit 3/2/09-C/O inflammation in upper back with pain began day before and is a recurrent porblem however first time seen for the problem. Assessment muscle sprain likely secondary to month of coughing. 3/10/09-requests referral to specialist. Office visit 3/17/09 C/O hives and persistent back pain.

Other Meds:

Lab Data: Currently being treated by Dr. at our family physician's office.

History: none 4/1/09-records received-Allergies:amoxicillin.

Prex Illness: none 4/1/09-records received-Began 2 months ago followed by cough, runny nose, sore throat.

Prex Vax Illns: none~ ()~~0~Patient|none~ ()~~0~Sibling|none~ ()~~0~Sibling

Vaers Id: **341476-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Feb-2009	18-Feb-2009	0	10-Mar-2009	11-Mar-2009	WA		11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anorexia, Dizziness, Skin discolouration, Vertigo

Symptom Text: Pt felt dizzy a few minutes after HPV vaccine. Pt also felt her L arm turning different color. Pt has not eaten whole day prior to vaccination. Pt given food & water & instructed to lie down until vertigo resolved. No change in color between arms noted by myself.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **341478-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	20-Sep-2008	02-Oct-2008	12	10-Mar-2009	11-Mar-2009	CA		11-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	000000	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Foetal disorder, Pregnancy

Symptom Text: I received my first and only dose of Gardasil in late September, I beleive it was the 20th. I found out in October that I was pregnant. My due date based on ultrasound was June 25, 2009 making the date of conception around October 2, 2008- after I received the vaccine. In January, the baby was diagnosed with Trisomy 18. He did not survive.

Other Meds: Multi Vitamin

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 341495-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Apr-2008	30-Apr-2008	0	11-Mar-2009	12-Mar-2009	FR	WAES0903USA00870	26-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Central nervous system inflammation, Incorrect route of drug administration, Visual acuity reduced

Symptom Text: Information has been received from the health authorities (reference numbers LL20090063 and LL0900064) concerning a 17 year old female patient with no relevant medical history who on 07-FEB-2008 was vaccinated with the first dose of GARDASIL (lot number, site and route not reported). On 30-APR-2008, the patient received the second dose of GARDASIL (lot number and site not reported) via an inappropriate route i.e. subcutaneous route instead of intramuscular route. On 05-OCT-2008 the patient presented with right visual acuity decreased. After work-up (clinical examination, MRI, no lumbar puncture because the patient refused it) diagnosis was first inflammatory event of central nervous system (or clinically isolated syndrome). There was a 100 percent recuperation after a bolus of Solumedrol 3 g. There was hospitalization (unspecified dates). The patient was vaccinated with a third dose of GARDASIL (lot number, site and route not reported) on 10-OCT-2008. Evolution: 3 months control MRI showed 2 new lesions without any gadolinium contrast uptake. There was no diagnosis of multiple sclerosis in this case due to the absence of temporal dissemination. At time of reporting the patient had not recovered from inflammation of central nervous system. The Health Authorities assessed the causal relationship between the reported reaction(s) and vaccination was "doubtful" (C1 S1 L1) according to the foreign method of assessment. Other business partner numbers included: E2009-01933. Additional information has been requested.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, 05?Oct08, diagnose was first inflammatory event of central nervous system; Magnetic resonance imaging, two new lesions without any gadolinium contrast uptake

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **341502-1** **Related reports:** 341502-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Feb-2009	18-Feb-2009	0	11-Mar-2009	12-Mar-2009	FR	B0563365A	12-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NJ00010		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Head injury, Syncope, Tonic clonic movements

Symptom Text: This case was reported by a regulatory authority (ES-AGEMED-630821440) and described the occurrence of syncope in a 12-year-old female subject who was vaccinated with TWINRIX pediatric (GlaxoSmithKline), GARDASIL (non-GSK). On 18 February 2009, the subject received unspecified dose of TWINRIX pediatric (intramuscular, unknown injection site), unspecified dose of GARDASIL (intramuscular, unknown injection site). On 18 February 2009, less than one day after vaccination with GARDASIL and TWINRIX pediatric, the subject experienced syncope followed by tonic clonic movements that lasted few seconds. The subject felt down with head trauma. The subject required observation during about two hours at emergency room. The regulatory authority reported that the events were clinically significant (or requiring intervention). On 18 February 2009, the events were resolved. The regulatory authority reported that the events were possibly related to vaccination with TWINRIX pediatric and GARDASIL. No further information is expected, this case has therefore been considered closed.

Other Meds:

Lab Data: UNK

History:

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **341502-2** **Related reports:** 341502-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	18-Feb-2009	18-Feb-2009	0	12-Mar-2009	13-Mar-2009	FR	WAES0903USA01010	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Syncope, Tonic clonic movements

Symptom Text: Initial information received on the 05-MAR-2009 by Health Authority (reference number ES-AGEMED-630821440) regarding an 11 year-old female who was administered on the 18-FEB-2009 a dose of a GARDASIL (lot# and batch# not reported) by intramuscular route (site not reported). On the same day the patient received a dose of TWINRIX (manufactured by GlaxoSmithKline) by intramuscular route (site not reported). In the report sent by the Health Authorities, syncope has been coded as adverse event with start/stop date on 18-FEB-2009. In the narratives it is reported that this syncope was accompanied with tonic-clonic movements, the patient fell and had a cranial traumatism. The events lasted for a few seconds. The patient remained in the emergency room under observation for a few hours. The patient recovered. Case reported as serious by the HA with other medically important condition as criteria. Other business partner numbers include: E2009-01972. Case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 341523-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	10-Mar-2009	10-Mar-2009	0	11-Mar-2009	13-Mar-2009	NY		16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2670AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Erythema, Oropharyngeal pain, Urticaria

Symptom Text: Given HPV & MENACTRA @ 08:30 AM Fever Pm - abd pain & facial hives - given BENADRYL - went ER @ 6 PM. Given IV steroids & BENADRYL - Home with ORAPRED & BENADRYL - face red & sore throat next AM 24 hr later.

Other Meds: No

Lab Data: Did strep which was Negative; CBC; MP; urine & mono

History: Allergy to milk & soy

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341531-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	15-Feb-2008	15-Feb-2008	0	11-Mar-2009	13-Mar-2009	WV		16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	170U	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Presyncope

Symptom Text: Vasovagal syncope- twice, oral fluids, juice remain supine Trendelenberg. She was treated in our facility.

Other Meds:

Lab Data:

History: None

Prex Illness: Respiratory Infection

Prex Vax Illns:

Vaers Id: 341554-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Aug-2007	01-Nov-2007	91	11-Mar-2009	17-Mar-2009	MN		24-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	09790	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Arthralgia, Asthenia, Back pain, Dizziness, Epicondylitis, Fatigue, Hypoaesthesia, Iliotibial band syndrome, Muscle spasms, Musculoskeletal pain, Nuclear magnetic resonance imaging, Pain, Paraesthesia, Vision blurred, Weight decreased

Symptom Text: October, 2007 - Back and Hip pain Winter, 2007/08 - addition of shoulder and elbow pain, ankle pain and weakness, increase in back and hip pain - medicated with Advil/Tylenol (OTC) March, 2008 - addition of tingling and numbness in arms and legs. Shooting pains in arms and legs. Extreme exhaustion and fatigue June, 2008 - Treated with Physical Therapy and Mobic/Advil. Had MRI of Lumbar spine on 7/07/08 August, 2008 - extreme pain when running. All of the earlier symptoms were still present. Intense muscles cramps in legs and arms, especially at night. Addition of muscle cramps in hands when writing or playing piano for a very short time (10 minutes). September, 2008 - All symptoms remain. Addition of hair loss, weight loss, increase in fatigue. blurry vision. lightheadedness, dizziness 3/19/09 records received-office visit 7/1/08-multiple complaints over sometimes, Active in gymnastics, somewhat knock-kneed. C/O left hip popping in and out with activity appears to be iliotibial band phenomena. Right knee and kneecap popping in and out with activity and some tightness in tendons in back with activity. Right elbow complaints with activity. Spot on left forearm been there a few months, looks like possible pencil lead in skin. Assessment: hip problem suspect iliotibial band. Knee problem looks like patellar malalignment. Elbow problem looks like tennis elbow phenomena. Referral to sports medicine. office visit 3/16/09- No complaints.

Other Meds: none

Lab Data: calcium ionized, CPK, total, gammaglobulin, lyme disease AB, Tissue transglutamin, Gliadin Antibody, 25-OH Vitamin D3, ANA Cascade, HLA B27, calcium, Free T4, MAgnesium, potassium, phosphorous, CRP, TSH, Hemogram - WBC, RBC, hemoglobin, hem

History: none 3/19/09-records received-environmental allergies.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **341576-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	14-Jul-2008	09-Aug-2008	26	11-Mar-2009	13-Mar-2009	GA		01-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1984U	2	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Balance disorder, Cerebellar ataxia, Choking, Confusional state, Cough, Dizziness, Dysarthria, Encephalitis viral, Gait disturbance, Headache, Neurological symptom, Tremor, Urinary tract infection

Symptom Text: 8-19-08 Slurred speech. 8-13-08 Equallibrium off. 3/18/09-records received for DOS 8/21-8/25/08-DC DX: Viral encephalitis. In ED C/O dizziness, slurred speech times 2 weeks and left arm tremor times 1 week. Presented with some initial neurolgoical changes including confusion and broad based gait, severe headache. Confusion was with slurring speech, arm tremors. 4/16/09-neuro letter received for DOS 9/29/08-evaluation of gait-Beginning 8/9/06 after C/O urinary tract infection and receiving tetanus boost and Z-pak C/O feeling dizzy and swaying gait. 3rd dose of Gardasil received on 7/14/08. Week later slurring of speech worse with fatigue, week later follwed with tremor. All symptoms progressed until hospitalization 8/22/08. Continues to fall when feeling thirsty. Coughs and chokes with liquids. Impression: cerebellar ataxia.

Other Meds:

Lab Data: 3/18/09-records received- MRI of head negative. Spinal tap showing elevated leukocytes, mostly lymphocytes but all other tests negative. All cultures negative, gram stains negative. past Epstein-Barr virus positive 4/16/09-records received

History: Penicillin; LORTAB 3/18/09-records received-Allergic to Penicillin V Potassium-itch.

Prex Illness: UTI, culture, negative 3/18/09-records received-Right inner ear infection/fluid 2 weeks ago.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341590-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	05-Dec-2008	10-Dec-2008	5	12-Mar-2009	13-Mar-2009	FR	WAES0903USA01007	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Myasthenia gravis, Thymus enlargement

Symptom Text: Initial information received on the 05-MAR-2009 by Health Authority (reference number ES-AGEMED-93082440) regarding an 11 year-old female who was administered on the 05-DEC-2008 a dose of a GARDASIL (lot# and batch# not reported) by intramuscular route (site of administration not reported). It is reported that 6 days after vaccination, on the 10-DEC-2008 the patient presented a myasthenia gravis. It is reported in the narratives of the report sent by Health Authorities but it hasn't been coded in the report, that the adverse event involves acetylcholine anti-receptors and enlarged thymus (start/stop dates have not been reported). It is reported that the patient was hospital admitted but admission and discharge dates have not been reported. Outcome is unknown. No further information reported. Other business partner numbers include: E2009-01971.

Other Meds: Unknown

Lab Data: Acetylcholine receptor antibody test, antiacetycholine receptor antibody positive

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341606-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Mar-2009	08-Mar-2009	4	12-Mar-2009	16-Mar-2009	OH		16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	
	VARCEL	MERCK & CO. INC.	1533X	1	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Rash pruritic

Symptom Text: Patient began noticing rash on chest, spreading to arms, flanks & legs. Reports that rash does itch. Patient also stated that she has been utilizing tanning bed 03-01-09.

Other Meds: ALEVE qd - has taken for approximately 2 wks.

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341609-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	05-Mar-2009	06-Mar-2009	1	12-Mar-2009	16-Mar-2009	WI		20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	2	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2553AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Father reports his daughter has had fever, up to 102.4, this morning. Ibuprofen takes fever down to 101.2.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **341610-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Feb-2009	25-Feb-2009	0	12-Mar-2009	16-Mar-2009	NJ		16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site swelling, Injection site warmth

Symptom Text: Rt arm red, swollen, firm, hot @ area of injection site for 48h after receiving Meningitis vaccine.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **341628-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	Unknown	Unknown		12-Mar-2009	17-Mar-2009	IN		17-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Skin papilloma, Visual field defect

Symptom Text: I never had any types of warts. After the gardasil injections, I got a filiform wart on my eyebrow that had to be removed because it affected my visual field.

Other Meds: Synthroid, Prilosec, Wellbutrin, Deplin, Singulair, Paxil, Tofranial

Lab Data:

History: Asthma, chronic sinusitis, anemia, depression, hypothyroidism, GERD

Prex Illness:

Prex Vax Illns:

Vaers Id: **341638-1 (S)** **Related reports:** 341638-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	10-Sep-2008	10-Oct-2008	30	12-Mar-2009	13-Mar-2009	VT		25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2661AA	0	Right arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Polyuria, Thirst, Type 1 diabetes mellitus, Vision blurred, Visual acuity tests normal, Weight decreased

Symptom Text: Mom is requesting VAERS done...one month after receiving MENACTRA & 1st GARDASIL on 9/10/08, Pt had blurred vision. 3 months later diagnosed with Type 1 Diabetes. 3/16/09 MR received from PCP including endocrine consult. Seen for !# yr WCC 9/10/08. Assessment: healthy. PE WNL. Vax given. Seen by ophth for intermittant blurry vision with visual acuity OK. Seen 1/29/09 with c/o onset excessive thirst, recent weight loss and increased UO. Reports feeling tired. Dx: New onset Diabetes Type I after labs. Referred to endocrine. Dx: IDDM.

Other Meds: None

Lab Data: Labs: Fasting glucose 247. UA (+) for glucose and mod ketones. Hgb A1C 11.1%.

History: None. PMH: acne.

Prex Illness: None noted

Prex Vax Illns:

Vaers Id: **341638-2 (S)** **Related reports:** 341638-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	10-Sep-2008	10-Oct-2008	30	27-Apr-2009	28-Apr-2009	--	WAES0904USA01469	28-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2661AA	0	Right arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Fatigue, Thirst, Type 1 diabetes mellitus, Urine output increased, Vision blurred, Weight decreased

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. On 10-SEP-2008 a 13 year old female patient with acne was vaccinated with the first dose of GARDASIL (Lot # 659184/0843X) intramuscularly into her left arm. Concomitant therapy on the same date included MENACTRA (Lot # U2661AA) (Sanofi Pasteur) intramuscularly into her right arm. Mom was requesting VAERS done one month after receiving MENACTRA and the first dose of GARDASIL on 10-SEP-2008. The patient had blurred vision. Three months later was diagnosed with type 1 diabetes. On 16-MAR-2009 a Magnetic Resonance was received from the primary care provider including endocrine consult. On 10-SEP-2008 the patient was seen for WCC (well child check up). The assessment: the patient was healthy; physical examination was within normal limits after the vaccines were given. The patient was seen by an ophthalmologist for intermittent blurry vision with visual acuity OK. On 29-JAN-2009 the patient was seen with complain of onset excessive thirst, recent weight loss and increased urinary output. It was reported that the patient was feeling tired. The patient was diagnosed with new onset diabetes type 1 after laboratories performed. The patient was referred to endocrine and was diagnosed with Insulin-Dependent Diabetes Mellitus (IDDM). A fasting glucose was performed: 247, Urinalysis (+) for glucose and mod ketones. Hgb A1C 11.1%. Standard lot check investigations were performed on lot # 659184/0843X. All in-process quality checks for the lot numbers in question were satisfactory. In addition, expanded lot check investigations were performed. The testing performed on the batches prior to release met all release specifications. The lots met the requirements of the research center and were released. The original reporting source was not provided. The VAERS ID # is 341638. No further information is available.

Other Meds:

Lab Data: fasting serum glucose, 247; urinalysis, positive for glucose; urinalysis, positive for mod ketones; serum hemoglobin test, 11.1%, A1C

History:

Prex Illness: Acne

Prex Vax Illns:

Vaers Id: **341650-1** **Related reports:** 341650-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	05-Mar-2009	06-Mar-2009	1	12-Mar-2009	16-Mar-2009	OH		24-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	9725103	2	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	C3070AA	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Axillary pain, Headache, Hypoaesthesia, Myalgia, Pain, Paraesthesia, Syncope, Tachycardia, Vertigo

Symptom Text: Headache, vertigo, tingling in arms, pain both axilla. 3/17/09-records received for EDvisit 3/6/09-C/O headache two epidsodes of syncope and body aches. Numbness in bilateral arms earlier that resolved and now feels weak all over. Subjective fevers. PE: tachycardic at 127, afebrile.Impression: Headache and myalgias status post vaccines, improved.

Other Meds:

Lab Data: None 3/17/09-records received- EKG normal.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **341650-2 (S)** **Related reports:** 341650-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	05-Mar-2009	06-Mar-2009	1	25-Mar-2009	26-Mar-2009	OH	WAES0903USA03657	26-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1702X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Asthenia, Dizziness, Headache, Pain, Paraesthesia

Symptom Text: Information has been received from a registered nurse (R.N.) concerning a 20 year old female with allergies to BENADRYL and BACTRIM who on 18-AUG-2008, 24-NOV-2008 and 05-MAR-2009 was vaccinated with a first, second and third dose of GARDASIL (lot # 1702X, 0.5 ml, IM into the left arm for dose 3), respectively. Concomitant therapy given on 05-MAR-2009 included ADACEL. On 06-MAR-2009 after receiving her third dose, the patient experienced dizziness, headache, weakness, pain and tingling in both arms. The patient sought medical attention via phone call to the physician's office. The patient was treated in the emergency room with IV fluids, COMPAZINE and TORADOL, and then released. The patient's heart rate in the emergency room was 124. An electrocardiogram (EKG) was performed with results within normal limits. As of 19-MAR-2009, the patient's symptoms have improved but she continued to have arm pain. The reporter considered the adverse events to be disabling. Additional information has been requested.

Other Meds:

Lab Data: electrocardiogram, within normal limits

History:

Prex Illness: Drug hypersensitivity; Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341652-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
4.0	F	01-Dec-2008	01-Dec-2008	0	12-Mar-2009	16-Mar-2009	NM		20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC526030AA		Right arm	Unknown	
	HEPA	MERCK & CO. INC.	AHAVB257AA		Right arm	Unknown	
	HPV4	MERCK & CO. INC.	1968U		Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Chills, Inappropriate schedule of drug administration, Injection site pain, Pyrexia

Symptom Text: One hour after injection c/o severe pain Lt arm-fever that afternoon - temp not checked -Fever with chills - Left school next day because of temp.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **341658-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	19-Oct-2007	19-Oct-2007	0	12-Mar-2009	16-Mar-2009	IA		20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Muscular weakness, Nausea, Pallor, Vomiting

Symptom Text: Within Minutes of receiving HPV vaccines, became light headed pale, nauseated, weak, vomited, had muscle weakness until next day. Mother refused to let patient have 3rd dose but never informed us of above until today, 3-10-09.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns:

Vaers Id: **341688-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Dec-2007	12-Dec-2007	0	13-Mar-2009	16-Mar-2009	--	WAES0802USA00806	16-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Failed induction of labour

Symptom Text: Information has been received from the mother concerning her 16 year old daughter with no medical history and no allergies reported, who on an unspecified date was vaccinated with the first dose of GARDASIL. On 12-DEC-2007, the patient was vaccinated with her second dose of GARDASIL, 0.5 ml. Concomitant therapy included prenatal vitamins. On 28-DEC-2007, the patient found out she was pregnant. Her last menstrual period (LMP) was on 06-DEC-2007 ("8 weeks 5 days" ago). The patient sought medical attention. On an unspecified date, the patient had blood work performed (unspecified). Her estimated date of delivery is 11-SEP-2008. The third dose of GARDASIL was not administered. Follow-up information was received on 09-MAR-2009 from a female at a pediatrician's office, who reported that on 16-SEP-2008 the patient delivered a healthy normal, female, who weighed 10 lbs 1 oz, by cesarean section for a failed induction of labor at 41 weeks gestation. It was noted that the patient had a maternal pregnancy weight gain of 60 lb. The patient brought her baby to the physician's office. The physician said the baby was "fine and well-no problems". It was reported that the patient had recovered from the c-section on an unspecified date and was "doing well also". Upon internal review, cesarean section was determined to be an other important medical event. No further information is available.

Other Meds: vitamins (unspecified)

Lab Data: hematology, blood work

History:

Prex Illness: Pregnancy NOS (LMP = 12/6/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341689-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	04-Mar-2008	04-Mar-2008	0	13-Mar-2009	16-Mar-2009	UT	WAES0804USA04091	30-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Failed induction of labour

Symptom Text: Information has been received from a medical assistant for the pregnancy registry for GARDASIL concerning a 15 year old female patient with type 1 diabetes mellitus and sulfonamide allergy who on 04-MAR-2008 was vaccinated IM in the right arm with the first 0.5 ml dose of GARDASIL (659182/1757U). Concomitant therapy included MENACTRA and insulin. The patient received her first dose of vaccine when she was pregnant. The physician did a vaginal exam (unspecified date) which found that the patient had a 16-18 week uterus size with a LMP of 07-DEC-2007, and an estimated delivery date of 12-SEP-2008. Unknown medical attention was sought in the office. Patient outcome was unknown. No product quality complaint was involved. Follow up information has been received from a certified medical assistant on 09-MAR-2009. It was reported that the patient delivered a healthy, normal male, a "few weeks early". The patient had an induction of labor secondary to her history of preexisting insulin-dependent diabetes. The induction failed and she had a cesarean section. The baby weighed a little over 7 lbs. The reporter said the mother recovered "fine" and the baby was released for adoption, so they have no further information on the baby beyond this. Upon internal review, induction of labor that failed was determined to be an other important medical event. Additional information is not expected.

Other Meds: Insulin

Lab Data: urine beta-human, 04/17/08, posit

History:

Prex Illness: Pregnancy NOS (LMP = 12/7/2007); Type 1 diabetes mellitus; Sulfonamide allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341741-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	27-Dec-2008	28-Dec-2008	1	13-Mar-2009	17-Mar-2009	OH		17-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site vesicles

Symptom Text: Rash of small blisters in a circular pattern around the injection site approximately 2 inches in diameter.-not sure if exact vaccination date is correct

Other Meds: ventolin inhaler

Lab Data:

History: Allergy to aleve and contact solution preservative.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 341745-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Feb-2009	14-Mar-2009	24	14-Mar-2009	16-Mar-2009	KS		01-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	2	Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain upper, Arthralgia, Contusion, Convulsion, Dizziness, Fatigue, Headache, Hypoglycaemia, Malaise, Muscle tightness, Myalgia, Nausea, Pain in extremity, Phonophobia, Photophobia, Presyncope, Respiratory tract congestion, Sensation of heaviness, Sinusitis, Syncope, Vertigo, Vision blurred, Visual impairment

Symptom Text: dizziness and seizures. 4/16/09 MR received from PCP from 2/18/09 to 4/13/09. Pt presented on 2/18/09 for 3rd Gardasil vaccine 1757U. RTO for f/u for recent grand mal seizure on 3/14/09, as well as c/o fatigue, stomach pain and dizziness. Pt also reports blurry vision and heaviness all over. PE (+) for bruising L shin. DX: Syncope and collapse. Very likely combination of hypoglycemia and vasovagal response. Syncopla episode with seizure-like activity. Returns 3/26/09 with continued c/o dizziness, H/A, arm heaviness and sharp pains, some congestion. PE (+) for vertigo with extraocular testing. DX: Syncope and collapse. Malaise and fatigue. H/A. Sinusitis-chronic. EEG and labs ordered. F/U 4/13/09 with c/o severe H/A which comes and goes x 3 days with photophobia and phonphobia, mild nausea, seeing spots prior to H/A and other visual disturbances. PE (+) for H/A and joint pain. MUscle tightness and tenderness of bilat pericervical and upper perithoracic tissues. To see chiropractor.

Other Meds:

Lab Data: Labs and Diagnostics: Head CT (+) for paranasal sinus mucosal disease, otherwise WNL. EEG WNL-except symmetric driving response for photic stim-possible migraine?. ECG WNL.

History: none. PMH: Asthma. Trigger finger release

Prex Illness: none

Prex Vax Illns:

Vaers Id: **341746-1 (S)** **Related reports:** 341746-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	12-Feb-2009	13-Feb-2009	1	15-Mar-2009	16-Mar-2009	VA		30-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Asthenia, Constipation, Convulsion, Decreased appetite, Dizziness, Ear pain, Encephalitis, Eye pain, Hallucination, Headache, Herpes virus infection, Meningitis viral, Migraine, Nausea, Neck pain, Night sweats, Pain, Phonophobia, Photophobia, Photopsia, Pyrexia, Rhinitis, Tinnitus, Tongue biting, Toothache, Vision blurred, Vomiting

Symptom Text: encephalitis 24 h after guardasil vaccination. Right temporal-occipital T2 flair on MRI with negative HSV PCR. 3/26/09 Received hospital medical records of 2/17-19/2009 & 3/2-3/17/2009 & GYN & Neuro clinic records. 2/17-2/19/2009 FINAL DX: Seizure & Migraine headache Records reveal patient experienced bifrontal HA w/neck pain, dizziness, photophobia, phonophobia, nausea, vomiting, flashing lights x 4-5 days. Was traveling to ER when had seizure & possible tongue biting. CT scan in outlying ER was neg & d/x to home w/outpatient neuro f/u. Now admitted, tx w/pain meds, antiseizure meds & anatinausea meds 3/2-3/17/2009 FINAL DX: presumptive herpes simplex virus meningitis Records reveal patient experienced intractable HA, stiff neck, retrobulbar eye pain, blurry vision, ear pain, teeth pain, tinnitus, N/V, decreased appetite, coryza, constipation, generalized weakness & vision flashes since 2/16, seen multiple times in ER & 1 admission for same. Had been tx inbetween with steroid taper w/temporary improvement. Several days prior to this admit developed fevers, night sweats, hallucination single episode & was essentially bedbound due to worsening pain when standing. Neurosurg, Neuro & ID consult done. Tx w/IV antibiotics, pain meds, IV caffeine, antinausea meds & antivirals. Improved slowly & was able to ambulate w/o HA & d/c to home on continued oral antiviral meds & to return for repeat MRI. GYN Clinic 2/12/2009 FINAL DX: HPV #1 administered, no Lot #s available. Neuro CLinic 2/23/09 FINAL DX: persistent migraine HA Tx w/steroid taper, IV antihistamine/antinausea meds & was instructed to return as scheduled.

Other Meds:

Lab Data: HSV PCR (-) Right temporal-occipital T2 flair on MRI LABS: Pap smear c/w HGSIL. Vag c/s (+)candida. Abdominal x-ray, CXR, MRA, spinal MRI, pelvic US, bilat LE doppler, EEG WNL. MRI head/neck c/w infectious meningoencephalitis. Blood

History: PMH: HA, TMJ, factor V Leiden deficiency, GERD, asthma, nonallergic rhinitis, abnormal Pap smear, CIN 1, smoker, s/p c-section delivery x 2 yrs prior. Family hx: asthma, DVTs, factor V Leiden heterozygous, MI, colon cancer.

Prex Illness:

Prex Vax Illns:

Vaers Id: **341746-2 (S)** **Related reports:** 341746-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	12-Feb-2009	16-Feb-2009	4	15-Apr-2009	16-Apr-2009	--	WAES0904USA00865	23-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Brain oedema, Convulsion, Headache, Pyrexia, Syncope

Symptom Text: Information has been received from a consumer concerning her daughter, a 20 year old female patient with no drug reactions or allergies and a history of factor V, who on 12-FEB-2009 was vaccinated with her first dose of GARDASIL (lot number, site and route not reported). Concomitant therapy included Albuterol. During the vaccination week, the patient experienced terrible headaches. On Monday 16-FEB-2009, the patient was taken to the hospital because she had fainting spells, seizures, fever and also had swelling of the brain once at the hospital. The brain biopsy, magnetic resonance imaging and blood work was performed with no result reported. She was hospitalized for three weeks and still was not recovered. Additional information has been requested.

Other Meds: Albuterol

Lab Data: brain biopsy, 02/16/09, no result reported; magnetic resonance, 02/16/09, no result reported; diagnostic laboratory, 02/16/09, blood work (no result reported)

History: Factor V deficiency

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341749-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	02-Feb-2009	07-Mar-2009	33	15-Mar-2009	17-Mar-2009	TN		17-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Back pain, Erythema, Muscle spasms, Nausea, Pityriasis, Rash macular

Symptom Text: After recieving first round of Gardasil shot- three weeks later noted small red spoches on chest area(Sat AM), Sun day felt weak, back cramps, and nausea. Mon AM and continuing- red spots darken and increased in number. Doctor diagnosed as pityriasis. Have found other forums where pityriasis is connected with the vaccine. Within one week of three spots- the rash has spread throughout entire chest, back, neck and now starting to form on arms and legs. Doctor claims unknown cause or cure.

Other Meds: genertic yaz (birth control pills)

Lab Data: pityriasis

History: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341752-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	09-Mar-2009	09-Mar-2009	0	13-Mar-2009	18-Mar-2009	CT		03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2825AA	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0651X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site induration

Symptom Text: 5 x7 cm induration approx 12 hrs after injected. No fever, HA respiratory symptoms, G1 symptoms.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341798-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		16-Mar-2009	17-Mar-2009	FR	WAES0810USA05028	17-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician from local health authorities in foreign country through the Sanofi Pasteur MDS GARDASIL on 23-OCT-2008. The case is not enrolled in the registry (patient's initials unknown). A 17 year old female patient received the first dose of GARDASIL (batch number not reported) on an unspecified date during the first trimester of her pregnancy. At the time of reporting the patient had no adverse effect. Follow up information received from the reporter by phone on 10-MAR-2009: Case upgraded to serious by the company. The patient requested a voluntary termination of pregnancy. The case is closed. Upon internal review, voluntary termination of pregnancy was determined to be an other important medical event. Other business partner numbers included: E2008-09930.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341799-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	22-Jul-2008	24-Jul-2008	2	16-Mar-2009	17-Mar-2009	FR	WAES0903USA01480	17-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Cough, Dyspnoea, Facial palsy, General physical health deterioration, Infection, Lividity, Loss of consciousness, Nasopharyngitis

Symptom Text: Case received from a healthcare professional on 05-MAR-2009. It was reported by a gynecologist that a 19-year-old female patient was vaccinated with a third dose of GARDASIL (batch number NH15200, lot number 1427U) IM into the upper arm on 22-JUL-2008. She sent with the reporting form a letter of the mother of the patient in which the AE's were described. Two days p.v. a series of infections (not otherwise specified) started. In the course she was treated for common cold and persisting cough. Her general condition worsened. End of November 2008 she experienced "facial palsies" which lasted for 1-2 seconds about 1 to 3 times a day. On 13-JAN-2009 she developed a seizure with unconsciousness for the first time during the night. The patient was hospitalized from 14-JAN-2009 until 19-JAN-2009. EEG, CT, MRI and lumbar puncture showed normal results. On 25-JAN-2009 she developed a mil fit with facial palsy for 1 or 2 minutes and dyspnoea but without unconsciousness. On 10-FEB-2009 she had a severe convulsion with unconsciousness, dyspnea and lividity of the lips. The final outcome was not reported. D1 (batch number NE35170, lot number 655101/0513F) and D2 (batch number NG14300, lot number 0467U) of GARDASIL administered on 22-NOV-2007 and on 07-FEB-2008 were well tolerated. Other business partner numbers include E200901962. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341800-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	10-Feb-2009	Unknown		16-Mar-2009	17-Mar-2009	FR	WAES0903AUS00045	17-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Adverse event, Syncope

Symptom Text: Information has been received from a pharmacist, via agency as part of a business agreement (manufacturers control No. CSL 2009 03 10 LS 2) concerning a female student who on approximately 10-FEB-2009, "approximately four weeks ago" was vaccinated with GARDASIL as part of a school vaccination program. Subsequently the patient was hospitalised (reason for hospitalisation was not reported). At the time of reporting on 10-MAR-2009, the patient had fully recovered. The vaccination program included approximately 100 students and there was one other adverse event reported of a female who fainted (NWAES 0903AUS00046). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341816-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	12-Mar-2009		16-Mar-2009	18-Mar-2009	--		18-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea, Pyrexia

Symptom Text: GARDASIL injection, fever headache, nausea

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341831-1** **Related reports:** 341831-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Mar-2009	16-Mar-2009	0	16-Mar-2009	17-Mar-2009	LA		19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0654X		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia oral, Pharyngeal hypoaesthesia

Symptom Text: Returned to facility approximately one hour post injection c/o numbness in throat moving to back of tongue and roof of mouth given Benadryl po at 1005 at 1030 stated numbness gone from back of throat and is decreased in tongue and roof of mouth, returned to class.

Other Meds: Singulair prn

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **341831-2** **Related reports:** 341831-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Mar-2009	16-Mar-2009	0	17-Apr-2009	06-May-2009	--	WAES0903USA02584	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia oral, Pharyngeal hypoaesthesia

Symptom Text: Information has been received from a nurse practitioner concerning a 13 year old female patient with no pertinent medical history and no known drug allergies who on 2-JUL-2008 was vaccinated with the first 0.5 ml IM dose of GARDASIL. On 16-MAR-2009 the patient received the second 0.5 ml IM dose of GARDASIL (lot # 661703/0651X). There was no concomitant medication. On 16-MAR-2009 the patient experienced numbness on her mouth and throat. No lab diagnostics studies were performed. At the time of reporting, the patient's numbness on her mouth and throat persisted. The patient sought medical attention via seeing the nurse practitioner. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341851-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Mar-2009	12-Mar-2009	0	16-Mar-2009	17-Mar-2009	WI		31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Urticaria

Symptom Text: C/O itchiness on nape of neck @ HS on 3/12/09. Dx with hives by MD on 3/13/09 Hives prominent on trunk, groin + axillary with intense itching.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **341856-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	04-Mar-2009	Unknown		16-Mar-2009	17-Mar-2009	DE		07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Chest pain, Dyspnoea, Musculoskeletal pain, Neck pain

Symptom Text: Pt had, chest pains, heaviness on chest, short of breath, neck and shoulder pain in right side where injection was given. 3/30/09 MR received from OBGYN. Normal exam 3/4/09. HPV#1 given. 4/3/09 Pt not seen by hospital, only reported to OBGYN. Now reports no further sx

Other Meds: LOESTRIN FE; Steroids

Lab Data:

History: Allergy, latex, Betadine. PMH: Allergies: Betadine, latex. ASCUS 1/30/08.

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341864-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	13-Nov-2007	13-Feb-2008	92	16-Mar-2009	17-Mar-2009	MI		02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0962F	0	Left arm	Intramuscular	
	FLU	SANOFI PASTEUR	2523AA	7	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Fatigue

Symptom Text: Fatigue, joint pain after immunization until 3/08.

Other Meds:

Lab Data: Positive, ANA

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341865-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Feb-2009	06-Feb-2009	0	16-Mar-2009	17-Mar-2009	FL		17-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site haematoma, Injection site swelling

Symptom Text: Swelling/hematoma at injection site. No redness.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341881-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	03-Mar-2009	06-Mar-2009	3	17-Mar-2009	18-Mar-2009	FR	WAES0903USA01883	18-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	41500 072010	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Acute leukaemia, Haematoma, Inappropriate schedule of drug administration, Injection site haematoma, Lip swelling

Symptom Text: Information has been received from a health professional and transmitted by the subsidiary (Reference number NL0903-054-IN) concerning a 28 year old female patient with no reported medical history who on 03-MAR-2009 was vaccinated with her second dose of GARDASIL (batch number 41500 072010, route not reported, in the right arm). Three days after the vaccination, that was on Friday, 06-MAR-2009, she developed massive hematomas, left as well as right sided and on her upper body as well as lower torso and on her right (injected) upper arm and elbow, under the right eye, right wrist, lower parts of her legs and upper legs and she also developed a swollen lip. The first dose of GARDASIL (lot number, site and route not reported) was administered on an unknown date by her father. The general practitioner referred the patient to an internist and stated that the hematologist suspected acute leukemia as the patient had low amounts of platelets in her blood. According to the reporter, there was a possibility that there was an underlying cause for the adverse event and that vaccination may have had a triggering effect. Other business partner numbers included: E2009-02052. Additional information has been requested.

Other Meds: Unknown

Lab Data: platelet count, low amounts

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **341891-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	08-Mar-2009	09-Mar-2009	1	17-Mar-2009	19-Mar-2009	--		19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Nausea, Oropharyngeal pain, Pyrexia

Symptom Text: Fever of 103 for 72 hours, severe sore throat and cough lasting more than a week, nausea.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341904-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	02-Mar-2009	02-Mar-2009	0	17-Mar-2009	18-Mar-2009	CO		31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	2	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB257AA	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Decreased appetite, Dizziness, Eye pain, Headache, Hypophagia, Immediate post-injection reaction, Nausea, Pyrexia

Symptom Text: Immediately after shot, had onset of headache dizziness. Onset of fever 12:00am 3/3/09, temp 103.9. Received Advil, water, cold pack. Headache, nausea, dizziness present AM 3/3/09. Also c/o joint pain, pain behind eyes- joint pain on right side of body. Advil brings fever to 101 measured. Denies headache relief. limited fluid intake while ill limited appetite.

Other Meds: None

Lab Data: Influenza test negative; Strep test negative

History: Allergies - Amoxicillin, Grasses; Adenoids removed for sleep apnea

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341910-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	M	Unknown	Unknown		17-Mar-2009	19-Mar-2009	WA		19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Patient was given 3 GARDASIL vaccines in 2008 by her PMD. PAP smear results on 3/4/09 shows LGSIL with HPV changes.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341911-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	24-Feb-2009	24-Feb-2009	0	17-Mar-2009	20-Mar-2009	IL		20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	IPV	SANOFI PASTEUR	A09962	0	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0847X	0	Right arm	Intramuscular	
	TYP	WYETH PHARMACEUTICALS, INC	B03472	0	Right arm	Intramuscular	
	YF	SANOFI PASTEUR	UF435AA	0	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Chest pain, Cough, Dyspnoea, Flushing, Hypersensitivity, Lacrimation increased, Pharyngeal erythema, Tonsillar inflammation, Wheezing

Symptom Text: See attached medical records.

Other Meds:

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **341920-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Jul-2008	13-Nov-2008	108	17-Mar-2009	19-Mar-2009	FL		01-May-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	A4BUB239BB	0	Left arm	Unknown	HPV4
MNQ	SANOFI PASTEUR	40540BB	0	Right arm	Unknown	
HPV4	MERCK & CO. INC.	0072X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abasia, Arthralgia, Back pain, Dandruff, Dry skin, Excoriation, Gait disturbance, Menstruation irregular, Oedema peripheral, Pain in extremity, Rheumatoid arthritis, Seborrhoea

Symptom Text: Within several days of her second shot - she was unable to walk without much pain to her feet. Within 2 weeks she was diagnosed with RA and now is on Enbrel shots every week. 3/23/09 MR received from rheum consult 11/14/08-2/9/09. Pt initially presented with acute onset of joint complaints, beginning in L 5th metacarpal, then bilateral feet. Joints are tender to touch. Also c/o of low back pain near the R SI joint and onset of dry scalp, dandruff and excoriation over the elbows, knees. PE (+) for joint tenderness and seborrhea. Impression: Recent onset seronegative inflammatory arthritis. Tx: Naprosyn, steroids, Embrel. 4/1/09 PCP note recd for DOS 11/11/08. Pt c/o hand swelling and pain, ankle pain which causes pt to limp as well as irregular menses. PE (+) for pain on passive motion. Imp: Irregular menses. L ankle pain, painful 5th finger L hand. Swelling L hand. Referred to rheumatology. HPV#2 given.

Other Meds:

Lab Data: MRIs Labs and Diagnsotics: HLA B27 (+). Alk phos (L) 34. Lyme (-). RF (-). ANA (-).

History: none PMH: none.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341932-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	18-Feb-2009	18-Feb-2009	0	17-Mar-2009	19-Mar-2009	WA		11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Cardiac murmur, Conductive deafness, Contusion, Fall, Haematotympanum, Head injury, Loss of consciousness, Neck pain, Skull fracture, Subarachnoid haemorrhage, Syncope, Vomiting

Symptom Text: Pt was given #2 HPV and left area went to pharmacy, we had a Fire Drill pt walking out to car and fainted. Hit head, LOC, was taken to Hospital found to have a skull fracture was airlifted to another hospital for treatment. 4/2/09 ER report received for DOS 2/18/09 with Final dx: Syncope. Head bleed. Shortly (~5 min) after receiving vax pt had a syncopal episode where pt fell backwards and hit head on sidewalk. LOC x several minutes. One episode of vomiting en route to ER. PE (+) for hemotypanum of the R ear, vomiting and pain at C4. Transfered to higher level of care for subarachnoid bleed. 5/11/09 MR received from transfer facility for DOS 2/18-19/2009 with dx: R occipital skull fx, L frontal contusion with presentation c/w vasovagal syncope. Cardiac and ENT consults. Systolic murmer noted on PE. Neuro exam WNL. ENT notes conductive hearing loss and possible R temporal bone fx on R. Will f/u on hearing loss as outpt.

Other Meds:

Lab Data: Labs and Diagnostics: Head CT (+) for subarachnoid bleed. X-ray Repeat CT (+) for evolution of frontal parenchymal contusion. C-spine WNL. ECG (+) for non-specific ST wave abnormality. WBC 16.0-21.79. Transthoracic Echo WNL. Likely "innoc

History: none PMH: none

Prex Illness: none

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341946-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	17-Mar-2009	17-Mar-2009	0	17-Mar-2009	20-Mar-2009	PA		20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Nausea

Symptom Text: Nausea, Dizzy, Weak

Other Meds: None

Lab Data: None

History: AR (Allergic Rhinitis)

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341956-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Dec-2008	17-Dec-2008	0	17-Mar-2009	19-Mar-2009	PA		31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	2	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2726AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Myalgia

Symptom Text: Fatigue, severe muscle aches all over body - sore muscles with touch. 3/20/09 Note received from PCP. Pt has not been seen at all since DOV. TC from parent 3/16/09 reporting fatigue, muscle aches-especially in arms since 3rd Gardasil in 12/2008. Will f/u PRN.

Other Meds: Takes Claritin redi - tabs

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 341971-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	05-Dec-2008	10-Dec-2008	5	11-Mar-2009	27-Mar-2009	TX	200803980	30-Mar-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2683A		Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA		Unknown	Unknown	
FLUN	MEDIMMUNE VACCINES, INC.	550552P		Unknown	Unknown	
HPV4	MERCK & CO. INC.	0381X		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Drug exposure during pregnancy, Nausea, Pyrexia, Vomiting

Symptom Text: Initial report was received 12 December 2008 from a health care professional. A 14-year-old female pregnant patient had received a left deltoid injection of MENACTRA, lot number U2683AA, and an injection of GARDASIL (manufacturer Merck), lot number 0381X, and an injection of BOOSTRIX (manufacturer GlaxoSmithKline), lot number AC52B030AA, and FLUMIST (manufacturer MedImmune), lot number 550552P on 05 December 2008 and five days later, she complained of fever 102 degrees Fahrenheit, nausea, vomiting and a stomach ache. The patient had her last menstrual period on 05 November 2008 and the duration of her pregnancy was reported as approximately eight weeks. Her medical history, concomitant medication usage and past obstetric history were unknown. At the time of the report, the patient's recovery status was unknown.

Other Meds:

Lab Data: Pregnancy Test: positive

History: The patient's medical and obstetric history were unknown at the time of the report. Concomitant medication usage was unknown.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341990-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		18-Mar-2009	19-Mar-2009	FR	WAES0903USA02179	19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye rolling, Muscle spasms, Reaction to previous exposure to any vaccine

Symptom Text: Information has been received from a gynaecologist concerning a 22 year old female patient who was vaccinated with a first dose of GARDASIL (lot number, injection route and site not reported) on an unspecified date. Three minutes post vaccination the patient experienced cramp like movements (reported term) and eyes rolling. The patient was laid down and she recovered immediately. An EEG for investigation will be carried out. The patient experienced similar reaction in the past after vaccination with tetanus toxoid (manufacturer, lot number and date of administration not reported). The reporting physician considered the eye rolling and cramp like movements to be other important medical events. Other business partner numbers included: E2009-02095. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Cramp; Eye rolling

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341991-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Dec-2008	05-Feb-2009	66	18-Mar-2009	19-Mar-2009	FR	WAES0903USA02172	19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eczema, Hyperaemia, Joint swelling, Vaccine positive rechallenge

Symptom Text: Information has been received from the Health Authority (reference number ES-AGEMED-120752341) regarding a 14 year old female who was administered on the 04-FEB-2009 the second dose of GARDASIL (lot # not reported) by intramuscular route (site of administration not reported). Prior dose had been administered on 01-DEC-2008. It was reported that 10 days after administering the first dose the patient began with dorsal hand moist eczema with hyperaemia and interphalangeal joint oedema. These events worsened 24 hours after vaccination with the second dose. The reporter considered the adverse experiences to be other important medical events. Other business partner numbers included: E2009-02128. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Eczema; Oedema; Hyperaemia

Prex Illness:

Prex Vax Illns:

Vaers Id: 341992-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-Sep-2008	20-Sep-2008	1	18-Mar-2009	19-Mar-2009	FR	WAES0903USA02171	19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anxiety, Balance disorder, Computerised tomogram normal, Dizziness, Ear, nose and throat examination normal, Gait disturbance, Hypotension, Immunology test normal, Inflammation, Lumbar puncture, No reaction on previous exposure to drug, Ophthalmological examination normal, Vertigo, Vision blurred

Symptom Text: Initial information received on 10-MAR-2009 from a Foreign Health Authority (reference number ES-AGEMED-413082438) regarding an 18 year-old female who was administered on 19-SEP-2008 the second dose of GARDASIL (batch number, lot number, route and site not reported). The patient doesn't have a relevant medical history. One day after vaccine administration, on the 20-SEP-2008, the patient experienced dizziness, blurry vision and spinning sensation (vertigo-like sensation). The patient went to the emergency room where they verified a mild hypotension they began the patient on fluid therapy and TORECAN, symptoms did not cease. She remained in observation for 24 to 36 hours. The ENT exploration, ophthalmology test and CAT scans were normal. The patient was discharged from the hospital with a 15 day antiinflamatory treatment (NSAIDs). When the treatment ended, on the 20-OCT-2008, the patient experienced a similar symptomatology in addition she also experienced balance disorder and gait disorder, the patient went to the hospital's emergency room once again. On the 23-OCT-2008 the patient was hospital admitted in the neurology ward for 10 days with no medication. A battery of microbiology tests were performed, including a lumbar puncture with CSF extraction, immunology tests were normal. A brain MRI was also performed and a mild inflammation at cerebellum level was detected that was considered as a possible cause of the symptomatology. The inflammation appeared to in remission so the patient was discharged from hospital without medication. The patient had received the first dose of GARDASIL (batch number, lot number, route and site not reported) on 10-JUL-2008 without problem. On the 02-JAN-2009 the patient received the third dose of GARDASIL without any complications. Currently, the patient is in psychological treatment and is taking ALPRAZOLAM to treat anxiety (the patient is scared that the episode will happen again). No further information has been reported.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, a mild inflammation at cerebellum level was detected

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **341993-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	09-Mar-2009	Unknown		18-Mar-2009	19-Mar-2009	WV	WAES0903USA02071	19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Migraine, Nausea, No reaction on previous exposure to drug

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female who on 09-JAN-2009 and 09-MAR-2009 was vaccinated with her first (lot number 661764/0650X) and second (lot number 661952/1129X) dose of GARDASIL 0.5ml IM into her deltoid respectively. Concomitant therapy included NUVARING. The patient did not have any reactions after the 1st dose of GARDASIL. On 09-MAR-2009, 2 hours after the vaccination the patient developed nausea. On 10-MAR-2009, one day after the vaccination the patient experienced a severe headache. Unspecified time the patient experienced migraine. The nurse practitioner felt an intervention to prevent serious criteria was "the patient received NSAIDs". The patient sought medical attention by phone and an office visit. The patient's outcome was recovering. Additional information has been requested.

Other Meds: NUVARING

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: 341994-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Oct-2007	10-Jan-2008	91	18-Mar-2009	19-Mar-2009	PA	WAES0903USA02043	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Anorexia, Asthma, Chest pain, Colitis, Crohns disease, Diarrhoea haemorrhagic, Dizziness, Dyspnoea, Gastrointestinal tube insertion, Impaired gastric emptying, Malaise, Nausea, Vomiting, Weight decreased

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female patient with no pertinent medical history, no drug reactions/allergies, who on 16-AUG-2007 was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL. On 11-OCT-2007, the patient was vaccinated intramuscularly with the second 0.5 mL dose of GARDASIL. There was no concomitant medication. On 10-JAN-2008 the patient was diagnosed with gastroparesis and was having abdominal pain. The patient had been hospitalized (dates of admission were not known by the reporter). On 11-FEB-2008, the patient was vaccinated intramuscularly with the third 0.5 mL dose of GARDASIL. The patient had had a nasogastric tube placed since the spring to Summer of 2008 for nutritional support. The reporter stated that the physicians were unable to determine the etiology of the diagnosis. At the time of the reporting, the patient had not recovered. Additional information has been requested. 3/27/09-records received for DOS 4/30-5/4/08-DC DX: Crohns Disease. Presented with 2 month history of abdominal cramping, bloody diarrhea and 28 pound weight loss. 3 month history of diarrhea, weight loss and intermittant abdominal pain. Records-DC DX for 7/28-7/30/08 gastroparesis. DC DX: 8/7-8/15/08-Chronic gastroparesis. Presented with malaise, anorexia and weight loss and NJ feeds. Severe abdominal pain one day prior to admission. DC DX:10/29-11/1/08-Gastroparesis, nausea and vomiting. C/O 2 days of abdominal pain and feeding intolerance. NJ feeding problems. Dizziness and feeling not like herself with shortness of breath and chest pains over past month when exerting. February 2008 onset of diarrhea nausea and vomiting. DC DX: 12/11-12/18/08-Neck pain. Colitis, gastroparesis, GERD, NJ tube, ashtma.

Other Meds: None

Lab Data: Unknown 3/27/09-records received- EGD, colonscopy and capsule study showed chronic ileitis and esophageal candidiasis. Stool C. difficle toxin A/B positive. ESR, CRP within normal limits. CT scan of abdomen thickened cecum and ascending co

History: None 3/21/09-records received-PMH: asthma and GERD. Allergies-cephalosporins, tape and morphine-rash.

Prex Illness:

Prex Vax Illns:

Vaers Id: 341995-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Sep-2008	01-Oct-2008	30	18-Mar-2009	19-Mar-2009	--	WAES0903USA01837	19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Amnesia, Apnoea, Cough, Dyspnoea, Gaze palsy, Headache, Hypoaesthesia, Loss of consciousness, Malaise, Migraine, Posture abnormal, Syncope

Symptom Text: Information has been received from a consumer concerning his 14 year old granddaughter with a history of migraine who in September 2008, was vaccinated with a dose of GARDASIL. In October 2008 (on an unspecified time after vaccination), the patient experienced abdominal pain and headaches. Her symptoms had been getting more pronounced and more frequent. Since December 2008, the patient had spent more time out of school than in school. On approximately 18-FEB-2009 ("three weeks ago") the patient was doing homework and was feeling well. Then she began to look unwell and laid down on the couch. As her grandparents watched, the patient's body started to "draw up", her hands became claws, and she developed numbness in her legs and hands. Then she developed extreme shortness of breath and coughing. Her head rolled back, her eyes crossed, she passed out and stopped breathing. Paramedics were called and she was taken to a hospital. This was about the seventh time the patient had gone to the ER in the last two months. Oxygen was given in the ambulance. By the time she reached the hospital the patient was responding. After this episode the patient lost her memory for a week and only recognized a few people. The patient was later released from the ER. In the last 2.5 months the patient had spent two nights in the hospital. While at a children's hospital for testing, the patient fainted and was admitted for testing for one week. The patient had had migraines lasting as long as a month. Numerous MRIs and CAT scans were performed. On 10-MAR-2009 (" Last night") the patient went to the ER. All tests had come up with no diagnosis. Unknown medications had not worked. At the time of reporting, the adverse events persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Migraine

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **341996-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Dec-2008	15-Dec-2008	14	18-Mar-2009	19-Mar-2009	FR	WAES0903USA01556	19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Lethargy

Symptom Text: Case considered as not medically confirmed transmitted by a sales representative from another company on 10-MAR-2009. Case poorly documented reported by a gynecologist (not identified). It was reported that a female patient on an unspecified date was vaccinated with a dose of GARDASIL. 15 days after she received the vaccine, the patient experienced "a neurological incident of the leg" and was hospitalized. The outcome was not reported. Additional information received by phone from the sales representative and also from the general practitioner on 13-MAR-2009. The case became medically confirmed. The patient was 14 years old. She received the third dose of GARDASIL in DEC-2008. 15 days later, the patient presented with lethargy and asthenia. The patient was hospitalized (unspecified dates). Magnetic Resonance Imaging showed fixation of central grey matter. There was no diagnosis reported. At the time of reporting, the patient's outcome was not specified. A new control MRI was scheduled 3 months later i.e. in APR-2009. Other business partner numbers include E2009-02064. Additional information has been requested.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, showed fixation of central grey matter

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **341997-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
43.0	F	12-Jan-2009	26-Jan-2009	14	18-Mar-2009	19-Mar-2009	FR	WAES0903USA01518	19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Haemoptysis, Haemorrhagic diathesis, Idiopathic thrombocytopenic purpura, Immediate post-injection reaction, Inappropriate schedule of drug administration, Rash erythematous

Symptom Text: Information has been received from a health care provider concerning a 43 year old female who on 12-JAN-2009 was vaccinated with GARDASIL. After two weeks of injection (approximately 26-JAN-2009) the patient developed red spots over the body which was immediate. She also had blood streak on coughing, bleeding tendency was positive, especially brushing of teeth. Her platelet count decreased to 7. She was treated by hematologist and recovered completely. The doctor diagnosed her as having idiopathic thrombocytopenia (ITP). A laser vaporization test was done on the patient (results not reported). After two weeks of that, there was red inflammated spots like mumps all over the body. She took treatment and has recovered. She is currently taking MEDIXON and IMURAN. Upon internal review idiopathic thrombocytopenia (ITP) was considered to be an other important medical event. Additional information is expected.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, (laser vaporization) - Results not reported; platelet count, 26?Jan09, 7

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **341998-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		18-Mar-2009	19-Mar-2009	--	WAES0903USA01470	19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Brain death, Tracheostomy

Symptom Text: Information has been received from a registered nurse concerning an adolescent female between 14 and 17 who was vaccinated with GARDASIL. The patient had an AE to GARDASIL that required the nurse to be trached. The patient was basically "brain dead". It was not reported whether the patients sought medical attention. Upon internal review brain dead and required to be trached were determined to be other important medical events. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 341999-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-May-2008	11-Sep-2008	114	18-Mar-2009	19-Mar-2009	NY	WAES0903USA00751	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abasia, Abdominal pain upper, Arthralgia, Asthenia, Back pain, Balance disorder, Cystitis, Dyspnoea, Fatigue, Gait disturbance, Headache, Hyperhidrosis, Movement disorder, Musculoskeletal chest pain, Myalgia, Nausea, Photophobia, Pyelonephritis, Pyrexia, Sensory loss, Syncope, Tenderness, Tremor, Urinary tract infection, Vomiting, Wheelchair user

Symptom Text: Information has been received from a nurse practitioner concerning 16 year old female who was intramuscularly vaccinated with 1st, 2nd and 3rd 0.5 ml doses of GARDASIL (1st lot #658560/1062U, 2nd lot#659439/1267U, 2nd lot#659439/1267U, 3rd lot#660553/0070X) on 24-SEP-2007, 19-NOV-2007 and 20-MAY-2008, respectively. Concomitant therapy included YAZ, MACROBID and "septim (ceptim)". On 11-SEP-2008 the patient experienced urinary tract infection. On 12-SEP-2008 she experienced fever, vomiting and severe back pain. She went to the ER. On 14-SEP-2008 she had headaches, couldn't move her head and was shaky. She was weak and couldn't walk up stairs. A CAT scan was negative. On 25-SEP-2009 she went to a medical center for leg weakness, severe headache, costal vertebral tenderness and photophobia. An MRI done was negative. The patient was treated with morphine drip for her headaches. She was suggested by someone that it could be fibromyalgia. Other lab diagnostics studies included: STD check, vaginal culture, "kidney test", "urinary tract infection (UTI) test" and "e-coli test". All tests done were negative except for the one for her UTI. It was unknown if the patient was ever admitted to a hospital for adverse events. The patient was recovering at the time of reporting. Follow up information was received from a physician who reported that the 16 year old female student with penicillin allergy and post concussion syndrome was intramuscularly vaccinated with 3 doses of GARDASIL (1st dose into right deltoid, 2nd and 3rd doses into the left deltoid). There was no illness at time of vaccination. On 11-SEP-2008, the patient presented in the physician's office with urinary tract infection (UTI), low back pain, blood and leukocytes in urine. She was prescribed MACROBID 100 mg, po, Bid 7. On 12-SEP-2008 she went to emergency room (ER) due to worse syndromes and suggested to perform CT scan. Pyelonephritis was treated with axid ceftin. Nausea, vomiting and fever were treated with pyridine. She also complained of joint pain, could n

Other Meds: YAZ; MACROBID

Lab Data: computed axial, 09/14/08, negative; magnetic resonance, 09/21/08, negative; diagnostic laboratory, STD negative; diagnostic laboratory, e-coli negative; spinal tap, 09/17/08, negative; diagnostic laboratory, vaginosis DNA probe negative; di

History: 4/1/09-records received-allergy:Penicillin

Prex Illness: Penicillin Allergy; Post concussion syndrome

Prex Vax Illns:

Vaers Id: **342000-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	09-Aug-2008	23-Aug-2008	14	18-Mar-2009	19-Mar-2009	FR	WAES0903PHL00003	19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Central nervous system lesion, Headache, Musculoskeletal stiffness, Vision blurred

Symptom Text: Information has been received from a physician concerning a 14 year old female who in 2008 was vaccinated with first and second dose of GARDASIL. Patient received third dose on 9-AUG-2008. No concomitant medications were given. On 23-AUG-2008 the patient experienced headache, stiff neck and blurring of vision and was hospitalized. MRI results done on approximately August 2008 show brain lesions were present. Subsequently, the patient recovered from headache, headache, stiff neck, blurring of vision and was discharged. In October 2008, the patient again experienced headache, stiff neck and blurring of vision and was hospitalized. MRI results done in October 2008 show lesion were increasing in size. Diagnosis made at that time was pseudotumor cerebri or benign endocranial hypertension. Subsequently, the patient recovered from headache, stiff neck and blurring of vision and was discharged. In November 2008, the patient experienced similar symptoms and was hospitalized. Subsequently, the patient recovered from headache, stiff neck and blurred vision and was discharged. In January 2009, the patient experienced headache, stiff neck and blurring of vision and was hospitalized. MRI results done in January 2009 show that lesions increased in size. Patient was treated with steroids which helped improve patient's condition. Subsequently, the patient recovered from headache, stiff neck and blurring of vision and was discharged. On 22-FEB-2009 the patient experienced the same symptoms and was hospitalized. Diagnosis made by the reporter is acute disseminated encephalomyelitis. The patient's acute disseminated encephalomyelitis persisted. The reporter felt that acute disseminated encephalomyelitis was possibly related to therapy with GARDASIL as there was no family history or other concomitant medications taken at the time of the event. The physician felt that the vaccine could possibly be one of the causes of acute disseminated encephalomyelitis. Additional information is not expected.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, ??Aug?08, lesions present; magnetic resonance imaging, ??Oct08, pseudotumor cerebri; magnetic resonance imaging, ??Jan?09, lesion increase in size

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342017-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	23-Feb-2009	24-Feb-2009	1	18-Mar-2009	20-Mar-2009	KY		20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0657X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Flushing, Nausea, Pyrexia, Urinary retention

Symptom Text: Soon after administer- flushed cheeks- then went home, nausea, urine retention and fever 102-103- condition persisted + Pt. went to ER-fu evaluation next day.

Other Meds: None

Lab Data:

History: BACTRIM; Angioedema

Prex Illness: None

Prex Vax Illns:

Vaers Id: **342030-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	12-Mar-2009	13-Mar-2009	1	18-Mar-2009	19-Mar-2009	MO		19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1702X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain, Rash pruritic

Symptom Text: Patient complained of a itchy, painful rash begining the day after the injection was recieved

Other Meds: None

Lab Data:

History: Migraine Headaches with Aura

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342032-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Feb-2009	17-Feb-2009	0	18-Mar-2009	19-Mar-2009	MO		19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2773AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2842AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Pruritus, Rash

Symptom Text: Approximately one hr. after receiving vaccinations c/o itching to left cheek then progressing to right cheek, chin and ankles. Red raised "pimple-like" rash. Progressively subsided after approx. five days.

Other Meds:

Lab Data:

History: not physician diagnosed allergy to dial soap

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342033-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Feb-2009	17-Feb-2009	0	18-Mar-2009	19-Mar-2009	MO		19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C2773AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1311X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2842AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash erythematous

Symptom Text: Approximately three hours following vaccination c/o itching on neck, cheeks and chest areas. Also reports accompanied by red,raised rash. Symptoms progressively improved and subsided after approximately five days.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **342035-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-May-2008	01-Jun-2008	5	18-Mar-2009	19-Mar-2009	LA		08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	2	Left arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Amenorrhoea, Weight increased

Symptom Text: She has not had a period after receiving her third vaccine. It's been ten months since she had a period.4/2/09-records received for DOS 3/17/09-office visit 25 pound weight gain since 8/08-last period 8 months ago.

Other Meds: none

Lab Data: Premature menopause 4/2/09-records received-Pelvic ultrasound WNL. DHEA 154 normal.Estradiol 23, LH 32.3 and FSH 96.5. Chromosome analysis normal.

History: none 4/2/09-menarche began at age 11 and everyother month very heavy and cramping.

Prex Illness: none

Prex Vax Illns:

Vaers Id: **342038-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	16-Mar-2009	18-Mar-2009	2	18-Mar-2009	19-Mar-2009	ID		19-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash erythematous, Rash papular, Skin warm

Symptom Text: Bilateral arms red, raised rash. Warm to touch.

Other Meds: Norvasc, Celexa, Metformin, Arin

Lab Data:

History: Allergic to Sulfa drugs. Currently diagnosed with HTN and insulin resistence.

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342045-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	18-Oct-2007	18-Oct-2007	0	18-Mar-2009	19-Mar-2009	TN		02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	0	Left arm	Unknown	
	FLU	UNKNOWN MANUFACTURER	500487P	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Asthma, Lethargy, Myalgia, Ovarian cyst ruptured, Pyrexia, Scar, Skin disorder, Vertigo

Symptom Text: Fever, severe abdominal pain; muscle aches, lethargic, has asthma now, also developed skin indentions (tissue break down up underneath the skin) indentions are circular in size, starting around the injection site and has spread throughout entire body; specialist have never seen anything like it; referred for further testing; indentions are not going away but permanently scarring my child, also experiencing vertigo. 3/23/09-records received for DOS 11/10/08-presented with C/O lesions to trunk and extremities- 3/30/09-records received-ED visit 11/2/08-C/O abdominal pain, DX: ruptured ovarian cyst.

Other Meds: the doctors office is showing two other shots Td Adult lot#c2775ap its hard to read the form given on 10/17/08; also monotz lot#u2426aa also given on 10/18/07; its very hard to read the lot numbers on the form.

Lab Data: several biopsies; performed by two dermatologist (specialist); regular dermatologist; plus regular doctor visits; and ultrasound and catscan of abdomen 3/23/09-records received-biopsy obtained.

History: none; my daughter was very healthy and athletic; so healthy she wouldn't drink but maybe two soft drinks a year; she is allergic to the fruit formula given before having a catscan; we discovered that whe she was hospitalized for severe abdominal going to her side

Prex Illness: all of the side effects started at the time of the vaccination and the skin indentions started shortly after the first shot

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342058-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Mar-2009	18-Mar-2009	0	18-Mar-2009	24-Mar-2009	CA		16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1426F	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2816AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness

Symptom Text: Dizziness and LOC x 30 sec, about 10 min after vaccination.

Other Meds:

Lab Data:

History: NKA

Prex Illness: Allergic rhinitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342060-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	05-Feb-2009	05-Feb-2009	0	18-Mar-2009	24-Mar-2009	MA		14-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0571X	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF457CA		Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Cold sweat, Dizziness, Pallor, Paraesthesia, Pulse pressure decreased, Tinnitus, Vision blurred

Symptom Text: Pt had a c/o feeling as though she were going to pass out as she was checking out with secretaries. Secretary called M.A. and they assisted Pt to sitting in chair. MA got me to check Pt. Pt stated she felt like she was going to pass out, had blurry vision, tingling to hands and ringing in her ears. BP 92/54, R 18, P 78 weak, Pt stated she felt clammy, Pt too weak to transfer to w/c -> exam room at that time. Color slightly pale. BP 96/60, P62. After sitting up 10" BP 98/62, P62, R-15 10" later BP 98/62 P60. Standing BP98/60 P60 R-15 color improved, clammy feeling gone, Pt stated she thinks it was made worse by becoming frightened by Sx's. Pt released to home once WNL- baseline.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **342094-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-May-2008	Unknown		19-Mar-2009	20-Mar-2009	--	WAES0806USA01608	20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Premature baby

Symptom Text: Information has been received from a registered nurse, for the Pregnancy Registry for GARDASIL concerning a 15 year old female with attention deficit/hyperactivity disorder who denied she was pregnant on 06-MAY-2008 and was vaccinated IM with a first 0.5 mL dose of GARDASIL (lot # 659437/1266U). Concomitant therapy on the same day included a dose of MENACTRA (Sanofi Pasteur). Other medications included "STRAITERA", but has stopped taking this. On 27-MAY-2008 the patient saw her family doctor and a pregnancy test confirmed the pregnancy. On 09-JUN-2008, the patient was seen in the health department office stating she was pregnant and was enrolled in the WIC program. The patient's LMP was reported to be 23-APR-2008. Follow-up information was received from the registered nurse via a completed pregnancy questionnaire. It was reported that the female patient had no concurrent medical conditions (also reported as unknown) and smoked 3 cigarettes per day when first pregnant. The patient had no previous pregnancy. On 09-JUN-2008 the patient stated that she was taking STRATTERA before pregnancy and did not take during pregnancy. The medication used during this pregnancy was unknown. The patient had some bleeding in early pregnancy. On 08-OCT-2008 a baby girl was delivered prematurely at 26 weeks gestation in a hospital. The baby weighed 1 pound and 11 ounces. The length was 12 inches. The head circumference was 21.5 inches. The baby had congenital heart and breathing problems. It was reported that the complication during labor/delivery, the diagnostic test during pregnancy and the infections or illnesses during pregnancy was unknown. Upon internal review, born prematurely at 26 weeks and birth weight 1 pound and 11 ounces were considered to be other important medical events. Additional information is not expected.

Other Meds:

Lab Data: Beta-human chorionic, 05/27/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = 4/23/2008); Attention deficit/hyperactivity disorder; Smoker

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342095-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	16-Feb-2009	16-Feb-2009	0	19-Mar-2009	20-Mar-2009	FR	WAES0903USA02175	20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Injection site erythema, Nausea

Symptom Text: Information has been received from a health authority (reference number ES-AGEMED-520783341) concerning a 14 year old female who on 16-FEB-2009 was vaccinated with a dose of GARDASIL by intramuscular route (site of administration not reported) (Lot# not reported). It was reported that 10 minutes after vaccine administration the patient presented with an injection site erythema and began with abdominal pain and nausea. The patient had recovered from the injection site erythema, recovery date not reported. According to the reporter the patient had not recovered from the other events. It had been reported that the patient was hospital admitted. Hospital admission and hospital discharge dates had not been reported. Case reported as serious by the HA with other medically important condition and hospitalization as criteria. Other company numbers included: E2009-02110. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342096-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	03-Jun-2008	03-Jun-2008	0	19-Mar-2009	20-Mar-2009	ND	WAES0807USA00388	20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Initial information has been received through the Merck Pregnancy Registry for GARDASIL from a registered nurse concerning a 20 year old female with a penicillin allergy and attention deficit/hypersensitivity disorder who on 03-JUN-2008 was vaccinated with the first dose of GARDASIL (LOT# 660387/1967U). There was no concomitant therapy. Subsequently, she became pregnant. On 06-AUG-2008, an ultrasound was performed with the result "looks okay". The date of her last menstrual period was 01-MAY-2008 and the estimated delivery date is 14-FEB-2009. The patient's outcome was unknown. The patient called the physician's office. Follow-up information has been received from a registered nurse to report the pregnancy outcome. On 15-JAN-2009 the patient delivered a normal, healthy male baby weighing 6 pounds 13 ounces. The baby's length was 19.5 inches and head circumference was 13.5 inches with unsure apgar score. There were no congenital anomalies. The baby wouldn't suck. He was placed in neonatal intensive care unit (NICU) and received tube feeding for 8 days. During pregnancy, there was no complication, infection and illness for the patient. The patient took prenatal vitamins daily. There was also no complication during labor/delivery. Additional information is not expected.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 08/06/08, looks okay

History:

Prex Illness: Pregnancy NOS (LMP = 5/1/2008); Penicillin allergy; Attention deficit/hyperactivity disorder

Prex Vax Illns:

Vaers Id: **342097-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Apr-2008	01-Apr-2008	0	19-Mar-2009	20-Mar-2009	FR	WAES0810AUS00174	20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abasia, Activities of daily living impaired, Amenorrhoea, Arthralgia, Bacterial infection, Cellulitis, Chest pain, Dyspnoea, Fatigue, Feeling abnormal, Headache, Insomnia, Lethargy, Malaise, Migraine, Muscular weakness, Phonophobia, Photophobia, Rash generalised, Vaccine positive rechallenge

Symptom Text: Information has been received from a pharmacist via CSL as part of a business agreement (manufacturer control # GARD 2008 10 30 003) concerning a 15 year old female who in March 2008, was vaccinated with the first dose of GARDASIL. In March 2008, after vaccination the patient experienced headaches and felt "off colour". Subsequently, the patient recovered from headache and feeling "off colour". In the last week of September 2008 ("last week of school term in September"), the patient was vaccinated with the second dose of GARDASIL. The patient felt fine for 2 weeks of school holidays and then in October 2008, the patient developed headaches following a bacterial infection in the foot with some cellulitis before experiencing extreme malaise. At the time of reporting, the patient had joint pain and muscle weakness in neck, back and legs and extreme malaise. The patient cannot walk or hold a phone to her ear and her headaches have subsided. It was also reported that anti-inflammatory treatment provided her with temporary relief. Information was received on 30-OCT-2008 contained the following adverse experiences: a bacterial infection in the foot with some cellulitis (October 2008). Follow up information was received from the reporting pharmacist, via CSL, as part of a business agreement (manufacturer control No. 2009 03 10LS1). In approximately April/May 2008 (previously reported as March 2008) the patient was vaccinated with her first dose of GARDASIL. In approximately May/June 2008, one month after vaccination with GARDASIL, the patient developed a body rash, a migraine-like headache which was not responsive to codeine, menstruation stopped for 3-4 months, pain in her joints, pain in her large leg muscles and limb weakness. These symptoms occurred on-and-off (each lasting for 7-14 days) with a total of three episodes with 3-4 weeks in between. In approximately August/September 2008 (previously reported as September 2008), the patient was vaccinated with her second dose of GARDASIL. Within 24 hours of vaccination wi

Other Meds: Unknown

Lab Data: magnetic resonance imaging, ??08, "nothing abnormal concluded"; diagnostic pathological examination, ??08, blood tests (not specified) - "nothing abnormal concluded"; diagnostic laboratory test, ??08, no markers for chronic fatigue or infla

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342098-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Nov-2008	09-Jan-2009	69	19-Mar-2009	20-Mar-2009	FR	WAES0903USA01649	20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Local swelling, Lymphadenopathy, Neck pain, Parotid gland enlargement, Thyroiditis subacute

Symptom Text: Information has been received from a healthcare professional concerning an 18 year old female who in approximately November 2008 or December 2008, was vaccinated with a second dose of GARDASIL. On 09-JAN-2009, she developed submaxillary adenopathies. On 14-JAN-2009 she underwent ultrasound of the neck and was diagnosed with an episode of subacute thyroiditis. She experienced the following symptoms two months post vaccination: pain in the neck, submaxillary cervical lymph nodes, fatigue, "voluminous" neck, mild nodule and hypertrophy of parotids. The symptoms lasted during one month or so. Laboratory tests revealed biological signs of inflammation: increased C-reaction Protein and Erythrocyte Sedimentation Rate, increased antithyroid antibodies (over 2000) and negative toxoplasmosis. According to the reporting physician, signs and symptoms could be due to viral infection, but not confirmed. But the reporter also evoked HASHIMOTO's thyroiditis. The patient was seen by an endocrinologist and an infectious diseases specialist who advised her to postpone the third injection. It was noteworthy that the patient had well tolerated previous vaccinations and had no relevant medical history. The subacute thyroiditis was considered to be an other important medical event by the reporter. Other business partner numbers included: E2009-02073. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, 14Jan09, subacute thyroiditis; serum C-reactive protein, ??09, increased; serum antithyroid antimicrosomal Ab, ??09, increased (over 2000); erythrocyte sedimentation rate, ??09, increased; Toxoplasma antibody screen, ??09, negat

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342100-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	18-Sep-2008	Unknown		19-Mar-2009	20-Mar-2009	FR	WAES0903USA02205	20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Immunodeficiency

Symptom Text: Information has been received from a specialist concerning a 20 year old female patient who on 18-SEP-2008 was vaccinated with her third dose of GARDASIL (lot number, batch number, route and site not reported). On an unspecified date, the patient presented with immunity system very down. At time of reporting, the outcome was not reported. The patient was hospitalized (unspecified dates). Other business partner numbers included: E2009-02172. No further information is available. The case was closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342101-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Dec-2008	16-Dec-2008	0	19-Mar-2009	20-Mar-2009	FR	WAES0903USA02177	20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Tremor

Symptom Text: Information has been received from a health authority (reference number ES-AGEMED-620793341) concerning a 16 year old female who on 16-DEC-2008 was vaccinated with a dose of GARDASIL by intramuscular route (site of administration not reported) (Lot# not reported). It was reported that on the same day of vaccine administration, the patient experienced loss of consciousness and limb tremor. The patient recovered on the same day. Case reported as serious by the HA with other medically important condition as criteria. Other company numbers included: E2009-02108. No further information was available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342108-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Feb-2009	02-Feb-2009	0	19-Mar-2009	23-Mar-2009	TX		23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X		Unknown	Unknown	
	MEN	UNKNOWN MANUFACTURER	UF24699		Unknown	Unknown	
	TDAP	UNKNOWN MANUFACTURER	C3027B410		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Agitation, Dyspnoea, Hypoaesthesia, Malaise, Nausea, Pain in extremity

Symptom Text: Feb-2-09 at 3:00 pm vaccines were given Within 5 minutes of vaccines, she was feeling nauseated and a numbness in right arm which started to spread to whole body, then was feeling shortness of breath and feeling very agitated. I took her back to the same nurse whom gave her the shots and she had my daughter lay down for about 15 minutes and while laying down my daughter started to have episode of feeling ill the nurse told her to lay down for 15 more minutes and then told her she was fine to go home.

Other Meds: No

Lab Data: When taken to hospital on Feb-3-09 doctor took blood work and stated there were all the electrolism found, which was probably causing the pain in her legs

History: No

Prex Illness: None was very healthy and happy until vaccines was given

Prex Vax Illns: None other than this one~ ()~~0~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342124-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	21-Feb-2009	22-Feb-2009	1	16-Mar-2009	02-Apr-2009	CA	WAES0902USA04614	16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash, Palpitations, Pelvic pain

Symptom Text: Information has been received from a physician concerning a female who on 21-FEB-2009 was vaccinated with first 0.5mL dose of GARDASIL. There was no concomitant medication. On 22-FEB-2009 the patient experienced heart racing, rash at injection site and pelvic pain. At the time of the report the patient had not recovered from the events. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342126-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Nov-2007	16-Feb-2009	473	16-Mar-2009	31-Mar-2009	CA	WAES0902USA04624	31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Human papilloma virus test positive

Symptom Text: Information has been received from a physician and medical assistant concerning a 18 year old female who received all 3 doses of GARDASIL. The patient received her third dose of GARDASIL in November 2007 (dates of other doses and lots were not available). Subsequently, the patient had a PAP and HPV test in December 2007 that were normal. On 16-FEB-2009 the patient had a HPV tested positive for high and low risk HPV and the result for her PAP test were normal. The patient was not recovered and sought unspecified Medical attention. Addition information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory 12/??/07 - HPV Test normal; diagnostic laboratory 02/16/09 - Positive for high and low risk HPV; Pap test 12/??/07 - Normal; Pap test 02/16/09 - Normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342127-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		16-Mar-2009	02-Apr-2009	VA	WAES0903USA00004	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a 14 year old female who was vaccinated with GARDASIL (Lot# not reported). After receiving the second dose of GARDASIL, the patient had fainted. The adverse event was improved on therapy. It was reported that the patient sought medical attention: in the physician's office. This was one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342128-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	21-Jan-2009	23-Jan-2009	2	16-Mar-2009	02-Apr-2009	--	WAES0903USA00009	16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash

Symptom Text: Information has been received from a registered nurse concerning an approximately 25 year old female who in November 2008, was vaccinated with the first dose of GARDASIL. On 21-JAN-2009 the patient was vaccinated with the second dose of GARDASIL (lot # not reported) 0.5 ml. On 23-JAN-2009 the patient experienced rash and itching on her trunk and side of neck. Subsequently, the patient recovered from the events. "They advised her not to get the third dose". The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342129-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	10-Dec-2008	10-Dec-2008	0	16-Mar-2009	02-Apr-2009	MN	WAES0903USA00013	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Flushing, Headache, Rosacea

Symptom Text: Information has been received from a nurse concerning a 13 year old female patient who on 10-DEC-2008 was vaccinated with her third dose of GARDASIL. The patient since 10-DEC-2008 had rosacea on the face that was worse in the evening. On 10-DEC-2008 later evening the patient had a bad headache, flushed face and achy joints. The patient had visited physician's office for medical attention. Follow-up information has been received from the nurse that the patient was vaccinated with her first dose of GARDASIL (lot # 659962/1740U) on 30-MAY-2008. The patient was vaccinated with her second dose of GARDASIL (lot # 659964/1978U) on 05-AUG-2008. The patient was vaccinated with her third dose of GARDASIL (lot # 660616/0570X) on 10-DEC-2008. The nurse stated that no labs were performed. A physician may ask if there was any correlation of rosacesa and GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342130-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	31-Mar-2009	--	WAES0903USA00033	31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a consumer concerning her daughter who was vaccinated with a dose of GARDASIL (dose, route and lot number not reported). The consumer reported that her daughter had experienced HPV infections after she had received a dose of GARDSIL. It was not specified if the patient sought medical attention. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342131-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	20-Feb-2009	21-Feb-2009	1	19-Mar-2009	23-Mar-2009	--	WAES0903USA00042	23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Loss of consciousness, Nausea

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female with not drug reactions or allergies who on 20-FEB-2009 was vaccinated with a second dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). On 21-FEB-2009 the patient experienced fatigue, nausea and dizziness. On 23-FEB-2009 the patient passed out while taking a shower. Subsequently, the patient recovered from these symptoms on 24-FEB-2009. She sought unspecified medical attention. Additional information has been requested.

Other Meds: hormonal contraceptives (unspecified); Merck Sharp & Dohme; lot number 660555/0279X; IM; dose unk.

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342132-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jul-2008	23-Feb-2009	237	19-Mar-2009	23-Mar-2009	--	WAES0903USA00043	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from an aunt concerning her 15 year old niece with asthma who in July 2008, completed her three doses GARDASIL. Subsequently this week on approximately 23-FEB-2009, the patient experienced PAP smear positive for HPV. Lot numbers are not available. The patient sought unspecified Medical attention. No further information provided. Additional information is not available.

Other Meds: None

Lab Data: Pap test, 02/23?/09, Positive.

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **342133-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	02-Apr-2009	--	WAES0903USA00052	16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue

Symptom Text: Information has been received from a nurse concerning a female patient who on unspecified dates was vaccinated with the first and the second 0.5 mL doses of GARDASIL. "Within a day" after receiving the first and second dose of GARDASIL, the patient experienced fatigue for about a week and then the patient recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342134-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	02-Apr-2009	CA	WAES0903USA00057	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a 0.5 ml dose of GARDASIL (Lot # not reported). Dose of the series was unknown. It was reported that the patient fainted after receiving GARDASIL. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342135-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Feb-2009	24-Feb-2009	1	16-Mar-2009	02-Apr-2009	CA	WAES0903USA00076	16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Rash

Symptom Text: Information has been received from a Medical Assistant concerning a 17 year old female patient with no pertinent medical history and no drug reactions or allergy who on 23-DEC-2008 was vaccinated with first dose of GARDASIL (Lot # 661703/0651X) 0.5ml, intramuscularly. On 23-FEB-2009 she received second dose of GARDASIL (Lot # 661703/0651X) 0.5ml, intramuscularly. There was no concomitant medication. On 24-FEB-2009 the patient experienced "rash" on both of her elbows and headache. There were no Laboratory Diagnostics Studies Performed. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342137-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Jan-2009	26-Jan-2009	0	16-Mar-2009	02-Apr-2009	CA	WAES0903USA00096	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Migraine, Nausea, Photophobia, Presyncope, Pyrexia

Symptom Text: Information has been received from a certified medical assistant concerning a 15 year old female with allergic rhinitis who on 26-Jan-2009 was vaccinated with the first dose of GARDASIL IM 0.5ml (lot# 651952/ 1129X). Concomitant therapy included NASONEX. On 26-Jan-2009 evening the patient developed a fever of 101.5 degrees F. a migraine-like headache, nausea, light sensitivity. She mentioned that the patient "almost pass out every time she stood up". There was no itching or hives noted. On an unknown date, the patient recovered from the events. The nurse mentioned that the patient's mother has declined to allow additional doses of GARDASIL for her daughter. The patient sought medical attention from her mother. Additional information has been requested.

Other Meds: NASONEX

Lab Data: Body temp 01/26/09 101.5 -

History:

Prex Illness: Rhinitis Allergic

Prex Vax Illns:

Vaers Id: **342138-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	26-Feb-2009	26-Feb-2009	0	16-Mar-2009	02-Apr-2009	IL	WAES0903USA00106	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Dyspnoea, Erythema, Lip swelling, Paraesthesia oral, Pruritus, Swelling face

Symptom Text: Information has been received from a physician concerning a 21 year old female with Raynaud's syndrome and hypertension who on 26-FEB-2009, at 9:40 AM, was vaccinated with the second 0.5ml dose of GARDASIL. Concomitant therapy included DIFLUCAN, ALLEGRA, albuterol, hypertension medications and an unspecified beta-blocker. On 26-FEB-2009, at 16:00 at work, the patient felt tingling of her lips. The patient went to bed and had "terrible sleep" that night. On 27-FEB-2009 the patient woke up with periorbital redness, swollen lips, swollen nose ("like Bozo the clown"), shortness of breath and chest pain. The patient also had a periorbital itching. The physician instructed the patient to take BENADRYL. At the time of this report, the patient's adverse events improved, the patient was not recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: albuterol; ALLEGRA; DIFLUCAN

Lab Data: Unknown

History:

Prex Illness: Raynaud's syndrome; Hypertension

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342139-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	18-Feb-2009	20-Feb-2009	2	16-Mar-2009	31-Mar-2009	NJ	WAES0903USA00120	31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female under 18 years old with no pertinent medical history who on 18-FEB-2009 was vaccinated with her first dose of GARDASIL (lot number, route and site not reported). There was no concomitant medication. On approximately 20-FEB-2009, 2-3 days after receiving vaccination the patient experienced syncope and went to the emergency room. Electroencephalography (EEG) and neuro-consult were performed with no result reported. The patient recovered from syncope after treating and was released from the emergency room on the same day. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342141-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	02-Apr-2009	--	WAES0903USA00502	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a consumer concerning her daughter who was vaccinated with a dose of GARDASIL (dose, route and lot number not reported). The consumer reporter that her daughter had experienced HPV infections after she had received a dose of GARDASIL. At the time of the report the outcome of the patient was unknown. It was not specified if the patient sought medical attention. This is one of two reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342142-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		16-Mar-2009	25-Mar-2009	VA	WAES0903USA00274	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning a patient who was vaccinated with a dose of GARDASIL (Lot# not reported). After receiving the dose of GARDASIL, the patient had fainted. The outcome of adverse event was not reported. It was not reported whether the patient sought medical attention. This was one of several reports from the same source. Additional information has been requested.

Other Meds: unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342143-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	26-Feb-2009	26-Feb-2009	0	16-Mar-2009	25-Mar-2009	NM	WAES0903USA00134	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Muscular weakness

Symptom Text: Information has been received from a licensed practical nurse concerning a 20 year old female patient with no medical history and drug reactions who on 26-FEB-2009 was vaccinated IM with the third 0.5 ml dose of GARDASIL (lot number 0947X, site not reported). There was no concomitant medication. The patient developed muscle weakness radiating from her right arm to the right legs two hours after vaccination. The patient stated that the muscle weakness began radiating to left side. She was sent to the neurologist on 26-FEB-2009. An unspecified neurological exam was negative for findings. On 27-FEB-2009, the patient recovered from the event. Additional information has been requested.

Other Meds: None

Lab Data: Diagnostic laboratory, 02/26/09, neurological exam: negative for findings.

History: None

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342144-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	02-Apr-2009	--	WAES0902USA04579	01-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Palpitations

Symptom Text: Information has been received from a nurse practitioner concerning a female who was vaccinated with the second dose of GARDASIL 0.5 mL. About an hour after receiving the vaccine, the patient experienced an episode of where her heart was racing and a shortness of breath. The patient's outcome was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342145-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	24-Mar-2008	24-Mar-2008	0	16-Mar-2009	02-Apr-2009	MD	WAES0902USA04576	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Inappropriate schedule of drug administration, Meconium in amniotic fluid

Symptom Text: Information has been received from a registered nurse, for the Pregnancy Registry for GARDASIL, concerning an 18 year old female who on 14-JAN-2008 was vaccinated intramuscularly with first 0.5mL vaccine (lot number 659653/1448U). Concomitant therapy included NUVARING. On 24-MAR-2008 the patient was vaccinated intramuscularly with the second dose of GARDASIL (lot number 658556/1060U). Subsequently, she became pregnant. The patient was hospitalized for delivery. On 16-JAN-2009 the patient delivered a baby boy who was 9 pounds and 4 ounces with APGAR of 9 and 9. The reporter mentioned that during labor there was "meconuim staining to the amniotic fluid". On 26-FEB-2009, the patient received the third dose of GARDASIL vaccine during a postpartum visit. Additional information has been requested.

Other Meds: NUVARING

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: **342146-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		16-Mar-2009	02-Apr-2009	--	WAES0902USA04551	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Infectious mononucleosis

Symptom Text: Information has been received from a physician's assistant concerning an approximately 17 year old female patient who was vaccinated with the first dose of GARDASIL (lot # not reported). Subsequently the patient experienced a headache and developed mononucleosis. Patient received the second dose of GARDASIL (lot # not reported) and subsequently experienced a headache and developed mononucleosis. Patient sought unspecified medical attention with the physician assistant. Patient already completed the GARDASIL series. Patient's present status is unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342147-1** **Related reports:** 342147-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	19-Feb-2009		16-Mar-2009	31-Mar-2009	TN	WAES0902USA04538	01-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain lower, Asthenia, Cough, Fatigue, Gastroenteritis viral, Injection site rash, Malaise, Myalgia, Nasal congestion, Nasopharyngitis, Nausea, Oropharyngeal pain, Pelvic pain, Premenstrual syndrome, Pyrexia, Sick relative, Vomiting, Wheezing

Symptom Text: Information has been received from a consumer concerning her 22 year old daughter, with no known drug reaction/allergies and no pertinent medical history, who on 26-AUG-2008, was vaccinated with the first of GARDASIL and on unspecified dates, was vaccinated with the second dose and third dose of GARDASIL. There was no concomitant medication. The reporter stated that her daughter started having side effects after getting the second dose of the GARDASIL vaccine. On 19-FEB-2009, the patient experienced nausea, rash at the injection site, abdominal pain, vomiting, muscle pain, weakness and complained of she felt sick all the time. The consumer stated that "she did seek medical attention and they keep telling it is a stomach virus". At the time of the report, the patient had not recovered. Additional information has been requested. 3/23/09 Received vaccine & PCP medical records of 12/4/08-2/24/2009. FINAL DX: none provided Records reveal patient experienced cold s/s of cough, fatigue, fever, nasal congestion, sore throat & wheezing on 12/4 & had sick family member. Dx w/acute nasopharyngitis & cerumen impaction. RTC 2/19/09 for routine GYN exam & HPV #2. RTC 2/20 w/colicky abdominal pain x 1 day. Exam revealed lower abdominal/pelvic pain thought to be premenstrual as due for depoprovera following wk. RTC 2/24 w/continued abdominal pain. No further records available. 3/23/09 Link w/342211.

Other Meds: None

Lab Data: None LABS: PAP smear WNL.

History: None PMH: PUD, depo-provera contraception.

Prex Illness:

Prex Vax Illns:

Vaers Id: **342147-2** **Related reports:** 342147-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	19-Feb-2009	20-Feb-2009	1	16-Mar-2009	02-Apr-2009	--	WAES0902USA04269	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0070X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain lower

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female patient with no pertinent medical history and no known drug allergies or reactions who on 26-AUG-2008 was vaccinated with the first dose of HPV intramuscularly (lot # not provided). On 19-FEB-2009 the patient was vaccinated with the second 0.5 ml IM dose of GARDASIL (lot # 660553/0070X). Concomitant therapy included DEP0-PROVERA). On 20-FEB-2009 ("the day after receiving the second dose"), the patient experienced lower abdominal pain. No lab diagnostics studies were performed. At the time of reporting, the patient's lower abdominal pain persisted. The patient was seen by the nurse practitioner. Additional information has been requested.

Other Meds: DEPO-PROVERA

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342148-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	M	Unknown	Unknown		16-Mar-2009	02-Apr-2009	--	WAES0902USA04537	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Off label use

Symptom Text: Information has been received from a consumer concerning her son with no pertinent medical history, no drug reaction/allergies, who on unspecified dates was vaccinated with two doses of GADRASIL. There was no concomitant medication. The reporter stated that her son was prescribed by physician to get GARDASIL and that her son never completed the GARDASIL series. No further information is available.

Other Meds: None

Lab Data:

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342149-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	12-Feb-2009	12-Feb-2009	0	16-Mar-2009	02-Apr-2009	IL	WAES0902USA04531	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site movement impairment, Injection site pain

Symptom Text: Information has been received from a 26 year old registered nurse, with no known medical history and drugs allergies, who two weeks ago was vaccinated with a first dose of GARDASIL intramuscularly into the left deltoid. There was no concomitant medication. Two weeks ago she had experienced severe injection site pain that had persisted and even intensified. She saw her primary physician for treatment. She had been treating with rest and ibuprofen. The pain had restricted movement in her left arm but not disabling. No laboratories studies performed. The patient sought medical attention through her primary physician. The patient recovered on an unspecified date.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342150-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Oct-2008	Unknown		16-Mar-2009	02-Apr-2009	--	WAES0902USA04526	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Palpitations

Symptom Text: Information has been received initially from a registered pharmacist who reported the pharmacy technician's daughter was given the third dose of GARDASIL on October 2008. The technician's daughter after reported a "racing heart". The caller stated that the patient was reporting that when she exercises her "heart goes really fast". It was reported that the patient had not recovered at the time of the report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342151-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	02-Apr-2009	--	WAES0902USA04519	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise

Symptom Text: Information has been received from a consumer concerning a female who was vaccinated with GARDASIL (Lot # not provided). After receiving GARDASIL, the patient got sick. The outcome of adverse event was not reported. It was not reported whether the patient sought medical attention. This was one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342152-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	02-Apr-2009	--	WAES0902USA04518	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Malaise

Symptom Text: Information has been received from a consumer concerning a female who was vaccinated with GARDASIL (Lot # not provided). After receiving GARDASIL, the patient got sick and was hospitalized. The outcome of adverse event was not reported. It was not reported whether the patient sought medical attention. This was one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342153-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		16-Mar-2009	02-Apr-2009	PA	WAES0902USA04517	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with GARDASIL (Lot # not reported). The patient experienced headaches after first and second dose of GARDASIL. The patient decided to stop therapy. The outcome of adverse event was not reported. It was reported that the patient sought unspecified medical attention. This was one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342154-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	18-Feb-2009	Unknown		16-Mar-2009	02-Apr-2009	--	WAES0902USA04500	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pruritus, Pyrexia, Rash, Vomiting

Symptom Text: Information has been received from a health professional concerning a patient who on 18-FEB-2009 was vaccinated with the first dose of GARDASIL. In February 2009, the patient experienced fever, nausea, vomiting, itching and rash. It was reported that the patient would not continue series. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342155-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	08-Jan-2009	08-Jan-2009	0	16-Mar-2009	02-Apr-2009	--	WAES0902USA04481	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Injection site pain, Nausea

Symptom Text: Information has been received from a physician concerning a 20 year old female patient with no pertinent medical history and no known drug allergies/drug reactions who on 08-JAN-2009 was vaccinated intramuscularly with the first dose of GARDASIL (Lot # 661046/0546X). There was no concomitant medication. It was reported that on 08-JAN-2009 after receiving the first dose of GARDASIL, the patient experienced dizziness, nausea and pain at the injection site. On 08-JAN-2009, the patient's vital signs after receiving GARDASIL were pulse 88, blood pressure 114/62, and neurological checks were within normal limits. It was reported that on an unknown date, after injection was given, the patient had gone to the emergency room due to her reactions. It was reported that she was given a lotion to apply to the injection site on her right arm. As of 25-FEB-2009 it was unknown if the patient continued to get the GARDASIL vaccine and she has recovered from the dizziness, nausea and pain at the injection site. Additional information has been requested.

Other Meds: None

Lab Data: blood pressure 01/08/09 114/6 - ; neurological examination 01/08/09 - within normal limits; total heartbeat count 01/08/09 88 -

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342156-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	18-Sep-2008	18-Sep-2008	0	16-Mar-2009	02-Apr-2009	TX	WAES0902USA04477	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Induced abortion failed

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for GARDASIL, concerning a 19 year old multiracial female with no history of pregnancies and no significant past medical history or concurrent medical conditions who on 18-SEP-2008 was vaccinated with the first dose of GARDASIL (lot #: 0947X). It was reported that the patient was pregnant at the time of vaccination. The patient's date of last menstrual period was 05-SEP-2008, estimated delivery date was 11-JUN-2009. 0n 31-OCT-2008, the patient took one dose of MIFEPROSTONE and MISOPROSTOL for attempted abortion. On 10-FEB-2009, ultrasound was performed to assess anatomy and confirm dates, which revealed that the patient was doing well and was at 22 weeks gestation. The estimated date of confinement (EDC) was 12-JUN-2009. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound 02/10/09 - dw, 22 week, EDC 6/12/09

History:

Prex Illness: Pregnancy NOS (LMP = 9/5/2008)

Prex Vax Illns:

Vaers Id: **342157-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jan-2009	08-Feb-2009	38	16-Mar-2009	31-Mar-2009	--	WAES0902USA04453	01-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Headache, No reaction on previous exposure to drug, Vomiting

Symptom Text: Information has been received from a consumer concerning a 15 year old female patient who started therapy in August 2009 with the first dose of GARDASIL. The caller reported that her granddaughter received all three doses of GARDASIL and was fine after the first and second dose. She received the third dose two weeks ago (January 2009) (lot # not reported) and "yesterday" (approximately 08-Feb-2009) woke up with a headache, stomach ache and threw up. No diagnostic tests or laboratory work was performed. The outcome was not reported. A product quality complaint was not involved. No further information was provided.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342158-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		16-Mar-2009	31-Mar-2009	--	WAES0902USA04362	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Coeliac disease

Symptom Text: Information has been received from a medical assistant concerning a 14 year old female who on unknown date was vaccinated with two doses of GARDASIL from another provider and was diagnosed with experienced celiac disease. At the time of reporting, 25-FEB-2009, the patient's celiac disease persisted.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342159-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		16-Mar-2009	02-Apr-2009	--	WAES0902USA04356	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Influenza like illness, Malaise, Nausea, Retching

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female patient with endometriosis who on unspecified dates was vaccinated with the first two doses GARDASIL (lot number not specified). There was no concomitant medication. The patient experienced nausea, "gagging", flu-like symptoms and felt miserable 2 weeks after she received the second dose of GARDASIL. At the time of reporting, 2-Feb-2009, the patient had recovered. Additional information has been requested.

Other Meds: None

Lab Data:

History:

Prex Illness: Endometriosis

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342169-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Feb-2009	11-Feb-2009	0	19-Mar-2009	20-Mar-2009	FL		20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	MSD0652X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: PATIENT NOTED HIVES ONCE AGAIN, ONLY THIS TIME WORSE, MOTHER GAVE PATIENT BENEDRYL AND PUT SOME CREAM ON HIVES TO RELIEVE THEM. REACTION UNREPORTED THE FIRST TIME THAT IT OCCURED ON THE CHILD. HIVES APPEARED WITHIN 15 MINS THE SECOND TIME THAT CHILD HAD SHOT

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **342177-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Mar-2009	19-Mar-2009	7	19-Mar-2009	20-Mar-2009	NJ		20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: supraclavicular lymphadenopathy on same shot was given for gardasil #1 and #2

Other Meds:

Lab Data: n/a

History: none

Prex Illness: none

Prex Vax Illns: supraclavicular lymphadenopathy~HPV (Gardasil)~1~17~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342178-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	11-Jun-2008	23-Jun-2008	12	19-Mar-2009	20-Mar-2009	CA		20-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Gluteous maxima	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Depression, Diarrhoea, Dysuria, Fungal infection, Headache, Micturition urgency, Panic attack, Pollakiuria, Urinary tract infection, Vaccine positive rechallenge, Vertigo, Vision blurred, Vomiting

Symptom Text: UTI like symptoms, frequent urination, burning on urination beginning 11 days after initial dose, continuing sporadically to present time, 9 months later. Treated twice with Macrobid, once with Augmentin. Also treated in March 09 for yeast infection. Persistant headache, vertigo, blurry vision incapacitating, beginning two months after second dose and continuing for another two months. During these months also experienced anxiety/panic attacks/depression, diarrhea, vomiting. Blood and urine tests all normal. MRI and CT scan revealed nothing. Pap test revealed abnormal cells at the moderate level. All symptoms were beginning to improve when the last dose was given because no one had yet connected the dots....Then exactly two months after the last dose all symptoms returned in full. Headache, blurry vision, vertigo, frequent and burning urination. Patient is now 3 months from the last dose of gardasil and is now starting to feel less bad!

Other Meds: generic ortho-tri-cyclen

Lab Data: Blood, urine, MRI, CT scan all normal. Pap test taken six months after initial dose revealed abnormal cells in moderate range.

History: none

Prex Illness: none

Prex Vax Illns: none~ ()~NULL~~In Patient|none~ ()~NULL~~In Sibling1|none~ ()~NULL~~In Sibling2

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342182-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Mar-2009	10-Mar-2009	7	19-Mar-2009	20-Mar-2009	CA		08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	2	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Agoraphobia, Anxiety disorder, Condition aggravated, Cough, Depression, Educational problem, Headache, Major depression, Nasal congestion, Obsessive-compulsive disorder, Panic attack, Pyrexia, Rhinitis, Sleep disorder, Social problem, Suicidal ideation, Vaccine positive rechallenge, Viral upper respiratory tract infection, Weight increased

Symptom Text: HPV #1, 8/18/08; HPV #2, 10/20/08; HPV #3, 3/3/09. Hospitalized within 2 weeks of each vaccine for severe depression exacerbation. 3/23/09 Received PCP vaccine records & medical records of 8/18/08-3/17/2009. FINAL DX: OCD, depression, suicidal ideation Records reveal patient experienced good health on 8/18/08 when received HPV #1. RTC 10/20 s/p hospitalization x 2 wks for depression & was continued psych meds & care. Had nasal congestion, HA & sleep disturbance x 3-4 days. No dx provided & received HPV #2. RTC 3/3/09 w/rhinitis, cough, fever x 4 days. Dx w/viral URI & received HPV #3. 3/26/09 Received multiple ER medical records: 9/5/2008 ER visit FINAL DX: Depression w/suicidal ideation Records reveal patient having SI. Meds given for UTI. Psych eval in ER & transfer to psych hospital. 11/8/2008 ER visit FINAL DX: Depression w/suicidal ideation Records reveal patient w/SI x 1-2 wks. Psych eval in ER & transferred to psych hospital. 3/10/2009 ER visit FINAL DX:Depression w/suicidal ideation Records reveal patient w/SI intermittently since 11/08, on multiple psych meds & seeing psychiatrist 2x/wk & was in outpatient program. Had dx at psych hospital recently of depression, OCD & anxiety disorder. Had 30# wt gain w/increased appetite. Parental divorce in process. Psych eval in ER & transferred to psych hospital. 3/16/2009 ER visit FINAL DX: Depression w/suicidal ideation Records reveal patient w/SI & plan for self harm, racing thoughts, insomnia. Psych eval in ER & transferred to psych hospital. 4/6/09 Received D/C summaries for 3 admissions: 9/6-9/17/2008 Final dx: OCD; major depressive disorder, recurrent. Records reveal s/s had been progressing since summer w/suicidal ideation, anxiety, panic attacks, OCD repetitive behaviors. Initial psych hospitalization. Parents had separated 1 yr prior & had multiple family/friend losses. Required constant attention while hospitalized due to anxiety. Tx w/multiple meds as well as psychotherapy. Slowly improved & d/c to home

Other Meds: LEXAPRO; ABILIFY; WELLBUTRIN; KLONOPIN

Lab Data: None LABS: all WNL. 9/5/08 Urine c/s (+). Drug screen neg.

History: Depression

Prex Illness: Depression

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342199-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	28-Nov-2008	03-Dec-2008	5	16-Mar-2009	02-Apr-2009	NY	WAES0902USA04044	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Influenza like illness, Pain, Pyrexia

Symptom Text: Information has been received from a nurse concerning a 24 year old female patient who on 28-NOV-2008 was vaccinated with first dose of GARDASIL (Lot # not reported). On 03-DEC-2008 the patient experienced flu like symptoms such as fever, body aches and headaches. On 18-FEB-2009 the nurse called the patient to found out why she did not show up the second dose of GARDASIL and the patient mentioned the experienced and decided not to get the rest of the series. There were no Laboratory Diagnostics Studies performed. At the time on the report on 23-FEB-2009 the patient was recovered. The patient did not seek medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342200-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	02-Apr-2009	--	WAES0902USA04071	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Guillain-Barre syndrome

Symptom Text: Information has been received from a physician's assistant concerning her relative, a female who on an unspecified date was vaccinated with GARDASIL. It was reported that the patient thought she developed GUILLAN-BARRE after receiving GARDASIL. The patient sought unspecified medical attention. Upon internal review GUILLAN-BARRE was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342201-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Feb-2009	Unknown		16-Mar-2009	02-Apr-2009	IL	WAES0902USA04072	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1297X	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0652X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Pallor, Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female student with no known medical history and drug allergies, who on 14-FEB-2009 at 10:00 was vaccinated with a second dose of GARDASIL (lot # 661766/0652X), intramuscularly into the right deltoid. Concomitant suspect therapy included hepatitis A vaccine (MSD) (lot # 658174/1297X), intramuscularly into the left deltoid on 14-FEB-2009. On 14-FEB-2009 at 10:00 after receiving the second dose of GARDASIL the patient became pale, and fainted for approximately 1-2 minutes. Blood pressure was 120/10. It was also reported that the patient was complaining of numbness in right arm. The patient also experienced fainting after the first dose of GARDASIL when she was 14 years old. No laboratories studies performed. No further information is available.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342203-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	02-Apr-2009	PA	WAES0902USA04176	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with three doses of GARDASIL (Lot # not reported). The patient experienced headaches after all three doses of GARDASIL. The outcome was not reported. It was reported that the patient sought unspecified medical attention. This was one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342204-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Oct-2008	01-Nov-2008	31	16-Mar-2009	02-Apr-2009	--	WAES0902USA04180	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Paraesthesia

Symptom Text: Information has been received from a consumer concerning her 16 year old daughter with allergy to AMOXICILLIN who in August 2008, was vaccinated with the first dose of GARDASIL (Lot # not provided), in OCT-2008, was vaccinated with the second dose of GARDASIL (Lot# not provided). Concomitant therapy included MENACTRA which she received with the first dose of GARDASIL. Then in the first week of November 2008, the patient started to have severe lower back pain. Then the back pain progressed over the week with some tingling in her legs. The patient then saw a physician who recommended physical therapy and to see a chiropractor. The patient had a MRI which showed everything was fine. The patient had been doing better with the physical therapy, but then two weeks ago the back pain started to bother her again. The reporter was not sure if the back pain and tingling in the legs was related to GARDASIL, but she decided not to give the third GARDASIL at this point in time. The patient was not recovered from back pain and tingling in her legs. She went to the doctor, chiropractor, physical therapy, MRI. This was one of several reports from the same source. Additional information has been requested.

Other Meds:

Lab Data: Magnetic resonance, everything was fine.

History: PENICILLIN allergy

Prex Illness:

Prex Vax Illns:

Vaers Id: **342205-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		16-Mar-2009	02-Apr-2009	OR	WAES0902USA04190	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site discolouration, Injection site scar

Symptom Text: Information has been received from a registered nurse concerning a 20 year old female patient with no pertinent medical history and no known drug allergies or reactions who in October 2008 was vaccinated with the first dose of GARDASIL. The patient had no problems with dose 1. On an unspecified date the patient was vaccinated with the second dose of GARDASIL vaccine at a different facility. Concomitant therapy included hormonal contraceptives (unspecified). Subsequently the patient experienced scarring at the injection site. There was a white ring at the injection site that was 2 and 1/2 centimeters in diameter and it looked like a "puncture scar". There was no pain and no swelling. No lab diagnostics studies were performed. At the time of reporting, the patient's scarring at the injection site persisted. The patient sought medical attention via office visit. Additional information has been requested

Other Meds: hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342206-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	02-Apr-2009	--	WAES0902USA04195	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain

Symptom Text: Information has been received from a nurse midwife concerning an unspecified number of patients who were vaccinated IM with the second dose 0.5ml dose of GARDASIL (lot number and site note reported). The patients had complained that the second dose hurt a lot more than the first. As of the report time, the outcome of the event was not reported. The patients had sought medical attention in the office. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342207-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		16-Mar-2009	02-Apr-2009	PA	WAES0902USA04198	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect storage of drug, Pain

Symptom Text: Information has been received from a physician concerning several hundred patient who on unspecified dates were vaccinated with doses of GARDASIL (lot number, route and site not reported). It was reported that the products had been predrawn and stored in the refrigerator for up to one week. No adverse effect reported except"it always stings". As of this report time, the outcome was not reported. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342208-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	02-Apr-2009	MA	WAES0902USA04249	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Migraine

Symptom Text: Information has been received form a physician concerning a female who was vaccinated with a 0.5 ml dose of GARDASIL. Subsequently the patient experienced a migraine. It was unknown what dose of series of GARDASIL vaccine migraine occurred after. No lot number was provided. At the time of reporting the patient was recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342209-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	02-Apr-2009	HI	WAES0902USA04250	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning a female patient who was vaccinated intramuscularly with her first 0.5 ml dose of GARDASIL. The patient experienced a rash "a few months after getting the first dose". The patient also developed a rash a few months after second dose of vaccine as well. It is unknown if the patient received her third shot or not. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342210-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	02-Apr-2009	--	WAES0902USA04252	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise

Symptom Text: Information has been received from a consumer concerning her daughter who became ill after received her second dose of GARDASIL. The consumer did not want to provide demographics nor explanation of the AE. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342212-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-Jan-2009	25-Feb-2009	50	16-Mar-2009	02-Apr-2009	GA	WAES0902USA04343	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anogenital warts, Vaginal lesion

Symptom Text: Information has been received from a physician assistant student concerning a 16 year old female who on 06-JAN-2009 was vaccinated with first dose of GARDASIL. There was no concomitant medication. On 25-FEB-2009 she was seen in the physician's office and was found to have genital warts. She and had two small warts in the inferior anus, lesions intravaginally and the entire area of perineal area covered with warts. The patient was asymptomatic. The patient admitted to having unprotected intercourse in mid December 2008. The patient had not recovered from the event at the time of the report. Lab studies performed included Papanicolaou test (results not reported). Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342213-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Jun-2008	01-Jul-2008	5	16-Mar-2009	02-Apr-2009	--	WAES0902USA04346	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amenorrhoea, Hypomenorrhoea

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter with no known medical history or drug allergies, who on 26-JUN-2008 or 28-JUN-2008 was vaccinated with a first dose of GARDASIL. The patient received a second dose of GARDASIL in July 2008 and a third dose of GARDASIL on 15-JAN-2009. It was also reported that the patient had a dose of hepatitis A vaccine on 15-JAN-2009. In July 2008 the patient started to have a light period, and since July 2007 she never had her menstrual period. No laboratories studies were performed. The patient sought medical attention through the health department. At the time of this report the patient had not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342214-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Jan-2009	12-Feb-2009	42	16-Mar-2009	02-Apr-2009	GA	WAES0902USA04350	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received form a 23 year old female patient, with no known drug reaction/allergies and no pertinent medical history, who in January 2009, was vaccinated with her first dose of GARDASIL. Concomitant therapy included vitamins (unspecified). The consumer reported that she experienced hair loss since 3 weeks ago when she received her first dose of GARDASIL vaccine. At the time of the report, the patient was recovering. The patient spoke to her physician seeking for medical attention. Additional information has been requested.

Other Meds: Vitamins (unspecified)

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342215-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Sep-2008	01-Oct-2008	7	20-Mar-2009	23-Mar-2009	FR	WAES0903NZL00010	23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1697U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion

Symptom Text: Information has been received from an agency via agency as part of a business agreement concerning a 17 year old female with convulsion who on 24-SEP-2008 was vaccinated with GARDASIL (Lot No. 1697U, Batch # NH48330). Concomitant therapy included lamotrigine. In October 2008, the patient experienced convulsions aggravated. The severity of convulsions aggravated was reported as not severe. At the time of reporting to the agency in October 2008, the outcome of convulsions aggravated was unknown. The agency considered that convulsions aggravated was possibly related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review, convulsions aggravated was considered an other important medical event. Additional information is not expected.

Other Meds: lamotrigine

Lab Data: Unknown

History:

Prex Illness: Convulsion

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342221-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Jan-2009	16-Jan-2009	3	20-Mar-2009	23-Mar-2009	FR	WAES0903USA02174	23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Petit mal epilepsy, Somnolence, Staring, Tremor

Symptom Text: Information has been received from the Health Authority (reference number ES-AGEMED-320772341) concerning a 14 year old female patient who was handicapped and presenting psychomotor retardation with a possible congenital ataxia. On 13-JAN-2009, the patient was vaccinated with a dose of GARDASIL (lot number, batch number and site not reported) by intramuscular route. On 16-JAN-2009, the patient presented with somnolence, tremor, absence seizure and staring. The patient recovered from absence seizure on an unspecified date. The outcome for the rest of the events was unknown. The patient is handicapped, presenting psychomotor retardation with a possible congenital ataxia. Case was reported as serious by the HA with other medically important condition as criteria. Other business partner numbers included: E2009-02118. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Psychomotor retardation; Congenital cerebellar ataxia; Handicap

Prex Vax Illns:

Vaers Id: **342222-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Nov-2008	27-Nov-2008	10	20-Mar-2009	23-Mar-2009	FR	WAES0903USA02173	23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Epilepsy, Headache, Incontinence, Loss of consciousness, Petit mal epilepsy, Somnolence

Symptom Text: Information has been received from the Health Authority (reference number ES-AGEMED-120770341) concerning a 14 year old female patient with dust-mite allergy, a history of asthma and family medical history of migraines who on 17-NOV-2008 was vaccinated with a dose of GARDASIL (site, lot number and batch number not reported) by intramuscular route. It was reported that 10 days after vaccine administration, on 27-NOV-2008, the patient presented with a temporary loss of consciousness, epilepsy equivalent, dizziness, incontinence, cephalgia, absence seizure and somnolence. The patient recovered from temporary loss of consciousness, epilepsy equivalent, dizziness, incontinence, and absence seizure on the same date (27-NOV-2008). The patient recovered from somnolence on an unspecified date. The patient had not recovered from cephalgia. Case reported as serious by the HA with other medically important condition as criteria. Other business partner numbers included: E2009-02122. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Asthma

Prex Illness: House dust mite allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342223-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
40.0	F	08-Jan-2009	18-Jan-2009	10	20-Mar-2009	23-Mar-2009	FR	WAES0903RUS00003	10-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 40 year old female who on 08-JAN-2009 was vaccinated with GARDASIL. On 18-JAN-2009 the patient experienced pain in upper arm. Subsequently, the patient recovered from pain in upper arm on approximately 18-FEB-2009. The reporter felt that pain in upper arm was related to therapy with GARDASIL. Pain in upper arm was considered serious as an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342224-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	03-Dec-2007	04-Dec-2007	1	20-Mar-2009	23-Mar-2009	FR	WAES0903COL00009	23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Malaise, Myalgia, Pyrexia, Rheumatoid arthritis, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a 24 year old female who on 03-DEC-2007 was vaccinated with GARDASIL. On 04-DEC-2007 the patient experienced fever, general malaise, myalgias, arthralgias and rheumatoid arthritis. On 11-DEC-2007 the patient recovered from fever and general malaise, myalgias and arthralgias became mild. In January 2008, the patient was vaccinated with the second dose of GARDASIL. Subsequently she experienced intermittent fever for 5 months, myalgias and arthralgias became severe and disabling. The patient was treated with corticosteroids and chloroquine. Patient's hemoglobin decreased to 7. The reporter felt that fever, general malaise, myalgias, arthralgias, fever and rheumatoid arthritis were related to therapy with GARDASIL. Myalgias, arthralgias and rheumatoid arthritis were considered to be disabling. Additional information is not expected.

Other Meds: Unknown

Lab Data: hemoglobin, ??Jan08, 7 mg/dl

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342225-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	19-Jun-2008	19-Jun-2008	0	20-Mar-2009	23-Mar-2009	MN	WAES0807USA00609	23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	3	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Foetal disorder, High risk pregnancy, Pre-eclampsia, Sinusitis, Uterine infection

Symptom Text: Initial information has been received through the Merck Pregnancy Registry from a medical assistant concerning a 19 year old female with asthma who on 22-OCT-2007 was vaccinated intramuscularly with the 0.5 ml first dose of GARDASIL and on 26-FEB-2008 was vaccinated intramuscularly with the 0.5 ml second dose of GARDASIL. On 19-JUN-2008 the patient was vaccinated intramuscularly with the 0.5 ml third dose of GARDASIL and she was pregnant at that time. The date of her last menstrual period was 28-APR-2008 and her estimated delivery date is 02-FEB-2009. No adverse events reported. The patient's outcome was unknown. The patient called the physician's office. Follow-up information has been received from a physician concerning a 19 year old female with moderate persistent asthma (better past couple of years) and allergies and a history of hospitalization due to her asthma prior to 1996. There was no history of pregnancy. It was reported that the patient received a prior dose of GARDASIL on 28-FEB-2007. Concomitant therapy included fluticasone nasal spray (during allergy season), montelukast sodium (MSD) and QVAR (since before pregnancy). On approximately 26-AUG-2008, during pregnancy, the patient experienced sinus infection. AUGMENTIN and amoxicillin were prescribed. The patient also used other medications for asthma including prednisone and ADVAIR. Ultrasounds were done in 4 times due to the patient was in high risk. All the results were normal. On 22-FEB-2009 the patient delivered a normal, healthy female baby weighing 7 pounds 2 ounces. The baby's length was 19.25 inches and head circumference was 13 inches with Apgar score 8/9. There were no congenital anomalies and other complications/abnormalities. On approximately 22-FEB-2009, during labor, the patient experienced pre-eclampsia and uterine infection. The patient underwent c-section and had meconium birth. The patient's outcomes were unknown. Upon internal review, c-section was determined to be an other important medical event. Additional information has been re

Other Meds: QVAR; fluticasone; SINGULAIR

Lab Data: Ultrasound, normal; Ultrasound, normal; Ultrasound, normal; Ultrasound, normal

History: Hospitalisation

Prex Illness: Pregnancy NOS (LMP = 4/28/2008); Asthma; Hypersensitivity

Prex Vax Illns:

Vaers Id: **342227-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Mar-2008	01-Mar-2008	0	16-Mar-2009	02-Apr-2009	CA	WAES0902USA04032	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Mobility decreased, Pain

Symptom Text: Information has been received from a consumer concerning her daughter (a 16 year old female) who in March 2008, was vaccinated with her first dose of GARDASIL. About 24 hours after receiving the vaccine (March 2008), the patient felt like there was stakes going through her arms and legs for about 2 weeks after receiving the vaccine. Caller stated it was intense pain and she had difficulty moving. At the time of the report (23-FEB-2009) patient had not received the second or third dose. It was reported that therapy with GARDASIL was discontinued in March 2008. The patient was recovered about 2 weeks after receiving the vaccine. The patient sought unspecified medical attention. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342228-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	21-Sep-2007	Unknown		20-Mar-2009	23-Mar-2009	FL	WAES0801USA00529	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0802U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy, Nausea

Symptom Text: Initial and follow-up information has been received from a certified medical assistant for the pregnancy registry for GARDASIL concerning a 22 year old female who on 21-SEP-2007 was vaccinated intramuscularly with the first dose of GARDASIL (658490/0802U). Subsequently, the patient discovered that she was pregnant (LMP=10-AUG-2007). The patient returned to the physician's office on 05-DEC-2007 because her cycle was late and the office performed a pregnancy test that was positive. During the 05-DEC-2007 office visit, the patient was asked to have an ultrasound obtained. The patient was seen in the office again on 26-DEC-2007 and had not yet had the ultrasound completed. The scheduled date for the ultrasound was unknown. Per the reporter, the pregnancy has been unremarkable thus far. No additional information was available. Patient outcome was not reported. Follow up information received on 13-MAR-2009 from an initial and an outcome pregnancy questionnaire stated that the patient had no concurrent medical conditions reported. Medication used during the pregnancy includes ZOFRAN in January 2008 through February for the treatment of nausea. The patient was also taken prenatal vitamins. There were not birth defects and infant complications in previous pregnancies, the patient had a previous full term delivery and no fetal deaths, spontaneous abortions and pre term deliveries. The patient had an elective pregnancy termination in May 2007 at 7 weeks from LMP. The products of the conception were examined. The patient did not experience infections or illness during pregnancy. The patient had an ultrasound and a serum alpha-fetoprotein test (MSAFP), both were normal. Upon internal review, elective termination was determined to be an other important medical event. No further information is available.

Other Meds:

Lab Data: ultrasound, normal; beta-human chorionic, 12/05/07, positive; serum alpha-fetoprotein, normal

History:

Prex Illness: Pregnancy NOS (LMP = 8/10/2007); Nausea

Prex Vax Illns:

Vaers Id: **342229-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	29-Jun-2007	31-Aug-2008	429	16-Mar-2009	02-Apr-2009	OH	WAES0902USA04019	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	2	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Gianotti-Crosti syndrome, No reaction on previous exposure to drug, Rash

Symptom Text: Information has been received from a nurse concerning her 20 year old daughter who was vaccinated with her third dose of GARDASIL (lot # not available). On "Labor Day weekend of 2008" approximately 31-AUG-2008 the patient developed "Giannati-crosti syndrome" 6 to 7 months after the patient received her third dose of GARDASIL. The patient had rashes on her feets, arms and face. The nurse noted that the patient did not have any adverse events with the first and second dose of GARDASIL. The patient had seen physician in office for medical attention. At the time of reporting the patient was recovering from the adverse events. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342233-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
38.0	F	07-Aug-2008	07-Aug-2008	0	16-Mar-2009	02-Apr-2009	IL	WAES0902USA04004	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anogenital warts, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a physician concerning a 38 year old female with no medical history or drug allergies who was intramuscularly vaccinated with the first, second and third 0.5 ml doses of GARDASIL (1st and 2nd lots #"0770X", 3rd lot #0573X) on 07-AUG-2008, 11-SEP-2008 and 03-FEB-2009, respectively. The patient developed reactivation of genital warts a few days after receiving her third dose of GARDASIL. She had negative culture for herpes. Subsequently, the patient recovered from reactivation of genital warts on an unspecified date. The patient visited family physician for medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Herpes simplex virus, negative

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342236-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Feb-2009	16-Feb-2009	0	16-Mar-2009	31-Mar-2009	NC	WAES0902USA04000	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a pharmacist concerning a 17 year old female patient with no pertinent medical history and no drug reactions or allergy who on approximately 16-FEB-2009 was vaccinated with first dose of GARDASIL (Lot # not reported). There was no concomitant medication. On approximately 16-FEB-2009 since vaccine was administered the patient experienced headache. At the time on the report on 23-FEB-2009 the patient was not recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342238-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Feb-2009	17-Feb-2009	0	16-Mar-2009	02-Apr-2009	IL	WAES0902USA03917	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1297X	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0940X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pallor

Symptom Text: Information has been received from a registered nurse concerning a 15 year old female patient with no pertinent medical history and no known drug allergies/drug reactions who on 17-FEB-2009 was vaccinated with the second dose of GARDASIL (Lot # 659655/0940X) intramuscularly into the left deltoid at 12:45. Secondary suspect therapy on 17-FEB-2009 included a second dose of hepatitis A virus vaccine inactivated (MSD) (Lot # 658174/1297X) intramuscularly into the right deltoid. It was reported that on 17-FEB-2009 at 13:00, the patient became pale and felt nauseated after receiving the second dose of GARDASIL for approximately 10 minutes. There were no laboratory tests performed. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342240-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	09-Oct-2008	09-Oct-2008	0	16-Mar-2009	02-Apr-2009	--	WAES0902USA03801	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site, Loss of consciousness

Symptom Text: Information has been received from a nurse practitioner concerning a 26 year old female patient with allergy to sulfa and asthma and a history of "brachial plexus" who on 09-OCT-2008 was vaccinated with the first 0.5 ml IM dose of GARDASIL (lot #660557/0072X). It was given in the left gluteal region. On 20-FEB-2009 the patient was vaccinated with the second 0.5 ml IM dose of GARDASIL (lot # 661764/0650X). Concomitant therapy included hormonal contraceptives (unspecified), montelukast sodium, ZYRTEC, albuterol, VERAMYST and ADVAIR. On 20-FEB-2009 the patient experienced passed out while she was still in the office. No lab diagnostics studies were performed. On 20-FEB-2009, the patient regained consciousness and recovered. The patient sought medical attention in the office. Additional information has been requested.

Other Meds: albuterol; ZYRTEC; VERAMYST; ADVAIR; hormonal contraceptives; SINGULAIR

Lab Data: None

History: Brachial plexus injury

Prex Illness: Asthma; Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **342246-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Feb-2009	20-Feb-2009	0	16-Mar-2009	02-Apr-2009	KS	WAES0902USA03797	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1208F	1	Unknown	Intramuscular	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HEP	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from a physician concerning a 16 year old female with no pertinent medical history and no known drug allergies who on 20-FEB-2009 was vaccinated intramuscularly with a second 0.5 ml dose of GARDASIL (Lot # 654741/1208F). On the same day she also received a dose of secondary suspect vaccine, hepatitis B vaccine (manufacturer unknown) and a dose of concomitant therapy, "meningitis vaccine" (manufacturer unknown). "Three minutes after administration of the second dose of GARDASIL", the patient fainted. She "quickly" recovered. No lab diagnostics studies were performed. It was reported that the lot number and date of administration of the first dose of GARDASIL were unknown. Unspecified medical attention was sought. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342247-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		16-Mar-2009	02-Apr-2009	MN	WAES0902USA03770	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received from a physician concerning a 23 year old female patient who was vaccinated with a 0.5 ml IM dose of GARDASIL. Subsequently ("within 1 day of receiving GARDASIL") the patient experienced a high fever (above 102.6F). Therapy with GARDASIL was discontinued. The patient sought medical attention via telephone. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342248-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	08-Jun-2007	08-Jun-2007	0	16-Mar-2009	25-Mar-2009	--	WAES0902USA03739	25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Blister, Headache, Influenza like illness, Rash

Symptom Text: Information has been received from a consumer concerning her 16 year old grand daughter (patient) who on 08-JUN-2007 was vaccinated with a first dose of GARDASIL 0.5 mL and on 04-AUG-2007 was vaccinated with a second dose of GARDASIL. There was no concomitant medication. On approximately 08-JUN-2007 ("shortly after first dose") the patient experienced flu like symptoms. She did not have much energy and a little rash. After the second dose, the patient experienced headaches, a rash. She broke out in "huge" blisters all over her back. In September 2007, the patient recovered. Third dose was never given. The patient sought unspecified medical attention. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342249-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	M	Unknown	01-Jul-2008		16-Mar-2009	02-Apr-2009	--	WAES0902USA03734	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Off label use

Symptom Text: Information has been received from a physician concerning a health care provider's 20 year old son who was vaccinated with the second dose of GARDASIL on unspecified date. In July 2008, the patient experienced headache after receiving the second dose of GARDASIL. On unspecified date, he recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342250-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	10-Feb-2009	11-Feb-2009	1	16-Mar-2009	02-Apr-2009	--	WAES0902USA03713	28-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Local swelling, Oropharyngeal discomfort, Swelling face

Symptom Text: Information has been received from a nurse concerning a 17-year-old female with no known relevant medical history nor drug allergy, who on 10-FEB-2009 was vaccinated IM with the first dose of 0.5 ml GARDASIL (lot # 661952/1129X) in her deltoid. There was no concomitant therapy. On 12-FEB-2009 the patient's mom called to office to seek medical attention concerning the patient's reaction that took place on 11-FEB-2009. The patient's face was described as "puffy from the neck up to her cheeks". The patient felt it was a little difficult to breathe and her throat "felt funny". She took BENADRYL 2 doses on 11-FEB-2009 and on 12-FEB-2009 she took CLARITIN. No laboratory test was performed. On an unspecified date, the patient recovered from the event. Her primary physician and school nurse felt the reaction was due to GARDASIL and recommended discontinuing the series. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342251-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Jan-2007	26-Feb-2007	42	16-Mar-2009	02-Apr-2009	MA	WAES0902USA03633	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0697F	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Myalgia, Pain, Pyrexia

Symptom Text: Information has been received from a physician concerning a 16-year-old white female student, with no known relevant medical history nor drug allergy, who on 15-JAN-2007 was vaccinated IM in her left deltoid with the first dose of GARDASIL (lot # 653650/0697F). Concomitant therapy included ALESSE, ASTELIN and RHINOCORT. On 26-FEB-2007, the patient experienced headache and myalgia. On 27-FEB-2007, her temperature was 101 degrees Fahrenheit. Medical attention was sought and the events required ER/DR visit. Laboratory test showed that all CBC and ESR were negative. On 23-MAR-2007, the patient was vaccinated IM in her left deltoid with the second dose of GARDASIL (lot # 653650/0697F). Subsequently on 24-MAR-2007, she experienced "ST" and headache. On 26-MAR-2007, her temperature was of 101.5 degrees Fahrenheit, she also experienced bodyache. The patient's outcome was unknown. No further information is available.

Other Meds: ASTELIN; RHINOCORT; ALESSE

Lab Data: Body temp, 02/27/07, 101; Erythrocyte, 02/27/07, negat; Body temp, 03/26/07, 101.5; Complete blood cell, 2/27/07 negat.

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342252-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Feb-2009	04-Feb-2009	0	16-Mar-2009	07-Apr-2009	LA	WAES0902USA03603	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Injected limb mobility decreased, Injection site pain, Injection site swelling, Injection site warmth

Symptom Text: Information has been received from a Registered Nurse concerning a 14 year old female with a history of back pain and pin in hip, and no drug reactions/allergies, who on 04-FEB-2009 was vaccinated with the first dose of GARDASIL (lot# 661766/0652X), 0.5 ml intramuscular into her left arm. There was no concomitant medication. On 04-FEB-2009 the patient experienced some pain as the injection went into her arm. This pain went away but then two weeks later the patient began to experience swelling of the injection site area. It was the size of a palm and was hot to the touch. There was no redness. The patient then wasn't able to lift up her arm because of the pain. She also developed numbness of her whole arm down to her hand. On 19-FEB-2009, it was numb nut only from the elbow down to her hand. It was not as tender but it still hurt. There was less swelling. On unspecified date, the patient sought unspecified medical attention, no lab diagnostics studies performed. The patient was not recovered. This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Back pain; Pain in hip

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342253-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	08-Jan-2009	Unknown		16-Mar-2009	07-Apr-2009	CO	WAES0902USA03589	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a physician concerning a 14 year old female who was vaccinated with the first dose of GARDASIL (lot# not reported) 0.5ml, injection four or six weeks ago. Concomitant therapy included hepatitis A virus vaccine (unspecified) and Mananjacocus. The patient experienced hives after getting first dose of GARDASIL. On unspecified date, the patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342254-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	21-Nov-2008	22-Nov-2008	1	20-Mar-2009	24-Mar-2009	MN	WAES0902USA03560	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Injection site erythema

Symptom Text: Information has been received form a nurse concerning a 23 year old female who on 21-NOV-2008 was vaccinated injection with the first dose of GARDASIL (lot # not reported). After received the first dose of GARDASIL, on 22-NOV-2008 the patient's face was red and she had redness at the site of where the band aid was. The patient recovered from adverse events after some time. The nurse reported that on 23-JAN-2009 they decided they were going to wait to give the second dose of GARDASIL. It was reported that the patient did not seek medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342263-1 (S)** **Related reports:** 342263-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Nov-2008	07-Jan-2009	51	20-Mar-2009	23-Mar-2009	FR	B0564815A	23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NG52730	1	Unknown	Intramuscular	
	TD	GLAXOSMITHKLINE BIOLOGICALS	XC12BM115C1		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal discomfort, Arthralgia, Henoch-Schonlein purpura, Leukocytoclastic vasculitis, Purpura

Symptom Text: This case was reported by a regulatory authority (ES-AGEMED-718657244) and described the occurrence of henoch-schonlein purpura in a 14-year-old female subject who was vaccinated with DITANRIX adult (GlaxoSmithKline), GARDASIL (non-GSK). Previous vaccination included GARDASIL (non-GSK) (Sanofi Pasteur MSD; intramuscular; unknown injection site) given on 22 September 2008. On 17 November 2008, the subject received unspecified dose of DITANRIX adult (intramuscular, unknown injection site), 2nd dose of GARDASIL (intramuscular, unknown injection site). On 7 January 2009, 51 days after vaccination with DITANRIX adult and GARDASIL, the subject experienced purpuric rash in legs, forearms and buttock. She also had joint pain and abdominal discomfort. In a skin biopsy performed on 20 January 2009, it was observed a leukocytoclastic vasculitis (henoch-schonlein purpura). The subject improved with prednisone treatment. Disease of fluctuating course. On 27 February 2009 the subject was not still recovered. She required hospitalization. At the time of reporting the events were improved. No further information is expected; this case has been considered closed.

Other Meds:

Lab Data: Skin biopsy, 20Jan2009, abnormal

History:

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **342263-2 (S)** **Related reports:** 342263-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Nov-2008	07-Jan-2009	51	25-Mar-2009	26-Mar-2009	FR	WAES0903USA03827	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal discomfort, Arthralgia, Henoch-Schonlein purpura, Purpura

Symptom Text: Information has been received from a Health Authority (reference number ES-AGEMED-718657244) on 18-MAR-2009 concerning a 14 year old female who was administered on 17-NOV-2008 the second 0.5 ml dose of GARDASIL (lot # not reported) by intramuscular route (site of administration not reported). On the same day the patient also received a dose of DITANRIX by intramuscular route (site not reported). It is reported that on the 07-JAN-2009 the patient presented with a purpuric rash on legs, buttocks and forearms, arthralgia and abdominal discomfort. According to the skin biopsy, performed on 20-JAN-2009 the patient presented a leukocytoclastic vasculitis (Shonlein-Henodi syndrome). The patient improved after treatment with prednisolone, with fluctuance. By the 27-FEB-2009 the patient had not completely recovered yet. Hospital admission was required (dates not informed). It was reported that the patient received the first dose of GARDASIL on 22-SEP-2008 intramuscularly. It was not reported whether the patient had any adverse event after this dose of vaccine or not. Other business partner numbers included: E200902370. No further information is available.

Other Meds: Unknown

Lab Data: skin biopsy, 20Jan09, positive results for leukocytoclastic vasculitis (Shonlein-Henodi syndrome)

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342281-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	14-Jan-2009	15-Jan-2009	1	20-Mar-2009	23-Mar-2009	PA		23-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lymphadenopathy

Symptom Text: Reactive Lymphadenopathy, cervical, BIL.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns: Same~HPV (Gardasil)~UN~16~In Patient

Vaers Id: **342287-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	09-Jan-2009	09-Jan-2009	0	20-Mar-2009	24-Mar-2009	OH		06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	0651X	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	U2824AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site rash, Injection site swelling, Injection site warmth

Symptom Text: Mom states that eve after a shower noted area was red & swollen with a pinpoint flat rash that extended down from injection site 3 fingers width. C/o being itchy & warm to touch. Gave BENADRYL that evening and in AM with ice to area. In AM, looked the same but improved over the day - It took a couple days to totally resolve.

Other Meds:

Lab Data: None

History: PCN allergy, gold sodium thiosulfate

Prex Illness:

Prex Vax Illns: rash~Varicella (Varivax)~2~10~Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342324-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Mar-2009	12-Mar-2009	3	21-Mar-2009	23-Mar-2009	SC		12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Muscular weakness, Paraesthesia

Symptom Text: Shortly after first shot, daughter started having weakness/tingling in left arm. Also, dizziness. Within a week after second shot, she began to have more weakness in both legs, tingling in both legs and left arm. Dizziness is worse. She feels very weak all over and doesnt feel like doing much. 3/23/09 Received PCP medical records of 1/9-3/9/2009. FINAL DX: migraine classical Records reveal patient was new patient on 1/9/09 & reported chronic vaginal infection x 2 yrs & HAw/photophobia & nausea. Examination revealed condyloma. Received HPV #1 & Menactra. Also tx w/oral BCP & verapamil for HA. RTC 3/9/09 for HPV #2. 5/12/09 Case closed as incomplete. Will reopen should additional information documenting high ASO titre & diagnosis of rheumatic fever as verbally reported by PCP become available.

Other Meds:

Lab Data: Emergency Room visit on March 20, 2009. Blood work and CT scan were performed. All tests came back inconclusive/negative. Dr. recommended not to get third round of vaccine for HPV.

History: None PMH: GC & chlamydia vaginal infections 11/08. Family hx: migraines.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342337-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Mar-2009	18-Mar-2009	0	20-Mar-2009	24-Mar-2009	CA		17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U287CA		Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3058AA		Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0652X		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash macular, Rash papular

Symptom Text: Within 5 minutes of receiving 3 vaccines - MENACTRA, ADACEL, and GARDASIL, pt developed a macular/papular rash L arm and trunk. BENADRYL dispensed - rash resolving within about 15-20 min. No wheeze. No h/o latex allergy.

Other Meds: none

Lab Data:

History:

Prex Illness: none

Prex Vax Illns:

Vaers Id: **342351-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	--	WAES0902USA03555	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has been received from a company representative concerning a female who was vaccinated with GARDASIL (LOT# not reported). After getting the GARDASIL, the patient had unknown AE and would be on TV that night. The outcome of the patient's adverse events was not reported. It was reported whether the patient sought medical attention. Attempts are being made to verify the existence of an identifiable patient and reporter. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342353-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-Feb-2009	06-Feb-2009	0	16-Mar-2009	07-Apr-2009	TX	WAES0902USA03553	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Influenza like illness, Pain, Pyrexia

Symptom Text: Information has been received from a 20 year old female healthcare student who on 6-FEB-2009 was vaccinated with a first dose of GARDASIL. On 6-FEB-2009 the patient reported she felt like she had the flu, was achy and had a fever. The patient was off work for about two days. The patient recovered on approximately 11-FEB-2009. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342354-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Dec-2008	01-Dec-2008	0	16-Mar-2009	07-Apr-2009	MS	WAES0902USA03545	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Diarrhoea, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, for GARDASIL, a Pregnancy Registry product, concerning a 14 year old female with asthma and no known drug allergies who in JUL-2008, was vaccinated IM with the first dose of GARDASIL 0.5 ml (Lot # 0151X), and in DEC-2008, was vaccinated IM with the second dose of GARDASIL 0.5 ml (Lot # 660389/1968U). The patient was pregnant at the time of vaccination (gestation-about- 5-6 months). Concomitant therapy included MSD, XOPENEX and albuterol inhaler (manufacturer unknown). The patient was currently experience diarrhea. The outcome of the patient's adverse events was not reported. It was reported that the patient sought medical attention: office visit. Additional information has been requested.

Other Meds: ALBUTEROL; XOPENEX; SINGULAR

Lab Data: Diagnostic laboratory, pregnancy.

History:

Prex Illness: Pregnancy NOS (LMP = 8/1/2008); Asthma

Prex Vax Illns:

Vaers Id: **342355-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	26-Jun-2008	26-Jun-2008	0	16-Mar-2009	07-Apr-2009	--	WAES0902USA03544	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a female 21 years old who on 14-DEC-2007 was vaccinated with the first doses of GARDASIL 0.5 ml. On 12-FEB-2008 the patient was vaccinated with the second dose of GARDASIL and on 26-JUN-2008 was vaccinated with the third dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). Subsequently in 2008 the patient had an abnormal pap smear result after completing the three doses of GARDASIL 0.5 ml. Disability and life threatening is unknown. The patient's abnormal pap smear persisted. The patient sought unspecified medical attention. Additional information is not available.

Other Meds: Hormonal contraceptives

Lab Data: Cervical smear, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342356-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	--	WAES0902USA03536	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse drug reaction

Symptom Text: Information has been received from a female consumer who on an unknown date, was vaccinated with GARDASIL (lot # not reported). Subsequently the patient experienced severe side effects. The patient was told that the reason she had the side effects was because she sat down for 15 minutes after administration. It was unspecified if the patient sought medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342357-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	PA	WAES0902USA03528	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Vaccine positive rechallenge

Symptom Text: Information has been received from a patient's mother concerning a 19 year old female who was vaccinated with second of GARDASIL. The patient's mother reported that after the administration of the second dose (unknown date), her daughter experienced rash around the umbilical and tops of both thighs. The patient was taken to a dermatologist and was prescribed an unspecified topical cream. The mother stated that the cream did not improve the systems but that rash resolved "eventually" on an unknown date. On an unspecified date, the patient was vaccinated with the third dose of GARDASIL. The reporter said that the patient developed a similar rash, with the same distribution, after the third dose. The mother stated that the second occurrence of the rash developed "just recently" and at the time of the report had not been resolved. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342358-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	17-Feb-2009	17-Feb-2009	0	16-Mar-2009	07-Apr-2009	PA	WAES0902USA03115	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 25 year old female who on 17-FEB-2009 was vaccinated with the first dose of GARDASIL (lot number, route an site of administration not reported). It was reported that "the patient was in the office to receive the first dose of GARDASIL and right after receiving the first dose the patient fainted". The physician reported that they had helped the patient up then she recovered, so she was ok to leave the office. The physician also mentioned that the patient did not have anything to eat before getting the first dose of GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342359-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Dec-2008	12-Dec-2008	10	16-Mar-2009	07-Apr-2009	VA	WAES0902USA03112	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a physician concerning a 17 year old female who on 02-DEC-2008 was vaccinated with the first dose of GARDASIL (lot no. and route not reported) and MENACTRA. On 12-DEC-2008 when the patient was done with the vaccination, she left the room and passed out in the elevator. The physician reported that the patient did not have injury when she passed out. The patient was brought back to the clinic and after a few minutes she was fine and left the clinic. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342360-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Sep-2008	01-Sep-2008	0	16-Mar-2009	07-Apr-2009	--	WAES0902USA03108	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash, Vaccine positive rechallenge

Symptom Text: Information has been received from the immunization coordinator concerning a 20 year old female patient who in approximately September 2008, was vaccinated with the first dose of GARDASIL. On an unknown date, was vaccinated with the second dose of GARDASIL. On 18-FEB-2008, the patient came in to receive the third dose of GARDASIL and mentioned that a day after receiving the first and second dose of GARDASIL she developed a rash on her abdomen, and then a couple days later the rash would resolve. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342361-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.6	F	26-Oct-2007	26-Oct-2007	0	16-Mar-2009	03-Apr-2009	KS	WAES0902USA03107	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1265U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Migraine

Symptom Text: Information has been received from a physician concerning a female patient who on 26-OCT-2007 was vaccinated with the first dose of GARDASIL (Lot # 659435/1265U) 0.5ml. On 18-JAN-2008 was vaccinated with the second dose of GARDASIL (Lot # 658556/1060U) 0.5ml. On 23-MAY-2008 was vaccinated with the third dose of GARDASIL (Lot # 660389/1968U) 0.5ml. Concomitant therapy included YAZ. The patient experienced headaches in the form of severe migraines specifically during her periods after receiving GARDASIL. At the time of the report, the patient had not recovered from the adverse event. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: YAZ

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342362-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	02-May-2008	02-May-2008	0	16-Mar-2009	07-Apr-2009	MN	WAES0902USA03106	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal non-stress test, Pyrexia

Symptom Text: Information has been received from a Registered Nurse for the pregnancy registry for GARDASIL, concerning a 25 year old female patient with anxiety disorder and papanicolaou smear abnormal in 2007 resulting in a loop electrosurgical excision procedure, who on 28-AUG-2007 was vaccinated with the first dose of GARDASIL (lot# 658558/1061U), on 30-OCT-2007 was vaccinated with the second dose of GARDASIL (lot# 659964/1978U) and on 02-MAY-2008, was vaccinated with the third dose of GARDASIL (lot# 659437/1266U) while pregnant. On an unspecified date, a non stress test was performed (results not provided). Concomitant therapy included LEXAPRO and PREVACID. The nurse reported that the patient who had completed the HPV vaccine series was hospitalized for delivery and delivered a healthy baby on 31-DEC-2008. The patient had a post partum fever. On 31-DEC-2008, the patient recovered. Additional information has been requested.

Other Meds: LEXAPRO; PREVACID

Lab Data: Unknown

History: Papanicolaou smear abnormal; Loop electrosurgical excision procedure

Prex Illness: Pregnancy NOS (LMP = Unknown); Anxiety disorder

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342363-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
38.0	M	13-Feb-2009	13-Feb-2009	0	16-Mar-2009	07-Apr-2009	--	WAES0902USA03105	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Off label use, Urine abnormality

Symptom Text: Information has been received from a physician concerning a 38 year old male with hypertension who on 13-FEB-2009 was vaccinated with a dose of GARDASIL. On 15-FEB-2009, the patient noticed "foaminess" to his urine. The patient was evaluated in the office on 16-FEB-2009 and a dipstick check of the urine revealed the presence of protein. Complete blood count, comprehensive metabolic panel, urinalysis, serum and urine protein electrophoresis, sed rate, ANA, urine microalbumin, and protein/creatinine ratio have been ordered but at the time of report, the results was pending. At the time of the report the patient was not recovered. The patient sought unspecified medical attention in the office. Additional information has been requested.

Other Meds: Unknown

Lab Data: urinalysis 02/16/09 - revealed the presence of protein.

History:

Prex Illness: Hypertension

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342364-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.5	F	03-Sep-2008	04-Sep-2008	1	16-Mar-2009	07-Apr-2009	NY	WAES0902USA03094	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	2	Unknown	Intramuscular	HPV4

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning a female who was vaccinated intramuscularly with a dose of GARDASIL (lot number not reported). The patient's mother reported to the physician that her daughter experienced nausea and vomiting for three days. The patient recovered on an unspecified date. The patient's mother believed that nausea and vomiting were related to therapy with GARDASIL. The patient did not seek for medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 342378-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-Aug-2008	01-Oct-2008	42	23-Mar-2009	24-Mar-2009	VA	WAES0903USA02570	21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Left arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Abdominal tenderness, Activities of daily living impaired, Chest pain, Chills, Dizziness, Eczema, Fatigue, Headache, Malaise, Nausea, Pyrexia, Tremor, Vomiting, Weight decreased

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter with no past medical history and no drug reactions or allergies who in August 2008, was vaccinated with the first dose of GARDASIL. In October 2008, the patient received the second dose of GARDASIL. There was no concomitant medication. The consumer reported that the patient developed a low grade fever and felt "sick" the day after receiving her second dose of GARDASIL. During October and November of 2008, the patient experienced intermittent "stomaches", nausea and vomiting. Starting December of 2008 until the time of this report, she had experienced persistent extreme stomach pains and vomiting. The patient had been examined by three gastroenteriologists who were not able to determine the cause of her symptoms. She had missed 60 days of school. Lab diagnostics studies included a stomach empty test, CAT scan and blood tests with no results available. At time of this report, the patient had not recovered. The patient sought medical attention by an office visit. Upon internal review, low grade fever, felt "sick", intermittent "stomaches", nausea, vomiting and persistent extreme stomach pains were considered to be disabling. Additional information has been requested. 3//25/09 MR received from parent which include several GI consults and diagnostic testing. Per MR pt began having intermittent vomiting in Sept 2008. Usually at night waking pt, accompanied by abdominal pain, H/A and associated with shaking/shivering/chills. Occ nausea. 6-7 lb wt loss. ROS (+) for fatigue and chest pain. PE WNL except for eczematous rash on hip, iliac crest and axilla. Some improvement with Reglan but now c/o dizziness. W/U essentially (-). No final DX. 2nd GI consult seen 1/9/09. PE (+) for tenderness to palpation of the epigastrium, RUQ and RLQ. Has missed 28 school days since Sept 08. Labs and diagnostics: Upper GI WNL. CBC WNL. Chem WNL. H. pylori (-). BX of esphagus and stomach WNL. Some inflammation of lamina propria of duodenum. Uppe

Other Meds: None

Lab Data: diagnostic laboratory, Stomach empty test - No results available; computed axial, No results available; diagnostic laboratory, Blood test - No results available. Labs and diagnostics: Upper GI WNL. CBC WNL. Chem WNL. H. pylori (-). BX of

History: None. PMH: none. NKDA

Prex Illness:

Prex Vax Illns:

Vaers Id: **342379-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	18-Feb-2009		16-Mar-2009	31-Mar-2009	--	WAES0902USA03093	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pallor, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female who was vaccinated with the second dose of GARDASIL (lot # not reported) 0.5ml intramuscularly. Concomitant therapy included SUDAFED taken that morning. On 18-FEB-2009 "the patient got very pale, curled up into the fetal position, and fainted". Later on the patient was conscious and "lying on sofa" In the doctor's office. Patient sought unspecified medical attention. No lab diagnostics studies performed. Events improved after stopping therapy and reappeared after reintroduction. Additional information has been requested.

Other Meds: SUDAFED

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342380-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Nov-2008	01-Dec-2008	24	23-Mar-2009	24-Mar-2009	FR	WAES0903USA03049	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Endoscopy upper gastrointestinal tract, Helicobacter infection, Iron deficiency anaemia, No reaction on previous exposure to drug, Rash, Stool analysis

Symptom Text: Initial information received by Foreign Health Authority (reference number ES-AGEMED-6186213144) regarding a 16 year old female who was administered on 07-NOV-2008 the second dose of GARDASIL (batch number not reported) site and route not reported. It is reported that 10 to 12 days after vaccination DEC-2008, exact date not reported, the patient presented asthenia, the patient presented dizziness episodes that increased progressively. On JAN-2009 the patient visited the emergency room. Objectively HB of 5.2 g/dl, is considered an evolved aenemia, the patient is diagnosed with an iron deficiency aenemia. It was decided not to transfuse, so the patient was prescribed 5 intravenous iron vials, the first was administered in the emergency room the rest to be administered by her primary care doctor. A treatment with oral iron is prescribed. One month later, Hb 11.1g/dl. The patient has a profile of nutritional deficiency, celiac disease is discarded. Helicobacter positive, eradication treatment prescribed (no other information reported). No other possible causes for aenemia have been determined. Mother denies any possible problems regarding the patient's diet. First dose of GARDASIL was administered on the 08-SEP-2008. No adverse events were reported. Case reported as serious by the HA with other medically important condition as criteria. On the 13-MAR-2009 a similar case was received from a health care professional regarding her daughter. Age at time of event, haemoglobin values and first analysis date, vaccination dates, medical history triglyceride levels decreased, helicobacter positivity match up for both cases. The patient's mother has reported that her daughter presented with exanthema in both arms from shoulder to hand that started on 15-16-JAN-2009 and finished one month later without treatment. The patient's mother has also reported that iron was administered on 20-JAN-09 and 23-JAN-09 (two dosage forms). It has also been reported that a gastroscopy and stool collection were performed. Some haemoglobin levels

Other Meds: Unknown

Lab Data: hemoglobin, ??Jan09, 5.2 g/dl; hemoglobin, ??Feb09, 11.1, g/dl

History:

Prex Illness: Blood triglycerides decreased

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342381-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	--	WAES0902USA02975	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal stiffness, Oedema peripheral, Pain in extremity

Symptom Text: Information has been received from a registered nurse concerning a female patient with a history of jump roping injury who was vaccinated with GARDASIL. Subsequently the patient reported that she experienced stiff, swollen and achy at the injection site in her arm. The reporter stated that later they found out the symptoms was having in the arm the patient did not receive GARDASIL in and the experience was from a jump roping injury. At the time of this report, the outcome was unknown. It is unspecified the patient sought medical attention.

Other Meds: Unknown

Lab Data: Unknown

History: Injury

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342391-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Apr-2008	01-Apr-2008	0	23-Mar-2009	24-Mar-2009	FR	WAES0903USA03102	17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial palsy

Symptom Text: Information has been received from a health professional concerning a female who in April 2008, was vaccinated with a second dose of GARDASIL. 4 days later the patient presented with facial palsy. At time of reporting the outcome was not specified. The case is closed. Other business partner numbers included E2009-02067. Upon internal review, facial palsy was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342397-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Feb-2009	12-Mar-2009	14	23-Mar-2009	25-Mar-2009	CT		01-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0279X	1	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB329CA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2825AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1785X	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Rash vesicular

Symptom Text: On 3/12/09 Pt presented here with vesicular like lesions to tip of nose and another vesicular like area with redness to left side of nose. Normal eye and facial exam. Cultures taken with rupture of one vesicle discussed with Opth to confirm that eye only needs TX if SX's develop. Tx: 1) Valtrex tab 1GM q 8hrs X 7 days 2) Zovirax Top Ointment 5% q 3h topically 7 days 3) Keflex 500mg QID 10 days.

Other Meds: None

Lab Data: 1) Herpes lesion rapid culture w/typing 2) Herpes lesion typing (3) wound culture

History:

Prex Illness: No

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342401-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	23-Nov-2007	01-Nov-2008	344	16-Mar-2009	07-Apr-2009	--	WAES0902USA02682	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Musculoskeletal pain, Oedema peripheral, Pain in extremity, Rheumatoid arthritis

Symptom Text: Information has been received from a consumer concerning her 28 year old daughter with no pertinent medical history, allergies or drug reactions, who was vaccinated with the first dose of GARDASIL, on 29-MAY-2007 and was vaccinated with the third dose in November 2008. There was no concomitant medication reported. The reporter stated that in November 2008 (also reported as about a month after receiving the last dose) her daughter started experiencing pain and swelling of feet and arms, especially on her left side. It was also reported that she woke up because of the pain in her extremities and shoulders. She was diagnosed with rheumatoid arthritis in December 2008. Laboratory test performed included "blood work" and "x-rays" (no results were provided). The patient's rheumatoid arthritis persisted. The patient sought unspecified medical attention. Follow up information has been received from a registered nurse concerning a 28 year old female with a history of mild dysplasia cervix who on 29-MAY-2007 was vaccinated intramuscularly (IM) in right deltoid (RD) with first 0.5mL dose of GARDASIL (lot number 657736/0389U), on 07-AUG-2007 was vaccinated IM in left deltoid with second 0.5mL dose of GARDASIL (lot number 657868/0523U) and on 23-NOV-2007 (previously reported as November 2008) was vaccinated IM in RD with third 0.5mL dose of GARDASIL (lot number 659437/1266U). There was no concomitant medication. The nurse reported that the she did not have information about the patient rheumatoid arthritis and therefore cannot comment on her condition. The nurse was unable to provide any information on the primary physician of the patient as she only had his/her last name. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Cervical dysplasia

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342403-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	13-Feb-2009	13-Feb-2009	0	16-Mar-2009	07-Apr-2009	MI	WAES0902USA02694	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: Information has been received from a certified medical assistant concerning a female who on 13-FEB-2009 was vaccinated with the first 0.5 ml dose of GARDASIL. At the same visit the patient was vaccinated with the second dose of VARIVAX. No additional information was provided for the first dose of VARIVAX. Concomitant vaccine included diphtheria toxoid/tetanus toxoid. After receiving the first dose of GARDASIL the patient fainted and got injured on her head. CAT scan has been performed. The patient recovered on unspecified dates. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342404-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Jul-2008	01-Jan-2009	184	16-Mar-2009	07-Apr-2009	MI	WAES0902USA02704	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Headache, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 13 year old female who in July 2008, was vaccinated with the first dose of GARDASIL. Concomitant therapy included FLONASE and PROVENTIL. After getting the first dose (onset date reported as January 2009), the patient experienced pain in hands, stomach ache and headache. Magnetic resonance imaging (MRI) was performed but the result was unknown. At the time of reporting, the patient's pain in hands and stomach ache and headache persisted. The patient will not be taking the second and the third dose of GARDASIL. Additional information has been requested.

Other Meds: PROVENTIL; FLONASE

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342405-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	--	WAES0902USA02705	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Exercise tolerance decreased

Symptom Text: Information has been received from a consumer via internet concerning a female who on an unspecified date was vaccinated with GARDASIL (lot number, injection site and route not reported). It was reported that the patient was offered a college scholarship for her athletic skills in track and field, and "now can barely run 50 yards without resorting to use an inhaler." The patient used a nebulizer every couple of hours as she could barely breathe. It was unknown if the patient sought any medical attention. The outcome of the patient's experience was unknown. Attempts are being made to verify the existence of an identifiable patient and reporter. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342406-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	26-Nov-2008	26-Nov-2008	0	16-Mar-2009	07-Apr-2009	--	WAES0902USA02709	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea, Pain, Vaccine positive rechallenge, Vomiting

Symptom Text: Information has been received from a nurse concerning a 17 year old female with no medical history and drug allergy who on 26-NOV-2008 was vaccinated with her first 0.5 ml dose of GARDASIL (lot # 660391/0063X). Concomitant therapy included Flu shot. The patient experienced dizziness, pain and nausea after getting the first dose of vaccine. It was also reported that after getting the second dose of GARDASIL (lot # 660391/0063X) on 02-FEB-2009 the patient experienced dizziness, pain, nausea and vomiting. The patient recovered on an unspecified date. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342408-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	--	WAES0902USA02879	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Human papilloma virus test positive, Inflammation, Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a 20 year old female patient who on an unspecified date was vaccinated with the third dose of GARDASIL (lot # not reported). 1 1/2 weeks later the patient developed an abnormal Pap smear showing "inflammation" and a positive test for HPV (type not specified). At the time of reporting, the outcome was unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: Pap test - inflammation

History: Unknown

Prex Illness:

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342409-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	Unknown	01-Jan-2009		16-Mar-2009	07-Apr-2009	--	WAES0902USA02904	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a consumer concerning her 12 year old daughter with no medical history and drug allergies who was vaccinated with three doses of GARDASIL (lot number unavailable) on unspecified dates. There was no concomitant medication. One month ago the patient experienced a rash around her eyes. At time of reporting, the patient did not recover. The patient was seen by her eye doctor for medical attention. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342410-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Aug-2008	25-Aug-2008	0	16-Mar-2009	26-Mar-2009	NC	WAES0902USA02914	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a physician for the Pregnancy Registry for GARDASIL, concerning a 17 year old female with no medical history and drug allergies who on 25-AUG-2008 was vaccinated with her second dose of GARDASIL. There was no concomitant medication. Subsequently the patient was pregnant and her LMP was 18-AUG-2008. She had a fetal ultrasound showing possible unspecified fetal abnormalities. Lab diagnostics studies included unspecified blood test and fetal ultrasound. The patient had an office visit for medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Ultrasound, possible unspecified fetal abnormalities.

History:

Prex Illness: Pregnancy NOS (LMP = 8/18/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342411-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Nov-2008	Unknown		16-Mar-2009	07-Apr-2009	CA	WAES0902USA02929	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a Medical Assistant concerning a 17 year old female who 12 weeks ago was vaccinated with the first dose of GARDASIL. On 17-FEB-2009 the patient learned she was pregnant. The patient came to the clinic. Type of pregnancy test that was conducted to patient was unknown. At the time of reporting, the patient was fine. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342412-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	--	WAES0902USA02935	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a female who was vaccinated with GARDASIL. Awhile back the patient fainted after vaccination. The patient was seen at the office. On unspecified date, the patient recovered. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342413-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Nov-2008	20-Nov-2008	0	16-Mar-2009	07-Apr-2009	KY	WAES0902USA02937	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 20-NOV-2008 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. Within two weeks after receiving GARDASIL (lot #661764/0650X), the patient experienced nausea and vomiting. The patient's mother stated that her daughter will not receive the other 2 doses of GARDASIL. About two weeks after being vaccinated, the patient recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342414-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Feb-2009	16-Feb-2009	0	16-Mar-2009	07-Apr-2009	NJ	WAES0902USA02962	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Back pain, Headache, Vomiting

Symptom Text: Information has been received from a Registered Nurse (R.N.) concerning a 16 year old female with a history of asthma and amoxicillin allergy who on 16-FEB-2009 was vaccinated intramuscularly with her first 0.5 ml dose of GARDASIL (lot # 661766/0652X). There was no concomitant medication. On 16-FEB-2009 the patient experienced the onset of vomiting, headache, abdominal and back pain a few hours after receiving the vaccine. The patient's mother called the office on 17-FEB-2009 and was suggested to give the patient MOTRIN and fluid replacement. At the time of reporting the patient was recovering. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Asthma

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342415-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	NV	WAES0902USA02969	11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthma, Vaccine positive rechallenge

Symptom Text: Information has been received from a medical assistant concerning her daughter with a history of RSV (respiratory syncytial virus infection) as a child who was vaccinated with the first 0.5 ml dose of GARDASIL. Subsequently the patient experienced asthma. On February 5th (year not specified) the patient received the second 0.5 ml dose of GARDASIL. It made the patient's asthma worse. At the time of reporting, the outcome was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data:

History: Respiratory syncytial virus infection

Prex Illness:

Prex Vax Illns:

Vaers Id: **342419-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	FL	WAES0902USA02669	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lethargy

Symptom Text: Information has been received from a physician concerning a female patient who on an unknown date was vaccinated with GARDASIL 0.5 mL IM. Subsequently, the patient became "lethargic" after getting GARDASIL. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342421-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Mar-2009	23-Mar-2009	0	23-Mar-2009	25-Mar-2009	MN		17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB329CA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0843X	0	Left arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B033BA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: Patient fainted and hit her head, applied ice pack and examined by Dr. Waited in clinic for 1/2 hour after and was fine. Did have a bump on her forehead from fainting.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **342426-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	--	WAES0902USA02388	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Malaise

Symptom Text: Information has been received from a physician concerning a 15 year old female who was vaccinated with a 0.5 ml dose of GARDASIL about a year ago. The patient has been chronically ill for a year since receiving GARDASIL and was hospitalized 4 times. The patient's outcome was unknown at time of reporting. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342427-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-Oct-2008	17-Jan-2009	100	16-Mar-2009	07-Apr-2009	WI	WAES0902USA02175	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	1	Unknown	Unknown	HPV4

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Migraine

Symptom Text: Information has been received from a consumer concerning her 13 year old daughter with drug allergies to codeine and IMITREX and no other pertinent medical history who on approximately 12-AUG-2008 ("6 months ago") was vaccinated with the first dose of GARDASIL. Then the patient received the second dose of GARDASIL and when she had her menstrual cycle. After that on 17-JAN-2009 ("26 days ago") the patient experienced a migraine. On 11-FEB-2009 the patient received the third dose of GARDASIL. There was no concomitant medication. The patient also happened to start her cycle again and experienced another migraine. The patient started her menstrual cycle when she was eight year old and she had never had migraines before. No lab diagnostics studies were performed. The patient's migraine persisted. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: HPV #3 2/11/2009, lot # 1311X

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **342428-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	CO	WAES0902USA02184	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a nurse concerning her daughter who on an unreported date was vaccinated IM with the second dose of GARDASIL. It was reported that the patient experienced fainting spells "in the months following her second dose of GARDASIL". The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342429-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	04-Feb-2009	09-Feb-2009	5	16-Mar-2009	07-Apr-2009	TX	WAES0902USA02194	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site urticaria

Symptom Text: Information has been received from a registered nurse concerning a 23 year old female patient with no pertinent medical history, no drug reactions/allergies, who on 04-FEB-2009 was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL (Lot # 661952/1129X). There was no concomitant medication. On 09-FEB-2009 the patient experienced hives. The presentation of the hives limited to the GARDASIL vaccine injection site. The patient called the practice. There were no laboratory or diagnostic tests performed. On 10-FEB-2009, the patient had recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342430-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Jun-2008	Unknown		16-Mar-2009	25-Mar-2009	TX	WAES0902USA02197	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Insomnia

Symptom Text: Information has been received from a licensed visiting nurse concerning a 15 year old female patient with no pertinent medical history and no know drug allergies, who on 26-JUN-2008 was vaccinated with the first dose of GARDASIL (lot# 660391/0063X) 0.5ml intramuscularly. There was no concomitant medication. Subsequently the patient experienced insomnia that lasted for a period of three weeks. Patient was seen at the practice. No lab diagnostic studies performed. At the time of this report the patient had recovered. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342431-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jan-2009	01-Jan-2009	0	16-Mar-2009	25-Mar-2009	OR	WAES0902USA02212	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Syncope, Tinnitus

Symptom Text: Information has been received from a physician concerning his granddaughter (a 15 year old female) with a family history of allergies who was vaccinated with the first dose of GARDASIL in the "last couple of weeks" (approximately January 2009) and had a severe reaction. The granddaughter was in the physician's office and collapsed. The granddaughter had a red face and ringing of unspecified ear. The patient recovered on an unknown date. The patient sought medical attention. No additional information was available.

Other Meds: None

Lab Data: Unknown

History: Hypersensitivity

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342432-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	19-Dec-2008		16-Mar-2009	26-Mar-2009	LA	WAES0902USA02237	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning his 22 year old daughter with no pertinent medical history and no known drug allergies who was vaccinated with all 3 doses of GARDASIL (lot numbers not reported) 0.5ml intramuscularly. Concomitant therapy included hormonal contraceptives (unspecified). Patient had a PAP test done on 22-MAY-2006 which was negative and on 19-DEC-2008 patient had a PAP test that revealed that she had mild cervical dysplasia. Physician reported that he did not have the dates of administration but said that his daughter finished GARDASIL series a year before she had the abnormal PAP test. Patient sought unspecified medical assistance. At the time of this report patient had not yet recovered. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: Pap test, 12/19/08, mild cervical dysplasia; Pap test, 05/22/06, negative.

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342433-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	22-Sep-2008	Unknown		16-Mar-2009	26-Mar-2009	--	WAES0902USA02269	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts, Smear cervix abnormal

Symptom Text: Information has been received from a patient with positive history of papilloma viral (HPV) who on 22-SEP-2008 and 08-DEC-2008 was vaccinated with the 1st and 2nd doses of GARDASIL respectively. She also had abnormal cells and genital warts before she was given GARDASIL. Subsequently her abnormal cervical cells had "gotten worse" and she believed it might have caused an "outbreak" of genital warts. The patient did not want to get the third dose of GARDASIL. At time of reporting, the patient did not recover. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Papilloma viral infection; Cervical pap smear abnormal; Genital wart.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342434-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	25-Jan-2009	01-Feb-2009	7	16-Mar-2009	26-Mar-2009	--	WAES0902USA02274	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Pain in extremity

Symptom Text: Information has been received from a registered nurse concerning a 17 year old female who on 25-JAN-2009 was vaccinated with a first dose of GARDASIL 0.5 mL. In February 2009 ("2 weeks later after getting the vaccine"), the patient experienced joint pain in ankle, legs and wrists. The patient sought unspecified medical attention. At the time of reporting, the patient's joint pain in ankle, legs and wrists persisted. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342435-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Jan-2007	01-Feb-2007	31	16-Mar-2009	26-Mar-2009	TN	WAES0902USA02276	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Alopecia areata

Symptom Text: Information has been received from a physician concerning a 21 year old female with attention deficit/hyperactivity disorder and a history of depression who in January 2007, was vaccinated with a first dose of GARDASIL. The physician stated the patient received three doses of GARDASIL but the dates of administration of the second and third dose were unknown. Concomitant therapy included CELEXA and ADDERALL tablets. In February 2007, the patient developed hair loss. On unknown date, the patient visited the office. In January 2009, the patient was examined and was diagnosed with alopecia areata. The patient was prescribed topical steroids and unspecified pulse systemic steroid therapy. The patient has noticed slight improvement in the symptoms. The physician added that thyroid levels, antinuclear antibody, sed rate, complete blood count, and comprehensive metabolic panel results were normal. Additional information has been requested.

Other Meds: ADDERALL tablets; CELEXA

Lab Data: Serum TSH, normal; Serum ANA, normal; Erythrocyte, normal; Complete blood cell, normal; Laboratory test, comprehensive metabolic panel results are normal.

History: Depression

Prex Illness: Attention deficit/hyperactivity disorder

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342436-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Aug-2008	01-Oct-2008	61	16-Mar-2009	26-Mar-2009	SC	WAES0902USA02390	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Muscle twitching

Symptom Text: Information has been received from a nurse concerning a female patient who in "August 2008" was vaccinated with the second 0.5 ml dose of GARDASIL. In "October 2008" the patient experienced bad muscle twitching. No lot number was provided. It was reported that therapy with GARDASIL was discontinued in "beginning of February 2009". The patient recovered from muscle twitching on an unspecified date. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342437-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	--	WAES0902USA02426	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Immediate post-injection reaction, No reaction on previous exposure to drug, Vision blurred

Symptom Text: Information has been received from a registered nurse (R.N.) concerning her daughter, a 14 year old female who was vaccinated with a second dose of GARDASIL (lot # not reported). Subsequently the patient experienced severe blurred vision and a headache immediately after the vaccination. The patient sought unspecified medical attention. The patient recovered 12 hours after dose was give. It was reported that the patient did not have any adverse reactions after the first dose of GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342438-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Feb-2009	02-Feb-2009	0	16-Mar-2009	07-Apr-2009	--	WAES0902USA02649	09-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Migraine

Symptom Text: Information has been received from a nurse practitioner concerning a 14 year old female with no pertinent medical History and no known drug reactions/ allergies, who was vaccinated with the second dose of GARDASIL. The nurse practitioner reported that on 02-FEB-2009 the patient experienced migraine headache after receiving the second dose of GARDASIL. Subsequently, the patient recovered from migraine. The patient sought medical attention and was seen at the practice. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342439-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	04-Feb-2009	05-Feb-2009	1	16-Mar-2009	07-Apr-2009	MD	WAES0902USA02167	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, No reaction on previous exposure to drug, Pain, Pyrexia

Symptom Text: Information has been received from a physician concerning a 24 year old female patient who on 04-FEB-2009 was vaccinated with the third 0.5 ml dose of GARDASIL (Lot # 661952/1129X). On 05-FEB-2009 the patient developed headache, body ache and fever up to 101 degrees. It was reported that the patient did not have any adverse effects after first dose of GARDASIL received on 3-JUL-2008 and second dose of GARDASIL vaccine, given on an unknown date. The patient sought unspecified medical attention. The patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: body temp 02/05/09 101 -

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342440-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	--	WAES0902USA02030	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Adverse event

Symptom Text: Information has been received from a consumer concerning her daughter who on an unspecified date was vaccinated with a dose of GARDASIL. The patient had been hospitalized four times after receiving GARDASIL. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342441-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	NY	WAES0902USA01667	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Information has been received from a physician concerning a 22 year old female patient who in approximately 2008 ("about a year ago") was vaccinated with the first dose of GARDASIL at a different physician's office. In approximately 2008 ("after receiving the first dose") the patient had experienced nausea and dizziness for about 24 hours post vaccination. Subsequently, the patient recovered. The patient sought medical attention via seeing physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342442-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Aug-2008	01-Aug-2008	0	16-Mar-2009	07-Apr-2009	WA	WAES0902USA01676	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a physician concerning a 16 year old female with a history of irregular periods who has not had her period since receiving her first dose of GARDASIL in August 2008. She received her second dose in October 2008 but has not yet received her third dose. Lot number was not available. At the time of reporting the patient was not recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Irregular periods

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342443-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	22-Jan-2009	Unknown		16-Mar-2009	07-Apr-2009	--	WAES0902USA01682	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus

Symptom Text: Information has been received from a consumer concerning his girlfriend with no medical history or drug allergy who on 22-JAN-2009 was vaccinated with the first dose of GARDASIL, 0.5ml. There was no concomitant medication. Subsequently the patient developed redness and itchiness at the injection site. The patient did not perform any lab diagnostics study. At the time of the report the patient was recovered. The patient did not seek medical attention. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342444-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Jan-2009	Unknown		16-Mar-2009	07-Apr-2009	CA	WAES0902USA01699	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash, Injection site vesicles, Rash

Symptom Text: Information has been received from a medical assistant concerning a female with AUGMENTIN allergy who on 22-JAN-2009 was vaccinated with the third dose of GARDASIL (lot # 661766/0652X). The patient developed a rash after her third dose of vaccine. The rash included blisters at injection site, rash from her mid forearm to her neck line on the injection arm and rash on her chest and back. BENADRYL had been prescribed. The patient received her first (lot # 660555/0279X) and second (lot # 661530/0575X) dose of GARDASIL on 01-JUL-2008 and 10-SEP-2008 respectively. At the time of reporting the patient was not recovered. The patient did not seek medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342445-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Sep-2008	02-Sep-2008	0	23-Mar-2009	25-Mar-2009	CA	WAES0902USA01705	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEP	MERCK & CO. INC.	NULL		Unknown	Unknown	
	IPV	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Fungal infection, Headache, Muscle spasms, Pain

Symptom Text: Information has been received from a consumer, for GARDASIL, a Pregnancy Registry product, concerning her daughter in law, an 18 year old female with no drug allergy who on 02-SEP-2008 was vaccinated with the first dose of GARDASIL while few weeks pregnant. Concomitant therapy included poliovirus vaccine (manufacturer unknown) and RECOMBIVAX HB. The patient was now 24 weeks pregnant and was experiencing some cramping, headaches, occasional spasm in the rib cage area, yeast infections and general body aches. She already had a yeast infection when getting GARDASIL and was prescribed and unspecified medication for it; however the infections were coming back. The patient performed pregnancy test and ultrasounds. The first ultrasound came back normal. The patient had a second ultrasound done. At time of the report the patient was not recovered. The patient sought medical attention. Additional information has been requested.

Other Meds:

Lab Data: Ultrasound, first came back normal.

History:

Prex Illness: Pregnancy NOS (LMP = 8/25/2008); Yeast infection.

Prex Vax Illns:

Vaers Id: **342446-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
31.0	F	06-Feb-2009	06-Feb-2009	0	16-Mar-2009	07-Apr-2009	--	WAES0902USA01707	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Injection site anaesthesia, Musculoskeletal pain, Neck pain, Pain in extremity

Symptom Text: Information has been received from a Nurse Practitioner (N.P.) concerning a 31 year old female who on 06-FEB-2009 was vaccinated intramuscularly in the left arm with her first 0.5 ml dose of GARDASIL (661046/0546X). Concomitant therapy included YASMIN, TOPAMAX, WELLBUTRIN, ALLI, aspirin and vitamins. On 06-FEB-2009 the patient developed pain in her injection arm after her initial dose of vaccine. The pain has persisted at the same intensity since then. The arm was not warm, not swollen, and not red. The pain was from the neck to below the elbow and at the time of reporting was from the shoulder to the elbow. The pain has been described as "feeling like she has been working too long at the computer." The patient also experienced numbness in the left arm the night of 09-FEB-2009 which resolved the morning of 10-FEB-2009. She has treated the pain with TYLENOL, aspirin, heat, and BEN GAY with no relief. Patient is considering not completing the series because of this reaction. Additional information has been requested.

Other Meds: aspirin; WELLBUTRIN; YASMIN; ALLI; TOPAMAX; vitamins (unspecified)

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342447-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	--	WAES0902USA01775	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Condition aggravated

Symptom Text: Information has been received from a case in litigation for WAES # 0902USA01678 from a consumer who reported "her daughter's anemia became worse after received a dose of GARDASIL." Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Anaemia

Prex Vax Illns:

Vaers Id: **342448-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	08-Jan-2007		16-Mar-2009	07-Apr-2009	NY	WAES0902USA01813	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Migraine, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning a 20 year old female patient who on 08-JAN-2007 was vaccinated with the first dose of GARDASIL (lot # 655619/1427F) 0.5 ml intramuscularly. On 22-JAN-2008 the patient received her second dose of GARDASIL (lot # 659657/1487U) 0.5 ml intramuscularly. On 08-JAN-2007 the patient experienced migraine headaches after the first dose. After the second dose, the patient experienced migraine headaches again. The patient also had the first two shots over a year apart. As of 11-FEB-2009, the patient had not received the third dose. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342449-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	PA	WAES0902USA01815	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Fatigue, Myalgia

Symptom Text: Information has been received from a physician concerning a female patient who on an unspecified date was vaccinated with a dose of GARDASIL (lot # not specified), intramuscularly. The patient experienced muscle pain, weakness and fatigue after receiving the GARDASIL vaccine. The physician indicated that the patient was planning report the events. The patient sought unspecified medical attention and underwent unspecified tests by a rheumatologist. At the time of reporting, the outcome of the event is unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342450-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-Feb-2008	01-Feb-2008	0	23-Mar-2009	25-Mar-2009	CA	WAES0902USA01848	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a 20 year old female with no medical history and drug allergies who in February 2008 was vaccinated with her first does of GARDASIL. Concomitant therapy included birth control pill (unspecified which one). The patient was fine at first after vaccination but later she started feeling dizzy and light headed for the rest of the day. She was fine the next day and was now recovered. However, she did not receive the other two doses of GARDASIL. The patient did not seek medical attention. Additional information has been requested.

Other Meds: Hormonal contraceptives

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342451-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Oct-2008	01-Oct-2008	0	16-Mar-2009	07-Apr-2009	--	WAES0902USA01871	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bladder disorder, Enuresis

Symptom Text: Information has been received from a Nurse practitioner (N.P.) concerning a 15 year old female who on 01-OCT-2008 was vaccinated with a 0.5 ml dose of GARDASIL (lot # 0947X). 01-OCT-2008 the patient experienced uncontrollable bladder symptoms and wet the bed overnight after receiving the vaccine. The patient recovered 24 hours after receiving the vaccine. It was reported that therapy with GARDASIL was discontinued on 01-OCT-2008. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342452-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Dec-2008	01-Dec-2008	0	16-Mar-2009	25-Mar-2009	--	WAES0902USA01879	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Haemorrhage

Symptom Text: Information has been received from a female , for GARDASIL who in December 2008, was vaccinated with GARDASIL (number in series not reported). Two days later the patient started to bleed for two weeks. The consumer reported she just took two home pregnancy test and both came out positive, but she was scheduled to go to see her physician this week to find out if she really was pregnant. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP= unknown)

Prex Vax Illns:

Vaers Id: **342453-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	29-Dec-2008	29-Dec-2008	0	16-Mar-2009	07-Apr-2009	NC	WAES0902USA02003	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB319AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypotension, Syncope

Symptom Text: Information has been received from a health professional concerning a 15 year old female with no known medical history, who on 29-DEC-2008 was vaccinated with a second dose of GARDASIL (lot # 661044/0548X), intramuscularly in the right arm at 16:45. Concomitant therapy included a second dose HAVRIX (lot # AHAVB319AA), intramuscularly in the left arm on 29-DEC-2009 at 16:45. On 29-DEC-2008 the patient received the GARDASIL vaccine in the right arm and HAVRIX in the left arm. The patient fainted but regained conscience immediately. After taking vital signs, the patients blood pressure was low. The patient was monitored until the blood pressure came up in about 15 minutes. The patient recovered on 29-DEC-2008. No further information is available.

Other Meds:

Lab Data: Blood pressure, 12/29/08, low

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 342471-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	19-Mar-2009	19-Mar-2009	0	23-Mar-2009	25-Mar-2009	OK		25-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Loss of consciousness, Syncope

Symptom Text: Syncope immediately following injection of HPV vaccine. No fall or injury. Rapid recovery - regained consciousness when client placed in suppine position.

Other Meds:

Lab Data:

History:

Prex Illness: none known

Prex Vax Illns: Nausea/Vomiting~HPV (Gardasil)~1~18~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342490-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	04-Feb-2009	04-Feb-2009	0	24-Mar-2009	25-Mar-2009	--	WAES0902USA00596	17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0186U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy, Ectopic pregnancy

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female patient with a history of pre-eclampsia and BELL's palsy during a prior pregnancy who on 04-FEB-2009 was vaccinated with the first IM dose of GARDASIL (655618/0186U) while she was pregnant. A pregnancy test and prenatal blood screen were performed. Her last menstrual period was 10-JAN-2009 and the estimated delivery date is 17-OCT-2009. The patient was started on prenatal vitamins (unspecified) and iron (unspecified). No adverse effect was reported. Follow-up information has been received from a registered nurse concerning the patient. It was reported that the patient was diagnosed with tubal pregnancy. The patient was admitted to the hospital the week of 16-FEB-2009 and a therapeutic abortion was performed. The date of the surgery was unavailable. On 04-MAR-2009 the patient was seen in the office and had fully recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Diagnostic laboratory, 02/??/09; Beta-human chorionic, 02/??/09, positive

History: Pre-eclampsia; Bell's palsy

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342491-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	04-Mar-2009	04-Mar-2009	0	24-Mar-2009	25-Mar-2009	FR	WAES0903PHL00007	17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Amnesia, Condition aggravated, Dizziness, Gaze palsy, Loss of consciousness, Musculoskeletal stiffness, Petit mal epilepsy

Symptom Text: Information has been received from a physician concerning 10 year old female, her daughter, with a history of cyanosis and motion-related loss of consciousness who on 04-MAR-2009 was vaccinated with first dose of GARDASIL. No concomitant medications were reported. On 04-MAR-2009 the patient experienced dizziness followed by stiffening, upward eye rolling and loss of consciousness which lasted for approximately three to four seconds. On 04-MAR-2009, the patient recovered from dizziness, stiffening, upward eye rolling and loss of consciousness. The patient said she did not remember any of the events that occurred. Post ictal events include epigastric pain and feeling very light. The reporter felt that the patient experienced absence seizure because of the symptoms mentioned. The reporter also mentioned that the patient had no apprehension or fear about receiving the vaccine, as the patient was the one insisting on getting the vaccination. The reporter felt that absence seizure was related to therapy with GARDASIL. Upon internal medical review, absence seizure was considered an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Cyanosis; Loss of consciousness

Prex Illness:

Prex Vax Illns:

Vaers Id: 342492-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Feb-2008	23-Jul-2008	173	24-Mar-2009	25-Mar-2009	FR	WAES0903USA00144	17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0510U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Headache, Nausea, Paraesthesia, Vertigo

Symptom Text: Information has been received from a gynaecologist concerning a 25 year old female who was vaccinated with a third dose of GARDASIL (lot# 0467U, batch# NG14290) into the deltoid muscle on an unspecified date. Four to six weeks post vaccination, the patient developed dizziness. The patient was hospitalized for clarification and diagnosis on an unspecified date. The patient had not recovered at the time of this reporting. The first dose of GARDASIL (lot# 0510U, batch# NG20180) was administered on 01-FEB-2008 and the second dose of GARDASIL (lot# not reported) was administered on an unspecified date. Toleration of the 1st and 2nd doses was not reported. Follow-up information was received on 12-MAR-2009. The reporting form and the hospital report were provided. On the reporting form only 2 doses of GARDASIL were mentioned. The second dose of GARDASIL, (lot# 0467U, batch# NG14290) was administered IM into the upper arm on 13-MAY-2008. On 03-SEP-2008 the patient was admitted to hospital because of prolonged vestibular vertigo with nausea and right-sided headache of unknown origin since about 6 weeks. A few days prior to hospitalization vertigo and nausea worsened. At admission neurological and orthopaedical investigation had been performed and showed normal results. On 03-SEP-2008 a CCT showed no pathologies. On 08-SEP-2008 the ears, nose, and throat investigation as a thermic examination of the external ear canal showed a transient slight reduced excitability of the right horizontal semicircular canal with complete central nerve system compensation. On 16-SEP-2008 a cardiological consultation was normal. Under treatment with rheological infusions including cortisone and pentoxifyllin (Pentoxifylline), the symptoms improved. For a short time the patient complained of paraesthesia of cheeks and lower extremities but a neurological examination showed no pathological findings. The patient denied further investigations to clarify the symptoms. The diagnosis of phobic vertigo and transient slight reduced excitability of the

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 03Sep08, a CCT showed no pathologies

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342493-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		24-Mar-2009	25-Mar-2009	--	WAES0903USA02949	17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Brain oedema, Convulsion

Symptom Text: Information has been received from a physician concerning a 21 year old female ("who is a family friend of the physicians") who was vaccinated with her second dose of GARDASIL at another physician's office. Two weeks later the patient experienced seizure and brain swelling and was hospitalized for two or three weeks. Therapy with GARDASIL was discontinued. On unspecified date, the patient recovered. The physician also reported the patient has now returned to college. Attempts to verify the existence of a patient have been unsuccessful. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342494-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Jan-2009	29-Jan-2009	0	24-Mar-2009	25-Mar-2009	FR	WAES0903USA03053	10-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Eye movement disorder, Facial palsy, Hypoaesthesia oral, Injection site pain, Neck pain, Vision blurred

Symptom Text: Information has been received from a health professional (nurse) concerning a 16 year old female who on "29-JAN-2009" was vaccinated with the first dose of GARDASIL by intramuscular route. It hasn't been reported whether the patient had any adverse event after this first dose or not. On 29-JAN-2009 the patient was vaccinated with the second dose of GARDASIL (batch number not provided) by intramuscular route in the deltoid. On 29-JAN-2009, after being vaccinated, the patient presented with pain in the arm where she was vaccinated. She recovered from this adverse event some days later. It is reported that on 25-FEB-2009 the patient presented facial palsy on half of the face, the patient could not close the left eye and had paralyzed lips, the patient attended the emergency room because she could not close the left eye. Symptoms started on 24-FEB-2009 when she felt tongue numbness, retro-joint pain and cervical pain. On 25-FEB-2009 she began feeling numbness in the lips and had blurry vision while blinking or looking downwards, the patient did not present dizziness. The patient was given eye drops, corticosteroids and DACORTIN (30 mg, 2 dosage forms/day) to treat adverse event. Neurological exploration was normal. The patient had difficulty looking upward and closing the right eye (the reporter has obtained the information from the patient's medical history, but she thinks that this is an error, it is the left eye). Tendon reflex was symmetrical. On 02-MAR-2009 the patient was referred to the ear-nose-throat doctor, who changed DACORTIN to 10 mg during 5 days. This doctor also prescribed NEUROBION 5000 by intramuscular route. Facial palsy, cervical pain, joint pain and pain in arm were considered to be other important medical events. Other business partner numbers include E2009-02183. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342495-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Mar-2008	01-Jul-2008	122	24-Mar-2009	25-Mar-2009	FR	WAES0903USA03142	17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Back pain, Monoparesis, Neuromyelitis optica, Paresis, Pyrexia, Syncope, Visual impairment

Symptom Text: Information has been received via a health authority concerning an 18 year old female patient who was vaccinated with a second dose of GARDASIL (Lot-no., injection site and route not reported) in May-2008. In Jul-2008 the patient experienced fever up to 38.5 degrees C for 10 days. In Oct-2008 she developed back pain and leg paresis for 2 to 3 weeks. In November 2008 she experienced pain in the hip and back, duration not reported. In Oct/Nov 2008 elevated values for antibodies (not otherwise specified). In Jan-2009 the patient experienced syncope, paresis of arm and leg, and almost blindness of an eye. Neuromyelitis optica was diagnosed on an unspecified date. The patient was hospitalized, dates not reported, and had not recovered at the time of reporting. The first dose of GARDASIL was administered in March 2008 and was well tolerated. Additional information has been requested. Other business partner numbers include E2009-02187 and PEI2009004696.

Other Meds: Unknown

Lab Data: body temp, ??Jul08, 39.5 Deg C, for 10 days; serum ANA, ??Oct?08, increased antinuclear antibody

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342496-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		24-Mar-2009	25-Mar-2009	CA	WAES0903USA03341	17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Systemic lupus erythematosus

Symptom Text: Information has been received from a physician concerning a patient was vaccinated with a dose of GARDASIL on an unspecified date. Subsequently the patient developed lupus after getting GARDASIL. The patient went to a rheumatologist who thought this was related to the vaccine. No information was known after how many doses this occurred. Upon internal review, lupus was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342520-1 (S)** **Related reports:** 342520-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Sep-2008	04-Oct-2008	4	24-Mar-2009	26-Mar-2009	NC		12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2688AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0548X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal discomfort, Abdominal pain, Activities of daily living impaired, Asthenia, Back pain, Chest pain, Convulsion, Dehydration, Gastrointestinal tube insertion, Haematochezia, Headache, Heart rate increased, Hypophagia, Hypotension, Pain in extremity, Pancreatic sphincterotomy, Paraesthesia, Peripheral coldness, Respiratory arrest, Similar reaction on previous exposure to drug, Staring, Syncope, Urinary tract infection, Vomiting

Symptom Text: Patient received her first shot 5/24/07 - she had soreness in her arm and headaches but tollerated them. On 10/1/2007 patient was at basketball practice and collasped on the gym floor with severe abdominal pain and chest pain. The abdominal pains remained. In March 2008 she began vomiting bile and the abdominal pains worsened. They continued to get worse and in June 08 she had her second shot. Again, her pain increased. She got her 3rd shot in September 2008. We were at the hospital 4 days after her 3rd shot with adominal pain, high pulse, low blood pressure, and chest pain. By December patient was beginning to have seizure like episodes of staring and not breathing for 30-45 seconds at a time. She was beginning to have lower back pain as well as the abdominal pain and chest pain. She began to complain of burning in her stomach - like it was on fire. She had a tingling sensation in her legs and her feet - complaining of them being on fire, but her feet were freezing cold when I would touch them. Patient had a few urinary track infections and several bouts with dehydration. She also had blood in her stool. She became very weak and has only been to school 4 full days since November 2008. Patient was on numerous types of medicine but nothing seemed to help because of these episodes. Everyime she would eat it would make it worse and would be especially more intense during her monthly cycle. She was on a feeding tube for over 3 weeks as well as hospitalized 3 different times. We have been to the ER over 13 times. Records received - 05/01/2009 - multiple ED visits and hospital admissions 10/04/2008 to 02/10/2009. Prior psych hx of ADHD, LD, anxiety reaction. GI hx chronic functional dyspepsia.ED evaluations for nausea, vomiting, abdominal pain. Diagnoses have included GERD, functional abdominal pain, biliary diskinesia, pancreatitis, pancreatic divisum.GI, med imaging, and psych consultations.Sugical procedures have included cholecystectomy, ERCP, MRCP, feeding tube. Diagnosis: Chronic generalized abdominal pain of

Other Meds: Foclin XR20 - discontinued November 2008 due do pain medicine (no school attendance) no need for focusing

Lab Data: Extensive Blood work up, Lactose intolerance test, Allergy testing, CT scans of abdomen and pelvis, Upper GI, 3 EKG tests, MRI on her brain, EGD test, Colonoscopy, Several abdominal ultra sounds, Gastro emptying, hyda scan, gallbladder remo

History: ADHD - beginning 2006 5/7/09-records received-PMH: ADHD.

Prex Illness: It is hard to tell which vaccine was the most damaging but I can tell you patient received her first shot 5/24/07 Lot #0186U (ri

Prex Vax Illns:

Vaers Id: **342520-2 (S)** **Related reports:** 342520-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-May-2007	24-May-2007	0	28-Apr-2009	29-Apr-2009	--	WAES0904USA01485	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0186U	0	Right arm	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal discomfort, Abdominal pain, Activities of daily living impaired, Allergy test, Asthenia, Back pain, Blood test, Chest pain, Colonoscopy, Computerised tomogram, Convulsion, Dehydration, Electrocardiogram, Feeling cold, Gallbladder operation, Gastric emptying study, Gastrointestinal tube insertion, Haematochezia, Headache, Heart rate increased, Hypotension, Lactose tolerance test, Nuclear magnetic resonance imaging brain, Oesophagogastroduodenoscopy, Pain in extremity, Paraesthesia, Peripheral coldness, Respiratory arrest, Staring, Syncope, Tenderness, Ultrasound abdomen, Urinary tract infection, Vaccine positive rechallenge, Vomiting, X-ray with contrast upper gastrointestinal tract

Symptom Text: This report was identified from a line listing obtained on request by the Company from the FDA under the Freedom of Information Act. A 14 year old female patient with Attention deficit/hyperactivity disorder beginning in 2006 was vaccinated into the right arm with the first dose of GARDASIL (Lot # 655618/0186U) on 24-MAY-2007, experienced soreness in her arm and headaches but tolerated them. On 01-OCT-2007 the patient was at basketball practice and collapsed on the gym floor with severe abdominal pain and chest pain. The abdominal pains remained. In March 2008 she began vomiting bile and the abdominal pains worsened. They continued to get worse and in June 2008 she had her second shot. Again, her pain increased. She got her third shot of GARDASIL (Lot #661044/0548X) on 30-SEP-2008 intramuscularly in her left arm. She was at the hospital 4 days after her third shot with abdominal pain, high pulse, low blood pressure, and chest pain. By December patient was beginning to have seizure like episodes of staring and not breathing for 30 to 40 seconds at a time. She was beginning to have lower back pain as well as the abdominal pain and chest pain. She began to complain of burning in her stomach- like was on fire. She had a tingling sensation in her legs and her feet- complaining of them being on fire, but her feet were freezing cold when she would touch them. Patient had a few urinary tract infections and several bouts with dehydration. She also had blood in her stool. She became very weak and had only been to school 4 full days since November 2008. Patient was on numerous types of medicine but nothing seemed to help because of these episodes. Every time she would eat it would make it worse and would be especially more intense during her monthly cycle. She was on a feeding tube for over 3 weeks as well as hospitalized 3 different times. She had been to the ER over 13 times. Labs diagnostics performed included extensive blood work up, lactose intolerance test, allergy testing, CT scans of abdomen and pelvis, upper GI, 3

Other Meds: FOCALIN XR, 20 mg

Lab Data: Unknown

History:

Prex Illness: Attention deficit/hyperactivity disorder

Prex Vax Illns:

Vaers Id: **342534-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Feb-2009	03-Feb-2009	0	24-Mar-2009	25-Mar-2009	FR	B0566052A	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ0010		Unknown	Intramuscular	
	TD	GLAXOSMITHKLINE BIOLOGICALS	XC12B019D1		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Clonic convulsion, Dizziness, Syncope

Symptom Text: This case was reported by a regulatory authority (# ES-AGEMED-918714344) and described the occurrence of syncope in a 14-year-old female subject who was vaccinated with DITANRIX ADULT (GlaxoSmithKline), GARDASIL (non-gsk). On 3 February 2009, the subject received unspecified dose of DITANRIX ADULT (unknown route and injection site), unspecified dose of GARDASIL (intramuscular, unknown injection site). On 3 February 2009, 5 minutes after vaccination with DITANRIX ADULT and GARDASIL, the subject experienced syncope with dizziness and clonic convulsion. The subject recovered and when she changed to another health center desk information, she experienced another syncope. The subject stayed some hours under observation and the event didn't recur. The mother stated that her daughter usually feels dizzy when she received a shot. This case was assessed as medically serious by GSK. On 3 February 2009, the events were resolved. The regulatory authority reported that the events were possibly related to vaccination with DITANRIX adult and GARDASIL. No further information is expected as the foreign regulatory authority has provided all the information available. This case has therefore been closed.

Other Meds:

Lab Data: UNK

History:

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342541-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Mar-2009	14-Mar-2009	8	24-Mar-2009	25-Mar-2009	NC	NC09013	15-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1317X	0	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	1129X	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB319AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy, Pruritus, Pyrexia, Rash generalised, Rash papular, Varicella

Symptom Text: Mom reports fever started 3/14/09. Rash started Sunday on chest & face. Itching. Swollen glands. Mucous in throat. Seen at ER- Dx chick pox. Seen at clinic- rash face, belly, neck, chest, arms, mouth and thighs. Papular rash on face + chest min influence to arms, some on abd, some lesions with clear tops. Given ZYTREC.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **342543-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Mar-2009	19-Mar-2009	2	24-Mar-2009	25-Mar-2009	MD		08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Vomiting

Symptom Text: GARDASIL given 3/17/2009. Patient got headache and vomiting on 3/19/2009 and 3/20/2009.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342550-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Feb-2009	21-Feb-2009	5	24-Mar-2009	25-Mar-2009	MI		08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Right arm	Unknown	
	TDAP	SANOFI PASTEUR	UF457CA	0	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2824AA		Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pruritus, Injection site urticaria

Symptom Text: Patient c/o itchy hives on Left deltoid appearing 5 days after injection.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342553-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Oct-2008	01-Oct-2008	0	24-Mar-2009	25-Mar-2009	--		15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Injection site mass, Injection site pain, Muscular weakness, Myalgia

Symptom Text: My primary care physician informed me on the use of GARDASIL and how it prevents cervical cancer. After reading a small pamphlet on the drug I agreed to be administered my first dose sometime in October 2008. One month after the first initial injection I got a golf ball size knot on my left shoulder exactly where the injection was given. I had such terrible deep within the muscle so I opted not to have another injection, but I wonder to this day what would have happened if I had, since my arm has never been the same. I still have some muscle weakness in that arm at the times along with pain where the injection was given. As well as less of strength in that arm. Now I told my MD my thoughts and concerns and he just said that maybe it was a good idea I didn't have another. But like I said what if I had. I am concerned with this drug. After my incident I have researched and found that I am not alone, GARDASIL has also been reported to cause moderate to severe migraines. I really think that more studies should be done on this drug. And until those studies have been done neither of my daughters will ever have that vaccine!

Other Meds:

Lab Data: My MD opted not to test me for any adverse reactions since she says "It's been a month, I just don't see it."

History: I falsely tested positive for HPV two years prior to receiving GARDASIL, that's why my MD wanted to administer the vaccine.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342560-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	12-Mar-2009	12-Mar-2009	0	24-Mar-2009	25-Mar-2009	PA		08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Left arm	Unknown	VARCEL
	MNQ	SANOFI PASTEUR	U2688AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Loss of consciousness, Pallor

Symptom Text: After receiving MENACTRA, in process of receiving GARDASIL, child became extremely pale and experienced LOC x about 15 seconds, slumping into chair. Head protected thru out. Given liquids and observed for 1/2 hour. Mentating well, no dizziness when ambulating when discharged.

Other Meds:

Lab Data: none

History:

Prex Illness: none

Prex Vax Illns: mother stated "it's happened before", non specific re date/type~Vaccine not specified (no brand name)~UN~0~Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342562-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Mar-2009	19-Mar-2009	0	24-Mar-2009	25-Mar-2009	AZ		01-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Dizziness, Heart rate normal, Hypoacusis, Pallor, Visual impairment

Symptom Text: (D:) BP 102/60; P 60 - R-12;- Pt feel lightheaded, skin tone change to pale. Saw spots, alteration in hearing (A:) Pt given Kool Aid to drink Patient lay on back on exam table, syst symptoms resolved, BP 102/60 P. 60 (R:) Symptoms resolved.

Other Meds: BENADRYL night before; vitamins

Lab Data:

History: Hx of lightheadness with BM last summer; hx of of hives

Prex Illness: None

Prex Vax Illns:

Vaers Id: **342565-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Mar-2009	18-Mar-2009	1	24-Mar-2009	25-Mar-2009	PA		08-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2668AA	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB257AA	0	Right arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0785X	1	Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0575X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: Redness, swelling (half dollar sized) at injection site of VARIVAX vaccine 24 hours prior.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns: ~DTaP + Hib (no brand name)~4~1~Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342569-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	27-Jan-2009	17-Feb-2009	21	24-Mar-2009	25-Mar-2009	NC		13-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0575X	2	Left arm	Intramuscular	FLU
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB257AA	1	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain lower, Dysuria, Eye infection, Malaise, Micturition urgency, Pallor, Pollakiuria, Rash erythematous, Urinary tract infection

Symptom Text: GARDASIL dose #3 1/27/09 2/17/09 - Dysuria with Lower Abdominal Pain UA - Large Blood, small leuks, Prot > 300 mg/DL cx-neg symptoms lasted 1 week - Repeat urine x 2 - normal. 4/3/09 Received vac records & PCP medical records for 2/17-2/26/2009. FINAL DX: UTI, dysuria Records reveal on 2/17/09 patient experienced pain w/urination, grequency & urgency x 1 day. Had just completed menses. Tx w/oral antibiotics. RTC 2/26 & had felt unwell since 1/27. Had eye infection 2/4, possible UTI 2/11 & now UTI w/abdominal pain & dysuria. Exam revealed erythematous blanching rash thought to be drug vs vaccine reaction. Antibiotic d/c. No further records available.

Other Meds:

Lab Data: LABS: Urine c/s of 2/17 no growth. UA 2/24 WNL.

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342594-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Jan-2009	20-Jan-2009	0	25-Mar-2009	26-Mar-2009	--	WAES0902USA00936	17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse and a nurse practitioner, for GARDASIL, a Pregnancy Registry product, concerning a 16 year old female patient who on 20-Jan-2009 was vaccinated with the first dose of GARDASIL (lot # 661764/0650X). The patient was pregnant. LMP was 04-JAN-2009, and estimated delivery date was 11-OCT-2009. The patient's mother had history of coagulation disorders, so blood work was taken on the patient with results pending to determine if the patient also had any unknown medical conditions that would affect the pregnancy. On 03-FEB-2009 urine pregnancy test was performed with positive result. The patient sought unspecified medical attention. Follow-up information was received from a nurse practitioner, for GARDASIL, a Pregnancy Registry product, concerning a 16 year old female patient with a history of 0 previous pregnancies and 0 of previous live births, who on 10-FEB-2008 (5 weeks from LMP) had a spontaneous abortion. The patient had not received any prenatal testing. The products of conception were not examined. The patient's mother had a history of coagulopathy which was not diagnosed. Upon internal review, spontaneous abortion was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, results pending; urine beta-human, 02/03/09, positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/4/2009)

Prex Vax Illns:

Vaers Id: 342595-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Sep-2008	Unknown		25-Mar-2009	26-Mar-2009	FR	WAES0903AUS00034	26-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Disability, Juvenile arthritis, Lymphadenopathy

Symptom Text: Information has been received from a physician, via CSL as part of a business agreement (manufacturer control No. 2009 03 03 JV2), concerning a 22 year old female who in September 2008, was vaccinated with GARDASIL. Subsequently the patient developed adult onset Still's disease. The patient's ferritin level was really high at 20,000 (units not specified). Additional information was received from the physician on 17-MAR-2009. It was reported that the patient was hospitalised and sustained a permanent or substantial disability from the adverse event of adult onset Still's disease. An erythrocyte sedimentation rate (ESR) was done and the result was 64 (unit not specified). A computerised tomography scan (CT) was also done which showed small cervical lymphadenopathy. The patient will undergo a biopsy to rule out a lympho-proliferative disorder. The patient will be started on prednisone soon as the severe inflammatory arthritis subsides. The reporting physician considered the causality of adult onset Still's disease as unknown. The adverse event of adult onset Still's disease was considered to be disabling by the reporting physician. Additional information is not expected.

Other Meds: Hormonal contraceptives (unspecified)

Lab Data: Computed axial tomography, 04Oct08, small cervical lymphadenopathy; Serum ferritin assay, 04Oct08, 20000, units not specified; Erythrocyte sedimentation rate, 04Oct08, 64

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 342596-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	08-Apr-2008	08-Apr-2008	0	25-Mar-2009	26-Mar-2009	AZ	WAES0809USA04651	15-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
TTOX	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
DTOX	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Large for dates baby

Symptom Text: Information has been received from a consumer, who was the guardian of the patient, for the Pregnancy Registry for GARDASIL, concerning a 14 year old female with no pertinent medical history or drug reactions or allergies who on 08-APR-2008 was vaccinated with a 0.5 ml dose of GARDASIL. On the same day, the patient was also vaccinated with VARIVAX (Merck), tetanus toxoid vaccine, diphtheria toxoid vaccine, meningococcal conj vaccine (unspecified), hepatitis A virus vaccine (unspecified) (manufacturer unknown) and "ACHD". Concomitant therapy included calcium (unspecified), iron (unspecified) and prenatal vitamins. It was reported that the patient would be delivering next week. There were no lab tests performed. It was reported that the patient had no ill effects from this. The patient sought unspecified medical attention via the physician. Follow-up information was received from a staff member in the physician's office via phone call. It was reported that the patient delivered a healthy and normal baby boy on 05-OCT-2008 via C-section. The C-section was performed because the baby was "like 12 lbs". The reporter did not have any additional information to provide. Upon internal review, the baby was "like 12 lbs" that required C-section was considered to be other important medical event. Additional information is not expected.

Other Meds: Calcium (unspecified); Iron (unspecified); Vitamins (unspecified)

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 12/28/2007)

Prex Vax Illns:

Vaers Id: **342597-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Dec-2007	Unknown		25-Mar-2009	26-Mar-2009	FR	WAES0903USA03777	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pneumothorax, Surgery

Symptom Text: Information has been received from Health Authorities (Ref nr: DHH-N2009-44151) concerning a 16 year old female who was vaccinated with the first dose of GARDASIL (batch nr unknown) via intramuscular route on 18-DEC-2007 on an unspecified site. She received the second dose of GARDASIL on 18-FEB-2008 and the third dose on 19-JUN-2008, both via intramuscular route (batch nr and administration site not reported). It was reported that the patient experienced a catamenial pneumothorax as from December 2007 and that this condition was recurring following GARDASIL injection. It was not clear whether the onset of the catamential pneumothorax occurred before or after the first GARDASIL injection of 18-DEC-2007. The patient underwent 2 surgical interventions and was considered as recovered with sequel (ae) in February 2009, no further details provided. It was specified that the patient has not been hospitalized. No relevant medical patient history reported, except allergy to grass and trees. No alcohol or tobacco abuse. Pneumothorax spontaneous was reported as other medically important condition. Additional information has been requested. Other business partner numbers include E2009-02314.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pollen allergy; Hypersensitivity

Prex Vax Illns:

Vaers Id: **342598-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	31-Jul-2007	22-Dec-2008	510	25-Mar-2009	26-Mar-2009	FR	WAES0903USA03778	17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epilepsy, No reaction on previous exposure to drug

Symptom Text: Information has been received from a Health Authority (reference number PEI2009004668) concerning a 12 year old female patient who on 31-JUL-2007 was vaccinated with her first dose of GARDASIL (lot number, site and route not reported) which was well tolerated. On 11-SEP-2007, the patient was vaccinated IM with her second dose of GARDASIL (lot number, site and exact date not reported). Post vaccination (exact date not reported), the patient developed absence epilepsy which was finally diagnosed on 22-DEC-2008. The patient's mother had absence epilepsy with few grand mal seizures. The reporting neuropaediatrician stated that even though there was a positive family history epilepsy could have been triggered by the GARDASIL vaccination. The patient had not recovered at the time of reporting. The event of epilepsy was considered to be an other Medical Event. Other business partner number included: E2009-02385. No further information is available. The file was closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 342599-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Nov-2008	07-Jan-2009	51	25-Mar-2009	26-Mar-2009	FR	WAES0903USA03827	26-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal discomfort, Arthralgia, Henoch-Schonlein purpura, Purpura

Symptom Text: Information has been received from a Health Authority (reference number ES-AGEMED-718657244) on 18-MAR-2009 concerning a 14 year old female who was administered on 17-NOV-2008 the second 0.5 ml dose of GARDASIL (lot # not reported) by intramuscular route (site of administration not reported). On the same day the patient also received a dose of DITANRIX by intramuscular route (site not reported). It is reported that on the 07-JAN-2009 the patient presented with a purpuric rash on legs, buttocks and forearms, arthralgia and abdominal discomfort. According to the skin biopsy, performed on 20-JAN-2009 the patient presented a leukocytoclastic vasculitis (Shonlein-Henodi syndrome). The patient improved after treatment with prednisolone, with fluctuance. By the 27-FEB-2009 the patient had not completely recovered yet. Hospital admission was required (dates not informed). It was reported that the patient received the first dose of GARDASIL on 22-SEP-2008 intramuscularly. It was not reported whether the patient had any adverse event after this dose of vaccine or not. Other business partner numbers included: E200902370. No further information is available.

Other Meds: Unknown

Lab Data: skin biopsy, 20Jan09, positive results for leukocytoclastic vasculitis (Shonlein-Henodi syndrome)

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342601-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	17-Mar-2009	17-Mar-2009	0	25-Mar-2009	26-Mar-2009	NY		02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1702X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Nausea, Pyrexia

Symptom Text: Severe Nausea, vomiting, fever + joint pain.

Other Meds: O yaz Oc's

Lab Data: Pt was seen in ER

History: Allergy to Antihistamines

Prex Illness: None

Prex Vax Illns:

Vaers Id: **342608-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	02-Feb-2009	02-Feb-2009	0	16-Mar-2009	07-Apr-2009	NJ	WAES0902USA01614	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	
	HEPA	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 17 year old female student (weight 134.8 pounds, height 65.5 inches) who on the afternoon of 02-FEB-2009 was vaccinated with the third dose of GARDASIL, intramuscularly in the arm. Concomitant suspect therapy included VAQTA. On 02-FEB-2009 the patient had a syncopal episode few minutes after receive the GARDASIL vaccine in the waiting room. The patient recovered immediately from syncope but had to lay for approximately 30 minutes. Syncopal episode was considered to be an other important medical event by the physician. Additional information is not expected.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342609-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	U	14-Jan-2009	14-Jan-2009	0	16-Mar-2009	07-Apr-2009	PA	WAES0902USA01435	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Oedema peripheral

Symptom Text: Information has been received from a physician concerning a 15 year old patient who on 14-JAN-2009 was vaccinated with the first dose of GARDASIL. Subsequently the patient experienced significant swelling of the upper arm. Approximately a six inch region of the upper arm swelled to double the normal size following the administration of the vaccine. The patient was tested and the physician found significantly elevated level of immunoglobulin E (IGE). Additional information has been requested.

Other Meds: Unknown

Lab Data: serum immunoglobulin E - significant elevated level of IGE

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342610-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	--	WAES0902USA01468	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site rash

Symptom Text: Information has been received from a health professional concerning a 15 year old female with no allergies who on an unspecified date was vaccinated with an "injection in the arm" (unspecified) of GARDASIL (lot number not available). The patient broke out with a rash at the injection site after receiving her first dose of GARDASIL. The onset was noted as one day after the vaccination. Unspecified medical attention was sought. The rash lasted for 2-3 weeks. Subsequently, the patient recovered from rash at injection site 2-3 weeks after vaccination. A product quality complaint was not involved. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 342611-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	--	WAES0902USA01470	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Metrorrhagia, Vaginal haemorrhage

Symptom Text: Information has been received from a nurse practitioner concerning her sister who was vaccinated with a first dose of GARDASIL in arm. On unknown date the patient experienced breakthrough bleeding and spotting. On unspecified date, the patient recovered from breakthrough bleeding and spotting. The patient sought unspecified medical attention. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342612-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	01-Jun-2008	Unknown		16-Mar-2009	07-Apr-2009	GA	WAES0902USA01481	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Formication, Smear cervix abnormal, Vaginal haemorrhage

Symptom Text: Information has been received from a 29 year old female consumer who in April 2008, was vaccinated with the first dose of GARDASIL. On June 2008, the patient received the second dose of GARDASIL. After receiving the second dose the patient began to experience abnormal vaginal bleeding, abnormal pap smears and the feeling of "bugs crawling on her skin". The symptoms had persisted since the second dose was administered. The patient called her physician office, but had not spoken with them yet. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342613-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	16-Jun-2008	16-Jun-2008	0	16-Mar-2009	27-Mar-2009	WA	WAES0902USA01500	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Bone scan, Borrelia burgdorferi serology, Hypothyroidism

Symptom Text: Information has been received from a consumer concerning her 14 year old daughter with sulfa allergy and with no previous medical history reported who on 15-OCT-2007 was vaccinated with the first dose of GARDASIL (Lot number 658490/0802U) and on 16-JUN-2008 with the second dose of GARDASIL (Lot number 659180/1758U). Concomitant therapy included LEVOTHYROXINE Na. Four months ago, approximately in September 2008, the patient experienced joint pain in her ankles and wrists after receiving GARDASIL. The reporter also noted that the patient had experienced hypothyroidism after she received GARDASIL. The patient's joint pain in her ankles and wrists and hypothyroidism persisted. Bone scan and blood work were performed to test for lymes disease (results were not provided). The patient sought medical attention with the physician. The consumer wanted to know if there have been any reports of these symptoms associated with the specific lot numbers that her daughter had received. A lot check has been initiated. Additional information has been requested.

Other Meds: LEVOTHYROXINE SODIUM

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **342614-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Apr-2008	01-Dec-2008	217	16-Mar-2009	27-Mar-2009	MI	WAES0902USA01507	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a certified medical assistant concerning a 17 year old female with asthma and no known drug allergies who on 06-AUG-2007, 15-OCT-2007 and 28-APR-2008 was vaccinated respectively with the first, second and third dose of GARDASIL, 0.5 mL, intramuscularly (dose 1 lot # 0927U, dose 2 lot # 658558/1061U, and dose 3 lot # 660387/1967U). Concomitant therapy included LOESTRIN (1.5/30). The medical assistant stated that the patient's mother called the office on 27-JAN-2009 because her daughter had had a headache for 7 weeks. It was reported that the patient was evaluated by an unspecified neurologist who could not find anything wrong. Laboratory tests including "hormones", prolactin, and thyroid were normal. At the time of reporting, the patient had not recovered. Additional information has been requested.

Other Meds: LOESTRIN 1.5/30

Lab Data: Diagnostic laboratory; "hormones" normal; Thyroid function test, normal; Serum prolactin test, normal.

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **342615-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	21-Jan-2009	21-Jan-2009	0	16-Mar-2009	07-Apr-2009	--	WAES0902USA01517	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye pruritus, Lacrimation increased, Photophobia

Symptom Text: Information has been received from a registered nurse concerning a 23 year old female patient with allergy to VICODIN who on 21-JAN-2009 was vaccinated with the first dose of GARDASIL (lot # 660616/0570X), 0.5 mL, intramuscularly. Concomitant therapy included NECON. The nurse reported that on 21-JAN-2009 the patient developed itchy, watery eyes with sensitivity to light, a few hours after receiving GARDASIL vaccine. The patient contacted the office by phone and was prescribed BENADRYL. The practitioner suggested that the patient not complete the vaccine series. At the tome of reporting, the patient had recovered. Additional information has been requested.

Other Meds: NECON

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **342616-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	--	WAES0902USA01531	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crying, Skin exfoliation, Swelling

Symptom Text: Information has been received from a consumer concerning someone she saw on the television news, a female who was vaccinated with GARDASIL of unknown dose and frequency on an unknown date for an unknown indication. The patient's relevant medical history, concomitant medications and relevant past drug history were unknown. Subsequently the patient was crying and her skin was peeling and swollen really bad. It was unknown if any laboratory testing had been performed. As of 07-FEB-2009, it was unknown if the patient continued to take GARDASIL and the outcome of the crying, skin that was peeling and swollen were unknown. The mother of the patient said that "she wished she had known, because her daughter would have never gotten GARDASIL". Additional information is not expected. Attempts made to verify the existence of an identifiable patient and reporter have been unsuccessful. This is one of several reports received from the same source.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342617-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	NC	WAES0902USA01588	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL. The patient's relevant medical history, concomitant medication, and past drug history were unknown. On unknown date, after being administered GARDASIL, the patient complained of getting "sick" more often. It was unknown if there was any laboratory data. As of 09-FEB-2009, it was unknown if she continued to receive GARDASIL and it was unknown if she continued to get "sick" more often. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342618-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	02-Feb-2009	02-Feb-2009	0	16-Mar-2009	07-Apr-2009	NJ	WAES0902USA01615	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 11 years old female patient who on 02-FEB-2009 at afternoon was vaccinated with the third dose of GARDASIL intramuscularly into her arm. Concomitant therapy included a second dose of HAVRIX,which administered on the same day intramuscularly into her arm. It was reported that on 02-FEB-2009 the patient had syncopal episode more than 5 minutes later in room. It was reported that the patient recovered in less 1 minute but had to lay on table for 1/2 hour. The reporting physician considered the syncopal episode to be other important medical event. Follow up information was received on 12-FEB-2009 from a physician who stated that the patient experienced syncope. It was reported that a blood pressure measurement and pulse rate count were performed (results not provided). It was reported that the physician allowed her to rest for 45 minutes. It was reported that intervention to prevent serious criteria was not actually required. The patient had recovered at the time of this report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Blood pressure, result not provided; Total heartbeat count, result not provided.

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342619-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	--	WAES0902USA01625	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Metrorrhagia, Vaginal haemorrhage

Symptom Text: Information has been received from a nurse practitioner concerning a female who was vaccinated with a first dose of GARDASIL in arm. On unknown date the patient experienced breakthrough bleeding and spotting. On unspecified date, the patient recovered from breakthrough bleeding and spotting. The patient sought unspecified medical attention. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342620-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	02-Feb-2009	02-Feb-2009	0	16-Mar-2009	07-Apr-2009	PA	WAES0902USA01635	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Pain

Symptom Text: Information has been received from a physician concerning a 23 years old female with allergy to CIPRO and a history of mitral valve prolapse who on 02-FEB-2009 was intramuscularly vaccinated with the first dose of GARDASIL. Concomitant therapy included birth control bills (manufacturer unspecified). The patient experienced headache and body ache. The patient had taken over the counter analgesics to treat her symptoms. At the time of reporting, the patient recovered. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: None

History: Mitral valve prolapse

Prex Illness: Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **342621-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	12-Jul-2007	16-Jan-2009	554	16-Mar-2009	07-Apr-2009	FL	WAES0902USA01636	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection, Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a 23 year old female with a history of papanicolaou smear abnormal in January 2006 but was not tested for HPV at that time. On 13-NOV-2006, the patient was vaccinated with the first dose of GARDASIL. On 15-JAN-2007, the patient was vaccinated with the second dose of GARDASIL (lot number was reported as 1426S, which is a available lot number of dexamethasone acetate). On 12-JUL-2007, the patient was vaccinated with the third dose of GARDASIL (lot # 658100/0525U). Concomitant therapy included ORTHO TRI-CYCLEN. On 16-JAN-2009 the patient experienced abnormal PAP smear that was positive for high risk HPV. The specific type of HPV she had was unknown. The patient was scheduled to have a colposcopy. Additional information has been requested.

Other Meds: ORTHO TRI-CYCLEN

Lab Data: Pap test, 01/16/09, abnormal without HPV test; Pap test, 01/??/06, abnormal which was positive for high risk HPV

History:

Prex Illness: Papanicolaou smear abnormal

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342622-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	OH	WAES0902USA01653	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Human papilloma virus test positive

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with a 0.5 ml dose of GARDASIL (lot # was not provided, dose of series was unknown. Before getting vaccine the patient took a HPV test with negative results. After getting vaccine, the patient got a HPV test with positive result. At the time of this report, the outcome was unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervix HPV DNA assay - negative; cervix HPV DNA assay - positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342623-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
33.0	F	01-Jan-2009	01-Jan-2009	0	16-Mar-2009	07-Apr-2009	OR	WAES0902USA00928	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Injection site induration, Injection site pain

Symptom Text: Information has been received from a registered nurse concerning a 33 year old female who was vaccinated with her first dose of GARDASIL (lot number not reported) 0.5ml IM into her left deltoid. There was no concomitant medication. Two days after administration, "a few week ago" the patient experienced soreness at the injection site. The patient then developed induration at the injection site. The patient was examined in the office but no treatment was prescribed. The current status of the patient was unknown. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342624-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	15-May-2007	Unknown		16-Mar-2009	07-Apr-2009	--	WAES0902USA00931	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a Nurse Practitioner concerning a 19 year old female who was vaccinated intramuscularly with her first, second and third dose of GARDASIL on 16-JAN-2007, 15-MAY-2007 and 23-NOV-2007 respectively. The patient experienced severe hair loss after receiving her second dose of GARDASIL (MAY 2007). She was sent to an endocrinologist for medical attention after the adverse experience occurred. Lot numbers were not available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342625-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	CA	WAES0902USA00934	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Neck pain, Pain in extremity

Symptom Text: Information has been received from a consumer concerning her daughter who developed soreness on her arm and neck after receiving a dose of GARDASIL. Lot # is not available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342626-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	29-Jan-2009	29-Jan-2009	0	16-Mar-2009	07-Apr-2009	--	WAES0902USA00935	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyspnoea

Symptom Text: Information has been received from an immunization coordinator concerning a 24 year old female patient. "Sometime last week" the patient was vaccinated with her first dose of GARDASIL 0.5 ml (lot number and site not reported). Subsequently the patient experienced shortness of breath and dizziness. Blood pressure was performed with no result reported. The patient also was checked her lungs, but no result was reported. "Soon after reaction" the patient recovered from shortness of breath and dizziness. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342627-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	05-Sep-2007	Unknown		16-Mar-2009	08-Apr-2009	FL	WAES0902USA00938	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Biopsy, Cervical dysplasia, Colposcopy, Dysplasia, Papilloma viral infection, Uterine cervical squamous metaplasia

Symptom Text: Information has been received from a physician concerning a female (approximately 24 year old) with history of an abnormal Atypical squamous cells of undetermined significance (ASCUS) PAP smear in 2006 and 2007 who was vaccinated with her first (lot#656048/0187U), second (657621/0387U) and third (658558/1061U) dose of GARDASIL on 06-MAR-2007, 07-MAY-2007 and 05-SEP-2007 respectively. Concomitant medications included unspecified birth control. They did not test for HPV at the PAP smear in 2007. She had another PAP smear in November 2007 which showed high grade dysplasia. The patient had a colposcopy which showed that she had high grade squamous epithelial lesions. She also had a cold cone biopsy on 21-DEC-2007 which came back positive for squamous metaplasia. The first PAP smear she received in 2008 was normal but the second came back as positive for HPV. She had another PAP smear in January 2009 that came back as normal. The outcome is unknown. The patient's sister also experienced an adverse event following vaccination (WAES# 0902USA01061). The patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Cervical smear, ?/?/06, abnormal ASCUS PAP smear; Cervical smear, ?/?/07, ASCUS; Cervical smear, 11/??/07, high grade dysplasia; Colposcopy, 11/??/07, high grade squamous epithelia lesions; Cervix conization, 12/21/07, positive for squamous

History: Atypical squamous cells of undetermined significance

Prex Illness:

Prex Vax Illns:

Vaers Id: **342628-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Jan-2009	22-Jan-2009	0	16-Mar-2009	07-Apr-2009	--	WAES0902USA00942	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, No reaction on previous exposure to drug

Symptom Text: Information has been received from a Nurse Practitioner (N.P.) concerning a 14 year old female with a history of contact dermatitis who on 22-JAN-2008 was vaccinated intramuscularly with the third 0.5 ml dose of GARDASIL. On 22-JAN-2009 the patient developed pain and soreness at the injection site after receiving the third dose of vaccine. As of 05-FEB-2009, the patient was not recovered. The patient received the first and second dose of GARDASIL on 12-JUL-2008 and 19-SEP-2008 respectively. She had not experienced any problems with the first two doses. Additional information has been requested.

Other Meds: None

Lab Data: None

History: Dermatitis contact

Prex Illness:

Prex Vax Illns:

Vaers Id: 342629-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	04-Feb-2009	05-Feb-2009	1	16-Mar-2009	03-Apr-2009	CA	WAES0902USA00951	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaphylactic reaction, No reaction on previous exposure to drug

Symptom Text: Information has been received from a consumer concerning her daughter (a 21 year old female) with diabetes as well as allergies to heat and penicillin who at 3:15 pm on 04-FEB-2009 was vaccinated intramuscularly with her second 0.5 ml dose of GARDASIL. Concomitant therapy included ATARAX, ADDERALL, NEXIUM and insulin. The patient had an anaphylactic reaction on 05-FEB-2009 (after 12:00 am). She was recovered on 05-FEB-2009. The patient received the first dose of vaccine on 03-FEB-2008. There was no reaction after the first dose. The patient did not seek medical attention. Additional information has been requested.

Other Meds: ATARAX; ADDERALL tablets; NEXIUM; insulin

Lab Data: None

History:

Prex Illness: Diabetes; Heat sensitivity; Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342630-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Aug-2008	Unknown		16-Mar-2009	07-Apr-2009	OH	WAES0902USA01036	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 01-MAY-2008 was vaccinated with the first dose of GARDASIL. On 02-AUG-2008 was vaccinated with second dose of GARDASIL (lot no. 660389/1968U) (site and route not reported). Concomitant therapy included hormonal contraceptives (unspecified). Physician reported that the patient experienced arthritic pain in her hand and back after second dose of GARDASIL. Physician reported that the patient saw another physician on 26-JAN-2009 for the pain. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342631-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Dec-2008	01-Dec-2008	0	16-Mar-2009	07-Apr-2009	CT	WAES0902USA01062	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a physician concerning an approximately 15 year old female patient who in December 2008, was vaccinated with her first dose of GARDASIL. It was reported that after receiving GARDASIL the patient experienced amenorrhea. Eventually patient did get her period again. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342632-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.5	F	01-Feb-2009	01-Feb-2009	0	16-Mar-2009	07-Apr-2009	LA	WAES0902USA01064	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Peroneal nerve palsy

Symptom Text: Information has been received from a medical assistant concerning a female patient who in approximately February 2009 finished the series of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). The patient experienced "foot drop". It is unknown if the patient sought medical attention. As of 06-FEB-2009 the patient had not recovered. Additional information has been requested.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342633-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	15-Jan-2009	Unknown		16-Mar-2009	07-Apr-2009	--	WAES0902USA01080	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash pruritic, Urticaria

Symptom Text: Information has been received from a 23 year old female patient with no pertinent medical history and no known drug allergies/drug reactions who on 15-JAN-2009 was vaccinated with the third 0.5 ml dose of GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified). It was reported that the patient had itchy rash/hives after receiving GARDASIL. A skin test was performed (results not reported). It was reported that the patient had not recovered at the time of the report. The patient sought unspecified medical attention. No further information is available.

Other Meds: Hormonal contraceptives

Lab Data: Allergen skin test

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342634-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	GA	WAES0902USA01104	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hair growth abnormal, Inappropriate schedule of drug administration, Smear cervix abnormal, Vaginal disorder

Symptom Text: Information has been received from a 29 year old female consumer who was vaccinated on an unspecified date with the second dose of GARDASIL 0.5 ml intramuscularly. The patient reported that the vaccine "really tore [her] whole body up" as it "ruptured in her vagina", she had an abnormal pap smear and it stopped her hair from growing. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342635-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Jan-2008	01-Nov-2008	289	16-Mar-2009	26-Mar-2009	KY	WAES0902USA01115	27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	2	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Musculoskeletal pain, Pain in extremity

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter with no pertinent medical history and no drug reactions or allergies who began the GARDASIL series around July of 2007 and finished the series in 2008 (lot # were not reported). Concomitant therapy included MINOCYCLINE. In approximately November 2008 the patient experiencing aching leg pain that began behind the back of her knees and then radiated to the front of her knees and thighs. The patient also has been experiencing pain in her shoulders. In January, the patient was seen by her physician for the pain. The patient had not recovered. Additional information has been requested.

Other Meds: MINOCYCLINE

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 342636-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
37.0	F	22-Oct-2008	08-Nov-2008	17	16-Mar-2009	26-Mar-2009	VA	WAES0902USA01120	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Pruritus generalised

Symptom Text: Information has been received from a 37 year old female with no allergy and medical history who on 18-AUG-2008 was vaccinated with a first dose of GARDASIL. On 22-OCT-2008, the patient was vaccinated with a second dose of GARDASIL. Concomitant therapy included oral OCELLA. On 08-NOV-2008 the patient experienced severe itching all over her body, mainly on her chest, back, stomach and all pressure points. On 13-NOV-2008 the patient was put on oral steroids. On 25-NOv-2008, the patient recovered from the events. The steroids did not work completely and received a second oral steroid which did help the itching. Additional information has been requested.

Other Meds: OCELLA

Lab Data: None

History: No

Prex Illness:

Prex Vax Illns:

Vaers Id: 342637-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		16-Mar-2009	26-Mar-2009	--	WAES0902USA00924	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood aluminium increased, Gastrointestinal pain, Pelvic pain, Weight decreased

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female patient with a history of appendectomy conducted in December 2007 and a gall bladder removed in April 2008 who was vaccinated with the first dose of GARDASIL. Four weeks later the patient experienced gastrointestinal and pelvic pain. The patient was diagnosed as having high aluminum content and lost approximately 10 pounds. At the time of this report, the patient recovered and was still undergoing nutrition therapy. It is unknown if the patient sought medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Appendicectomy; Cholecystectomy

Prex Illness:

Prex Vax Illns:

Vaers Id: **342638-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Dec-2008	Unknown		16-Mar-2009	26-Mar-2009	--	WAES0902USA00894	15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Pruritus, Urticaria

Symptom Text: Information has been received from a consumer concerning her daughter who in December 2008, was vaccinated with a first 0.5 ml dose of GARDASIL. "Four weeks later", the patient developed hives and experienced itchiness and joint pain. Unspecified medical attention was sought. At the time of the report, 05-FEB-2009, the patient had not recovered. No additional information was provided.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342639-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	20-Jan-2009	22-Jan-2009	2	16-Mar-2009	07-Apr-2009	ID	WAES0902USA00485	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypersensitivity, Injection site hypersensitivity, Oedema peripheral, Pruritus, Urticaria

Symptom Text: Information has been received from a physician concerning a female with a history of injection site reaction (vaccine unknown) who was vaccinated with the first dose of GARDASIL 0.5ml (Lot number not provided). Subsequently the patient experienced "allergic reaction" at the injection site. The outcome of the adverse event was unknown. The physician was not going to give the patient the rest of the series. It was reported that the patient sought unspecified medical attention. Additional information has been received from a physician concerning the 22 year old female with allergies to CECLOR, AUGMENTIN and PENICILLIN who on 20-JAN-2009 was vaccinated IM with the second dose of GARDASIL 0.5ml in the arm (Lot number 661766/0652X). "2 days after the vaccine administration" (on 22-Jan-2009), the patient developed lower extremity pruritis. "On third day" (on 23-Jan-2009) the patient experienced swelling of hands, pruritis of the feet and scattered "hives" by description. The symptoms resolved at time of exam. The patient reported similar prior reaction to CECLOR. Further information is not available.

Other Meds: YAZ; ALDARA

Lab Data:

History: Injection site reaction

Prex Illness: Allergic reaction to antibiotics; Penicillin allergy

Prex Vax Illns:

Vaers Id: **342640-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Nov-2008	05-Jan-2009	40	16-Mar-2009	07-Apr-2009	--	WAES0902USA00488	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysmenorrhoea, Menorrhagia, Menstruation irregular

Symptom Text: Information has been received from a healthcare worker concerning her daughter, a 15 year old female with no pertinent medical history and no known drug allergies who on 26-NOV-2008 was vaccinated intramuscularly with the first 0.5 mL dose of GARDASIL. There was no concomitant medication. On 05-JAN-2009 the patient began a 15 days menstrual cycle. She experienced irregular menstrual and cramping after vaccination. On 26-JAN-2009 the patient was vaccinated intramuscularly with the second 0.5 mL dose of GARDASIL. On 02-FEB-2009 the patient experienced pain with her menstrual cycle. The patient took MIDOL tablets but the cramping did not subside. The patient never had cramping and irregular cycles prior to the first dose of GARDASIL. The patient's symptoms persisted. The patient sought medical attention by consultation with nurse practitioner. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342641-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	TN	WAES0902USA00535	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Alopecia areata

Symptom Text: Information has been received from a physician concerning a nurse's daughter who was vaccinated with GARDASIL a year ago. Coincidentally, the patient started losing her hair about the same time. The patient has subsequently been diagnosed with alopecia areata. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342642-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	SC	WAES0902USA00570	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling abnormal

Symptom Text: Information has been received from an office manager concerning a female patient who in 2008 was vaccinated with the first dose of GARDASIL (lot # not reported). The reporter stated that she over heard another office staff member stating that the patient received the first dose of GARDASIL and she felt like she "was dying". The patient never called about the experience at the time it happened. The patient didn't sought medical attention. Her outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342643-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Dec-2008	02-Dec-2008	0	16-Mar-2009	07-Apr-2009	WV	WAES0902USA00575	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Back pain, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse for the Pregnancy Registry for GARDASIL concerning an 18 year old female patient who on 26-Feb-2008 was vaccinated intramuscularly with a 0.5ml dose of GARDASIL (lot# 658100 / 0525U) , on 22-Apr-2008 with the second dose (lot # 657617 / 0384U) and on 02-Dec-2008 with the third dose (lot# 661530 / 0575X). On 02-Feb-2009 the patient developed lower back pain and went to the emergency room. She had an urine test and an ultrasound that showed that she was 31 weeks pregnant. She was given a due date of 07- Apr-2009 (LMP 01-Jul-2008). The patient had no signs or symptoms of pregnancy prior the ER visit. She had no complications thus far and will be having a baby girl. Additional information has been requested.

Other Meds: Unknown

Lab Data: Ultrasound 02/02/09 - 31 weeks pregnant; Urinalysis 02/02/09 - positive

History:

Prex Illness: Pregnancy Nos (LMP = 7/1/2008)

Prex Vax Illns:

Vaers Id: **342644-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	07-Apr-2009	PA	WAES0902USA00579	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a Nurse concerning a female patient who was vaccinated with the first dose of GARDASIL (Lot # not reported). Patient broke out in hives all over her body after receiving the first dose of vaccine. The patient sought medical attention with the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342645-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	26-Nov-2007	27-Nov-2007	1	16-Mar-2009	07-Apr-2009	NJ	WAES0902USA00589	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	VARCEL	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lip swelling, Urticaria

Symptom Text: Information has been received from a consumer concerning her 14 year old daughter who on 26-NOV-2007 was vaccinated with a 0.5 ml dose of GARDASIL. Secondary suspect therapy included Varicella virus vaccine live (manufacturer unknown). Concomitant therapy included influenza virus vaccine (unspecified). The patient sought unspecified medical attention. It was reported that "24 to 36 hours after receiving the vaccine" the patient experienced hives and lip swelling. The patient recovered " a couple of days later". Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342646-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Jan-2009	15-Jan-2009	1	16-Mar-2009	07-Apr-2009	WA	WAES0902USA00619	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Nausea, Pyrexia

Symptom Text: Information has been received from a physician concerning a 12 year old female patient with no drug reactions or allergy who on 14-JAN-2009 was vaccinated with first dose of GARDASIL (Lot # not reported). There were no concomitants medications. On 15-JAN-2009 the patient experienced high fever, weakness and nauseated. The patient sough unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342647-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	29-Apr-2008	29-Apr-2008	0	16-Mar-2009	07-Apr-2009	--	WAES0902USA00628	04-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Dyspnoea, Herpes simplex, Hypoaesthesia, Insomnia, Irritability, Lymphadenopathy, Palpitations, Paraesthesia, Tension, Tremor

Symptom Text: Information has been received from a physician concerning a 20 year old female patient with no pertinent medical history and no known allergies/drug reactions who on 25-Jan-2008 was vaccinated with the first dose of GARDASIL (lot#659962/17400) 0.5ml intramuscularly. The patient received the second dose of GARDASIL (lot# 660389 / 1968U) 0.5ml intramuscularly on 29-Apr-200. Concomitant therapy included ~~~~ 4/8/09 GYN records received. OV 1/28/08 with HPV#1 given-1740U. HPV#2 given-1968U. Report states no prior rxn to vaccine. 4/21/09 Office notes received from PCP for 2 OVs 3/4/09 with dx: Anxiety and 3/24/09 with DX: Herpes simplex oral-resolving. First seen for c/o 1-2 month hx of anxiety, tenseness, tremoulousness, palpitations, dyspnea, irritability, insomnia and difficulty relaxing r/t heavy school load. PE WNL. Returned 3/24/09 with R sided oral cold sore and swollen gland under the neck, now resolving. Pt reports no other c/o.

Other Meds: Minocycline

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342648-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	04-Dec-2008	06-Dec-2008	2	16-Mar-2009	08-Apr-2009	PA	WAES0902USA00849	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inflammation, Local reaction

Symptom Text: Information has been received from a nurse concerning a 11 year old female patient who on 04-DEC-2008 was vaccinated with GARDASIL (lot# 661530/0575X). Concomitant therapy included MENACTRA and ADACEL. She received the vaccines in the other arm the same day. On 06-DEC-2008 the patient had a slight local reaction as her arm was inflamed. The patient was given KEFLEX. No further information is available.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342649-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	16-Jan-2007	01-Sep-2007	228	16-Mar-2009	08-Apr-2009	--	WAES0902USA00858	11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	HPV4

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Biotin deficiency, Contusion, Thyroid function test abnormal

Symptom Text: Information has been received from a consumer concerning her daughter, a 21 year old female with no medical history or drug allergy who was vaccinated with all 3 doses (first dose on 16-JAN-2007) of GARDASIL. There was no concomitant medication. Subsequently the patient started loosing her hair in fall 2007, before getting the third dose, she always had very thick hair and she lost about 35-40% of it already. The caller also mentioned that she started experiencing excessive bruising on her legs around the same time the hair loss started. The bruising was all gone, and the hair was not coming out as bad as it use to. She had multiple tests (including tested vitamin levels (a little low on Biotin), thyroid test, Cushing's disease test, PCOS and urine test) done to see what was wrong. She had thyroid test done and it did spike but when the second test was done it came back normal. All other tests came back normal as well. At the time of the report the patient was not recovered. The patient sought medical attention. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory - Cushing's disease test: normal; serum biotin test - a little low on Biotin; thyroid function test - first test-it did spike; thyroid function test - second test - normal; venous blood pCO(2) - polycystic ovarian synd

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342650-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	12-Jun-2008	13-Jun-2008	1	16-Mar-2009	08-Apr-2009	PA	WAES0902USA00881	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0152X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Injection site pruritus, Injection site urticaria

Symptom Text: Information has been received from a physician's assistant concerning a female patient who in October 2008 was vaccinated with the third dose of GARDASIL (lot number not reported). In December 2008, the patient developed low-grade SIL. At time of reporting the outcome was unknown. The patient sought unspecified medical attention. Follow up information was received from the physician's assistant who reported the patient was intramuscularly vaccinated with the second dose of GARDASIL (lot # 0152X) into the left deltoid at 10:00 on 12-JUN-2008. At 08:00 on 13-JUN-2008 the patient developed hive like lesion on left deltoid to left arm and mild itching. It lasted half of a day and went away by itself. The patient did not call medical office for reporting the above symptoms. Additional information is not expected.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342651-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	19-Sep-2008	01-Oct-2008	12	16-Mar-2009	08-Apr-2009	NJ	WAES0902USA00883	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Information has been received from a nurse concerning a patient who was vaccinated with a dose of GARDASIL and may have an unspecified reaction to GARDASIL. At the time of reporting the outcome was unknown. Follow up information was received from the nurse concerning the 20 years old female patient who on 23-JUL-2008 was vaccinated with the first dose of GARDASIL. On 10-SEP-2008 the patient was vaccinated with the second dose of GARDASIL. The patient experienced hair loss in October, 2008, after receiving the second dose of HPV. On 03-JAN-2009 the patient was vaccinated with the third dose of GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342652-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	18-Mar-2009	18-Mar-2009	0	25-Mar-2009	26-Mar-2009	MO	MO-2009-08	26-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2733AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: After vaccination, patient collapsed to floor - fainting lasted 5 seconds or less. BP 118/80, no dizzness, nausea, headache. Left with mother walked out of clinic.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **342653-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Mar-2009	24-Mar-2009	0	25-Mar-2009	26-Mar-2009	GA		26-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Immediate post-injection reaction, No reaction on previous exposure to drug, Presyncope

Symptom Text: Pt experienced vasovagal reaction within one minute following injection of HPV # 3. She was sitting on the exam table during vaccine administration. Nurse completed administration, applied bandage, & turned to put syringe in sharps container. Pt fell off table and hit back/side of head on the floor. Pt was observed for approximately 30 minutes and examined by physician before being allowed to leave office. We feel that this was a vasovagal reaction not related to the vaccine itself. Pt has had two other Gardisil vaccines without any problems.

Other Meds: Vyvanse

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342684-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Mar-2009	24-Mar-2009	1	25-Mar-2009	26-Mar-2009	TX		15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2827CA	0	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0933X	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1544X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Injection site pruritus, Oedema peripheral

Symptom Text: L arm red and swollen all around back of arm approximately 5 1/2 inches long. Pt. states site itches.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342687-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		25-Mar-2009	26-Mar-2009	CA		26-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	NULL	0	Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	0653X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Head injury, Syncope

Symptom Text: Pt was waiting in line about 15 minutes after receiving iz and fainted, hitting head on wall and floor. Received immediate medical attention. VSS. nl neuro exam after incident. Pt fully recovered within an hour.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **342693-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	Unknown	Unknown		16-Mar-2009	08-Apr-2009	--	WAES0902USA00476	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Headache

Symptom Text: Information has been received from a nurse practitioner concerning a 24 year old female who on unspecified dates was vaccinated with the first and second doses of GARDASIL by IM. After receiving the vaccines, the patient experienced headache, fatigue and tiredness. The patient's symptoms resolved after sleeping for about 4 hours. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342694-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Dec-2008	01-Dec-2008	0	16-Mar-2009	08-Apr-2009	--	WAES0902USA00470	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Dizziness, Headache

Symptom Text: Information has been received from a consumer, concerning her daughter who in October 2008 and December 2008, was vaccinated with her first and second dose of GARDASIL IM (lot number and site not reported) respectively. Since the patient got her second dose vaccine, she experienced light headedness, headaches and stomach pain. The patient's adverse events were recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342698-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Jan-2008	22-Jan-2008	0	26-Mar-2009	27-Mar-2009	--	WAES0803USA04511	17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0523U	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Herpes simplex, Wound dehiscence

Symptom Text: Information has been received from a health professional through the Merck pregnancy registry concerning a 17 year old female who on 22-JAN-2008 was vaccinated with the first dose of GARDASIL (lot# 657868/0523U). On 26-MAR-2008 the patient came to the physician's office for the second dose and told the nurse that she was "3 to 4 months pregnant" (LMP = 31-DEC-2007). The patient did not receive the second dose. No adverse reactions were reported and no other information was available. Follow up information has been received from the nurse practitioner who indicated that the baby was born on 02-SEP-2008 at 39 weeks of gestation by cesarean-section was performed because the baby failed to descend the birth canal. The mother remained in the hospital for an extended 6 days total because her cesarean-section wound dehisced. The mom had also experienced "out break of HSV" two weeks prior to delivery on approximately 19-AUG-2008, and was treated with Valtrex. The date the baby was developmentally normal, "cheerful" and "thriving". She reported that were not known birth defects, the baby is normal. She also mentioned that the baby was seen in the office on 19-MAR-2009 for some nasal congestion "like a any child in a day care". The mother of the baby was in school and shared care with the foster mother. Upon internal review, C-section performed because the baby failed to descend was determine to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data:

History:

Prex Illness: Pregnancy NOS (LMP = 12/31/2007); Foster care

Prex Vax Illns:

Vaers Id: **342699-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Nov-2007	01-Dec-2007	9	26-Mar-2009	27-Mar-2009	FR	WAES0902CAN00101	10-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Anogenital warts, Papilloma viral infection, Rash pruritic

Symptom Text: Information has been received from an Agency and a physician concerning a 17 year old (grade 12) not sexually active female (no contact), nulli gravida, menstruation irregular, non-smoker, denies the use of alcohol, asthma, hypersensitivity (no details provided) and a family history of breast cancer, bone cancer and leukemia who on 22-NOV-2007 was vaccinated with GARDASIL (lot # field illegible). Concomitant medications included unspecified asthma medications and unspecified allergy medications. On approximately 29-NOV-2007 the patient experienced HPV type(s) 16 (initially reported as localized itchy rashes (areas of localization illegible)). On 04-FEB-2008 the patient underwent a gynecological examination which revealed an abnormal external genitalia. The patient had clusters of condylomatous like lesions down both sides of both labia majora. She had some isolated small condylomatous type lesions scattered about the perineal area (looked flat to the gynecologist). The patient's vagina and cervix were grossly normal. A Pap smear was taken (no results provided). On 04-FEB-2009 a colposcopy was performed and on external genitalia the above areas were noted. The physician could not see any vascular markings. The gynecologist was suspicious that these were actually condylomata. Under local anesthetic a small one was removed using a punch biopsy. Bleeding was controlled with Monsel solution. It was reported that the punch biopsy was positive for HPV type(s) 16. Additional information has been received from a physician concerning a 17 year old female with asthma exercise induced (previously reported as asthma) and rhinitis allergic (previously reported as hypersensitivity). On approximately 01-DEC-2007 (previously reported as approximately 29-NOV-2007) the patient experienced HPV type(s) 16. The physician reported that the patient was without prior sexual activity (previously reported) presented with biopsy positive (previous reported) for type 16 condylomata on external genitalia within two weeks of receiving first do

Other Meds: Unknown

Lab Data: colposcopy, 04Feb08, suspicion of condylomata; skin biopsy, 04Feb08, bleeding controlled with Monsel solution; positive for HPV type(s) 16; gynecological examination, 04Feb08, see narrative for details; diagnostic laboratory test, 21Feb08,

History: Family history of cancer

Prex Illness: Not sexually active; Nulli gravida; Asthma exercise induced; Rhinitis allergic; Hypersensitivity; Menstruation irregular; Non-sm

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342700-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	26-Jan-2009	16-Mar-2009	49	26-Mar-2009	27-Mar-2009	WA	WAES0903USA00408	27-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Blighted ovum, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician, for the Pregnancy Registry for GARDASIL, concerning a 23 year old female who was vaccinated with the first or second dose of GARDASIL 0.5ml (Lot# not reported). Couple days later, the patient called the office and informed that she think she was pregnant. The patient had a home pregnancy test, the result was not reported. The outcome of adverse event was unknown. It was reported that the patient sought unspecified medical attention. Follow-up information was received from the registered nurse who reported that the patient on 26-NOV-2008 was vaccinated with the first dose of GARDASIL (Lot# not reported), on 26-JAN-2009 was vaccinated with the second dose of GARDASIL (Lot# not reported) 0.5ml. The registered nurse reported the patient was not pregnant when she received GARDASIL. The patient's LMP Was unknown. On an unspecified date, the patient miscarried. An ultrasound on 16-MAR-2009 showed "blighted ovum and no gestational sack". Upon internal review, the miscarried and blighted ovum were determined to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: ultrasound, 03/16/09, blighted ovum and no gestational sack

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vaers Id: 342701-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Mar-2009	13-Mar-2009	1	26-Mar-2009	27-Mar-2009	--	WAES0903USA02617	17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Blindness, Cyanosis, Deafness, Loss of consciousness, Pallor, Sensation of heaviness, Similar reaction on previous exposure to drug

Symptom Text: Information has been received from a physician assistant concerning a 16 year old female with no allergies who on 12-NOV-2008 was vaccinated with the first dose of GARDASIL. On 12-MAR-2009 the patient was vaccinated with the second dose of GARDASIL . Concomitant therapy included MENACTRA on 12-MAR-2009 into opposite arm, LEXAPRO and RECLIPSEN. On 13-MAR-2009, almost exactly 24 hours after administration, she experienced blacking out, legs feeling like "dead weight", her lips turned blue, she had an ashen color to her skin, and she could not see or hear. She visited the physician assistant who admitted her to the hospital. She was given saline and was monitored on telemetry for cardiac function. She also had a CT scan (results not reported). She was discharged after 24 hours. Her blood pressure was 94/54. The patient recovered on an unspecified date. The patient's mother also told the physician assistant that after the first dose similar symptoms occurred but no black-outs. The symptoms occurred 24 hours after receiving first dose but the patient did not seek medical attention and had recovered. The events occurring 13-MAR-2009 were considered to be disabling. Additional information has been requested.

Other Meds: RECLIPSEN; LEXAPRO

Lab Data: Blood pressure, 03/01?/09, 94/54

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342702-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	26-Apr-2008	26-Apr-2008	0	26-Mar-2009	27-Mar-2009	NJ	WAES0903USA03061	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0073X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for the pregnancy registry for GARDASIL, concerning a 24 year old female patient with no known drug allergies, who on 26-APR-2008 was vaccinated with her first dose of GARDASIL (lot# 654272/0073X). There was no concomitant medication. On 08-APR-2008 the patient had her LMP and in MAY-2008 (6 weeks from her LMP), the patient had an elective termination. At the time of reporting the outcome of the patient was unknown. Subsequently, the patient again experienced vaccine exposure during pregnancy and an elective termination of pregnancy while on therapy with GARDASIL (MSD, WAES_0903USA04267). Upon internal review elective termination was considered as an Other Important Medical Event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 4/8/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342703-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	08-Apr-2009	--	WAES0902USA00462	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who was vaccinated with three dose of GARDASIL. Subsequently the patient "contracted HPV" after getting all three dose of GARDASIL. The patient underwent a Pap test. The patient's contracted HPV" persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 342704-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	16-Jan-2009	16-Jan-2009	0	16-Mar-2009	08-Apr-2009	TX	WAES0902USA00461	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia

Symptom Text: Information has been received from a physician concerning a 20 year old female patient with no drug reaction/allergies history who on 16-JAN-2009 was vaccinated with her first dose of GARDASIL (lot # 661046/0546X) IM. Concomitant medication included oral contraceptive. The patient had an abnormal pap result from a specimen taken on 16-JAN-2009. The PAP result was low Grade Squamous Intraepithelial Lesion with both high risk and low risk HPV. The patient had visited office for medical attention. The outcome of the patient's adverse effect was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: serum prostatic acid - abnormal PAP-low grade Squamous Intraepitheliel Lesion

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342705-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	16-Mar-2009	16-Mar-2009	0	26-Mar-2009	27-Mar-2009	FR	WAES0903USA03704	17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chest discomfort, Dyspnoea, Fatigue, Intensive care, Vertigo

Symptom Text: Information has been received from a physician concerning a 25 year old female with a history of drug hypersensitivity (chest tightness and dyspnea) of unknown drug name who on 16-MAR-2009 at 10:00 was vaccinated IM with the first 0.5 mL dose of GARDASIL. On 16-MAR-2009 at 14:00, the patient experienced dyspnea and chest tightness and was hospitalized. She felt mild dyspnea and chest tightness. At 17:00, she felt severe dyspnea, chest tightness and vertigo. Therefore she came to the ICU of the general hospital and was treated with DEMEROL and DEPO MEDROL and oxygen until 21:00. The patient was completely conscious when she came to the ICU. After that, the patient's condition was better and the hospital let her come home, but she still felt tired and asked to stay in the hospital, so she stayed in the ICU. The patient was then transferred to an internal department for follow up. The patient was discharged recovered at 02:00 17-MAR-2009. The physician reported that it was unknown if the patient's dyspnea and chest tightness were related to therapy. The reporting physician considered dyspnea and chest tightness were other important medical events. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Drug Hypersensitivity

Prex Illness:

Prex Vax Illns:

Vaers Id: **342706-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Feb-2009	09-Feb-2009	0	26-Mar-2009	27-Mar-2009	FR	WAES0903USA03779	16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1883U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Paraesthesia, Pharyngeal oedema, Pruritus, Vomiting

Symptom Text: Information has been received from a Health Care Professional on 17-MAR-2009 concerning a 16 year old woman who was vaccinated with a first dose of GARDASIL (lot # 1883U, batch # NH50860) on 09-FEB-2009. The same evening the patient felt nauseous and vomited. The nausea and vomiting continued for 1 week with 2-3 vomits per day. On 12-FEB-2009 the patient developed pruritus on the body. The symptoms worsened gradually and on 15-FEB-2009 there was also prickling sensations and symptoms in the throat and she visited an emergency unit. At the hospital she felt throat swelling and was treated with BETAPRED, (12 single doses) and EPINEPHRINE (IM, injection). On advice from the physician on the hospital she stopped taking oral contraceptives YASMIN which she stated taking on 06-FEB-2009. After this treatment she got better but pruritus was continuing and on 18-FEB-2009 the patient got prescription on ATARAX and BETAPRED. On 05-MAR-2009 the patient was fully recovered. The physician considered YASMIN as suspected cause of at least some of the adverse events but cannot rule out GARDASIL as causative agent. The adverse experiences were considered to be other important medical events. Other business partner numbers included: E2009-02340. No further information is available. Case is closed.

Other Meds: YASMIN

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342707-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Dec-2008	25-Dec-2008	2	26-Mar-2009	27-Mar-2009	FR	WAES0903USA03828	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	
	TD	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Urticaria, Viral infection

Symptom Text: Information has been received from a health authority (reference number ES-AGEMED-818649244) regarding a 14 year old female with no medical records related with epilepsy or convulsive episodes who on 23-DEC-2008 was vaccinated with a dose of GARDASIL (batch# not reported). On the same date the patient received a dose of DITANRIX (route and site of administration not reported). 3 or 4 days after vaccination the patient presented urticaria that had been ongoing. On FEB-2009, exact date not reported, the patient visited the doctor due to a clinical picture compatible with viriasis. The patient was prescribed with Rino-Ebastel, also a special diet was advised and cotton clothing was recommended. The cutaneous clinical picture was not related to the vaccine. On the 25-FEB-2009 while the patient was attending a class she presented a convulsion, she was taken to hospital where she remained under observation for 24 hours. She did not present another convulsive episode, epileptogenic focus was found and a treatment was prescribed (treatment information not reported). No further problems were reported. According to reporter, events were not considered to be related with treatment. It was reported to the HA by a vaccination center. Case reported as serious by the HA with other medically important condition as criteria. Other business partner number included E2009-02352. The case was closed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342708-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	07-Jan-2009	09-Jan-2009	2	26-Mar-2009	27-Mar-2009	FR	WAES0903USA03830	17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a health authority (reference number ES-AGEMED-018669344) regarding a 14 year old female who on 7-JAN-2009 was vaccinated with a dose of GARDASIL (batch# not reported) by intramuscular route (site of administration not reported). It was reported that 48 hours after vaccine administration, the patient presented a convulsion. The patient had a previous pneumologic pathology with hydrocephaly and an isolated epileptic crisis with no current treatment. The patient recovered, date not reported. Case reported as serious by the HA with other medically important condition as criteria. Other business partner numbers included E2009-02367. The case was closed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Hydrocephalus; Epileptic seizure

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342709-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	30-Jun-2008	05-Oct-2008	97	26-Mar-2009	27-Mar-2009	NJ	WAES0903USA04267	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for the pregnancy registry for GARDASIL, concerning a 25 year old female patient with no known drug allergies, who on 26-APR-2008 was vaccinated with her first dose of GARDASIL (lot# 654272/0073X), on 30-JUN-2008 with the second dose of GARDASIL (lot# 0250X) and on 30-OCT-2008 with the third dose of GARDASIL (lot# 660620/0571X). There was no concomitant medication. On 05-OCT-2008, the patient had her LMP and had an elective termination of pregnancy in December 2008. At the time of reporting the outcome of the patient was unknown. The patient experienced an elective termination in May 2008 after the first vaccination with GARDASIL (MSD, WAES: 0903USA03061). Upon internal review elective termination was considered as an Other Important Medical Event. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Termination of pregnancy - elective

Prex Illness:

Prex Vax Illns:

Vaers Id: **342718-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jul-2008	01-Jul-2008	0	26-Mar-2009	27-Mar-2009	FR	WAES0903USA03820	17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Convulsion, Fatigue, Loss of consciousness, Malaise, Musculoskeletal stiffness, Urinary incontinence

Symptom Text: Information has been received from a general practitioner on 11-MAR-2009, concerning an adolescent female (15 or 16 years old) who was vaccinated with the first dose of GARDASIL (batch number not reported) via intramuscular route in her deltoid in July 2008. 2 to 3 minutes later the patient felt unwell and experienced loss of consciousness with urine incontinence and convulsive seizure. The patient presented with stiffness, arms curled up and stiff jaw. She had recovered in 5 minutes after being lied down with legs up. She experienced fatigue and had no memory of the adverse event. To be noted that the patient was sitting while vaccination. The reporter mentioned that it was not a lipothymic malaise. The case is closed. Upon internal review, the convulsive seizure was considered as other medically important condition. No further information is available. Other business partner numbers include E2009-02167.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342719-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	26-Dec-2008	Unknown		16-Mar-2009	08-Apr-2009	--	WAES0902USA00455	04-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Menstruation irregular

Symptom Text: Information has been received from a nurse concerning a female with no medical history or allergy who on 26-DEC-2008 was vaccinated with the first dose of GARDASIL IM, 0.5 ml (lot# 660616/0570X). There was no concomitant medication. Subsequently the patient experienced an irregular menstrual cycle. The patient's irregular menstrual cycle persisted. The patient was seen at the practice. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342720-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	01-Aug-2007	Unknown		16-Mar-2009	08-Apr-2009	NJ	WAES0902USA00450	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a 22 year old female who was vaccinated with three dose of GARDASIL between February 2007 and August 2007 (lot number not provided, 1st dose 0.5ml). In 2009 the patient had PAP test on unspecified sate and results came in as HPV positive. The patient sought unspecified medical attention and did not recover at time of reporting. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, ?/?/09, HPV positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342721-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	Unknown	Unknown		16-Mar-2009	08-Apr-2009	--	WAES0902USA00427	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Headache, Migraine

Symptom Text: Information has been received from a consumer concerning herself (a 24 year old female) with migraine who received the first two doses of GARDASIL already and noticed increased incidents of headaches and migraines after getting the first dose. She was diagnosed with migraines before starting the GARDASIL, however she experienced more often since starting the therapy. At the time of reporting the patient was not recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Migraine

Prex Vax Illns:

Vaers Id: **342722-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	15-Jan-2009	15-Jan-2009	0	16-Mar-2009	08-Apr-2009	NJ	WAES0902USA00426	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a 21 year old female with no pertinent medical history or drug allergy who on 20-NOV-2008 was vaccinated with a first dose of GARDASIL. On 15-JAN-2008 was vaccinated with a second dose of GARDASIL. Concomitant therapy included vitamins (unspecified) and birth control pills. On 15-JAN-2009 the patient was performed a papanicolaou (PAP) smear which came back positive. At the time of reporting, the patient's PAP smear positive persisted. Additional information has been requested.

Other Meds: Hormonal contraceptives; Vitamins (unspecified)

Lab Data: Cervical smear, 01/15/09, positive

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **342723-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	08-Apr-2009	--	WAES0902USA00425	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Smear cervix abnormal

Symptom Text: Information has been received from a nurse practitioner concerning a female who was vaccinated with 3 doses of GARDASIL on unspecified dates. Subsequently she had an abnormal pap. The patient did not have an abnormal PAP prior to receiving GARDASIL. The outcome was unknown at time of reporting. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342724-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	08-Apr-2009	--	WAES0902USA00287	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a registered nurse concerning her daughter who on an unknown date was vaccinated with a dose of GARDASIL. The patient was experiencing severe headaches. No further information is available.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342725-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		16-Mar-2009	08-Apr-2009	--	WAES0902USA00281	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a registered nurse reporting that she received an e-mail from a woman who stated that she received the complete GARDASIL series and has now tested positive for HPV. It was reported that the woman is not the nurse's patient. Attempts are being made to verify the existence of an identifiable patient and reporter. Follow-up information was received from the RN, who is a senior member of an HPV Health Board, and stated that she receives and responds to many anonymous emails. She indicated that on the patient's email, the woman mentioned that she was diagnosed with HPV but could not confirm the strain. The nurse stated that she is waiting for the woman to provide this information and will call back when/if she receives it. The nurse stated that there was no way for her to determine the name of the patient since the emails are anonymous. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342726-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	11-Jun-2008	11-Jun-2008	0	16-Mar-2009	08-Apr-2009	CA	WAES0902USA00256	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0525U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Nausea, Syncope

Symptom Text: Information has been received from a medical assistant concerning an 18 year old female with asthma, bipolar disorder, LEXAPRO and PAXIL allergy and a history of obesity, varicella and bulimia who on 14-MAR-2008 was vaccinated IM with the first 0.5 ml dose of GARDASIL (lot # : 659655/1486U) and on 11-JUN-2008 was vaccinated IM with the second 0.5 ml dose of GARDASIL (lot # : 658100/0525U). Concomitant therapy included PROZAC, LAMICTAL, LITHIUM, TOPAMAX, ADDERALL, SEROQUEL and RESTORIL. On 11-JUN-2008, after administration of her second dose of GARDASIL, the patient experienced nausea and syncope. Subsequently, the patient recovered from nausea and syncope. The patient sought medical attention by office visit. Additional information has been requested.

Other Meds: ADDERALL tablets; PROZAC; LAMICTAL; LITHIUM; SEROQUEL; RESTORIL; TOPAMAX

Lab Data: Unknown

History: Obesity; Varicella; Bulimia

Prex Illness: Asthma; Bipolar disorder; Sulfonamide allergy; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **342727-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	29-Jan-2009	Unknown		16-Mar-2009	08-Apr-2009	NY	WAES0902USA00221	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysuria, Pollakiuria, Pyrexia, Urinary tract infection

Symptom Text: Information has been received from a Registered Nurse concerning a 22 year old female with psychiatric disorders and a history of pyelonephritis who was vaccinated intramuscularly with her second 0.5 ml dose of GARDASIL (lot#660616/0570X) on 29-JAN-2009. There was no concomitant medication. Subsequently, the patient developed urinary tract infection. After receiving the dose, she complained of high fever of 102 degrees F along with burning sensations when she urinates. She also had increased frequency of urination. Urine analysis showed presence of leukocyte, protein, but no blood. The patient was treated with CIPRO for 1 week. Urine culture was negative. At the time of reporting the patient was recovered. The patient had received her first dose of GARDASIL on 16-OCT-2008. The patient sought medical attention and was seen by the nurse. Additional information has been requested.

Other Meds: None

Lab Data: urinalysis, presence of leukocyte, protein, but no blood; urine culture, negative

History: Pyelonephritis

Prex Illness: Psychiatric disorder NOS

Prex Vax Illns:

Vaers Id: **342728-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	08-Jan-2009	08-Jan-2009	0	16-Mar-2009	08-Apr-2009	PA	WAES0902USA00215	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy, Loss of consciousness

Symptom Text: Information has been received from a certified medical assistant (C.M.A) concerning a 19 year old female with no medical history and no known allergies who on 08-Jan-2009 was vaccinated with the first dose of GARDASIL (lot#0947X) and as the patient was about to pay at the front desk her eyes rolled back and the person at the front desk went around and caught the patient before she hit the ground. It was reported that when the patient was caught she started to come to and eat in the office for about 19 minutes and then was fine to leave the office. The patient was recovered on 08-Jan-2009. Follow up information was received from a certified medical assistant concerning the 19 year old female patient with no pre-existing allergies, birth defects, or medical conditions who on 08-Jan-2009 was vaccinated intramuscularly in the right arm with the first dose of GARDASIL (lot# 0947X). There was no illness at the time of vaccination. On 08-Jan-2009 at 12:00 pm the patient passed out in office approximately 10 minutes after being vaccinated with the vaccine. The patient was recovered on 08-Jan-2009. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data:

History: Private Funds

Prex Illness: Private Doctor / Hospital

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342729-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Jan-2009	Unknown		16-Mar-2009	08-Apr-2009	--	WAES0902USA00185	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal distension, Drug exposure during pregnancy, Weight increased

Symptom Text: Information has been received from a consumer, for GARDASIL, a Pregnancy Registry product, concerning her daughter an 18 year old female with an unspecified sexually transmitted disease who received unspecified pills for the infection who on 22-JAN-2009 (2 weeks ago on a Thursday) was vaccinated with the first dose of GARDASIL. The physician said the patient was not pregnant, but the mother believed she was, because "her stomach is really swollen and she used to be thin". At the time of the report the outcome of the patient was unknown. The patient was seen by the physician in office. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 12/2/2008); Sexually transmitted disease; Infection

Prex Vax Illns:

Vaers Id: **342730-1 (S)** **Related reports:** 342730-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Mar-2009	19-Mar-2009	1	26-Mar-2009	27-Mar-2009	NY		28-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B028AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1312X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Headache, Intensive care, Intraventricular haemorrhage, Nausea, Vomiting

Symptom Text: Headache, vomiting approximately 36 hrs after vaccine administration. Admitted to SICU on 3/21/09 for observation and close monitoring for Intraventricular hemorrhage. 4/8/09-records received-DC DX Left ventricular hemorrhage. Presented on 3/21/09 with C/O severe headache since Thursday with vomiting and nausea occasional.

Other Meds: None

Lab Data: MRI; MRA; CT 4/8/09-records received-WBC increased 11.4, hemoglobin decreased 11.1 and hematocrit decreased 33.7. BUN low 3.0 and Creat low 0.6. CT head demonstrated left periatrial/periventricular hemorrhage with intraventricular hemorrha

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **342730-2 (S)** **Related reports:** 342730-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Mar-2009	19-Mar-2009	1	01-May-2009	04-May-2009	--	WAES0904USA01476	04-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1312X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Headache, Intensive care, Intraventricular haemorrhage, Vomiting

Symptom Text: This report was identified from a line listing obtained on request by the company from the FDA under the Freedom of Information Act. An 18 year old female with no pertinent medical history who on 18-MAR-2009 was vaccinated with a second dose of GARDASIL (Lot # 661846/1312X) intramuscularly into the left arm. Concomitant therapy included TDAP. On 19-MAR-2009 approximately 36 hours after vaccination she experienced headache and vomiting. On 21-MAR-2009 she was admitted to surgical intensive care unit for observation and close monitoring for intraventricular hemorrhage. Magnetic resonance imaging, magnetic resonance angiography of brain, computed axial tomography were performed. Headache, intensive care, intraventricular haemorrhage and vomiting were considered to be immediately life-threatening. No further information is available. A standard lot check investigation was performed. All in-process quality checks for the lot # 661846/1312X in question were satisfactory. In addition, an expanded lot check investigation was performed. The testing performed on the batch prior to release met all release specifications. The lot met the requirements of the Center and was released. This was originally reported by a consumer. The VAERS # ID is 342730.

Other Meds:

Lab Data: magnetic resonance; magnetic resonance; computed axial

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 342754-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Dec-2007	20-Mar-2008	106	16-Mar-2009	07-Apr-2009	MD	WAES0805USA03343	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a registered nurse, for the Pregnancy Registry for GARDASIL, concerning a 17 year old female with no previous medical history and no known allergies who on 05-DEC-2007 was vaccinated with her first dose of GARDASIL (Lot# not reported). On 14-MAY-2008, the patient was vaccinated with her second dose of GARDASIL (Lot# not reported) and tested as pregnant with an office pregnancy test. The patient stated that her LMP was last week (estimated LMP = 07-May-2008). LMP or gestation was uncertain. There was no concomitant medication. There were no problems reported. Unknown medical attention was sought in the office. The patient's outcome is unknown. Follow up information was received from registered nurse and phone call. It was reported the patient's last menstrual period (LMP) was 20-MAR-2008 (previously reported as "estimated LMP = 07-May-2008") and estimated delivery date (EDD) was 02-JAN-2009. On 20-AUG-2008 the patient had serum alpha-fetoprotein test (MSAFP) done and the result was negative. The mother declined amnio testing. On 20-AUG-2008 (at 14 weeks gestation) ultrasound did show sonographic markers for trisomy however the repeat ultrasound in 18-DEC-2008 was normal. On 24-DEC-2008 the patient delivered a 7 pounds 7 ounces male baby without complication during pregnancy or labor/delivery and without infection or illnesses during pregnancy. It had been a vaginal delivery and there were no congenital anomalies. The baby had spent one week in the hospital with fever of unknown origin and received unspecified antibiotics but was otherwise healthy and normal. The patient had returned for postpartum visit since. Her baby was "fine". No further information was available.

Other Meds: None

Lab Data: ultrasound, 08/20/2008, sonographic markers for trisomy; ultrasound, 12/18/08, normal; beta-human chorionic, 05/14/2008, pregnant; serum alpha-fetoprotein, 08/20/2008, negative

History:

Prex Illness: Pregnancy NOS (LMP = 3/20/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342755-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	17-Dec-2007	17-Dec-2007	0	16-Mar-2009	07-Apr-2009	MO	WAES0712USA08122	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Gestational diabetes

Symptom Text: Information has been received from the Merck Pregnancy Registry from a 22 year old female with no pertinent medical history who on 17-DEC-2007 was vaccinated IM with a first dose of GARDASIL vaccine (lot #659437/1266U). Concomitant therapy included ZOLOFT. It was reported that the patient was vaccinated while she was pregnant. Last menstrual period was 19-NOV-2007 and estimated date of delivery was 25-AUG-2008. It was reported that there was no adverse event involved. There were no laboratory or diagnostic tests performed. Follow-up information received from the patient who reported that she had developed gestational diabetes during the pregnancy. She delivered the baby at term. The baby was healthy and normal "and has had a few colds".

Other Meds: ZOLOFT

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 11/19/2007)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342756-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	09-Jan-2008	09-Jan-2008	0	16-Mar-2009	08-Apr-2009	--	WAES0804USA01176	04-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Oligohydramnios

Symptom Text: Information has been received from a certified nurse midwife concerning a 23 year old pregnant female who is bipolar and has a history of depression, anxiety, abnormal pap test and had a loop electrosurgical excision procedure. On 02-NOV-2007 the patient was vaccinated IM with the first dose of GARDASIL vaccine (lot # 658563/1063U). On 09-JAN-2008 the patient was vaccinated IM with the second dose of GARDASIL vaccine (lot #659437/1266U). The last menstrual period was reported to be on 10-JAN-2008. An urine pregnancy test was performed with positive results. On 12-JAN-2008 a maternal serum alpha-fetoprotein test was performed within normal results. On 05-MAR-2008 an ultrasound was performed (NP). It was also reported that this is the patient's first pregnancy. The estimated delivery date is 16-OCT-2008. The certified nurse midwife reported she wishes to register the patient on the pregnancy registry. Follow-up information has been received from certified nurse midwife concerning the patient, who was also reported to be a smoker with no history of previous pregnancies. On 01-MAY-2008, MSAFP screening test as performed and results were within normal limits. It was reported he mother developed oligohydramnios during the pregnancy. On 21-OCT-2008, 41.1 weeks from the last menstrual period, the patient delivered a normal male baby who weighted 7 pounds and 13.8 ounces. His length was 19 feet. His Apgar score was assessed to be 8/9. No complications occurred during the labor. No further information is available.

Other Meds: Unknown

Lab Data: ultrasound, 03/05/08 - INP; urine beta-human - positive; serum alpha-fetoprotein, 05/01/08 - within normal limits

History: Depression; Anxiety; Papanicolaou smear abnormal; Loop electrosurgical excision procedure

Prex Illness: Pregnancy NOS (LMP = 1/10/2008) Bipolar disorder; Smoker

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342757-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	11-Apr-2008	01-Mar-2008	-41	26-Mar-2009	27-Mar-2009	GA	WAES0804USA02884	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour

Symptom Text: Information has been received from a 22 year old white female consumer (medical assistant), for the pregnancy registry for GARDASIL, who on 11-APR-2008 was vaccinated IM with the second 0.5 ml dose of GARDASIL. On the same day she received her second dose she found out she was pregnant. It was unknown whether medical attention was sought. Patient outcome was unknown. No product quality complaint was involved. Follow-up information was received which reported that on 28-JUL-2008, an ultrasound was performed (second trimester) and the results were normal. It was reported that there were no previous pregnancies, full term deliveries, pre-term deliveries, spontaneous abortions (miscarriages), elective terminations or fetal deaths (stillbirths). Follow up information has been received from the consumer with no concurrent medical conditions, who reported that on 23-NOV-2008 she delivered a normal and healthy female baby weighing 6 lb and 7 oz and length 19 in. There was complications or abnormalities, she reported an erratic heart rate and breathing difficulties of the baby who born at 36 weeks. No complications during the pregnancy and labor/delivery, no congenital anomalies and no diagnostic test during the pregnancy was performed. The patient had group B strep during her pregnancy. Additional information is not available.

Other Meds: Unknown

Lab Data: ultrasound 7/28/08 - normal, second trimester

History:

Prex Illness: Pregnancy NOS (LMP - 3/11/2008)

Prex Vax Illns:

Vaers Id: **342758-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	21-Apr-2008	21-Apr-2008	0	26-Mar-2009	30-Mar-2009	MN	WAES0805USA01280	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood calcium decreased, Drug exposure during pregnancy, Gonorrhoea, Nausea, Staphylococcal infection

Symptom Text: Information has been received through the Merck Pregnancy Registry via a physician concerning a 19 year old female with a history of tobacco abuse and cannabis abuse who on 20-Feb-2008 was vaccinated with the first dose of GARDASIL 0.5ml, IM, (lot #, not reported). Concomitant therapy included prenatal vitamins (manufacturer unknown). On 21-Apr-2008 the patient was given the second dose of GARDASIL 0.5ml, IM to the left deltoid, (lot # 659655/14860). After the patient received her second dose, she later reported her pregnancy. Unspecified medical attention was sought and routine prenatal tests (data and names unspecified) were performed with results not reported. Therapy has been discontinued as of 07-May-2008. Patients last menstrual cycle was reported on 20-Feb-2008, her due date was calculated to be 26-Nov-2008. No adverse events were reported. No product quality complaint was involved. Follow-up information has been received from a physician concerning a female patient with nicotine dependence, THC use during pregnancy and a history of abnormal Papanicolaou smear and no previous pregnancies. It was reported that on 4-Apr-2008, on 22-Jul-2008 and on 10-Sep-2008 routine screening test were performed, all of them within normal results. On 26-Nov-2008, 39+ 0 weeks from the last menstrual period, the patient delivered a normal healthy female baby weighing 5 pounds 5 ounces. The baby's length was 19 inches, her APGAR score 9/9 and her head circumference was 11 1/2 inches. It was reported that during the pregnancy the patient developed a meticillin resistant staphylococcus aureus (MRSA) abscess which was treated with Clindamycin (Unspecified) 150mg, QID during 7 days. Also the patient was taking calcium + vitamin D (unspecified) , 500/200 mg, BID for the treatment of poor calcium mass, fish oil (unspecified) , 500 mg daily for nutrition and metoclopramide (unspecified), 5mg, QID/ PRN for the treatment of nausea. It was also reported that on an unspecified date the patient had gonorrhea infection.

Other Meds: Vitamins

Lab Data: Diagnostic Laboratory 04/04/08 - routine prenatal tests WNL; Diagnostic Laboratory 07/22/2008 - routine prenatal tests WNL; Diagnostic Laboratory 09/10/2008 - routine prenatal tests WNL

History: Cannabis abuse; Papanicolaou smear abnormal

Prex Illness: Pregnancy NOS (LMP = 2/20/2008); Tobacco abuse; Nicotine dependence

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342759-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Sep-2007	07-Sep-2007	0	26-Mar-2009	30-Mar-2009	--	WAES0805USA02022	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0868F	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Dyspepsia, Nausea, Urinary tract infection, Vaginitis bacterial

Symptom Text: Information has been received from through the Merck Pregnancy Registry via a nurse, concerning a 19 year old female with a history of asthma, and no reported concomitant medications or allergies, who on 07-SEP-2007 was vaccinated with the first dose of GARDASIL 0.5ml, IM (Lot # 653736/0868F). The second dose of GARDASIL (Lot # 658563/1063U) was administered on 09-JAN-2008. It was reported that the patient was eight months pregnant and had sought medical attention on an unspecified date. Unspecified pregnancy lab work has been completed through the obstetrician. The expected date of delivery was calculated to be 12-JUN-2008. No outcome information has been provided. No product quality complaint was involved. Follow-up information has been received from the nurse practitioner concerning the patient. She stated that the patient has not been seen in the office since June 2008. Follow-up information has been received from a nurse practitioner concerning the patient. It was reported that she had a normal, vaginal delivery at 39 +3/7 weeks on 21-JUN-2008. The baby who's gender was not specified, weighted 6 lb and 1 oz, and had APGAR scores of 9 and 9. The baby appeared normal on exam and on her postpartum exam the patient stated that everything was fine for her and her baby. However, the patient is not bringing her baby to the pediatric clinic that she went to, so there is no newborn exam notes on the baby. The nurse also reported prenatal information. The patient's LMP was 15-SEP-2007 and her estimated delivery date was 25-JUN-2008. On 17-Oct-2007, early in the first trimester, the patient was treated with BACTRIM for a urinary tract infection. She had routine prenatal screening test, a QUAD screen and MID-trimester anatomy survey ultrasound, which were both within limits. She was prescribed several other medications for use during her pregnancy. On 07-NOV-2007 she was orally treated with PHENERGAN, 25 mg, as needed every 6 hours for the treatment of nausea until DECEMBER 2007. From 04-JAN-2008 to

Other Meds:

Lab Data: diagnostic laboratory - prenatal screening test: WNL; diagnostic laboratory - QUAD screen test: WNL; ultrasound - within normal limits

History: Asthma

Prex Illness:

Prex Vax Illns:

Vaers Id: 342760-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	04-Dec-2007	15-Feb-2008	73	16-Mar-2009	08-Apr-2009	--	WAES0805USA02898	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1266U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Premature labour, Urinary tract infection

Symptom Text: Initial and follow up information has been received from a certified nurse midwife for the Pregnancy Registry for GARDASIL, concerning a 22 year old white female with bipolar disorder and allergic reaction to KEFLEX and no previous pregnancies who on 03-OCT-2007 was vaccinated with a first dose of GARDASIL (lot # 658558/1061U). On 04-DEC-2007 the patient was vaccinated with a second dose of GARDASIL vaccine (lot # 659437/1266U). Concomitant therapy included SEROQUEL (lot # not reported) and ABILIFY for the treatment of bipolar disorder. The patient's LMP was reported as 15-FEB-2008. The patient's pregnancy was verified with an office pregnancy test during an office visit on 24-MAR-2008. An ultrasound performed on 01-APR-2008 revealed a 6.4 week intrauterine pregnancy. On an unspecified date in April 2008, therapy with quetiapine fumarate and aripiprazole was discontinued. The patient sought unspecified medical attention. No problems were reported. Follow up information has been received from a certified nurse midwife concerning a female patient concerning a female patient (Rh negative) who was vaccinated with a first and the second dose of GARDASIL on 03-OCT-2007 and 04-DEC-2007. Concomitant therapy included WELLBUTRIN SR, SEROQUEL (reported) and ABILIFY. The patient was treated for pre-term labor (2008) with TERBURALINE and was also treated for an urinary tract infection (2008) with MACROBID and AMOXICILLIN. On 27-OCT-2008 (36 weeks from LMP) delivered a healthy female baby (7 lb 8 oz, 20 in length, head circumference 13.75 cm and APGAR score 8 at 1 minute/ 9 at 5 minutes). The patient had not had a Group B strep test done so she was treated with AMPICILLIN 2 grams IV one time dose . She also received a dose of RHOGAM. Additional information is not expected. (Rh negative)

Other Meds: ABILIFY; WELLBUTRIN SR; SEROQUEL

Lab Data: Ultrasound, 04/02/2008, 6.4 weeks IUP; Beta-human chorionic, 03/24/2008, positive

History:

Prex Illness: Pregnancy NOS (LMP = 2/15/2008) Bipolar disorder; Allergic reaction to antibiotics; Rhesus antibodies negative

Prex Vax Illns:

Vaers Id: **342761-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	21-May-2008	Unknown		16-Mar-2009	08-Apr-2009	DE	WAES0805USA05753	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anaemia, Dehydration, Drug exposure during pregnancy, Platelet count decreased, Premature labour, Vomiting

Symptom Text: Initial information and follow up has been received from a physician for the pregnancy registry for GARDASIL concerning a 24 year old female who on 21-May-2008, was vaccinated with her second dose of GARDASIL (lot# 659655/1486U) and found out on 27-May-2008 that she was pregnant. The patient's estimated LMP was 28-Apr-2008. Follow up information was received which reported that patient's concurrent medical condition included hypertension, and the patient smoked half a pack of cigarettes per day during pregnancy. Concomitant therapy included Tylenol and vitamins (unspecified). The patient had ultrasounds (no results reported) and blood test positive for down's syndrome (however the baby was normal). During pregnancy she developed anemia, platelets decreased, vomiting and dehydration. On 27-Dec-2008, 35 weeks gestation, the patient gave birth to a female infant weighing 5 pounds and 5 ounces. The length was 19 inches. The infant was normal. There was no congenital anomaly. There were n complications during delivery. No further is available

Other Meds: Tylenol, Multivit

Lab Data: Chromosomal analysis ?/?/08 posit - Down's syndrome; Platelet count ?/?/08 - Decreased

History:

Prex Illness: Pregnancy NOS (LMP = 4/28/2008) Hypertension; Smoker

Prex Vax Illns:

Vaers Id: **342762-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	29-Apr-2008	29-Apr-2008	0	16-Mar-2009	03-Apr-2009	MA	WAES0805USA05935	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Beta haemolytic streptococcal infection, Drug exposure during pregnancy

Symptom Text: Information has been received from a consumer and a nurse practitioner for the Pregnancy Registry for GARDASIL concerning herself, a 26 year old female with no medical history, and no drug reactions/allergies, who on 29-APR-2008 was vaccinated with her first dose of GARDASIL (lot # unspecified). On 02-May-2008 (three days later), the patient became pregnant (LMP estimated as 15-Apr-2008). Concomitant therapy included azithromycin (ZITHROMAX). The patient sought unspecified medical attention. At the time of this report the outcome was unknown. No further information available. Follow-up information received on 17-FEB-2009 from a nurse practitioner who reported the patient is Hispanic and has a history of smoking 2-5 cigarettes a day which she stopped with pregnancy, and an abnormal PAP s/p LEEP. Patient has had a previous pregnancy, no previous full term deliveries and a miscarriage. On 15-Jul-2008 patient had an ultrasound, which showed 12 weeks and 4 days pregnant ERA normal. On 13-AUG-2008 patient had a MSAFP testing with normal results. The lot # of the first dosage of GARDASIL received is 659180/1758U. Concomitant medications during pregnancy included prenatal vitamins (unspecified) which patient started taking on 18-JUN-08 (27 mg of Iron and folate 1mg daily) and on 08-JAN-2009 penicillin (unspecified) 3000000 international units every 4 hours for the treatment of bacterial infection due to streptococcus, group B. Date of last menstrual period on 18-APR-2008 (previously reported as 15-APR-2008) and estimated delivery date on 23-JAN-2009. Patient had a normal baby on 09-JAN-2009, male, who weighed 2975 grams, length 49 cm, Apgar score 9/9, head circumference 33.5 cm. No congenital anomalies or other complications or abnormalities. No complications during pregnancy, or during labor and/or delivery. No further information is available.

Other Meds: ZITHROMAX, vitamins (unspecified)

Lab Data: ultrasound, 7/15/08, 12W 4D; serum alpha-fetoprotein, 08/13/08, negative;

History: Papanicolacu smear abnormal; Smoker

Prex Illness:

Prex Vax Illns:

Vaers Id: **342763-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	29-May-2008	29-May-2008	0	16-Mar-2009	08-Apr-2009	MN	WAES0806USA03410	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Inappropriate schedule of drug administration

Symptom Text: Information has been received through the pregnancy Registry for GARDASIL from a nurse concerning a 20 year old female with no pertinent medical history and no history of drug reactions or allergies who on 04-Feb-2008 was vaccinated intramuscularly with the first 0.5ml dose of GARDASIL. On 07-May-2008 the patient had her last menstrual period. On 29-May-2008 the patient was vaccinated intramuscularly with the second 0.5ml dose of GARDASIL (lot# 659964/1978U). Concomitant medication included doxycycline for the treatment of a chlamdia infection. On an unspecified date, a pregnancy test revealed the patient was pregnant. The patient had not experienced any known symptoms. On 07-Jul-2008, an ultrasound was performed, the results were within normal limits. The patient sought medical attention with a physician office visit. The patient was pregnant once previously, and it was a pre-term delivery. Follow up information has been received from a physician on 16-Feb-2009. It was reported that the 20 year old female patient was vaccinated on 14-Feb-2008 with the first dose of GARDASIL. The patient delivered a healthy baby on 06-Feb-2009. The pregnancy was normal except for induction for advance cervical dilation. On 16-Feb-2009, the patient was vaccinated with the third dose of GARDASIL. Additional information has been requested.

Other Meds: doxycycline 100 mg

Lab Data: Ultrasound 07/07/08 - Within normal limits; Beta-human chorionic - positive

History: Early onset of delivery

Prex Illness: Pregnancy NOS (LMP=5/7/2008) Chlamydial infection

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342764-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Nov-2007	29-May-2008	210	16-Mar-2009	08-Apr-2009	TX	WAES0807USA01851	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anaemia, Drug exposure during pregnancy, Inappropriate schedule of drug administration, Infection, Premature labour

Symptom Text: Initial information has been received from an 18 year old female with no pertinent medical history or drug reactions or allergies, for the Pregnancy Registry for GARDASIL. In November 2007, the patient was vaccinated with the first dose of GARDASIL. In June 2008, the patient received "her second dose of GARDASIL while pregnant". There was no concomitant medication. The patient did not know she was pregnant at the time of vaccination. As of 10-JUL-2008, the patient was one and a half months pregnant. The patient did not seek medical attention. Follow-up information was received from the physician which reported that the vaccine was not administered in her office. The patient had no previous pregnancy and a history of papanicolaou smear abnormal. The LMP of the patient was 23-MAY-2008. The estimate delivery date was 27-FEB-2009. ON 25-AUG-2008, ultrasound was performed for twin pregnancy and the results revealed normal twins. ON 15-SEP-2008, maternal serum alpha-fetoprotein screening was performed and the results were normal. Follow-up information has been received from a completed pregnancy questionnaire. On approximately 03-SEP-2008, the patient developed infection. On 03-SEP-2008, the patient was prescribed ROCEPHIN, 250 mg once and AZITHROMYCIN, 1 gram once for the treatment of infection. The outcome of infection was not specified. On approximately 01-DEC-2008, the patient developed anemia. On 01-DEC-2008, the patient was prescribed REPLIVA, daily for the treatment of anemia. The outcome of anemia was not specified. On 22-JAN-2009, the patient delivered normal twins baby girls with no congenital anomalies at the 33.3 weeks gestation. It was considered prematurity. One of the baby weighed 3 pounds 14 ounces and another weighed 3 pounds 10 ounces. The Apgar scores of both babies were 8/9. It was reported that there was no complication during pregnancy and delivery. Additional information is not expected.

Other Meds: None

Lab Data: Ultrasound, 08/25/08, normal twins; serum alpha-fetoprotein 09/15/08, normal.

History: Papanicolaou smear abnormal

Prex Illness:

Prex Vax Illns:

Vaers Id: **342765-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	19-May-2008	19-May-2008	0	16-Mar-2009	08-Apr-2009	MN	WAES0807USA03262	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1757U	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Beta haemolytic streptococcal infection, Chlamydial infection, Drug exposure during pregnancy, Vaginitis bacterial

Symptom Text: Initial and follow-up information has been received from a nurse, for the Pregnancy Registry for GARDASIL, concerning a 23 year old female smoker with a history of one pregnancy which the infant had gastroschisis and was pre-term premature rupture of fetal membranes at 32 weeks and pre-term delivery. On 19-MAY-2008 the patient was vaccinated intramuscularly with the first 0.5 ml dose of GARDASIL (lot no. 659182/1757U) into the right deltoid. There was no concomitant medication. The patient is now pregnant. On 18-JUN-2008 the patient had ultrasound done for dating and the result was normal embryo. On an unspecified date the patient had routine blood and laboratory tests done and no results reported. No problems reported. The patient sought unspecified medical attention. Follow-up information has been received from a complete pregnancy questionnaire. The patient was taking prenatal vitamin, 1 tablet daily in the entire pregnancy. On approximately 15-SEP-2008 the patient developed bacterial vaginosis. On 15-SEP-2008, the patient was prescribed metronidazole, 500 mg, twice a day for 7 days for the treatment of bacterial vaginosis on 15-SEP-2008, the patient developed chlamydia. On 16-SEP-2008, the patient was prescribed ZITHROMAX, 1 gram once for the treatment of chlamydia. On an unspecified date, the patient developed Group B streptococcal infection. The outcome of the events was unknown. On 07-FEB-2009, the patient delivered a normal baby girl with no congenital anomalies for complications at the 40 weeks gestation. The baby weighted 7 pounds and 4 ounces. The length was 21 inches (53.3 cm). The Apgar score was 8/9 and the head circumference was 33.5 cm. It was reported that there was no complication during pregnancy and delivery. Additional information is not expected.

Other Meds: vitamins (unspecified)

Lab Data: ultrasound, 06/18/08, normal embryo

History: Premature labor; Premature rupture of membranes

Prex Illness: Pregnancy NOS (LMP = 5/2/2008); Smoker

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342766-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Jun-2008	02-Jun-2008	0	16-Mar-2009	08-Apr-2009	--	WAES0807USA04636	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Unknown	Intramuscular	

Seriousness: NOT SERIOUS, ER VISIT

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a licensed practical nurse through the pregnancy registry for GARDASIL concerning an 18 year old female with asthma and amoxicillin allergy who on 02-JUN-2008 was vaccinated with a first dose of GARDASIL (Lot # 659962/1740U) 0.5 ml intramuscularly. Concomitant therapy included prenatal vitamins. The nurse reported that the patient who received her first dose of GARDASIL is pregnant. No complications are reported. Medical attention was sought. On 19-JUN-2008, ultrasound revealed the patient had 10.1 weeks gestation at that time (gestation also reported as 5 weeks). Date of LMP was 09-APR-2008. Estimated date of delivery is 14-JAN-2009. There was no product quality complaint. Follow up information was received from a licensed practical nurse concerning an 18 year old female who on 02-JUN-2008 was vaccinated with a first dose of GARDASIL (Lot # 659962/1740U). Concomitant therapy included vitamins (unspecified). The LPN reported that on 19-JUN-2008 an ultrasound was performed which showed 10.1 weeks of gestation and confirm due date. On 22-AUG-2008 a routine ultrasound was performed: no problems were seen. The patient declined a Maternal Serum Alpha Fetoprotein Test. Date of LMP was 09-APR-2008. Estimated date of delivery is 14-JAN-2009. Follow up information was received from the pregnancy registry which reported that the patient delivered a normal healthy male baby on 15-JAN-2009. APGAR SCORE 8/9, weight: 8 pounds. The baby had no congenital anomalies, complications or abnormalities. The nurse reported fetal malpresentation and non reassuring fetal heart rate tracing during labor. It was also reported by the licensed practical nurse that the lot no. of first dose of GARDASIL was 661764/0650X (previously reported as Lot # 659962/1740U). Additional information has been requested.

Other Meds: vitamins (unspecified); vitamins (unspecified)

Lab Data: ultrasound, 06/19/08, 10.1 weeks gestation; ultrasound, 08/22/08, routine: No problems seen

History:

Prex Illness: Pregnancy NOS (LMP = 4/9/2008); Asthma; Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342767-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		16-Mar-2009	08-Apr-2009	--	WAES0901USA03966	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypoaesthesia, Injection site pain, Sensation of heaviness, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning many patients that complain of pain after receiving GARDASIL. The nurse practitioner also reported that it "appears to be the most painful vaccination." Follow up information was received on 02-FEB-2009 from a nurse practitioner who stated that all the patients she has given GARDASIL too have complained that it was very painful, their arms went numb and felt heavy. The nurse practitioner felt this was why a lot of patients faint with the vaccine. The actual number of patients was not reported. This is one of several cases from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342768-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	06-Nov-2008	06-Nov-2008	0	16-Mar-2009	07-Apr-2009	MI	WAES0901USA04179	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Muscle spasms, Vomiting

Symptom Text: Information has been received from a Licensed Practical Nurse (L.P.N.) for GARDASIL, a Pregnancy Registry product, concerning an 18 year old pregnant female smoker with no drug allergies who received her second dose of GARDASIL on 06-NOV-2006. Date of initial dose was unspecified. No details about the first or second dose of GARDASIL are known as another office administered them. Concomitant therapy included LEXAPRO which was discontinued on 16-nov-2008. An ultrasound showed patient was 5 weeks and 6 days pregnant at time of GARDASIL administration (LMP: 05-OCT-2008). Follow-up information was received from the a physician concerning the 18 year old white female smoker with no previous pregnancies and a history of depression who on 06-NOV-2008 was vaccinated with a dose of GARDASIL though a clinic. The patient had a LMP of 05-OCT-2008, became pregnant and had an EDD of 04-JUL-2009. On 16-NOV-2008 ultrasound was done in the emergency room due to vomiting and cramping the ultrasound indicated 7 weeks gestation and on 21-JAN-2009 serum alpha-fetoprotein test negative. The patient sought medical attention by visiting the physician's office. Additional information has been requested.

Other Meds: LEXAPRO

Lab Data: ultrasound 11/??/08 - 5 weeks and 6 days gestation at time of vaccine; ultrasound 11/16/08 - 7 weeks gestation; serum alpha-fetoprotein 01/21/09 - negative

History: Depression

Prex Illness: Pregnancy NOS (LMP = 10/5/2008) Smoker

Prex Vax Illns:

Vaers Id: **342775-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	31-Dec-2008	31-Dec-2008	0	26-Mar-2009	27-Mar-2009	--		27-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Hypotension, Pallor, Syncope, Tremor

Symptom Text: She came in for labs and for a Gardasil vaccination. She was vaccinated, and then while having labs drawn, she became lightheaded and fainted. Mother reports that she was having seizure like shaking while she was out. She did not hit her head, it was a very short period before she responded, was slightly pale, but otherwise herself. No postictal changes. BP low in the 70's initially. She had some ginger ale and cornbread and responded well. After about half an hour she had an excellent BP of 110/70. BP remained stable free standing and walking out.

Other Meds: methylphenidate,

Lab Data:

History: none

Prex Illness: Excessive daytime sleepiness

Prex Vax Illns:

Vaers Id: **342787-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	02-Sep-2008	02-Sep-2008	0	26-Mar-2009	27-Mar-2009	NJ		27-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0573X	1	Left arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Asthenia, Blood heavy metal increased, Diarrhoea, Dizziness, Eating disorder, Headache, Hypoaesthesia, Immediate post-injection reaction, Lethargy, Mental impairment, Myalgia, Pain in jaw, Weight decreased

Symptom Text: Immediate weakness, lethargic, muscule pain in all extremities. Continued to remain ill for months with dizziness, stomach pains, diahrea, numbness in arms, hands and fingers, jaw pain, unable to eat for prolonged periods (going from 103 lbs to 89 lbs) Experienced mental fuzziness and continues to feel numb on left side of body. Bad headaches. Is still being treated by Kinesiologist for high levels of metal in body. Had full blood work-up on 3/21/09. Continues to experience illness due to vaccine. Was perfectly healthy prior to second vaccine .

Other Meds:

Lab Data: Diagnosed with TMJ. Full blood work-up shows signs of Epstein Barre

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342803-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Mar-2009	25-Mar-2009	1	26-Mar-2009	30-Mar-2009	CA		08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF452BA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1423X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Pain, Pyrexia

Symptom Text: High fever, achy all over body and nauseated. Discussed possible reaction versus onset of viral illness. To treat fever and push fluids. If not better by next day, to be seen. To call if they have any questions.

Other Meds: Multivitamins; calcium; ST JOHNS WORT

Lab Data: none

History: ADHD

Prex Illness: none

Prex Vax Illns:

Vaers Id: **342819-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	01-Feb-2008	01-Mar-2008	29	27-Mar-2009	30-Mar-2009	--	WAES0803USA00457	30-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a Certified Nurse Midwife concerning a female with a penicillin allergy who on 01-FEB-2008 was vaccinated IM with the first dose of GARDASIL. Subsequently the patient became pregnant. Her LMP is 14-JAN-2008. The patient received a PAP test and was positive for HPV. Follow up information was received from the C.N.W. who reported that the patient had terminated the pregnancy in March 2008. Upon internal review, pregnancy termination was considered to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Pap test; Cervix HPV DNA assay, positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/14/2008); Penicillin allergy

Prex Vax Illns:

Vaers Id: **342820-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	25-Oct-2007	Unknown		27-Mar-2009	30-Mar-2009	HI	WAES0803USA03393	10-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1264U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion, Drug exposure during pregnancy

Symptom Text: Information has been received from an office manager and a physician, for the Pregnancy Registry for GARDASIL, concerning a 23 year old female who on 25-OCT-2007 was vaccinated with a 0.5 mL first dose of GARDASIL (Lot # 658488/1264U). On 22-JAN-2008 the patient was vaccinated with a 0.5mL second dose of GARDASIL (Lot # 659657/1487U). At the end of January the patient had a positive pregnancy test (LMP: 15-Jan-2008, EDD: 21-OCT-2008) and is now two months pregnant. The patient sought unspecified medical attention. Follow up information was received from a healthcare worker who reported that at the time of reporting the patient had not "actually" delivered her baby, although, "everything was fine now." Upon internal review, implied pregnancy loss was considered as an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: beta-human chorionic, 01/??/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/15/2008)

Prex Vax Illns:

Vaers Id: 342821-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Mar-2009	05-Mar-2009	0	27-Mar-2009	30-Mar-2009	--	WAES0903USA03647	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0052X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Anaphylactic reaction, Food allergy, Lip swelling, No reaction on previous exposure to drug, Pruritus, Respiratory distress

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female with history of mild reaction (itching) to orange who on 23-DEC-2008 was vaccinated with the first dose of GARDASIL (Lot# not reported), on 5-MAR-2009 11:00 AM was vaccinated IM with the second dose of GARDASIL (Lot# 655604/0052X) in the upper deltoid. On 05-MAR-2009 the patient had an anaphylactic reaction. The patient left the office at 11:45 AM with no reactions. The patient went back to school, had basketball practice and around 4 PM ate an orange and took a shower. The patient's lips at an unspecified time started to swell. The mother of the patient called the office and the patient went back to the office. The patient arrived at the office at 4:30 PM and the patient went into respiratory distress. The patient was treated with Epipen, Benadryl and a breathing treatment while waiting for the ambulance. The patient's "pulse ox" was 78 when she 1st arrived at the office. The patient's "pulse ox" was 92 or 93 after treatment and when the ambulance arrived. The patient was taken to medical center. The nurse practitioner checked on the patient at 7 PM and the patient had fully recovered and was released that same night. The mother of the patient mentioned that the patient had shown a mild reaction (itching) to an orange before. The nurse practitioner mentioned there had been reports of people having reactions after eating oranges in her center. The nurse practitioner would not giving the 3rd dose of GARDASIL. The patient did not have any problems with the 1st dose of GARDASIL. It was reported that the patient sought medical attention: in the office. Respiratory distress, lip swelling and anaphylactic reaction were determined to be other important medical events, and life threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pulse Oximetry 03/05/09, 78 ; Pulse Oximetry 03/05/09, 92-93

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342822-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Oct-2008	Unknown		27-Mar-2009	30-Mar-2009	AZ	WAES0903USA04016	17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Ovarian cyst, Surgery

Symptom Text: Information has been received from a medical assistant concerning a 15 year old female who in approximately March 2008 and in October 2008, was vaccinated with first and second doses GARDASIL (dose, route and lot number not provided). The medical assistant reported that on 13-FEB-2009 the patient had surgery for ovarian cysts. The reporter stated that the patient was hospitalized (name, address and phone number of hospital unspecified) but did not specify how long the patient was in the hospital. The reporter considered ovarian cysts as an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342823-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Feb-2009	18-Feb-2009	2	27-Mar-2009	30-Mar-2009	FR	WAES0903USA04402	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	JEV	UNKNOWN MANUFACTURER	VMR1617F	2	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1316U	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abscess drainage, Injected limb mobility decreased, Injection site abscess, Injection site erythema, Injection site inflammation, Injection site pain, Injection site swelling, Malaise, Pyrexia

Symptom Text: Information has been received from a paediatrician concerning a 16 year old female who was vaccinated with a first dose of GARDASIL (lot# 1316U; batch # NH45640) I.M. into the left upper arm on 16-FEB-2009. Concomitantly, she was vaccinated with a third dose of spring-summer encephalitis virus vaccine (FSME Immun, lot VMR1617F, Man Baxter) I.M. into the left upper arm. On 18-FEB-2009 the patient developed severe injection site inflammation with swelling, redness and pain. On 23-FEB-2009 she developed malaise and fever. The injection site inflammation increased and high inflammatory parameter (not otherwise specified) were detected. On 24-FEB-2009 abscess on the vaccinated arm was detected by sonography. Abscess drainage was performed on the same day and the patient was treated with antibiotics. At the time of reporting the patient still complained about decreased mobility of arm, she had not recovered. The reporter assessed the reaction to be an other important medical event. The reporter assessed the reaction to be related with GARDASIL and not with FSME-Immun. Other business partner's numbers includes: E2009-02381. Additional information has been requested.

Other Meds:

Lab Data: diagnostic laboratory test, 23Feb09, high inflammatory parameter; ultrasound, 24Feb09, abscess on the vaccinated arm; abscess drainage, 24Feb09, abscess drainage

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342835-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Oct-2007	05-Nov-2007	13	27-Mar-2009	30-Mar-2009	NC		02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2427AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1263U	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue

Symptom Text: 1 wk. after pt. received vaccine she started c/o feeling tired. Pt had several weeks of fatigue symptoms that continued until Feb. 2008. Several different laboratory evaluations were performed and nothing could be related to pts. symptoms. Mom saw a television talk where another female child had similar problems. So mom wanted this reported. Mom is also a nurse and is concerned the vaccine may have been the reason for fatigue s/s for so long.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **342848-1** **Related reports:** 342848-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	24-Apr-2008	24-Apr-2008	0	27-Mar-2009	30-Mar-2009	NY		06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Headache, Hypotension, Migraine, Syncope

Symptom Text: Headaches and Fatigue increasing in first 6 months after, leading up to dizzy and fainting spells, low blood pressure, and Migraines. Still experiencing the Headaches, Migraines, Fatigue, Hypotension, and Dizziness.

Other Meds: OrthoTriCyclin Lo. I have been on it since August 2005 and never experienced problems.

Lab Data: EKG, MRI, Bloodwork, Urine Analysis

History: Allergic to Nuts, Latex,Cats and Seasonal Plants

Prex Illness: No

Prex Vax Illns: Health Problems including Fainting~HPV (Gardasil)~1~22~Patient

Vaers Id: **342848-2** **Related reports:** 342848-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	24-Apr-2008	01-Jul-2008	68	17-Apr-2009	06-May-2009	NY	WAES0904USA00022	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Headache, Hypotension, Lyme disease, Syncope

Symptom Text: Information has been received from a nurse practitioner concerning a 22 year old female with pertinent medical history of birth control who on 24-APR-2008 was vaccinated with first 0.5mL dose of GARDASIL (route not reported, lot number 658556/1060U). Concomitant therapy included TRI-SPRINTEC. The nurse practitioner reported that the patient experienced fainting, dizziness and headache after getting first dose. Subsequently the patient was diagnosed with Lyme disease. At the time of reporting patient had not recovered from the event. No labs studies were performed. The patient sought unspecified medical attention. Follow up information has been received from a nurse practitioner concerning a 22 year old Caucasian female with no illness at the time of vaccination, who on 24-APR-2008 was vaccinated in the right deltoid with first 0.5mL dose of GARDASIL (route not reported, lot number 658556/1060U). Concomitant therapy included TRI-SPRINTEC. The nurse practitioner reported that on a telephone call made by the patient on 27-MAR-2009, she stated that had had dizziness, fainting, low blood pressure and headaches since she received the second dose. The patient did not receive a second dose of GARDASIL. She was diagnosed with Lyme disease and was being treated with doxycycline. The patient received the first dose on 24-APR-2008. There were no complaints at the visit on 25-JUN-2008. On 29-AUG-2008, the patient had her annual exam; she refused GARDASIL but had no complaints at the time. The patient was diagnosed with Lyme disease on Jun-2008. The patient called on 07-OCT-2008 and reported that she fainted in the subway and was taken to an emergency room. It was reported that the patient was being care of elsewhere. Outcome was reported as unknown. Additional information is not expected.

Other Meds: TRI-SPRINTEC

Lab Data: Unknown

History:

Prex Illness: Contraception

Prex Vax Illns:

Vaers Id: **342865-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Mar-2009	27-Mar-2009	0	28-Mar-2009	30-Mar-2009	MI		30-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	1	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1781X	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: FELT DIZZY AND LIGHTHEADED, FELT BETTER ONCE SHE LAID DOWN ON THE EXAM TABLE FOR ABOUT 20 MINS

Other Meds: UNKNOWN

Lab Data:

History: N/A

Prex Illness: NONE

Prex Vax Illns: DIZZINESS~HPV (Gardasil)~2~15~In Patient

Vaers Id: **342883-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Feb-2009	17-Feb-2009	0	27-Mar-2009	30-Mar-2009	FR	B0565752A	10-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NJ02270		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Gaze palsy, Malaise, Salivary hypersecretion, Syncope, Tonic clonic movements

Symptom Text: This case was reported by a regulatory authority (#ES-AGEMED-230889440) and described the occurrence of vasovagal syncope in a 11-year-old female subject who was vaccinated with TWINRIX pediatric (GlaxoSmithKline), GARDASIL (non-GSK). On 17 February 2009, the subject received unspecified dose of TWINRIX pediatric (intramuscular, unknown injection site, lot number not provided), unspecified dose of GARDASIL (intramuscular, unknown injection site). On 17 February 2009, less than one day after vaccination with GARDASIL and TWINRIX pediatric, the subject experienced vasovagal syncope. The subject experienced two sickness episodes including fall, tonic clonic movements, maxilla rigidity, sialorrhea and ocular retroversion. During the episodes the subject has the perception of what's going on. It's not clear if there was really It's not clear if there was really loss of consciousness. The regulatory authority reported that the events were clinically significant (or requiring intervention). On 18 February 2009, the events were resolved. The regulatory authority reported that the events were possibly related to vaccination with TWINRIX pediatric GARDASIL. No further information is expected; this has therefore been considered closed.

Other Meds:

Lab Data: UNK

History:

Prex Illness: Unknown

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342902-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Nov-2008	27-Nov-2008	10	27-Mar-2009	31-Mar-2009	CA		16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Respiratory disorder

Symptom Text: 10 days after GARDASIL (#2) Pt developed acute respiratory problems. "Lack of breath" after thanksgiving dinner.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342904-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	24-Mar-2009	26-Mar-2009	2	27-Mar-2009	30-Mar-2009	MT		02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	42843AA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0652X	0	Right arm	Unknown	
	HEPA	MERCK & CO. INC.	0933X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Induration, Local reaction

Symptom Text: Local reaction - redness and induration on left deltoid.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342912-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	26-Mar-2009	26-Mar-2009	0	27-Mar-2009	31-Mar-2009	NH		17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema, Pain, Urticaria

Symptom Text: Pt received HPV (GARDASIL) #2 in L deltoid. Here for TI DM follow-up, not acutely ill. Within < 1 min, pt c/o pain, and erythema noted. I was called in. Within < 3 mins, pt developed urticaria that spread from L deltoid to shoulders - to R arm. No SOB/wheezing or throat symptoms. Gave BENADRYL 50 mg and XYZAL 5 mg - decrease urticaria and decrease deltoid edema.

Other Meds: LANTUS; NOVOLOG; insulins

Lab Data:

History: TI DM; no known allergies but positive eosinophils

Prex Illness: none

Prex Vax Illns: Urticaria~Influenza (no brand name)~2~7~Patient

Vaers Id: 342916-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Mar-2009	26-Mar-2009	1	27-Mar-2009	31-Mar-2009	TX		01-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1131X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2727AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abnormal behaviour, Dizziness, Dysarthria, Feeling hot, Flushing, Headache, Hyperhidrosis, Nausea, Syncope, Vertigo

Symptom Text: Dizziness, nausea, headache, slurred speech. 4/17/09 MR received from PCP from 3/25 to 3/27/2009. Seen for PE and vax 3/25/09. Seen 3/26/09 for c/o dizziness, feeling hot, flushed and sweaty. Pt has vertigo when eyes are closed. Also had 1st dose Straterra that am. DX: prob viral, possible vaccine rxn. Seen again 3/27/09 for continued dizziness and "zoning out". Sways when standing. Eyes puffy, lightheaded, hot sweats. DX: Probable Gardasil rxn-dizzy, H/A, faint. Back to normal by 4/2/09

Other Meds:

Lab Data: CBC; CMP; ESR; CPK; UA Labs: CK 456, otherwise WNL.

History: ADD PMH: ADHD

Prex Illness:

Prex Vax Illns:

Vaers Id: **342930-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Mar-2009	20-Mar-2009	3	30-Mar-2009	31-Mar-2009	KY		04-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1775X	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0067X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister, Pyrexia, Scab, Varicella

Symptom Text: Mother brought patient to the clinic on 3/23/09 to be evaluated by RN. Child was "covered" in pox. Some were still in the vesicule stage, but most were crusted over. Mother stated that outbreak started on 3-20-09 (3 days after vaccination) mother stated that patient may have had low grade temp at onset of illness. Spoke with mother by phone on 3/25/09. Stated all vesicules now crusted.

Other Meds:

Lab Data: Had first dose of varicella before first birthday (7-9-97)

History:

Prex Illness: Brother (age 10) had outbreak of varicella 2wks prior to patients outbreak.

Prex Vax Illns:

Vaers Id: **342945-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Jan-2008	03-Jan-2008	0	30-Mar-2009	31-Mar-2009	TX	WAES0805USA01355	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a physician for the pregnancy registry for GARDASIL concerning a 14 year old female who on 03-JAN-2008 was vaccinated with GARDASIL (lot number unspecified). Concomitant therapy included prenatal vitamins (unspecified). The patient's LMP is reported as 10-Dec-2007. An ultrasound was performed on 29-Apr-2008. Follow up information was received from a healthcare professional who reported that the patient did deliver a baby by cesarean section in September 2008. Upon internal review, cesarean section was considered to be an other important medical event. Additional information has been requested.

Other Meds: Vitamins (unspecified)

Lab Data: ultrasound, 04/29/08

History:

Prex Illness: Pregnancy NOS (LMP = 12/10/2007)

Prex Vax Illns:

Vaers Id: **342946-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	09-Jun-2008	09-Jun-2008	0	30-Mar-2009	31-Mar-2009	PA	WAES0808USA02136	16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a nurse, for the Pregnancy Registry for GARDASIL, concerning a 15 year old female with no relevant medical history or allergies who on 09-JUN-2008 was vaccinated with a third 0.5 ml dose of GARDASIL (lot number, injection site and route not reported). There was no concomitant medication. Subsequently, the patient was pregnant. Laboratory test included prenatal lab work, HIV test and hemoglobin electrophoresis (results unspecified). Unspecified medical attention was sought. Follow-up information was received from a registered nurse concerning the female patient with anemia. The patient was performed a ultrasound on 01-OCT-2008 (result unspecified). On 17-FEB-2009 the patient delivered a female baby, weight 3421 gram, length 20.75 inch, Apgar score 8/9. The nurse reported that the infant was normal, but she also reported that the there were congenital anomalies and other complications and abnormalities (detail unspecified). Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 5/17/2008); Anaemia

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342947-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	01-Aug-2007	01-Sep-2007	31	30-Mar-2009	31-Mar-2009	FR	WAES0903AUS00079	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chemotherapy, Epstein-Barr virus infection, Mumps, Neoplasm malignant

Symptom Text: Information has been received from a 27 year old female, via CSL, as part of a business agreement (manufacturer control No. 2009 03 23 SL3), who in August 2007, was vaccinated with her first dose of GARDASIL. In September 2007, four weeks after vaccination with GARDASIL, the patient developed mumps. In approximately January 2008 the patient was vaccinated with her second dose of GARDASIL. Subsequently, in approximately April 2008, "a few months post-dose two", the patient was diagnosed with Epstein-Barr virus and was hospitalised. The Epstein-Barr virus was "cancerous in nature" and subsequently, the patient underwent six months treatment with chemotherapy. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342948-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Feb-2009	18-Feb-2009	5	30-Mar-2009	31-Mar-2009	FR	WAES0903USA04189	31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Dizziness, Nausea, Viral infection, Vomiting

Symptom Text: Information has been received from a Health Authority concerning a 13 year old female patient with hypothyroidism and no known drug allergies/drug reactions, who on 13-FEB-2009 was vaccinated with the first dose of GARDASIL (Lot # not reported) intramuscularly. Concomitant therapy included LEVOTIROXINA 50.0 ug daily. It was reported that on 16-FEB-2009 the patient experienced dizziness, vomiting and nausea. It was reported that the patient was prescribed corrective treatment with metoclopramide 20-30 mg/day and the treatment was started on 17-FEB-2009. However nausea and vomiting persisted and the patient could not tolerate neither food nor water. It was reported that on 18-FEB-2009 the patient consulted and was diagnosed with a viral infection. It was reported that the patient recovered from nausea, dizziness and vomiting in three days. It was reported that the patient also recovered from viral infection. It was mentioned that previous history of adverse reactions to other drugs was unknown. Other business partner numbers include E2009-02479. No further information is available.

Other Meds: Levotiroxina (Levothyroxine Sodium)

Lab Data: Unknown

History:

Prex Illness: Hypothyroidism

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342950-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	01-May-2008	01-Jun-2008	31	30-Mar-2009	31-Mar-2009	FR	WAES0903USA04405	10-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT No reaction on previous exposure to drug, Rash, Skin discolouration

Symptom Text: Information has been received from a gynaecologist concerning a 20 year old female patient who in April 2008, was vaccinated with her first dose of GARDASIL (lot number, site and route not reported) and was well tolerated. In May 2008, the patient received her second dose of GARDASIL (lot number, site and route not reported). Four weeks post the vaccination, the patient developed exanthem from which she recovered on an unknown date with remaining white spots. In Oct 2008, the patient was admitted to a dermatological clinic. At the time of reporting the patient still had the white spots. The reporter was informed about this event at the time of reporting. Up to now he had no hospital report. Other business partner number include: E2009-02386. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **342951-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	27-Dec-2008	10-Jan-2009	14	30-Mar-2009	31-Mar-2009	FR	WAES0903USA04635	16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema multiforme, Mucocutaneous rash, Skin lesion

Symptom Text: Case received from Foreign Health Authority on 19/03/2009 under reference 2009-00751. It was reported that a 19 years old female adult received her second dose of GARDASIL (date and site of administration not reported. Batch No. not reported) approximately on 27/12/2008. Approximately 15 days later, on 10/01/2009 she experienced erythema multiform with muco-cutaneous involvement. She was seen by a dermatologist, who made the diagnosis and who excluded other potential causes of the symptoms, like concomitant infection, other drugs or other allergies. She was treated with local steroid agents (product not reported). The symptoms lasted three weeks and were resolving at the time of this report. Follow up 17/03/2009. NO flu symptoms which could explain the symptoms. No other medication involved. Herpes infection was excluded. Mycoplasma infection excluded. Skin lesions: mainly the arms and upper body parts. NO lateral lesions, therefore Herpes has been ruled out. The primary reporter and the Health Authority classified this case as "serious". Other business partner numbers include E2009-02430.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342953-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Mar-2009	19-Mar-2009	0	30-Mar-2009	31-Mar-2009	FR	WAES0903USA04614	17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Blood pressure normal, Diarrhoea, Dizziness, Headache, Laboratory test normal, Malaise, Paraesthesia, Vomiting

Symptom Text: Case received from a physician on 20-MAR-2009. A 16 year old female with no relevant medical history reported received the first dose of GARDASIL (batch number not reported) via intramuscular route on 19-MAR-2009. 5 minutes later the patient experienced dizziness during more than 5 minutes. The dizziness disappeared after the torso was bent forward. At 14pm she felt general malaise and sat down. The patient had light brown diarrhoea from after 14pm. At 17pm she felt almost as she would faint and then vomited her lunch (2 chocolate cream sandwiches and a cola). She also felt tingling in her feet considered as paraesthesia by the physician. At 18 pm she went to the hospital emergency. Occipital pain without further description was mentioned. Patient's body temperature was at 37 'C, the physician did not consider it as being clearly fever. Her blood pressure was normal. She had no previous similar episode in the past. She had recovered after spending the night at the hospital for observation. She was discharged on 20-MAR-2009. Lab tests conducted showed normal results with negative salmonella typhi. More information expected regarding other tests and second dose re-challenge. Other business partner numbers include E2009-02534.

Other Meds: None

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342954-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Mar-2009	20-Mar-2009	1	30-Mar-2009	31-Mar-2009	NC		02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB330AA	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Gait disturbance, Nausea, Vomiting

Symptom Text: Awakened with joint pain, & nausea vomited 1 time - joint pain worsened thru the day, difficulty walking. Next day less pain, still had nausea 3rd d. - better till later pm - joint pain again did not last long - appetite - better 4 + 5 d. - attended school - less achy.

Other Meds: 0 DATE OF VACCINE ml

Lab Data: None

History: seasonal allergies

Prex Illness: 0 illness

Prex Vax Illns:

Vaers Id: **342971-1 (S)** **Related reports:** 342971-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Feb-2009	04-Mar-2009	19	30-Mar-2009	31-Mar-2009	FR	D0060963A	31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	AHABB119BA	0	Unknown	Unknown	
	JEV	UNKNOWN MANUFACTURER	11B	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NG29050	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Amnesia, Encephalitis

Symptom Text: This case was reported by a foreign regulatory authority (#DE-Pei-PEI2009005743) and described the occurrence of primary AE in a 16-year-old female subject who was vaccinated with TWINRIX adult (GlaxoSmithKline). Co-suspect vaccinations included (non-GSK) GARDASIL (Sanofi Pasteur MSD) and tick-borne encephalitis vaccine (FSME-IMMUN adult, Baxter). Previous vaccinations included the first two doses of GARDASIL vaccine (non-GSK) (GARDASIL, Sanofi Pasteur MSD), given on 21 November 2007 and 30 March 2008. On 13 February 2009 the subject received the first dose of TWINRIX adult (0.5 ml, unknown, unknown deltoid), the first dose of FSME-IMMUN adult (0.5 ml, unknown, unknown deltoid) and the third dose of GARDASIL (0.5 ml, unknown, unknown deltoid). Approximately 19 days post vaccination with TWINRIX adult, FSME-IMMUN adult and GARDASIL, on 04 March 2009, the subject experienced encephalitis with acute arising amnesia. The subject was unable to recognise attachment figures any longer. The subject was hospitalised for an unknown period of time. The events were confirmed by cranial magnetic resonance tomogram (MRT) including cerebral angiogram, cranial computed tomogram (CCT), cerebrospinal fluid (CSF) examination and serology. By differential diagnosis explicitly not excluded was dissociative amnesia, a psychiatric disorder of the dissociative (conversion) disorder spectrum. At the time of reporting, on 13 March 2009, the events were unresolved. The vaccination courses with TWINRIX adult, FSME-IMMUN adult and GARDASIL were discontinued. No further information will be available.

Other Meds:

Lab Data: UNK

History:

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **342971-2 (S)** **Related reports:** 342971-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Feb-2009	04-Mar-2009	19	31-Mar-2009	01-Apr-2009	FR	WAES0903USA04637	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	JEV	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1201U	2	Unknown	Unknown	
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	AHABB119BA		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Amnesia, Encephalitis, No reaction on previous exposure to drug

Symptom Text: Case received from health authority on 23-Mar-2009 under HA reference no. PEI2009005743. It was reported that a 16-year-old female patient was vaccinated with a third dose of GARDASIL (Batch # NG29050, Lot# 1201U) into the upper arm on 13-Feb-2009. Concomitantly the patient was vaccinated with a dose of FSME-Immun Erwachsene (Baxter, lot# not reported) into the upper arm and with TWINRIX (ERWACHSENE (GSK, lot# AHABB119BA) into the upper arm. On 04-Mar-2009 the patient developed encephalitis with acute amnesia ("she had not recognized closely related persons anymore"). The patient was hospitalized on an unspecified date. Cranial MRI (with angiography), CCT, CSF investigations and serology confirmed diagnosis of encephalitis. According to the reporting physician, a psychic disease of the spectrum of dissociative disorders (dissociative amnesia) was not ruled out. The patient has not recovered at time of reporting. It was reported that the patient received her first dose and second dose of GARDASIL (Lot numbers not reported) on 21-NOV-2007 and 03-MAR-2008, respectively and were well tolerated. Other business partner numbers include E2009-02495.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **342995-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	27-Mar-2009	27-Mar-2009	0	30-Mar-2009	31-Mar-2009	FL		31-Mar-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TD	UNKNOWN MANUFACTURER	NULL		Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Injection site swelling, Myalgia, Pyrexia

Symptom Text: swelling of injection site, low-grade temperature, muscle soreness, fatigue

Other Meds: NONE

Lab Data:

History: Gardisal was the vaccine given on 3/27/09. It wasn't listed above

Prex Illness: None

Prex Vax Illns:

Vaers Id: 342998-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	30-Sep-2008	07-Oct-2008	7	30-Mar-2009	30-Mar-2009	OK		01-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety, Dizziness, Fatigue, Headache, Hyperventilation, Loss of consciousness, Muscle tightness, Nausea, No reaction on previous exposure to drug, Presyncope, Syncope, Tinnitus, Tremor

Symptom Text: Clients mother call to Health Department on 03/30/09, received 1st HPV 07/29/08 at Health department, no adverse reactions after this vaccine. Received 2nd HPV 09/30/08 at other Health Department. Reports 1-2 weeks after 2nd dose, daughter experiencing "blackout spells and severe headaches." Reports client had 1st seizure on 03/29/09. Has appointment with PCP this week. 4/2/09-records received for DOS 4/1/09-office visit after near syncope for past 6 months, usually can tell when they are coming on becomes lightheaded and roaring sensation in ears with occasional nausea. occurring about every other week. Headaches occurring weekly. Almost blakced out and had tremors muscles in arms and legs felt tight. Tired afterwards. Episodes began after gardasil vaccine and depoprovera, Assessment: near syncopal episodes. R/O possible seizure disorder. Episode of hyperventilation due to anxiety syndrome. 4/16/09-records received 4/1/09-C/O near syncope for past 6 months lightheaded and roaring sensation in ears and nauseated feeling with them. Headaches weekly. Tremors. Blackout spells and tired. Started depoprovera. Episode of hyperventilation due to anxiety syndrome. 4/8/09-office visit for blackout and near fainting episodes-Assessment:vasovagal event with convulsive syncope followed by hyperventilation syndrome. Prone to syncope and presyncope.

Other Meds: Unknown

Lab Data: Unknown 4/2/09-records received-Labs WNL.

History: Unknown

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **343022-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Jan-2009	17-Mar-2009	47	31-Mar-2009	01-Apr-2009	FR	WAES0903HUN00005	01-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Bite, Contusion, Convulsion, Delirium, Epilepsy, Loss of consciousness, Psychomotor skills impaired, Tongue haemorrhage

Symptom Text: Information has been received from a physician concerning a 16 year old female with a history of drug hypersensitivity to SUMETROLIM (rash, 1995), AUGMENTIN (rash, 2001) and WILPRAFEN (rash, 1997) who on 29-JAN-2009 was vaccinated with the first dose of GARDASIL, and at 6 am on 16-MAR-2009 with the second. There was no concomitant medication. The patient went on vacation between 27-FEB-2009 and 06-MAR-2009 where she ate much salad, but was not sick. At 11pm at night on 17-MAR-2009 the patient was asleep for 30-60 minutes when her mother heard strange noises from her room and checked on the patient. The patient's tongue was bleeding, she was delirious and was convulsing. Ambulance was called, and the patient was taken to the emergency room. The reporting investigator (gynaecologist who administered the vaccine) wrote on the report that the neurologist (unspecified) feels that the event is not related to therapy with GARDASIL. The below information was included in the patient's discharge report: The patient was taken to the emergency room in the hospital by ambulance. On the night of 17-MAR-2009 the patient lost her consciousness, her next memory is the arriving ambulance staff. The patient's family heard strange noises from her room, ran to her, the patient was delirious and did not recognize her family, her tongue was bleeding. Convulsions were not noted, and by the time the ambulance arrived (about 20 minutes) the patient was generally clear. The patient is normally developed and fed. Oedema, icterus and cyanosis cannot be detected. Mycoderms are normal, tongue normal, on the left side there is a small bruise due to bite, small amount of blood clump. Normal chest and breathing. Normal heart sounds. Normal abdomen. The patient is conscious, clear, oriented. Normal blood pressure, heart rate and ECG. Urgent laboratory examination was performed after midnight. Neurological examination: Based on heteroanamnesis the family found her in her room, most probably she was having an epyleptic attack. In approx. 20 minutes

Other Meds:

Lab Data: blood pressure measurement, 17Mar09, 131/75 Hgmm; electrocardiogram, 17Mar09; arterial blood O2 saturation, 17Mar09, 97%; urine glucose, 17Mar09, 6 mmol/l; total heartbeat count, 17Mar09, 100 /min; WBC count, 18Mar09, 7.8 G/l; atypical lymp

History: Drug hypersensitivity

Prex Illness:

Prex Vax Illns:

Vaers Id: **343023-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	30-Nov-2007	12-Dec-2007	12	31-Mar-2009	01-Apr-2009	--	WAES0803USA01775	01-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arrested labour, Caesarean section, Cephalo-pelvic disproportion, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse practitioner, for the Pregnancy Registry for GARDASIL, concerning a 24 year old female with a history of lactose intolerance and 1 miscarriage who on 30-NOV-2007 was vaccinated with a 1st dose of GARDASIL (lot# 659055/1522U). Concomitant therapy included prenatal vitamins. Subsequently, 2 to 3 weeks after getting her vaccination the patient became pregnant (LMP 12-dec-2007). It was reported that on 31-JAN-2008 the patient has an ultrasound, routine obstetrical diagnostic tests, and cystic fibrosis screening (results negative). It was reported that on 28-FEB-2008 the patient had serum alpha-fetoprotein test (results within range). No adverse event was reported. Follow up information was received from a charge nurse who stated that the patient delivered a healthy and normal male, at term, on 16-SEP-2008. It was reported that the patient's labor progressed to second stage, when she had an arrest of descent and was diagnosed with CPD for this birth. It was reported that the patient had a cesarean section. The reporter stated that the patient had an uncomplicated prenatal course, with the usual pregnancy related complains, nothing more. No further information is available.

Other Meds: Unknown

Lab Data: ultrasound, 01/31/08, 7w5d, reason for test: Dates; diagnostic laboratory, 01/31/08, routine laboratory tests for pregnancy; diagnostic laboratory, 01/31/08, negat; Cystic fibrosis screening; serum alpha-fetoprotein, 02/28/08 within, screen

History: Lactose intolerance

Prex Illness:

Prex Vax Illns:

Vaers Id: **343025-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		31-Mar-2009	01-Apr-2009	FR	WAES0903USA01162	01-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Autoimmune disorder, Vasculitis

Symptom Text: Information has been received from a health care professional. This case concerns a 15 year old female patient who was administered on an unspecified date with a dose of GARDASIL (batch number not reported) route and site not reported. After vaccination (date not reported) the patient experienced an autoimmune vasculitis. At the time of reporting, the outcome is unknown. It is unknown if the patient sought medical attention. Vasculitis was considered to be an other important medical event. Other business partner numbers include E200902493.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343026-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		31-Mar-2009	01-Apr-2009	--	WAES0903USA04572	01-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Paralysis

Symptom Text: Information has been received from a consumer concerning his granddaughter (a female patient of unknown age) who experienced paralysis after getting the first 0.5 ml dose of GARDASIL. Lot# was not provided. The patient was hospitalized and at the time of reporting she was still in hospital. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 343027-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Mar-2009	13-Mar-2009	3	31-Mar-2009	01-Apr-2009	--	WAES0903USA04669	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Gluteous maxima	Unknown	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Burning sensation, Cerebrovascular accident, Confusional state, Conversion disorder, Dysarthria, Dyskinesia, Hypoaesthesia, Local reaction, Loss of consciousness, Musculoskeletal stiffness, Pain in extremity, Paralysis, Postictal state, Rash, Speech disorder, Tenderness

Symptom Text: Information has been received from a physician concerning a 15 year old female patient with atypical seizure disorder (started following an episode of head trauma) characterized by lip smacking and dysarthria (not tonic clonic movements). She was on treatment for this. On 10-MAR-2009, the patient was vaccinated with the first dose of GARDASIL (Lot # 661841/0653X) in the right buttock and had only minor localized tenderness. Subsequently, in March 2009 the patient developed paralysis, dysarthria, pain in legs and "stroke-like symptoms". In follow-up, the physician reported that on 13-MAR-2009, 3 days after the dose, the patient developed a rash in the distribution of her quadriceps on both legs which lasted 3 days before resolving. ON 17-MAR-2009, 1 week after the dose, the patient developed dysarthria without other seizure symptoms. There were no new medications or change in medications. The patient was admitted to the hospital for evaluation: EEG, CT, CBC, blood chemistries all came back normal. She was discharged without any specific treatment. On 24-MAR-2009, the patient saw her neurologist for the dysarthria. An MRI with gadolinium was negative. That evening at home she stood up and lost consciousness. The patient complained of numbness in her right arm and leg. On 25-MAR-2009, the patient had been complaining of burning pain in the right leg (front and back) without focality. There were no objective physical findings. At the time of reporting, the patient's dysarthria persisted. Upon internal review, paralysis and stroke-like symptoms were considered to be other important medical events. Additional information has been requested. 5/7/09 Hospital notes received from 3/18/09 to 3/19/09. FINAL DIAGNOSIS: Seizure Disorder Unwitnessed seizure, mother states prolonged postictal phase, confused, slurred and repetitive speech. Additional seizure in ED, shaking, eyes rolling, tongue moving, arms flexed. Returned to previous postictal state. PE WNL other than dialated pupils. Consider possible conversion diso

Other Meds: Unknown

Lab Data: Electroencephalography, came back normal; Computed axial, came back normal; Magnetic resonance, negative; Complete blood cell, came back normal; Blood chemistry, came back normal Report received 5/7/09 - DOS 3/18/08-3/19/09 LABS: Metabo

History:

Prex Illness: Convulsion disorder

Prex Vax Illns:

Vaers Id: **343029-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	22-May-2007	01-Apr-2008	315	31-Mar-2009	01-Apr-2009	--	WAES0903USA04692	01-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a nurse practitioner concerning a 25 year old female with no allergies who on 22-MAY-2007 was vaccinated IM with the first dose of GARDASIL (lot# 657621/0387U). In April 2008, eleven months later, the patient experienced seizure. A magnetic resonance imaging (MRI) was performed (result unknown). Subsequently, the patient recovered from seizure. On 22-OCT-2008 the patient received the second dose of GARDASIL (lot# 661530/0575X) IM 0.5mL. The patient sought medical attention at the practice. Upon internal review, seizure was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **343030-1 (S)** **Related reports:** 343030-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Oct-2007	11-Jan-2008	92	31-Mar-2009	01-Apr-2009	FR	WAES0903USA04762	01-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Anaphylactic shock, No reaction on previous exposure to drug, Psychotic disorder

Symptom Text: Information has been received from a health authority (reference number PEI2009004916) via a physician concerning a 16 year old female with a history of developmental delay who was vaccinated with a second dose of GARDASIL (lot # and injection site not reported) IM on 10-JAN-2008. One day p.v., on 11-JAN-2008, the patient experienced an allergic shock. Subsequently she developed an unspecified psychosis. She was hospitalized for ten weeks and recovered "with sequelae" (not specified). First vaccination with GARDASIL on 11-OCT-2007 was well tolerated. Other business partner numbers included: E2009-02497. No further information is available. File closed.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Developmental delay

Prex Vax Illns:

Vaers Id: **343030-2 (S)** **Related reports:** 343030-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Oct-2007	11-Jan-2008	92	02-Apr-2009	03-Apr-2009	FR	WAES0903USA05333	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypersensitivity, No reaction on previous exposure to drug, Psychotic disorder, Shock

Symptom Text: Case received from the Health Authority on 23-MAR-2009 under the reference number PEI2009004916. It was reported by a physician that a 16-year-old female patient with a history of developmental retardation was vaccinated with a second dose of GARDASIL (lot number and injection site not reported) IM on 10-JAN-2008. One day p.v. , on 11-JAN-2008, the patient experienced an allergic shock. Subsequently she developed an unspecified psychosis. She was hospitalized for ten weeks and recovered "with sequelae" (not specified). First vaccination with GARDASIL on 11-OCT-2007 was well tolerated. File closed. Shock, allergic reaction and psychosis were considered disabling. Other business partner numbers included E200902497. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Developmental delay

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343064-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	20-Mar-2009	Unknown		31-Mar-2009	01-Apr-2009	MI		01-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1720X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration

Symptom Text: No adverse event, dose given 3 weeks to soon.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **343112-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	03-Mar-2009	03-Mar-2009	0	31-Mar-2009	01-Apr-2009	AZ	AZ0903	01-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2829AA	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB239AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0843X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Blood pressure decreased, Nausea

Symptom Text: After administration of GPV, patiient expressed feeling weak and nausea. Provider was notified and patient was taken to tx room. Initial BP was 104/69; dropped 94/52; NS 500ml was ordered + bolus: between 11:30-11:40; patient improved, was alert.

Other Meds: N/A

Lab Data: none

History: None

Prex Illness: None

Prex Vax Illns: N/A~ ()~NULL~~In Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343114-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	24-Mar-2009	Unknown		31-Mar-2009	01-Apr-2009	CA		01-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea, Headache, Hemiparesis, Pharyngeal oedema, Swollen tongue

Symptom Text: PATIENT CALL A DAY AFTER AND COMPLAINS OF DIFFICULTY IN BREATHING, HEAD PAINS, SWOLLEN TONGUE/THROAT, AND LEFT SIDE WEAKNESS ABOUT 15 MINUTES AFTER VACCINE WAS GIVEN. PATIENT RETURN TO FOLLOW-UP A DAY AFTER VACCINE WAS GIVEN. PATIENT WAS ADVISED TO DRINK MORE WATER AND PRESCRIBED SINGULAIR 10MG QZ AND PERIACTIN 4MG TID.

Other Meds: NO KNOWN MEDICATION

Lab Data: NO

History: ALLERIC TO PENICILLIN AND SULFUR ABOUT THE AGE OF 6 AND 7 YEARS OLD - PENICILLIN = STOP BREATHING, LOC, REQUIRED CPR; SULFUR = WEAKNESS IN LEG; WAS HOSPITALIZED.

Prex Illness: NO ILLNESS

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343121-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	30-Mar-2009	30-Mar-2009	0	31-Mar-2009	02-Apr-2009	OR		02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	0933X	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3068AA	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1783X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Syncope

Symptom Text: Fainted aprox 5 min after vaccination received. Recovered quickly.

Other Meds: None known

Lab Data:

History:

Prex Illness: None known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343126-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	31-Mar-2009	31-Mar-2009	0	01-Apr-2009	02-Apr-2009	MN		02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	UNKNOWN MANUFACTURER	DON'T KNOW	1	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	DON'T KNOW	1	Right arm	Intramuscular	
	HEPA	UNKNOWN MANUFACTURER	DON'T KNOW	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Dyskinesia, Immediate post-injection reaction, Loss of consciousness, Malaise

Symptom Text: Upon injection, My daughter immediately put her head back and said I don't feel very good. I feel like I'm going to faint. The nurse was standing behind her I was in front of her and she passed out in my arms. The attending nurse and I laid her back on the table and she started to involuntarily jerking. I put my head out of the door and started calling for help. The whole incident lasted less than a minute. I was scared to death. I have never seen an immediate reaction to a vaccine before. I understand that there are three shots to be given. She will not get the remaining two shots. At first I thought my daughter just fainted, When we arrived home we looked up fainting on the internet to reassure my daughter that she would be fine and all I saw was all these web sited on the HPV vaccine. This also gave me cause for concern. I guess at this point I would take my chances with the virus then have my daughter get any more adverse reactions. When I read the side effects on the (What you need to know sheet) It said that the HPV vaccine does not appear to cause andy serious side effects. (?) Then I found all these web sites where people have died and fainted with seizures, Severe illness, Vomiting. None of these symptoms were listed on the (What you need to know) informational sheet. Why not? If I had known any of this she would not have received this injection. I will continue to monitor my daughter through the night. I pray this is all the reaction she will have with this vaccine. Thank you for your time in this matter.

Other Meds: NO

Lab Data:

History: NO

Prex Illness: NO

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343135-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	19-Mar-2009	19-Mar-2009	0	31-Mar-2009	01-Apr-2009	CA		01-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1496X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Paraesthesia oral, Swelling face

Symptom Text: Tingling around mouth with swelling spreading over both cheeks over period of several days. Applied steroid cream which helped -> course last 5 days until gone. Negative -> SOB. Negative wheezing. Positive vague HA x 24 hr.

Other Meds:

Lab Data:

History: PCN - hives

Prex Illness:

Prex Vax Illns:

Vaers Id: **343137-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	27-Feb-2009	03-Mar-2009	4	31-Mar-2009	01-Apr-2009	MN		12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Arthralgia, Colitis, Cough, Decreased appetite, Epistaxis, Eye discharge, Fatigue, Genital lesion, Headache, Pain in extremity, Pharyngitis, Pyrexia, Rhonchi, Swelling

Symptom Text: 1. 2 lesions on labia - lidocaine jelly, ACYCLOVIR 200 mg/ 2tsp TID 5cc TID. 2. Fever 100.2. 3. Coughing for 3 days. 4. Colitis x 3+ days. 5. Pharyngitis. 6. Eyes sticky. 7. Pains in hands and feet. Nystatin suspension 1 tsp swish and swollen qid x 2 wks. 7. Pains in feet and fingers - arthralgias - referral. 8. Epitaxis. 9. Headaches. 10. Fatigue home from school 3-13 -> 3/23 then half days. 11. Decreased appetite. 12. Lungs diffuse scattered rhonchi - z pack rheumatologist.

Other Meds:

Lab Data: CBC - CRP - mono - negative; H simplex; urine culture; strep for A; labia cx - negative

History:

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343139-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	31-Mar-2009	31-Mar-2009	0	31-Mar-2009	01-Apr-2009	CA		01-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	0933X	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0940X	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: About 6 minutes after administering HPV vaccine, patient fainted. No history of fainting in the past.

Other Meds: None

Lab Data:

History:

Prex Illness: URI

Prex Vax Illns:

Vaers Id: **343154-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Jan-2008	09-Jan-2008	0	01-Apr-2009	02-Apr-2009	NE	WAES0803USA01840	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Inappropriate schedule of drug administration

Symptom Text: Information and follow up has been received from a physician for the Pregnancy Registry for GARDASIL concerning a 18 year old female with sulfonamide allergy and a history of low grade squamous intraepithelial lesion who on 12-DEC-2007 was vaccinated with her first dose of GARDASIL (lot# not reported). There was no concomitant medication. On 09-JAN-2008 the patient was vaccinated with her second dose of GARDASIL (lot# not reported) and then learned she was pregnant after a positive pregnancy test. The patient's estimated LMP was 04-FEB-2008 with an EDD of 13-NOV-2008. On 20-MAR-2008 the patient had an ultrasound to check dating. On an unspecified date, the patient began taking prenatal vitamins (unspecified). It was reported that the patient had no previous pregnancies. Subsequently the patient experienced no adverse event and on an unspecified date she sought unspecified medical attention at her physician's office. Follow-up information has been received from a completed questionnaire. On 08-NOV-2008, 38 weeks from her LMP, the patient delivered a live normal male infant weighing 7 pounds 8 ounces via spontaneous vaginal route. The infant was 20.25 inches in length and 13 inches in head circumference, with an Apgar score of 8/9. No congenital anomalies, complications or abnormalities were reported. Medication during her pregnancy included prenatal vitamin (unspecified) once daily. There were no complications, infections or illnesses during her pregnancy and delivery. Pediatric medical records were received and reviewed and the following experience was identified: On 12-DEC-2008, the 35-day-old infant presented to the clinic with his mother. His mother noticed purulent material in his eyelashes for the past month. He was doing well otherwise and had breast feeding every 3 hours. He has not had any fevers, illness or problems with constipation. There was no passive tobacco smoke exposure. Physical examination regarding his eyes revealed: Positive red reflex bilaterally. No conjunctival infection but he has purulen

Other Meds: Vitamins (unspecified)

Lab Data: Ultrasound, 03/20/08, dating; Beta-human chorionic, positive

History: Low grade squamous intraepithelial lesion

Prex Illness: Pregnancy NOS (LMP = 2/4/2008); Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **343157-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	15-Jan-2009	15-Jan-2009	0	01-Apr-2009	02-Apr-2009	CT	WAES0901USA02732	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy, Vaginal haemorrhage

Symptom Text: Information has been received from a nurse for GARDASIL, a Pregnancy Registry product, concerning a 21 year old female with no medical history or drug allergy who was vaccinated with the first dose of GARDASIL (lot # 660553/0070X) IM, 0.5ml, on 02-OCT-2008. The patient was pregnant when she was administered her second dose of GARDASIL (lot # 660616/0570X) IM, 0.5ml, on 15-JAN-2009. There was no concomitant medication. No adverse effect reported. The patient performed urinalysis, pregnancy test. Her LMP was 12-NOV-2008. The patient sought medical attention by office visit. At the time of the report the outcome of the patient was unknown. Follow-up information has been received from a physician concerning a patient who had ultrasound on 03-FEB-2009 for vaginal bleeding and the test indicated the fetus was 6 weeks and 3 days intrauterine gestation. The patient had elective termination on 06-FEB-2009 (6 weeks and 6 days from LMP). The products of conception were not examined. It was unknown if the fetus normal. Upon internal review, elective termination was determined to be an other important medical event. No further information is available.

Other Meds: None

Lab Data: ultrasound, 02/03/09, 6 weeks 3 days intrauterine gestation

History:

Prex Illness: Pregnancy NOS (LMP = 11/12/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343159-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Mar-2009	05-Mar-2009	0	01-Apr-2009	02-Apr-2009	FR	WAES0903USA04761	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dyspnoea, Flushing, Pruritus, Pyrexia, Swelling, Urticaria

Symptom Text: Initial case was reported by a consumer to a company representative on 20-MAR-2009. Additional information was received on 24-MAR-2009. It was reported that a 16-year-old female was vaccinated with GARDASIL (batch#, route and site of administration not reported) on 05-MAR-2009. Five minutes after vaccination the patient developed breathing problems, urticaria, and fever. She was treated with BETAPRED (15 tablets), CETRIZINE and BRICANYL. She was sent home in the evening and with prescription of decreasing dose of BETAPRED. On 13-MAR-2009, when the dose was decreased to 2 tablets of BETAPRED, she was worse in the night and in the morning, she went to emergency unit with breathing difficulties, flushing and pruritus. She was treated with an injection of adrenaline (mfr unk), BETAPRED (15 tablets), allergy medicine (mfr unk, one tablet, sublingual) and BRICANYL. She was admitted to hospital during the day. She again started a decreasing medication scheme. On 16-MAR-2009 she was worse again and was treated again with BETAPRED (15 tablets) and cortisone (mfr unk). She was still on medication with cortisone at the time of reporting and was swollen as a consequence of cortisone treatment. Breathing difficult, urticaria, fever, pruritus and flushing were considered to be an other important medical event by the reporter. The patient has allergy to nuts, shellfish, pollen and cats as well as exercise induced asthma. Other business partner numbers include: E2009-02483. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Allergy to nuts; Shellfish allergy; Pollen allergy; Allergic to cats; Asthma exercise induced

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343161-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	23-Mar-2009	23-Mar-2009	0	01-Apr-2009	02-Apr-2009	FR	WAES0903USA04806	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0747X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bradycardia, Convulsion, Hypotension, Immediate post-injection reaction, Loss of consciousness, Tonic clonic movements

Symptom Text: Information has been received from a physician concerning a 19 year old female with atopic eczema, allergy to nuts and allergy to pineapple who on 23-MAR-2009 was vaccinated intramuscularly in the left deltoid with first dose of GARDASIL (dose not reported) (Batch number NJ40530, lot number 0747X). Concomitant therapy included Minulet. The physician reported that five to ten minutes post vaccination the patient experienced hypotension with loss of consciousness, bradycardia (around 50 beats/minute), convulsion and tonic clonic movements. The episode had a short duration (unspecified) and the patient had recovered without any medication having only legs elevated. It could had been a vasovagal reaction. Hypotension, bradycardia, loss of consciousness, convulsion, and tonic clonic movements were considered Other Important Medical events. Other business partner numbers included: E2009-02650. Additional information has been requested.

Other Meds: Minulet

Lab Data: Unknown

History:

Prex Illness: Atopic eczema; Allergy to nuts; Food allergy

Prex Vax Illns:

Vaers Id: **343162-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Mar-2009	25-Mar-2009	0	01-Apr-2009	02-Apr-2009	--	WAES0903USA04863	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Immediate post-injection reaction

Symptom Text: Information has been received from a medical assistant concerning a 16-year-old female with no medical history or allergies who on 25-MAR-2009 was vaccinated with the first dose of GARDASIL (lot# 660557/0072X) 0.5ml IM into the left deltoid. Concomitant therapy included MOTRIN. A minute after the vaccination, the patient developed dizziness and convulsion. The patient stayed at the office and was observed. The patient recovered in seconds. Upon internal review, convulsion was considered to be an other important medical event. Additional information has been requested.

Other Meds: MOTRIN

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **343163-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		01-Apr-2009	02-Apr-2009	--	WAES0903USA04907	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a licensed practical nurse (L.P.N.) who was told by a patient's mother that she heard from someone concerning 2 female children who were vaccinated with doses of GARDASIL on an unspecified date. Subsequently the patients experienced seizures. At the time of reporting, the outcome were unknown. Upon interview review, seizures was considered to be an other important medical event. Attempts are being made to verify the existence of an identifiable patient and reporter. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **343164-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	Unknown		01-Apr-2009	02-Apr-2009	NC	WAES0903USA04916	24-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Carcinoma in situ, Colposcopy abnormal, Dysplasia, Human papilloma virus test positive, Smear cervix abnormal

Symptom Text: Information has been received from a physician concerning a 19 year old female who was vaccinated with unknown how many doses of GARDASIL. On unknown date the patient had positive PAP tests for carcinoma in situ. It was believed that the patient was HPV positive prior to GARDASIL as the patient was sexually active. The patient was in office on 26-MAR-2009. Upon internal review, had positive PAP tests for carcinoma in situ was determined to be an other important medical event. Additional information has been requested. Follow-up from Merck: On 14-APR-2009, in addition to supplying the above information, a nurse reported that this female pt. was seen initially in their office on 14-APR-2008 because of an abnormal PAP with atypical cells. Another PAP was performed on 14-APR-2008 which detected HPV type 18 and 16 by a molecular diagnostic study. The physician then performed a specific type test and type 16 was detected. The final diagnosis was that high grade epithelial lesion (HSIL) could not be excluded. A colposcopy was performed on 30-APR-2008 along with biopsies at 10, 12, 3, and 6 o'clock with ECC. The 10 and 12 o'clock positions showed low grade mild dysplasia. The 3 o'clock position showed high grade mild dysplasia, while the 6 o'clock position showed high grade, carcinoma in situ with ECC High Grade. A cold knife cone biopsy performed on 16-JUN-2008 showed cervical carcinoma in situ, but no invasive tumor was identified. Sylvia reported that a repeat PAP was performed on 22-OCT-2008 which was negative and benign for changes. The patient was scheduled for another PAP on 14-APR-2009. According to the office, the April 14, 2009 pap was negative also.

Other Meds: Unknown

Lab Data: Serum prostatic acid, positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **343165-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Feb-2009	17-Feb-2009	0	01-Apr-2009	02-Apr-2009	FR	WAES0903USA04957	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye movement disorder, Fall, Masked facies, Muscle rigidity, Salivary hypersecretion, Syncope, Tonic clonic movements

Symptom Text: Information has been received from a Health Authority (reference number ES-AGEMED-230889440) concerning an 11 year old female who on 17-FEB-2009 was vaccinated with a dose of GARDASIL (batch number not reported) by intramuscular route (site of administration not reported). The same day the patient was vaccinated with a dose of TWINRIX (batch number not reported) by intramuscular route (site of administration not reported). According to the reporter's narrative, the patient had 2 fainting episode with fall, tonic clonic movements, maxillary rigidity, sialorrhea and ocular deviation. During the episodes the patient was aware of what was happening, thus it is not clear if there was a loss of consciousness. The reporter has coded vasovagal syncope and tonic clonic movements as adverse events. Case reported as serious by the HA with other medically important condition as criteria. Other business partner numbers included E2009-02684. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343166-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Jan-2009	01-Feb-2009	27	01-Apr-2009	02-Apr-2009	FR	WAES0903USA04959	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Ovarian cyst

Symptom Text: Information has been received from a Health Authority (reference number ES-AGEMED-118715344) concerning a 16 year old female who on 05-JAN-2009 was vaccinated with a second dose of GARDASIL (batch number not reported) route unknown, site not reported. Prior dose of GARDASIL was administered on 04-NOV-2008 by unknown route. It has not been reported whether the patient presented any adverse event after this first dose of vaccine or not. In February 2009, exact date not reported, the patient diagnosed with a fast growing giant ovarian cyst. According to the reporter the event is not related to vaccination, but the vaccination coincides in time with the beginning of first symptoms. Case reported as serious by the HA with other medical important as criteria. Case is closed. Other business partner numbers included E2009-02677. No further information was available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343167-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Dec-2008	17-Dec-2008	1	01-Apr-2009	02-Apr-2009	FR	WAES0903USA04967	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Computerised tomogram, Convulsion, Electroencephalogram

Symptom Text: Initial information received on the 26-MAR-2009 by the foreign Health Authority (reference number ES-AGEMED-130888440) regarding a 12 year-old female who was administered on the 16-DEC-2008 a dose of GARDASIL (batch number not reported) by intramuscular route (site of administration not reported). It is reported that several hours after receiving vaccination, on the 17-DEC-2009 in the morning, the patient experienced a convulsion while sleeping, (seen by the patient's mother) thus she was taken to the hospital emergency room. While in hospital the patient presented another convulsion episode. A CAT scan and electroencephalogram were performed on the 17-DEC-2008, results are pending. Currently the case is under study. Case reported as serious by the HA with other medically important condition as criteria. No further information has been reported. Relevant test/laboratory data: A CAT scan and electroencephalogram were performed on the 17-DEC-2008, results are pending. Other business partner numbers included E2009-02672. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **343168-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	14-Feb-2009	14-Feb-2009	0	01-Apr-2009	02-Apr-2009	FR	WAES0903USA05023	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Clavicle fracture, Fall, Haematoma, Immediate post-injection reaction, Injection site erythema, Injection site pain, Loss of consciousness, Tongue biting

Symptom Text: Information has been received from the health authorities in a foreign country under reference number BS20090154 and BS0900145 concerning a 19 year old female with no relevant medical history reported who on 14-FEB-2009 was vaccinated with GARDASIL (batch number not reported) via intramuscular route. During the injection the patient experienced a severe injection site pain, the physician slowed down the end of the injection the patient complaint with injection site pain during the injection. Between 40 to 60 seconds after vaccination the patient fall down from the physician's table, probably a vasovagal malaise with loss of consciousness, frontal hematoma, tongue biting. Arterial pressure was at 11/7, pulse rate at 65. She had an injection site erythematous plaque (diameter=15 cm). The fall induced a fracture of her clavicle leading to the patient's hospitalization. Therefore, at time of reporting the patient had recovered with sequelae. The physician remained very astonished and did not want to vaccine anymore with GARDASIL. The health authorities assessed the causal relationship between the reported reactions and vaccination as "probable" according to the foreign method of assessment. Other business partner number included E200902685.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343169-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	15-Nov-2007	15-Nov-2007	0	01-Apr-2009	02-Apr-2009	FR	WAES0903USA05024	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from the foreign health authorities under reference number NC20090120 concerning a 20 year old female with neither relevant medical history nor medical history of convulsive crisis reported on 15-NOV-2007 was vaccinated with GARDASIL (batch number not reported) via intramuscular route. On the same day the patient presented with typical convulsive crisis of a few seconds. EEG and cerebral scan were normal. No other episode. The patient refused other doses of GARDASIL. At time of reporting, the patient had recovered. Convulsion was considered to be an other important medical event. Other business partner number included E200902646.

Other Meds: Unknown

Lab Data: Computed axial tomography, normal; electroencephalography, normal

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **343171-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	27-May-2008	17-Jun-2008	21	01-Apr-2009	02-Apr-2009	FR	WAES0903USA04764	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1068U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Venous thrombosis

Symptom Text: Case received from a foreign health care professional on 23-MAR-2009. It was reported by gynecologyst that a 19 years old female patient with a medical history of heterozygote Factor V mutation was vaccinated with a first dose of GARDASIL (batch # NH06410, lot number: 1068U) IM into the upper arm on 27-MAY-2008. Concomitant treatment include BELLARA since June-2005. On 17-Jun-2008 the patient developed pelvic vein thrombosis with formation of collaterals and was hospitalized on the same day. Antiphospholipid syndrome was suspected. The patient had been treated with MARCUMAR. The patient fully recovered end of JUL-2008. A causal relation to the vaccine considered to be "likely" on the reporting form. Other business partner include E2009-02494.

Other Meds: hormonal contraceptive (unspecified)

Lab Data: Unknown

History: Factor V Leiden mutation

Prex Illness:

Prex Vax Illns:

Vaers Id: **343172-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Mar-2008	Unknown		01-Apr-2009	02-Apr-2009	FR	WAES0903NZL00008	02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0597F		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site abscess

Symptom Text: Information has been received from an agency, via CSL, as part of a business agreement, concerning a 15 year old female who on 30-MAR-2008 was vaccinated with GARDASIL (Lot # 655423/0597F, Batch # NE43240, Expiry date 26-MAY-2009). Subsequently, after vaccination, the patient experienced injection site abscess which required intervention. The severity of injection site abscess was reported as severe. At the time of reporting to the agency in June 2008, the outcome of injection site abscess was unknown. The agency considered that injection site abscess was probably related to therapy with GARDASIL. The original reporting source was not provided. The agency considered the event of injection site abscess to be medically significant. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343173-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Oct-2008	01-Nov-2008	31	01-Apr-2009	02-Apr-2009	FR	WAES0903NZL00007	01-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1283U		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Arthropathy, Condition aggravated, Diabetes mellitus, Hypertension, Myalgia, Uveitis

Symptom Text: Information was obtained from the agency as part of a business agreement, concerning an 18 year old female with insulin-dependent diabetes and Iridocyclitis (unspecified), who on 01-OCT-2008 was vaccinated with GARDASIL vaccine, intramuscularly, as prophylaxis (Lot No. 1283U, Batch No. NJ 02260). Subsequently, on 01-NOV-2008, the patient experienced arthropathy, hypertension, myalgia, aggravated diabetes mellitus and uveitis and was hospitalized. The patient's arthropathy, hypertension, myalgia, aggravated diabetes mellitus and uveitis were reported as severe. At the time of reporting to the agency in February 2009, the patient had not yet recovered from arthropathy, hypertension, myalgia, aggravated diabetes mellitus and uveitis. The agency reported relationship of arthropathy, hypertension, myalgia, aggravated diabetes mellitus and uveitis to therapy with GARDASIL as unclassified. The original reporting source was not provided. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Diabetes mellitus insulin-dependent; Iridocyclitis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343237-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Mar-2009	30-Mar-2009	0	01-Apr-2009	02-Apr-2009	NC		02-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1312X	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0125Y	1	Right arm	Subcutaneously	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B028AA	0	Left arm	Intramuscular	
FLU	SANOFI PASTEUR	U2828AA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB330AA	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2688AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Client became dizzy after vaccination

Other Meds:

Lab Data:

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **343238-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Feb-2009	09-Feb-2009	6	01-Apr-2009	02-Apr-2009	TX		08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Acute sinusitis, Asthenia, Crying, Ear pain, Headache, Nasal congestion, Oropharyngeal pain, Otitis externa, Pallor, Pyrexia, Rhinorrhoea, Vomiting

Symptom Text: several fevers a day, bad headaches with fever, sore throat, stopped up nose or runny, weak, upset stomach and vomiting, pale skin, cried because generally miserable most of the time.4/7/09-records received for DOS 3/24/09-office visit 3/24/09-C/O right ear pain increased temperature for about a month, headache, vomiting nausea all started after Gardasil injection. Now in clinic with C/O runny nose, sore throat, headache, right ear pain, sinus drainage for few days. One month ago received 2nd gardasil vaccine and started having fever. Assessment: right sided external otitis. Acute sinusitis. Office visit 4/1/09-No fever doing well, no hearing problem. Signs and symptoms improved. Assessment: right sided swimmer's ear improved. Acute sinusitis improved.

Other Meds: vitamins

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns: fever,headach,vomiting, upset stomach,sore throat, runny or stopped up nose,weak,pale, and cried most of the time.~HPV (Gardasil)~2~13~Patient

Vaers Id: **343257-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	26-Mar-2009	27-Mar-2009	1	01-Apr-2009	02-Apr-2009	TX		06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Asthenia, Back pain, Chlamydial infection, Gait disturbance, Headache, Injection site pain, Musculoskeletal pain, Neck pain, Oral contraception, Pain

Symptom Text: Gardasil shot was given. Pain starting in arm of injection site, quickly moved to shoulders and neck. Within two days it included the entire back and hips. Now, nearly a week later it is painful for her to walk and she is complaining that her entire body feels as if it is bruised. 4/8/09-records received-offcie visit 3/26/09-chlamydia positive. First gardasil vaccine received. Oral contraception. 5/1/09-records received for telephone call from parent, C/O headaches, pain and weakness for several days after injection.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **343265-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-Mar-2009	27-Mar-2009	0	01-Apr-2009	02-Apr-2009	AZ		02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	FLU	SANOFI PASTEUR	U2750AA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1312X	2	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Immediate post-injection reaction, Loss of consciousness, Tooth injury

Symptom Text: Pt was given GARDASIL vaccine was informed would have to wait 20 minutes to be observed, pt was sitting on exam table after injection passed out - falling forward hitting cabinet broke tooth & cut to head. Pt observed stabilized.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343271-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	16-Mar-2009	17-Mar-2009	1	01-Apr-2009	02-Apr-2009	TX		02-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Local swelling, Pruritus, Rash, Swelling face

Symptom Text: Pt reports woke up the morning after the injection with "puffy face and L side of neck" which turned into a rash. States also had some rash on stomach and R finger which has not lasted as long as the rash on face and neck. States went to ENT for ear infection and he told her it was a "stress rash" and to take BENADRYL. She states arm where she got injection is fine. Pt denies any SOB c the rash, just itching. States not sure she wants to get next injection. Pt will call back with any additional information about the rash

Other Meds: LOESTRIN 24

Lab Data: None

History: NKDA

Prex Illness: None Known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343297-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		02-Apr-2009	03-Apr-2009	NC	WAES0903USA04905	24-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Carcinoma in situ, Cervical conisation, Cervix carcinoma

Symptom Text: Information has been received from a physician concerning a 16 year old female patient who completed GARDASIL series. The patient was HPV positive prior to receiving vaccine as sexually active. A few months ago the patient experienced positive PAP tests for carcinoma in situ. The physician did a "cone procedure" and now her PAP was clear and she was considered recovered. The patient sought medical attention via going to office. The physician considered positive PAP tests for carcinoma in situ to be an other important medical event due to cone procedure. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, positive for carcinoma in situ; PAP test, clear

History:

Prex Illness: Papilloma viral infection; Sexually active

Prex Vax Illns:

Vaers Id: **343298-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	Unknown	Unknown		02-Apr-2009	03-Apr-2009	MA	WAES0903USA03214	03-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 20 year old female patient with no pertinent medical history and no known drug allergies who on an unspecified date was vaccinated with the first dose of GARDASIL (Lot # unknown), IM 0.5 mL, and on 11-MAR-2009 was vaccinated with the second dose of GARDASIL (Lot # 659655/0940X) 0.5 mL, intramuscular administration. It was reported that the patient was pregnant and was administered GARDASIL. The patient was given PLAN B which was not effective. LMP was 12-FEB-2009 and EDD was 19-NOV-2009. Laboratory test performed on an unspecified date included PAP smear, GC/Chlamydia and beta hCG. No adverse effect was reported. The patient sought unspecified medical attention. Follow-up information was received from a registered nurse, via telephone call, indicating that the patient was planning to terminate the pregnancy. The nurse reported that the reason for terminating the pregnancy was that the patient and her husband "were not ready for a family". Upon internal review, "Termination of pregnancy" was considered to be an other important medical. Additional information has been requested.

Other Meds: None

Lab Data: Pap test; cervix C.; urine beta-human

History:

Prex Illness: Pregnancy NOS (LMP = 2/12/2009)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343315-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	26-Mar-2009	27-Mar-2009	1	02-Apr-2009	06-Apr-2009	NJ		06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0229X	1	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2666AA		Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C2904AA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Mobility decreased, Pyrexia

Symptom Text: 105 fever 12 hours later. Headache, couldn't move arms and legs.

Other Meds:

Lab Data: None

History: No

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343317-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Mar-2009	24-Mar-2009	0	02-Apr-2009	06-Apr-2009	NC		06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	2	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2668AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Paraesthesia, Sensation of heaviness

Symptom Text: Injection about 15:40. Approximately 17:30 became dizzy light headed, face tingled and broke out in a sweat. Lasted about 30 min. Later arms and legs felt heavy x 12 hr.

Other Meds: ALLEGRA D

Lab Data: None

History: No known

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343332-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Mar-2009	13-Mar-2009	0	02-Apr-2009	06-Apr-2009	AZ		06-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	UF452AA	4	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	08T5X	0	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	42683AA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	1535X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Cyanosis, Gaze palsy, Immediate post-injection reaction, Pallor, Tremor

Symptom Text: Patient turned pale a minute after receiving all 4 vaccines, then her lips turned blue 1/2 minute later, she had a seizure, with her eyes flipping upwards, then arms were shaking. The whole episode lasted 1-1/2 minutes. She had same reaction 3 yrs ago, when blood was taken for lab tests.

Other Meds:

Lab Data: EEG Pending

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343342-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	31-Mar-2009	02-Apr-2009	2	02-Apr-2009	07-Apr-2009	MA		07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1756X	1	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Skin nodule

Symptom Text: 0.1 cm in diameter nodule, palpable.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 343348-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Feb-2009	22-Feb-2009	2	02-Apr-2009	06-Apr-2009	NY		22-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0702X	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB330CA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Arthralgia, Cellulitis, Cough, Dizziness, Erythema, Gait disturbance, Joint swelling, Oedema peripheral, Pyrexia, Rash maculo-papular, Upper respiratory tract infection, Viral pharyngitis

Symptom Text: 2/22/09 to 2/24/09 Fever by report from mom. 2/27/09 Patient began experiencing ankle pain. 2/28/09 Ankle began to swell with redness. 3/1/09 Patient seen in the office with bilateral lower leg swelling and redness from ankles to below knees. Fever 101.7F. Pt diagnosed with cellilitis and started on oral Clindamycin. 3/3/09 Pt continued to have fever to 104 and swelling. Also redness with streaking up bilateral inner thighs noted. Pt referred to ER and was admitted for IV Clindamycin. 3/3/09 to 3/6/09 Pt hospitalized for IV clindamycin with slow partial resolution of swelling and redness. At discharge, pt still had redness on lower 2/3 of lower leg but signifantly less swelling. Pt discharged home on oral Clinda. 3/11/09 Pt had drug reaction on Clindamycin so antibiotic was stopped. 3/18/09 Pt re-evaluated: fading redness on lower legs with minimal swelling mostly localized to lateral right achilles. No pain or tendereness. 3/25/09 Swelling almost completely resolved, redness fading, no pain or tenderness. 4/6/09-records received-office visit 2/28/09-fever 37 degrees 4 days ago, ankle pain, dizzy after receipt of vaccines. 3/1/09-both ankles swollen started 3-4 days ago, no trauma. Cough, Rash on legs only. Bilateral leg swelling and erythema. Assessment:questionable cellulitis. Presented to ED 3/4/09-pain in legs red and swelling of legs. Macular papula rash on belly and chest. Pain when walking. Fever up to 104 prior to arrival. Assessment: cellulitis. 3/25/09 office visit C/O cold.Assessment viral pharyngitis and URI. 4/15/09-records received for DOS 3/3-3/4/09-DX:Cellulitis. Bilateral cellulitis of lower extremities. -C/O painful red legs, 5-6 days history of bilateral leg pain increasing in severity accompanied by fever. Onset as muscle pain without fever then minimal redness and increasing pain.

Other Meds: Benzaclin topical gel

Lab Data: Doppler U/S normal. X-rays of legs normal. 3/2/09 WBC 13.0 (N80,L14,M5,E1, CRP 154.8 mg/L, ESR 70 mm/1hr; ANA, RF, Lyme normal. 3/9/09 wbc 6.1, ESR 49 mm/1hr, CRP 11.5 mg/L, Antistreptolysin O Ab 4.7 (normal(. 4/6/09-records rec

History: Acne

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343379-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
44.0	M	26-Mar-2009	Unknown		02-Apr-2009	06-Apr-2009	MN		06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, No adverse event

Symptom Text: None

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343382-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	31-Mar-2009	31-Mar-2009	0	02-Apr-2009	06-Apr-2009	AR		06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Nausea

Symptom Text: Nausea 15 min after GARDASIL Dizziness 30 min after vaccine still c/o dizziness, now on 4/2 , got vaccine on 3/31/09

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **343394-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Feb-2008	02-Feb-2008	0	18-Mar-2009	14-Apr-2009	IL	A0709448A	14-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0384U	0	Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB211AA	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Heart rate increased, Hypotension, Presyncope

Symptom Text: This case was reported by a healthcare professional and described the occurrence of near fainting in a 13-year-old female subject who was vaccinated with HAVRIX (GlaxoSmithKline), GARDASIL. The subject's medical history included MRSA infection of the skin. On 2 February 2008 at 09:30 the subject received 2nd dose of HAVRIX (.5 ml, left arm) and the 1st dose of GARDASIL. On 2 February 2008, 12 hours after vaccination with GARDASIL and HAVRIX, the subject experienced near fainting, low blood pressure and rapid heartbeat. The subject was seen in the emergency room. At the time of reporting the outcome of the events were unspecified. On 28 February 2008 follow-up was received via the healthcare professional. She reported that on 02 February 2008, the subject experienced near fainting, low blood pressure and rapid heartbeat. The events resolved on 08 February 2008. On 11 February 2008, diagnostic test for influenza, CBC, ESR and CPK were normal. A CT scan of the head, chest x-ray and EKG were also normal. She considered that the events were not serious and she considered that the events were possibly related to the use of HAVRIX. She also stated that she was unsure which product were suspect.

Other Meds:

Lab Data: Blood pressure, 02Feb2008, low; CBC, 11Feb2008, normal; CT scan, 11Feb2008, normal; Chest x-ray, 11Feb2008, normal; Creatine phosphokinase, 11Feb2008, normal; Electrocardiogram, 11Feb2008, normal; Erythrocyte sedimentation rate, 11Feb2008,

History: MRSA Infection. History: MRSA infection of the skin. No known drug allergies. No adverse events following previous vaccinations.

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **343415-1** **Related reports:** 343415-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	12-Feb-2008	01-Jan-2009	324	03-Apr-2009	06-Apr-2009	CA	WAES0903USA01463	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	2	Right leg	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anal haemorrhage, Anogenital warts, Papilloma viral infection, Skin lesion

Symptom Text: Information has been received from a medical assistant concerning her 16 year old daughter who on 11-FEB-2008 was vaccinated the third dose of with GARDASIL. During the last week of February 2009, the patient experienced anal bleeding and approximately 3 lesions around the anus. She was treated by a physician assistant in the office. The lesions were at that time "burned off". One week later the bleeding returned and the daughter had more than 30 lesions around her anus. Follow-up information was received from the physician's assistant concerning the 16 year old female patient with no known allergies and no illness at time of vaccination who on 04-APR-2007 was vaccinated IM with the first dose of GARDASIL (lot #: 655503/0012U) into the left thigh, on 21-AUG-2007 was vaccinated IM with the second dose (lot #: 658556/1060U) into the right thigh and on 12-FEB-2008 was vaccinated IM with the third dose (lot #: 657736/0389U) into the right thigh. In approximately January 2009, the patient developed multiple warts on rectum. On 05-MAR-2009, rectum biopsy was performed. The tissue of genital wart (rectum) was tested. It was reported the specimen consisted of a single tan, irregularly shaped tissue fragment measuring 0.3x0.3x0.2 cm. The surface was regular. The margin was inked black. The physician's diagnose by the rectum biopsy was condyloma. There was viral cytopathic effect characteristic of HPV infection. No high-grade dysplasia was seen. The patient was treated with podophyllin and "hyphinkater". Multiple warts on rectum/condyloma and characteristic of HPV infection were considered to be other important medical events. Additional information has been requested.

Other Meds: Unknown

Lab Data: rectal biopsy, 03/05/09, condyloma

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **343415-2** **Related reports:** 343415-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	11-Feb-2008	23-Feb-2009	378	22-Apr-2009	08-May-2009	CA	WAES0903USA01463	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anal haemorrhage, Anorectal disorder

Symptom Text: Information has been received from a medical assistant concerning her 16 year old daughter who on 11-FEB-2008 was vaccinated with the third dose of GARDASIL. During the last week of February 2009, the patient experienced anal bleeding and approximately 3 lesions around the anus. She was treated by a physician assistant in the office. The lesions were at that time "burned off". One week later the bleeding returned and the daughter had more that 30 lesions around her anus. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **343416-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Feb-2009	03-Feb-2009	0	03-Apr-2009	06-Apr-2009	FR	WAES0903USA04934	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TD	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Dizziness, Immediate post-injection reaction, Myoclonus, Syncope

Symptom Text: Initial information received on the 26-MAR-2009 from a Foreign Health Authority (reference number ES-AGEMED-918714344) regarding a 14 year-old female who was administered on 03-FEB-2009 a dose of GARDASIL (lot# not reported) by intramuscular route (site not reported). On the same day the patient also received a dose of DITANRIX (GlaxoSmithKline, route unknown, site not reported). 5 minutes after vaccination the patient experienced dizziness, syncope and a convulsion (as myoclonias). The patient recovered. Before leaving the health center, the patient presented another syncope. The patient was kept in observation for a few hours. She did not present any further symptoms so she was discharged. The mother has informed that the patient normally gets dizzy with needles. The reporter has coded this adverse events as convulsions and syncope. Case reported as serious by the HA with other medically important condition as criteria. Other business partner numbers include: E2009-02690.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343417-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Jan-2009	23-Jan-2009	0	03-Apr-2009	06-Apr-2009	FR	WAES0903USA04956	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1068U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness

Symptom Text: Initial information received on the 26-MAR-2009 from the foreign Health Authority (reference number ES-AGEMED-008770334) regarding a 14 year-old female who was administered on 23-JAN-2009 a dose of GARDASIL (lot# 1068U, batch# NG43220) by intramuscular route (site of administration not reported). It is reported that on the 23-JAN-2009, 30 minutes after vaccine administration, the patient experienced dizziness with loss of consciousness. The patient recovered 4 hours later. No further information has been reported. Case reported as serious by the HA with other medically important condition as criteria. Other business partner numbers include: E2009-02689. Case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343419-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Sep-2008	27-Mar-2009	191	03-Apr-2009	06-Apr-2009	NY	WAES0903USA05483	11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0063X	2	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Aggression, Anxiety disorder, Myalgia, Verbal abuse

Symptom Text: Information has been received from a physician concerning a 12 year old female with allergies to Augmentin who on 10-OCT-2007, 17-JAN-2008 and 17-SEP-2008 was vaccinated IM 0.5 mL with the first (lot# 658554/0928U), second (lot# 658488/1264U) and third (lot# 660391/0063X) doses of GARDASIL. There was no concomitant medication. After the third vaccination, the patient developed muscle aches and "went berserk at home" on an unspecified date. The patient's mother called the physician on 30-MAR-2009 to report that the patient "went berserk" and was hospitalized in the "psych ward". The patient's symptoms persisted. Additional information has been requested. 4/20/09-records received-for DOS 3/27-4/3/09-DC DX:anxiety disorder NOS. Admitted for a period of explosive outburst earlier. Punished for not oing to school. Punched wall. Refuses to go to school, did not sleep at night verbally abusive, few epsiodes of physical aggression towards property. Screaming. Parent felt threatened.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343424-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	09-Mar-2009	09-Mar-2009	0	03-Apr-2009	06-Apr-2009	FR	WAES0903USA05564	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, No reaction on previous exposure to drug

Symptom Text: Case received from the Health Authorities through a nurse on 26-MAR-2009. A 12 year old female patient received the first dose of GARDASIL (batch number not reported) via intramuscular route on 09-MAR-2009. 20 minutes later the patient experienced convulsion described as momentary therefore the patient had recovered in a few minutes. There were no previous reactions to the same drug. There was no re-challenge. There were no previous reactions to other drugs. Convulsion was reported as an other important medical event. The case was closed. No further information is available. Other business partner numbers include E2009-02743.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343425-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Mar-2009	10-Mar-2009	0	03-Apr-2009	06-Apr-2009	FR	WAES0903USA05568	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0779X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Case received from the Health Authorities on 26-MAR-2009. A 16 year old female patient with strawberries allergy received a dose of GARDASIL (batch number: NJ32820, lot #: 0779X) via intramuscular route on 10-MAR-2009. On 10-MAR-2009, the patient experienced convulsion for a few minutes. The patient was sent to the hospital for observation. Previous adverse reactions to any other drug was unknown. Convulsion was reported as an other important medical event. The case was closed. Other business partner numbers include E2009-02738. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Fruit allergy

Prex Vax Illns:

Vaers Id: **343427-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Oct-2008	21-Oct-2008	0	03-Apr-2009	06-Apr-2009	FR	WAES0903USA05579	06-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Facial palsy, Muscle spasms, Pain

Symptom Text: Information has been received from a health authority concerning a 17 year old female who on 21-OCT-2008 was vaccinated with her first dose of GARDASIL (lot number, route and site not reported). Approximately 2 hours p.v. the patient developed cramps of the whole day. The patient was hospitalized on unspecified date for 4 weeks. She was discharged on 11-NOV-2008 (unclear documentation whether hospitalization was due to the events). On 23-JAN-2009 the patient developed bell's palsy and was hospitalized on 23-JAN-2009, several investigations (not otherwise specified) were carried out but didn't reveal pathological findings. The patient also reported severe pain (localization and start date not reported). The patient has not recovered at the time of reporting. Other business partner numbers included E2009-02558. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343462-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	19-Mar-2009	19-Mar-2009	0	03-Apr-2009	06-Apr-2009	CA		27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Immediate post-injection reaction, Pain in extremity, Syncope

Symptom Text: Patient fainted for a few seconds after that patient had major headache, in addition patient pain on upper right arm.

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **343494-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Sep-2008	18-Sep-2008	15	03-Apr-2009	06-Apr-2009	IL		13-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2570AA		Left arm	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Generalised non-convulsive epilepsy, Headache, Speech disorder, Staring, Tremor, Unresponsive to stimuli

Symptom Text: approx two weeks after my daughter got the 1st Gardisil vaccine shot she started having seizures, she has no family history of seizures and has always been a healthy person. she is now on medication to help control the seizures (keppra)500 mg in the morning and 1000 mg at night. 4/8/09 neuro consults received dated 12/30/2008 and 1/20/2009. Pt in for evaluation of ? seizures following multiple episodes of shaking of left arm, staring and unresponsiveness. Episodes first began in late summer 2008 which consited of just arm shaking lasting less than a minute. In 11/2008 pt c/o H/A and parent noticed pt with L arm shaking, dropped the object pt was holding, staring and unresponsive. Pt reports awareness of event but was unable to speak. Resolved after approx 1 minute. In early 12/2008 pt found apparently sleeping on bathroom floor. Slept 2 hrs after event. Sent for EEG which was abnormal and c/w non-convulsive primary generalized epilepsy. F/U 1/20/09 with continued episodes. In addition, pt again found on BR floor apparently sleeping. Started on Keppra although unclear if episodes are seizures.

Other Meds:

Lab Data: My daughter has received cat scans.EEG's and Labs and Diagnostics: EEG abnormal x 2. Brain MRI WNL. Head CT WNL.

History: PMH: 36 wk premie. Family hx of seizures in paternal aunt.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343537-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	10-Oct-2008	Unknown		06-Apr-2009	07-Apr-2009	FR	WAES0903AUS00032	07-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0582U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Condition aggravated, Juvenile arthritis, Oropharyngeal pain, Respiratory tract infection, Rhinorrhoea

Symptom Text: Information has been received from a physician via CSL as part of a business agreement (manufacturer control # CSL 2009 02 23 JV1) concerning a female with polyarticular juvenile arthritis who was vaccinated with GARDASIL. Subsequently the patient experienced a flare of polyarticular juvenile arthritis. The patient is part of a trial conducted by a children's hospital and a flare was defined as more than 40% increase in swollen joint count and a more than 40% increase in patient global assessment. It was reported that an increase in three of six criterion is equivalent to a flare. Follow up information was received from a the physician on 26-MAR-2009 concerning an 18 year old female with no allergies, no adverse experiences following previous vaccination and with osteopenia and nausea secondary to methotrexate and on long term treatment for polyarticular juvenile arthritis, who on 10-OCT-2008 was vaccinated on the left deltoid with the first dose of GARDASIL (Batch J2299, Lot No. 657874/0582U, Expiry date 26-FEB-2010). Concomitant therapy included methotrexate, MOBIC, ondansetron, calcium (unspecified) and calcitriol. The patient developed a respiratory tract infection a few days post immunisation described as sore throat, runny nose and more pain on the joints of the hands. On 15-OCT-2008 the patient experienced a minor flare of arthritis activity. Clinically there was increased activity in several small hand joints but no increase in inflammatory markers. The patient was treated with 2 weeks of oral prednisone with full resolution of symptoms. The reporting physician considered that the minor flare of arthritis activity could be attributed to interrcurrent infection or immunisation. The adverse event of minor flare of arthritis activity was considered to be an other important medical event by the reporting physician. Additional information is not expected.

Other Meds: calcitriol; calcium (unspecified); meloxicam; methotrexate; ondansetron

Lab Data: Unknown

History:

Prex Illness: Polyarticular juvenile rheumatoid arthritis, acute; Arthritis; Nausea; Osteopenia

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343557-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Mar-2009	23-Mar-2009	0	06-Apr-2009	08-Apr-2009	HI		27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1423Y	1	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyskinesia, Pallor, Syncope

Symptom Text: Syncope 5 minutes after HPV (GARDASIL) vaccine lasted about 1 minute with L arm jerking X 3 sec pale looking referred to ER. BP 100/80, HR 78, RR 18, O2 sat 97%.

Other Meds:

Lab Data: EKG-WNL, Accucheck 99. ER Labs: CBC Normal, BMP normal except glucose 192

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 343581-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Nov-2008	18-Nov-2008	7	06-Apr-2009	08-Apr-2009	CT		21-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0575X	2	Left arm	Intramuscular	
FLU	SANOFI PASTEUR	U2756AA	2	Left arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B029AA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2726AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Asthma, Atopy, Back pain, Body temperature increased, Cough, Ear pain, Headache, Joint effusion, Joint swelling, Lymph node palpable, Nasal congestion, Oropharyngeal pain, Pharyngeal erythema, Pharyngitis, Presyncope, Respiratory tract congestion, Rhinorrhoea, Sinusitis

Symptom Text: swelling pain of both knees. 4/13/09 MR and vax info received from PCP. In for 14 yr WCC with normal exam 11/11/08. Vax given. Returned 12/22/08 with c/o several day hx of cough, runny nose, ear pain, chest congestion and sore throat. PE (+) for red throat, stuffy nose, few small nodes. Assess: Asthma. Pharyngitis. Returned 2/12/09 with c/o sore throat and cough, H/A, presyncope. PE (+) for T=101.5'F, nasal congestion, pharyngeal erythema, shiners. Assess: Sinusitis. Fever. Pharyngitis. Returned 2/17/09 with same c/o as 2/12/09. Additionally, back pain with coughing. PE (+) for red throat, few nodes and stuffy nose. Sent for CXR. Assess: Asthma. Returned 3/30/09 with c/o knee pain and swelling x 5 months. No injury other than foot injury prior to that. PE (+) for swollen knees with fluid in joints. Assess: joint pain and swelling.

Other Meds: Advair, Albuterol Singulair

Lab Data: CBC, diff, sed rate, ANA ASO RF Lyme all normal. Labs: Rapid strep (-). Flu (-) CXR WNL. MCV 29.3 (H). RF (-). ESR 5. ASO 165 (H). ANA (-).

History: PMH: asthma. foot injury

Prex Illness: Asthma, Foot injury

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343586-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	31-Mar-2009	01-Apr-2009	1	06-Apr-2009	08-Apr-2009	AL	AL0905	08-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB24TAA	0	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0333X	1	Right arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0653X	1	Left arm	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB452AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Induration, Skin warm, Swelling, Tenderness

Symptom Text: Varicella given 3/31/09 approx. 10:30am. Pt. noticed it was tender an swollen 4/01/09 approx. 6:30 pm. 4/02/09 area red, raised, hot to touch & increased tenderness. Red area approx. 60mm x 50mm & area at induration apprx. 40mm x 25mm. Pt. temp. 97.3 No diff. breathing, shortness fo breath or other problems. Referred to MD for evaluation.

Other Meds:

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343591-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Jul-2007	17-Sep-2007	59	06-Apr-2009	08-Apr-2009	OK		21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0515U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Alopecia, Cough, Ear pain, Erythema, Fatigue, Headache, Mononucleosis syndrome, Oropharyngeal pain, Pharyngitis, Upper respiratory tract infection

Symptom Text: Unexplained sudden and severe hair loss resulting in many visits to dermatologists over the last year and a half. This has resulted in meds prescribed by two dermatologists without significant results. Our daughter has also experienced several episodes of mono-like symptoms resulting in visits to the campus doctor and local doctor with negative test results. She continues to be extremely fatigued even when well-rested and has unexplainable headaches. 4/8/09 PCP notes received. Pt seen 3/23/07 for OV with c/o planter's wart on foot, anxiety r/t school work and difficulty focusing, keratosis on arms and allergy sx. PE (+) for allergic facies, boggy nares with some throat drainage. Sent for derm consult and allergy meds prescribed. 1st HPV vax given. Seen again 7/6/07 with c/o URI with ear pain, cough and sore throat. Assess: Nasal Pharyngitis. Per TC with MD-not aware of any AE from vax. Has not been seen since 7/6/07 visit. 4/14/09 Derm consults received. Pt presented 6/19/08 with c/o warts: thumb and plantar, and 8 month hx of hair loss. Generalized hair thinning noted. Warts removed and shampoo rx. Returned 7/10/08 for wart and mole check. F/U 3/19/09 for warts, acne and hair loss from the scalp. PE (+) for circular patches of hair loss with moderate flaking and minimal erythema of the scalp.

Other Meds: Clobex and luxiq foam for hair loss. If no results, the next step is cortisone shots into the scalp.

Lab Data: Continuous and ongoing lab/blood work to determine cause of fatigue, mono-like illnesses and extreme hair loss. Labs: CBC WNL. TSH 1.87 (N)

History: Hives when taking meds containing red dye. PMH: Planter's wart on foot, anxiety r/t school work and difficulty focusing, keratosis on arms and allergy sx. Mono-summer 2007

Prex Illness: None

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343612-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Nov-2008	26-Nov-2008	25	07-Apr-2009	08-Apr-2009	FR	WAES0903AUS00084	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Autopsy, Hypertrophic cardiomyopathy, Sudden death

Symptom Text: Information has been received from a physician, via agency, as part of a business agreement (manufacturer control No. GARD 2009 03 27 LS2), concerning a 23 year old female who in November 2008 was vaccinated with GARDASIL. Concomitant therapy included hormonal contraceptives (unspecified) in the form of a vaginal contraceptive ring. On 26-NOV-2008, a few days after vaccination with GARDASIL the patient died suddenly. The cause of death was attributed to hypertrophic cardiomyopathy. It was reported that an autopsy was performed (report not provided). A few days prior to her death, the patient had visited her physician to discuss contraception. She was not taking any other drugs other than contraception and had no underlying conditions or hereditary conditions. The reporter considered that hypertrophic cardiomyopathy was not related to therapy with GARDASIL, stating "I'm sure it was not directly related". Additional information has been requested.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Unknown

History:

Prex Illness: Contraception

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343617-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Apr-2008	19-May-2008	20	07-Apr-2009	08-Apr-2009	FR	WAES0809USA03978	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received via Sanofi Pasteur MSD. Case initially received on 04-Aug-08. It was reported by a gynecologist, for the Pregnancy Registry for GARDASIL, concerning a 16 year-old female with a history of pain in arm and thorax after the first dose of GARDASIL (WAES# 0803USA03005) who was vaccinated with a second dose of GARDASIL (lot no., route, injection site not reported) on 29-APR-08. At the time of reporting the patient was pregnant (gestation week 11), expected date of delivery on 24-FEB-09. So far, the patient had not experienced any adverse event. Follow-up information was received by pregnancy follow-up reporting form on 24-MAR-2009 and by phone call with the gynecologist on 27-MAR-2009. Upon receipt of new information, this case was upgraded to serious: Abortion was induced on the patient's wish in the 11th week of pregnancy. Up to then the pregnancy was timely and without pathologies. Case closed. Other business partner number includes E2008-07430.

Other Meds: Unknown

Lab Data: Unknown

History: Pain in arm; chest pain

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343618-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Mar-2009	Unknown		07-Apr-2009	08-Apr-2009	FR	WAES0904MEX00002	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning an 18 year old female with history of forceps delivery who in 2009 was vaccinated with GARDASIL first dose and in approximately March-2009 second dose. In 2009, the patient experienced seizures (dates, characteristics, duration and treatment not reported). The outcome and causality were not provided. Upon internal review seizure was considered as other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Forceps delivery

Prex Illness:

Prex Vax Illns:

Vaers Id: **343619-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	01-Jan-2009	09-Feb-2009	39	07-Apr-2009	08-Apr-2009	FR	WAES0904USA00113	08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Demyelination

Symptom Text: Information has been received from the health authority on 01-APR-2009 under reference number NC20090132. A 26 year old female patient received an injection of GARDASIL (Batch and lot number not reported) in October 2008 and another dose of GARDASIL in January 2009, both doses were administered via intramuscular route. On 09-FEB-2009, the patient presented with a flare of demyelination. At the time of reporting, the patient had recovered. Evolution was favorable. She was giving cortico therapy. The patient had medical history of transitional multiple sclerosis of which first manifestation could date to the adolescence period when she presented an episode of hypoaesthesia of fingers of both hands during several months and resolved after magnesium treatment. Her mother had post partum dysthyroidism. Her sister had auto immune dermatomyositis since the age of 11. The health authorities assessed the causal relationship between the reported reaction and vaccination as doubtful (C1 S1 I1) to the foreign method assessment. Demyelination was considered to be an other important medical event. Other business partner numbers included: E2009-02887. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Hypoaesthesia

Prex Illness: Multiple sclerosis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343620-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	18-Jun-2008	Unknown		07-Apr-2009	08-Apr-2009	--	WAES0904USA00158	27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Drug exposure during pregnancy, Induced labour, Pre-eclampsia, Premature labour

Symptom Text: Information has been received from a Nurse Practitioner for the Pregnancy Registry for GARDASIL concerning an 18 year old female patient with no drugs reactions or allergies who on 11-APR-2008 was vaccinated with a first dose of GARDASIL (Lot# not reported). On 18-JUN-2008 she received third dose of GARDASIL (Lot# not reported). On 01-APR-2009 she received third dose of GARDASIL (Lot# not reported). There was no concomitant medication. When the patient received first and second dose of vaccine she became pregnant. The patient experienced pre-eclampsia and the physician had to induce delivery and used magnesium sulfate during labor. The patient was hospitalized. Delivery was at 36 weeks and 4 days. The patient had a healthy baby boy on 27-JAN-2009. In July - 2008 Cervical smear was performed and showed normal results. The patient sought medical attention was at office. The Nurse practitioner considered pre-eclampsia and premature to be other important medical events and life threatening. Additional information has been requested.

Other Meds: None

Lab Data: cervical smear, 07/??/08, normal

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343632-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	08-Jul-2008	08-Jul-2008	0	07-Apr-2009	08-Apr-2009	MA		08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: 1st GUARDISIL vaccine administered 7/8/08 pt report hives all over body within hours of injection lasting 3-4 days. Tx with BENADRYL.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343638-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	18-Oct-2007	18-Oct-2007	0	07-Apr-2009	09-Apr-2009	PA		10-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	DT	CONNAUGHT LABORATORIES	U1956CA	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0524U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncopal event.

Other Meds:

Lab Data:

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343645-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Dec-2008	21-Feb-2009	80	07-Apr-2009	08-Apr-2009	NY		08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0572X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Protracted headache

Other Meds:

Lab Data: NLG; CBC; metabolic profile; Lyme antibody

History:

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343651-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	31-Mar-2009	31-Mar-2009	0	07-Apr-2009	09-Apr-2009	KY		10-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cyanosis, Disorientation, Dyskinesia, Gaze palsy, Musculoskeletal stiffness, Pallor

Symptom Text: Immediately following injection pt. became stiff, eyes rolled in back of head, bluish + orange around mouth, + pt. was having jerking motions of entire body. Pt. lowered to floor protected from self injury. 15 seconds elapsed from beginning to end of episode. Pt sat up A & D x 4, skin pale W/D. RC 20 O2 Sat 97% P: 76 B/P 98/56.

Other Meds: Claritin

Lab Data: Blood Sugar 108/Pt. to local ER for precautionary check.

History: Hay Fever

Prex Illness:

Prex Vax Illns:

Vaers Id: **343673-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	31-Mar-2009	02-Apr-2009	2	07-Apr-2009	08-Apr-2009	KY		08-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abnormal behaviour, Agitation, Anger

Symptom Text: Received 3rd dose of Gardasil on 3/31/09 On 4/2/09 she had an episode where she became very angry and agitated and had behavior not like her normal behavior. Mom said better after that day but concerned behavior related to vaccine

Other Meds: Brevoxyl and Duac

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **343699-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Feb-2008	04-Feb-2008	0	08-Apr-2009	09-Apr-2009	KS	WAES0810USA00442	21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cervical dysplasia, Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a nurse for the pregnancy registry for HPV concerning a female with a history of vulvar condyloma with Trichloroacetic acid (TCA), treatment who was already pregnant when she was vaccinated IM with GARDASIL on 04-FEB-2008. The patient sought unspecified medical attention. At the time of this report, the patient was 9 months pregnant. Follow up information has been received from the physician reporting that other medication during this pregnancy included Prenate Advance and Meningitis (MCVH) immunization on 04-FEB-2008. The patient had a possible kidney stone in summer of 2007 and smoked marijuana during the early pregnancy. On 11-MAR-2008, the patient had a PAP exam which was abnormal/atypical squamous cells of undetermined significance. The patient was also screened for cystic fibrosis for which she was a negative carrier. On 17-MAR-2008, the patient had an ultrasound because she was unsure of her last menstrual period and it was normal, the EDC was 29-SEP-2008. On 21-APR-2008, the patient had a maternal serum alfa-fetoprotein test (AFP) which was normal. On 22-JUL-2008, the patient had sonogram for size less than dates which was normal. On 19-SEP-2008, the patient had another sonogram for size greater than dates which revealed fetal prominence of left renal pelvis. On 04-OCT-2008, the patient delivered a normal male baby vaginally. The baby had the cord wrapped around the left shoulder but there was not a complication. Pediatric medical records were received and reviewed and the following experiences were identified: On 04-OCT-2008 (baby's date of birth the baby's birthweight: 3684 grams (8 lbs, 2 ozs), length was 20.5 inches, head circumference was 35 1/2, apgars: 7/9, temperature: 99.5, Pulse: 144, respiratory rate: 52. The baby was given 1mg of PHYTONADIONE IM and ERYTHROMYCIN ointment to eyes. On examination he was noted to have molding head, bruising and caput left caephalohematoma, and mongolian spot. His skin was pink and he had some acrocyanosis. He passed his hearing

Other Meds: PRENATE; phytonadione

Lab Data: Ultrasound, 03/17/08, normal; Ultrasound 07/22/08, normal; ultrasound, 09/19/08, normal; Chest X-ray, 10/04?/08, (Baby)- streaky markings bilaterally possibly consistent with wet lung or infiltrate; chest X-ray, 10/06/08, (Baby) - uncha

History: Kidney stone

Prex Illness: Pregnancy NOS (LMP = Unknown); Vulval wart; Prenatal care; Cannabis abuse

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343700-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		08-Apr-2009	09-Apr-2009	--	WAES0904USA00519	09-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Basedows disease, Facial palsy

Symptom Text: Information has been received via an internet blog from a consumer concerning her daughter who was vaccinated with a dose of GARDASIL. In the middle of the patient's series she "had a bout of Bell's palsy that paralyzed the right side of her face". Two months later, patient was diagnosed with Grave's disease. The doctor says an immune reaction to something he can't determine is most likely responsible. Upon internal review, a bout of Bell's palsy and Grave's disease were considered to be other important medical events. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **343701-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		08-Apr-2009	09-Apr-2009	MA	WAES0904USA00310	09-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dysarthria, Flank pain, Hypoaesthesia, Local reaction, Loss of consciousness, Pain, Paraesthesia, Paralysis, Rash, Tenderness

Symptom Text: Information has been received from via the physician of a patient whose mother found the current case online. The current case concerns a female patient who on an unspecified date was vaccinated with a dose of GARDASIL. The mother of the other patient stated that the current patient had the "exact same problem" as her daughter: minor localized tenderness, developed a rash, dysarthria without other seizure symptoms, had loss of consciousness, complained of numbness and tingling, pain in side, burning pain, paralysis and stroke-like symptoms. The patient sought a specialist. Attempts are being made to verify the existence of an identifiable patient and reporter. Upon internal review, paralysis and stroke-like symptoms were considered to be other important medical events. This is one of several cases from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343703-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Mar-2009	25-Mar-2009	9	08-Apr-2009	09-Apr-2009	FR	WAES0904USA00215	09-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Fatigue, Headache, Hepatitis, Influenza, Jaundice, Myalgia, Photophobia

Symptom Text: Case received from a general practitioner on 01-APR-2009. An 18 year old female patient with no relevant medical history reported received the first dose of GARDASIL (batch number not reported) on 16-MAR-2009. On 25-MAR-2009 the patient experienced muscular pain, fatigue, cephalgia and photophobia. She was hospitalized (unspecified date). As per the physician of the hospital it was an adverse effect linked to the vaccination. On 27-MAR-2009 they diagnosed a flu syndrome. On 31-MAR-2009 she had a subicterus. Biological work-up (unspecified date) revealed increased bilirubin, SGOT at 900, transaminases at 1000, diagnosis was a hepatitis. At time of reporting the patient had not recovered. Other business partner numbers include E200902894.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 31Mar09, transanminases at 1000; serum aspartate aminotransferase, 31Mar09, 900; total serum bilirubin, 31Mar09, increased

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **343704-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		08-Apr-2009	09-Apr-2009	--	WAES0904USA00203	09-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Convulsion

Symptom Text: Information has been received from a physician concerning a 17 year old female who was vaccinated with her second dose of GARDASIL, 0.5 mL, IM. The physician stated that the patient's mother had contacted him and questioned him about the vaccine. It was reported that the patient had been having seizures "almost every day" since getting the second dose. She had been "to a lot of specialists" who had not been able to make a diagnosis. The reporter was not the patient's physician. It was unknown if there were any seizures after the first shot or if they only appeared after it was reintroduced. The patient would not be completing the series. The patient had not been able to go to school because of this experience. As of 01-APR-2009 the patient had not recovered. Laboratory diagnostic studies performed included "all kinds of different tests" (results not provided). Upon internal review the patient's seizure was considered to be an Other Important Medical Event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343705-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		08-Apr-2009	09-Apr-2009	FR	WAES0904PHL00002	09-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Multiple sclerosis

Symptom Text: Information has been received from a female who was vaccinated with GARDASIL. The initial reporter's patient received information from a colleague regarding another female who was vaccinated with GARDASIL and subsequently experienced acute disseminated encephalomyelitis or multiple sclerosis. Upon internal medical review, multiple sclerosis is considered an important medical event. No further information is available. Attempts are being made to verify the existence of an identifiable patient and reporter.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **343706-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Nov-2008	05-Nov-2008	2	08-Apr-2009	09-Apr-2009	FR	WAES0903USA05576	09-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0569U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Asthenia, Fatigue, Headache, Muscular weakness, Nausea, Presyncope

Symptom Text: Information has been received from a foreign health authority (reference number ES-AGEMED-289273439) concerning a 14 year-old female with no relevant history who was administered on 03-NOV-2008 the second dose of GARDASIL (lot number 0569U, batch number NG39340) by intramuscular route (site of administration not reported). On the 05-NOV-2008 the patient began with nausea (which ceased), asthenia, fatigue, muscular weakness and cephalgias. Currently the patient presents cephalgia, asthenia and muscular weakness, especially in lower limbs, the patient is unable to do sports, also the patient easily gets fatigue. It is reported that upon hospital admission (admission and discharge dates not reported), the patient presented a presyncopal clinical picture. The patient has recovered from the presyncopal clinical picture on an unspecified date. Electrocardiogram, echocardiogram and a brain MRI were performed on 2008 (exact date not reported) with normal results. Other business numbers include E2009-02761. No further information has been reported.

Other Meds: Unknown

Lab Data: electrocardiogram, ??08, normal; magnetic resonance imaging, ??08, brain-normal; echocardiography, ??08, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **343709-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Nov-2008	18-Nov-2008	1	08-Apr-2009	09-Apr-2009	FR	WAES0812USA00315	09-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1526U	1	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthma, Condition aggravated, No reaction on previous exposure to drug

Symptom Text: Information has been received from a general practitioner on 21-NOV-2008. A 14-year-old female patient with medical history of asthma and who had well tolerated the first dose of GARDASIL (unspecified date) received the second dose of GARDASIL (dose, batch number, route and lot number not reported) in November 2008. 48 hours later the patient experienced a crisis of asthma with difficult recovery. The patient had recovered in a few days. There was no other information. Follow-up information has been received reporting that the patient's mother had eczema. The patient received the vaccine (batch#NH36020, lot# 1526U) via intramuscular route in her left deltoid on 17-NOV-2008. The patient presented with 2 crisis of asthma of moderate intensity within 24 hours (previously reported as 48 hours). She had recovered on an unspecified date. There was no local reaction. She had no concomitant treatment. She had corrective treatment with VENTOLINE which was not very effective therefore the patient also had cortisone orally and antihistamines. The physician suggested her to have antihistamines before the next injection of GARDASIL as a precautionary principle. Follow up information has been received through a letter on 02-APR-2009. Case was upgraded to serious. The patient received a third dose of GARDASIL (dose, batch number, route and lot number not reported) on an unspecified date. 24 hours after, she experienced a crisis of asthma which led her to a short hospitalization. It is noteworthy that she had been given antihistamines the day before the injection. According to the reporter, the crisis of asthma had been provoked by the injection. As the time of reporting, the outcome was not specified. Other business partner numbers include E2008-10845. No further information is available.

Other Meds: cough, cold and flu therapies (unspecif

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **343715-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Nov-2007	01-Mar-2008	95	08-Apr-2009	09-Apr-2009	--	WAES0805USA03810	09-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a nurse practitioner, for the Pregnancy Registry for GARDASIL, concerning a 15 year old female with iron deficiency anaemia and no known drug allergies who on 27-NOV-2007 was vaccinated intramuscularly with a 0.5 ml first dose of GARDASIL (Lot# 658554/0928U). On 16-MAY-2008, the patient was vaccinated intramuscularly with a 0.5 ml second dose of GARDASIL (Lot# 659964/1978U). The patient was asked if she was pregnant before each dose which she denied. After receiving the second dose, the patient said she might be pregnant. Blood work for pregnancy in the office confirmed the pregnancy (LMP March 2008). There was no concomitant medication. Unspecified medical attention was sought in the office. The patient's outcome is unknown. Follow-up information was received which reported that the patient terminated pregnancy. A phone call was made on 06-APR-2009 but no further information obtained. Upon internal review, the patient terminated pregnancy was considered to be other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: Serum beta-human, 05/16/08, pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 3/1/2008); Iron deficiency anaemia

Prex Vax Illns:

Vaers Id: 343716-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	12-Feb-2008	12-Feb-2008	0	08-Apr-2009	09-Apr-2009	CA	WAES0803USA00673	09-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Incisional drainage, Labour complication, Wound

Symptom Text: Information has been received from a physician assistant concerning a 24 year old pregnant female with a history of penicillin allergy who on 12-FEB-2008 was vaccinated IM with the first 0.5 mL dose of GARDASIL (lot # 658556/1060U). Concomitant therapy included vitamins (unspecified). On 26-FEB-2008 the patient was examined in the doctor's office and the pregnancy was confirmed by urine pregnancy test. The patient was referred to an obstetrician for care. No problems were reported. The patient's status is unknown. Follow up information received on 13-MAR-2008. It was reported that the patient a female with a history of depression, upper endoscopy for pill stuck in her throat in 2004, and ex-smoker was given a dose of GARDASIL (lot # 658556/1060U) and she knew she was pregnant. The expected delivery date is 26-OCT-2008. It was also reported that the patient was treated with ZOLOFT for depression and that she stopped therapy with ZOLOFT in August 2007. The patient stopped smoking on 26-FEB-2008. There were no previous pregnancies, full term deliveries, pre-term deliveries, spontaneous abortion, elective terminations or fetal defects. Follow up information received from an outcome pregnancy questionnaire on 02-APR-2009 stated that the patient's husband had Methicillin Resistant Staphylococcus aureus (MRSA). Concomitant medication includes prenatal vitamins started on 26-FEB-2008. The patient had no complications during pregnancy and delivered a normal female liveborn on 04-NOV-2008 at 40 6/7 weeks from LMP, who had 7 pounds 12 oz weight and 21 inches length. Apgar score was 4/8/9 and head circumference was 13 inches. The patient had a C/section due to failure to progress. The patient had a wound and an incision and drainage was performed at the physician's office. The patient was prescribed VICODIN or TYLENOL for pain after the incision and drainage of the wound. Laboratories studies performed include a glucose tolerance test (GTT) on 01-AUG-2008, 83 mg/dl. Follow up information received on 03-A

Other Meds: vitamins (unspecified)

Lab Data: Urine beta-human, 02/26/08, positive; Glucose tolerance test, 08/01/08, 83mg/d

History: PENICILLIN allergy; depression; Endoscopy; Ex-smoker

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343729-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	23-Mar-2009	23-Mar-2009	0	08-Apr-2009	09-Apr-2009	FR	WAES0904KOR00004	09-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Injection site pain, Loss of consciousness, Pyrexia

Symptom Text: Information has been received from a physician concerning a female who on 23-MAR-2009 was vaccinated with the first dose of GARDASIL. After the first vaccination of GARDASIL on 23-MAR-2009 the patient experienced injection site pain and fever on a same day. The patient felt her condition was bad. The patient's fever is persisting for one week. On 01-APR-2009 the patient experienced loss of consciousness and was hospitalized via ER. The recovery status of injection site pain, fever and loss of consciousness was not reported so far. The physician reported that the causality between these symptoms and GARDASIL was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343730-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		08-Apr-2009	09-Apr-2009	FR	WAES0904USA00228	09-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Angiopathy, Chest pain

Symptom Text: Information has been received from a Health Authority (reference number 091049) concerning a female patient who on an unspecified date was vaccinated with GARDASIL (lot number, site and route not reported). On an unspecified date, the patient experienced chest pain and vascular disorder other (causalities not reported). The events were considered as other medically important events. This case was one out of two similar cases reported by the same reporter. See linked E2008-11961 (WAES # 0812USA05352). Other business partner numbers include: E2009-02736. No further information is available. The case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343739-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	30-Jan-2009	30-Jan-2009	0	08-Apr-2009	15-Apr-2009	CA		15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Palpitations, Vomiting

Symptom Text: 1st GARDASIL 1-30-09 - At 2nd appt for GARDASIL 4-2-09 pt. described symptoms from first IZ admin. stated had severe headache with vomiting and heart palpitations the evening after IZ administration.

Other Meds: None

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343756-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	31-Mar-2009	01-Apr-2009	1	08-Apr-2009	09-Apr-2009	TX		01-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Left arm	Intramuscular	HPV4

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dysstasia, Fatigue, Gait disturbance, Hypersensitivity, Lymph node pain, Lymphadenopathy, Malaise, Pain, Pelvic pain

Symptom Text: I had the HPV vaccine Gardisil on March 31, 2009. The next day I was feeling soar and tired, but did not think anything about it. By Friday evening (April 3) I was still feeling tired, my body was aching, in general I did not feel well. I also noticed that my lymph nodes in me neck and groin were very swollen and very painful. This continued throughout the weekend and did not get better. It became very painful to sit, stand and walk. Pain radiated through my pelvis, so I went to an urgent care clinic on Monday March 6th. There I went through a pelvic exam, palpation of my swollen glands, lab work and an ultrasound. I recieved a shot of rochephin and rocephin to take at home for 10 days, in case there was some kind of infection. I have had no fever. My sonogram was normal, other than showing my swollen glands. Labs are not back yet, but I believe they will be normal. However I still have painful swollen neck and groin glands. The groin glands are bothering me the most. 4/13/09-records received for DOS 9/6/08-C/O allergies. 4/6/09-C/O swollen glands and not feeling very good.

Other Meds: I take lo estrin 24 daily, No other daily home medications, No other medications were taken that week, I do recieve allergy shots nut skipped the week of March 31, 2009

Lab Data: Pelvic exam- noramal, palpation of swollen glands, labds including a cbc- results not back, pelvic sonogram- normal, other than swollen glands

History: Seasonal allergies, have been reciebing allergy shots weekly for 3 1/2 years, No allergies to yeast. I have never had a reaction to any vaccine before this one 4/13/09-records received-PMH:migraines.

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343764-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	19-Dec-2008	28-Feb-2009	71	08-Apr-2009	10-Apr-2009	OR		28-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	C3032AA	5	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1311X	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB258AA	1	Left arm	Intramuscular	

Seriousness: EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain, Biopsy bone marrow, Blood bilirubin increased, Diarrhoea, Fatigue, Hepatic enzyme abnormal, Hepatic failure, Hepatitis, Hepatitis viral test, Hepatomegaly, Jaundice, Pharyngitis, Rash erythematous, Rash papular, Rash pruritic, Splenomegaly, Urine analysis abnormal, Urine bilirubin increased, Urobilin urine present, Vomiting

Symptom Text: At time and the months up to March there was no local or systemic reaction to any of the Immunizations given on 12/19/08. On March 3 patient came to the office with s/sx of fatigue, abd pain,and jaundice. UA done showed 3 plus Bilirubin and 2 plus Urobilirubin. She had hepatomegaly and splenomegaly and pharyngitis. Labs revealed Epstein Barr Positive IgG antibody which may indicate a past infection-mono. Patient returned to the clinic with severe jaundice, Negative Hepatitis panel with abnormal Hepatic levels. Was consulted with Pediatric Infectious Disease Specialist, repeat labs showed increases in liver enzymes and bilirubin level and US showed enlarged grossly thickened gallblader wall, mild hepatomegaly and mod splenomegaly. There was no evidence of bilary duct obstruction or pancreatic abnormality noted. Hospital consulted and patient was admitted where her hepatic levels continued to rise as well as her INR. She was at hospital for almost three weeks and a bone marrow was done. She was discharged 4/5/2009 and her hepatic functions and INR are continuing to be monitered. This form is filled out at the request of physicians in the event the vaccines contributed to the illness. We can send copies of hospital visit and labs if needed. Dr. is calling this "seronegative hepatitis". 4/16/09-records received-for DOS 3/17-4/5/09-DC DX:DC DX: Liver failure. Rash. Presented with sudden onset of emesis,l abdominal pain, diarrhea and jaundice 3 weeks prior to admission. Developed erthematous pruritic papular rash.

Other Meds: none

Lab Data: May fax if needed copies of labs and reports 4/16/09-records received-Transaminases elevated. Needle biospy showed acute hepatitis without necrosis. Hepatitis differential diagnosis is infectious versus autoimmune. Skin biopsy showed slig

History: None known

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343776-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	08-Apr-2009	08-Apr-2009	0	08-Apr-2009	15-Apr-2009	CA		15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Syncope

Symptom Text: Pt had syncopal episode after GARDASIL. Did not fall, guided to chair by me & aroused with ammonia & cold wet cloth. No seizure act. Pulse always present. Given water & granola bars

Other Meds: OCP

Lab Data:

History: Has history of fainting

Prex Illness: None

Prex Vax Illns:

Vaers Id: **343777-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	U	Unknown	Unknown		09-Apr-2009	10-Apr-2009	VA	WAES0904USA00201	10-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from a physician concerning an 11 year old patient who was vaccinated with GARDASIL (lot number, route and site not reported). Subsequently the patient died. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **343779-1** **Related reports:** 343779-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	23-Oct-2008	27-Oct-2008	4	09-Apr-2009	10-Apr-2009	FR	WAES0904USA00794	10-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Aphasia, Dizziness, Headache, Heart rate increased, Paraesthesia, Vaccine positive rechallenge

Symptom Text: Case linked to non serious case E2009-02945 (same patient, same reporter, different events). Case received from a physician on 12-MAR-2009. The 13 year old female adolescent received on 23-OCT-2008 the first dose and on 27-NOV-2008 the second dose of GARDASIL (Lot #, batch # and site of administration not reported) IM. Four days after the first vaccination she developed headache, paraesthesia and anomia. The patient has the fear to lose consciousness. No itching, skin reactions, no asthma, no swallowing disorders. She recovered after foot reflex zone massage. A few hours after the second dose was administered on 27-NOV-2008 she developed dizziness and paraesthesia and experienced high pulse rate and anxiety. Again she recovered after foot reflex zone massage. Upon internal review anemia was considered a medically significant event. Other business partner numbers include E2009-02182. No further information is available.

Other Meds: Unknown

Lab Data: Total heartbeat count, high pulse rate

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **343779-2** **Related reports:** 343779-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	23-Oct-2008	27-Nov-2008	35	13-Apr-2009	14-Apr-2009	FR	WAES0904USA01211	14-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Aphasia, Dizziness, Heart rate increased, Paraesthesia, Similar reaction on previous exposure to drug, Vaccine positive rechallenge

Symptom Text: An adolescent female patient (height 140cm, weight 40kg) received on 23-OCT-2008 the first dose (D1) and on 27-NOV-2008 the second dose (D2) of a GARDASIL (batch number, lot number, route and site not reported). A few hours after the second dose administered on 27-NOV-2008 she complained about dizziness, paraesthesia, anomia, high pulse rate and anxiety. Again reflexology was done. At the time of reporting the patient was in a good general condition. No meningism, reaction of the eyes inconspicuous, cursory neurologic status inconspicuous, integument bland. To be noted that the patient experienced headache, paraesthesia and anomia after D1 (WAES#0904USA00794). Upon internal review anomia was considered a medical significant event. Other business partner numbers included E200902945. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 26Feb09, Stabk and Segm. 45.3; basophil count, 26Feb09, 7.3; eosinophil count, 26Feb09, 7.3; lymphocyte count, 26Feb09, 47.4; monocyte count, 26Feb09, 7.3; platelet count, 26Feb09, 294; serum C-reactive protein,

History: Premature baby; Oxygen saturation low; Icterus; Headache; Paraesthesia; Anomia

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343780-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Jan-2009	24-Jan-2009	10	09-Apr-2009	10-Apr-2009	FR	WAES0904USA00764	10-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Epilepsy, No reaction on previous exposure to drug

Symptom Text: Initial information received on 31-APR-2009 from a health care professional regarding a 14 year old female who on 14-JAN-2009 was vaccinated with the third dose of GARDASIL (batch number not reported) route and site not reported. It was reported that 10 days post vaccination, exact date not reported, the patient suffered convulsions and an epileptic seizure. The patient was hospital admitted and was discharged 8-9 days later completely recovered. Previous doses were administered on the 26-JUN-2008 and second dose on the 02-SEP-2008 with no adverse events. No further information reported. Other business partner numbers include E2009-02840.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **343781-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	31-Dec-2007	31-Dec-2007	0	09-Apr-2009	10-Apr-2009	FR	WAES0904USA00763	10-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Activities of daily living impaired, Anorexia, Anxiety, Arrhythmia supraventricular, Asthenia, Dizziness, Eye pain, Headache, Hypotension, Nausea, Ocular hyperaemia, Sinus tachycardia, Syncope, Tachycardia paroxysmal

Symptom Text: Information has been received on 30-MAR-2008 through a company representative from a health care professional concerning an adult female (exact age not reported) had no allergies or toxic habits and had an appendectomy and plastic surgery breast augmentation with implant, who was vaccinated with the first and second and the third dose of GARDASIL vaccine (batch number not reported) on 31-OCT-2007, 31-DEC-2007 and 29-APR-2008 respectively. According to the report sent by one of the doctors, a cardiologist, it was reported that a few months ago, exact date not reported, the patient visited the doctor due to paroxistic tachycardia, dizziness and syncope. The patient reported that these symptoms began months ago. The first syncope episode occurred on the 31-DEC-2008, the day she received the second dose of GARDASIL vaccine. From that day on, the patient presented a varied clinical picture with several symptoms including asthenia, adynamia, nausea, appetite loss, diffuse abdominal pain, hyperemia appeared in both eyes. Several times a fainting sensation and tachycardia had had preceded the hypotension episodes, these occurred while resting or during normal activity, they were not triggered by a stressful situation. She attended the emergency room several times , due to these events, and the patient would often be diagnosed with an anxiety attack, this fact had hidden and delayed the proper diagnosis. According to information sent by the reporter: Physical examination: baseline ECG, echocardiogram, stress test and Holter ECG were all normal. In the arterial pressure Holter test a sustainable hypotension was found. Several ECG were performed during tachycardia and hypotension crisis, sinus tachycardia and some episode of atrial rhythm was registered, atrial rhythm showed a similar frequency to the sinus. The patient was initially attended by ophthalmologist due to the ocular hyperemia and ocular pain. Initially it was thought to be a pheochromocytoma or a similar tumor vs carcinoid. Routine blood tests with hemogram an

Other Meds: Unknown

Lab Data: electrocardiogram, normal; echocardiography, normal; cardiac pharmacological stress test, normal; Holter monitoring, normal; Holter monitoring, arterial pressure Holter test: a sustainable hypotension was found; diagnostic laboratory test,

History: Appendicectomy; Breast cosmetic surgery

Prex Illness:

Prex Vax Illns:

Vaers Id: **343782-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		09-Apr-2009	10-Apr-2009	FR	WAES0904AUS00002	10-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Crepitations, Feeling abnormal, Subcutaneous emphysema, Wrong technique in drug usage process

Symptom Text: Information has been received in a published article concerning a 21 year old female who was vaccinated with GARDASIL. Subsequently, approximately 2 hours after receiving her GARDASIL, the patient presented to a hospital emergency department complaining of a 'funny feeling' in the skin overlying the left deltoid muscle. There were no other symptoms. Physical examination revealed her to be systemically well. There was a small punctum in the mid zone of the skin overlying the left deltoid muscle, with a surrounding zone of crepitus several millimeters in diameter. Neurovascular examination of the affected limb was unremarkable. A diagnosis of subcutaneous emphysema secondary to quadrivalent HPV vaccination was made and the patient was reassured and discharged. Subsequently, the patient's recovery from subcutaneous emphysema secondary to quadrivalent HPV vaccination was uneventful with complete resolution over 3 days. The author concluded that it appeared that subcutaneous emphysema secondary to quadrivalent HPV vaccination was not related to therapy with GARDASIL itself but due to an error in the injection technique. Additional information is not expected. A copy of the published article is attached as further documentation of the patient's experience.

Other Meds: Unknown

Lab Data: Physical examination, systemically well; Neurological examination; neurovascular examination of the affected limb was unremarkable

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 343791-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Mar-2009	13-Mar-2009	1	09-Apr-2009	13-Apr-2009	NE		13-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2683AA	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cyanosis, Fatigue, Lethargy, Loss of consciousness, Pallor, Sensation of heaviness, Similar reaction on previous exposure to drug, Syncope, Vaccine positive rechallenge

Symptom Text: Patient is a 16-year-old female who presents today with mother. The patient states she was with her mom earlier getting her prom dress fitted when she blacked out. Her mom states her face when pale and her lips turned blue in color. The patient was out for about 2 minutes. She did not fall to the floor, because her mom was able to hold her up. The patient did stated that she had her knees locked while she was standing. She did say everything went black. When she woke up she did remember where she was at. She was very tired upon waking up and is still very lethargic. She did receive a GARDASIL shot in her right shoulder yesterday and meningitis shot in her left shoulder yesterday. Patient did have a similar episode back in November, the day after her first GARDASIL shot was given. The patient denies any vision changes, headache, nausea, chest pain, shortness of breath, bladder or bowel changes. She states she is still very tired and her legs feel very heavy. 4/10/09 ER record received for DOS 3/13-14/2009 with D/C DX: Syncopal event 2' to Gardasil. Depression. Pt presented after episode where pt had episode of pallor then LOC with lip cyanosis. Similar event after receiving 1st Gardasil vax. PE (+) for pallor and leg heaviness with difficulty lifting legs. Admitted for observation. D/C'd in am after ambulating.

Other Meds: Unknown

Lab Data: EKG-Normal limits. Labs and Diagnostics: Head CT WNL. CBC WNL. Chem WNL except CO2 low at 20.2. EKG WNL.

History: None. PMH: Febrile seizures. On OCs

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343794-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Apr-2009	01-Apr-2009	0	09-Apr-2009	15-Apr-2009	PA		27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2668AA	0	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0570X	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pyrexia, Vomiting

Symptom Text: 24 hours dizziness, vomiting low grade fever resolved spontaneously.

Other Meds:

Lab Data:

History: Minor syncopal event with vaccination GARDASIL 10/18/07

Prex Illness:

Prex Vax Illns:

Vaers Id: **343795-2 (S)** **Related reports:** 343795-1; 343795-3

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	15-Dec-2008	26-Feb-2009	73	14-Apr-2009	20-Apr-2009	MA		20-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chest pain, Cough, Pain in extremity, Pulmonary embolism

Symptom Text: Received GARDASIL vaccine mid Nov 08. Started OCPS 2 weeks later in Dec 08 and then received 2nd GARDASIL vaccine. During this time period she noted lower extremity pain, cough and chest pain treated with antibiotics. Symptoms continued. Feb 09 CTA with pulmonary embolic.

Other Meds:

Lab Data: 1) Factor V Leiden positive for heterozygous carrier

History: 2) Strong FMH; 3) Concurrent OCP use

Prex Illness:

Prex Vax Illns:

Vaers Id: **343795-3 (S)** **Related reports:** 343795-1; 343795-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Nov-2008	15-Dec-2008	31	04-May-2009	08-May-2009	--		08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	1	Right arm	Intramuscular	
	FLU	SANOFI PASTEUR	AFLUA373BA	0	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Unevaluable event

Symptom Text: Please refer to report already submitted

Other Meds: NECON .5/35 1 pack

Lab Data: Factor V Leiden (L) Hct

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **343797-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	13-Jun-2008	01-Aug-2008	49	09-Apr-2009	16-Apr-2009	VA		21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1967U	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain lower, Abdominal pain upper, Abdominal tenderness, Activities of daily living impaired, Back pain, Body temperature increased, Constipation, Fatigue, Nausea, Oropharyngeal pain, Otitis media, Pharyngitis, Pneumonia, Renal pain, Respiratory tract congestion, Retching, Urinary tract infection, Wheezing

Symptom Text: During the course on the vaccines, patient has developed debilitating abdominal pain. 4/15/09 MR received 5/5/08 to 4/13/09. 15 yr WCC 6/13/08 with normal exam. Recent US (+) for splenomegaly. HPV#1 given. HPV and MCV4 given 8/18/08. Retuned 9/2/08 with c/o ST, chest congestion. DX: LOM, pharyngitis, pneumonia. Returned 9/8/08 with fatigue, nausea and dry heaves. Wheezing on PE. DX: wheezing. improved with nebs. Returned 9/11/08 with stomach and back pain near rib cage. ? gas/constipation. Returned 10/7/08 with cold sx, chest pain/heaviness and hard to breath. DX: URI. Returned 11/19/08 with ST, neck swelling and fatigue. DX: Pharyngitis/Fatigue. ? Reactivated Mono. 11/21/08 LOM, Pharyngitis. Returned 12/10/08 with c/o stomach and back pain x 1 month. sharp pains near kidneys. PE (+) for abd tenderness. DX: Abd pain. Referred to GI. Seen 12/24/08. PE WNL. Impression: Chronic Abd Pain. Sent for tests. Back to PCP 1/29/09 with UTI. Returned 2/23/09 with c/o lower abd pain, severe x 4 days. Low grade temp. Pt reports missing a lot of school. Some constipation. Return to GI 2/25/09. PE (+) for tenderness to palpation of RLQ. DX: Recurrent abd pain. By 4/4/09 pt homebound. Continued sx.

Other Meds:

Lab Data: ULS, CT scan, blood work all normal. Labs and Diagnostics: KUB (+) (+) for scybala. UC (+) for 100K colonies. Colonoscopy WNL. Abd US (+) for borderline hepatomegaly. Splenomegaly resolved. Pelvic US WNL. CRP (-). Helicobacter (-). ESR 1

History: PMH: Mono-LLQ tenderness 5/5/08 with liver and spleen palpable at rib cage. Allergy to Biaxin

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343798-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	25-Mar-2009	26-Mar-2009	1	09-Apr-2009	15-Apr-2009	MA		15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	UF457DA		Left arm	Unknown	
	HPV4	MERCK & CO. INC.	1312X	2	Right arm	Unknown	
	VARCEL	MERCK & CO. INC.	1147X	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Insomnia, Pyrexia, Tremor

Symptom Text: Fever 103 at 10:45 am 3/26/09, shaking. Poor sleep night of 3/25/09.

Other Meds: VENTOLIN HFA

Lab Data: CBC

History: Exercise- Induced Bronchospasm

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343826-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	26-Mar-2009	26-Mar-2009	0	09-Apr-2009	15-Apr-2009	KY		15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	2	Right arm	Intramuscular	
	HEPA	MERCK & CO. INC.	0933X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity

Symptom Text: Appointment at 10:15am, pt. called 9:15pm complaining of right arm pain, not red, no fever, vomiting and stomach ache; ate out.

Other Meds: none

Lab Data: none

History: none

Prex Illness: acne

Prex Vax Illns:

Vaers Id: **343830-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Apr-2009	04-Apr-2009	3	09-Apr-2009	15-Apr-2009	MI		15-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0515X	1	Left arm	Subcutaneously	
	TDAP	SANOFI PASTEUR	C2865AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0651X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Rash, Urticaria

Symptom Text: Patient received #2 VZV, #1 HPV, and #1 Tdap (had 5 previous DTP vaccines) 4-1-09 at the HC. At the OV on 4-1-09 patient also had a viral gastroenteritis, was afebrile. While away, early AM on 4-4-09 patient developed a rash and SOB, taken to ER and diagnosed with "urticaria". Previous to rash child had been eating Cheetos and red Gatorade. Returned to the HC 4-9-09 to see Dr. for re-check ER visit. No symptoms or rash at recheck appointment.

Other Meds:

Lab Data: none

History: No known allergies

Prex Illness: Afebrile, gastroenteritis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343849-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	25-Mar-2009	25-Mar-2009	0	09-Apr-2009	10-Apr-2009	IA		04-May-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2551AA	0	Left arm	Intramuscular	
DTAP	SANOFI PASTEUR	C2865AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0570X	0	Right arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Urinary tract infection

Symptom Text: Pt developed acute abdominal pain - 2 hrs after injection of (1) GARDASIL; (2) MENACTRA, (3) TDAP. Pt was evaluated in ER - diagnosis acute UTI. 48 hrs later admission to hospital. Tx IV's and antibiotics.

Other Meds: None

Lab Data: Increased CBC; UA; Blood cultures negative

History: H.O. benign brain tumor (resected 2007); peritoneal shunt present.

Prex Illness: None - well exam that day

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343850-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Mar-2009	19-Mar-2009	0	09-Apr-2009	17-Apr-2009	CA		17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1750X	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: Oval hyperemic swelling on Rt upper arm at injection site 1"/1'/2"

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **343863-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Mar-2008	20-Mar-2008	0	10-Apr-2009	13-Apr-2009	NY	WAES0804USA01379	13-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Wrong drug administered

Symptom Text: Information has been received from a health professional for GARDASIL, a Pregnancy Registry product, concerning a female who became pregnant during the series of vaccinations. The patient was being seen at a different clinic for the series. The patient received her first dose "a few months ago" (date unspecified). The patient's LMP was 10-Jan-2008. The patient returned to the clinic two weeks ago for a pregnancy test and was inadvertently administered a second dose of GARDASIL. On approximately 20-MAR-2008, the patient was vaccinated with her second dose of GARDASIL (lot number unspecified). Concomitant therapy included PEDIARIX and a third vaccine (name not known at the time of report). The patient has had a urine pregnancy test that was positive and blood work completed. She also had an ultrasound performed on 26-Mar-2008 and the results are pending. The patient has not reported any difficulties thus far. Follow up information was received from a Licensed Practical Nurse who reported that the patient had not returned to her clinic, the patient received her prenatal care at another clinic. The L.P.N had gotten in contact with the patient's mother. It was reported that the pregnancy ended in spontaneous abortion at five months (approximately on 10-JUN-2008). The patient was RH negative and had not received any Rhogam in preparation for the pregnancy. The patient's doctor stated that this was the reason for the miscarriage and that it was not related to the vaccination with GARDASIL. The L.P.N indicated that the patient is pregnant again and "everything was going well with the pregnancy". No further information is available.

Other Meds:

Lab Data: diagnostic laboratory, 03/20?/08, posit -; ultrasound, 03/26/08 - pending; urine beta- human, 03/20?/08 posit - erythrocyte Rh antigen, negat -

History:

Prex Illness: Pregnancy NOS (LMP = 1/10/2008)

Prex Vax Illns:

Vaers Id: **343864-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Jun-2008	16-Jun-2008	15	10-Apr-2009	13-Apr-2009	AZ	WAES0902USA01068	13-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Complication of delivery, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse for the pregnancy registry for GARDASIL concerning a 17 years old female patient with no pertinent medical history and no known drug allergies/drug reactions who in June 2008 was vaccinated with the second dose of GARDASIL. There was no concomitant medication. It was reported that the patient had not received the third dose and it has been determined to be pregnant. it was reported that on 02-FEB-2009 a prenatal ultrasound was performed and it revealed a normal pregnancy. Last menstrual period was approximately 16-JUN-2008 and the estimated delivery date was on 25-MAR-2009. The patient sought medical attention with a office visit. Follow up information from a registered nurse concerning the patient with a history of Chlamydia and no concurrent medical conditions who in June 2008 was vaccinated with the second dose of GARDASIL (lot # unknown). Date of last menstrual period was 18-JUN-2008 and estimated conception date unknown. The estimated delivery date was 25-MAR-2009. Follow up information from a registered nurse concerning the female patient who on 16-MAR-2009 delivered a normal male baby without congenital anomalies weighting 2945 gm, apgar score 6/7 (38 6/7 weeks from LMP). Complications during delivery included nuchal cord x1 (tight), and resuscitation was performed at delivery and the baby was admitted to the special care nursery for grunting. During pregnancy there were no complications, infections or illnesses, and no diagnostic tests were performed. Upon internal review, nuchal cord x1 (tight) requiring resuscitation was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound, 02/02/09, revealed a normal pregnancy

History: Chlamydial infection

Prex Illness:

Prex Vax Illns:

Vaers Id: **343865-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	14-Feb-2009	19-Mar-2009	33	10-Apr-2009	13-Apr-2009	FR	WAES0904CAN00014	13-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Confusional state, Convulsion

Symptom Text: Information has been received from a pharmacist concerning a 17 year old female who on 14-FEB-2009 was vaccinated with the second dose of GARDASIL vaccine, lot # not available. On 19-MAR-2009 the patient experienced seizures and confusion and was hospitalized. On approximately 19-MAR-2009 lab test and scan investigation were negative (no other details provided). The pharmacist reported that the patient may have Asperger Syndrome (pharmacist was not sure). In April 2009 the patient was being seen by a psychiatrist. The pharmacist reported that the mother claimed that seizures and confusion were due to GARDASIL. No further information is available.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, 19?Mar09, negative; Computed axial tomography, 19?Mar09, negative; Psychiatric therapy, ??Apr09

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **343866-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	12-Aug-2007	15-Sep-2007	34	10-Apr-2009	13-Apr-2009	FR	WAES0904USA00544	13-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1339F	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Amenorrhoea, Flushing, Heart rate irregular, Lividity, Paraesthesia, Peripheral vascular disorder, Skin exfoliation, Syncope, Weight decreased

Symptom Text: Information has been received from a general practitioner that his 19 year old daughter was vaccinated with a second dose of GARDASIL (lot number not reported) IM into the upper arm on unspecified date in 2007. "Between 2nd and 3rd vaccination" (third dose of GARDASIL was administered in FEB-2008) the patient experienced amenorrhoea and weight loss 17-18 kilogram up to the time of reporting. Concomitant therapy included hormonal contraceptives. The patient was hospitalized on a not reported date for gynecological and internistic examinations. Results were not reported. a psychotherapeutic investigation was carried out and showed no pathological results. At the time of reporting the patient felt well but suffered still from lost weight and amenorrhoea. Follow up information received on 2-Apr-2009. It was reported by a general practitioner who sent the reporting form and the doctor's letter that the patient was vaccinated with a first dose of GARDASIL, lot# 1339F batch #: N F23310 into the deltoid muscle on 12-AUG-2007. Mid of SEP-2007 the patient developed syncopes, flush and irregular pulse rate. Since May-2008 until Nov-2008 the patient experienced a weight loss of 15 kg. Since Oct 2008, paresthesia of the extremities. Additionally, she developed desquamation of the face skin. On 19-AUG-2008 the patient was referred to the cardiologist. A doctor's letter was provided. It was reported that she experienced recurrent circulatory disorder when sitting or lying. Occasionally, she had lividity of the finger nail and legs. Echocardiography showed normal results as well as ergometry. No indication of a myocardial ischemia induced on effort and circulatory dysregulation. According to the cardiological results there was no indication of a structural cardiovascular disease. The cardiologist assumed that the syncopes were based on a neurocardiogenic cause. No medication was recommended. Laboratory findings showed on 31-OCT-2007 normal values for thyroid (total T3 and T4). On 18-FEB-2008, hepatitis Bs antibody titer showed 3

Other Meds: hormonal contraceptives (unspecified)

Lab Data: total serum thyroxine, 31Oct07, Normal values; total serum triiodothyronine test, 31Oct07, Normal values; serum hepatitis B Ab, 18Feb08, 35, Normal range not reported; total serum cortisol, 18Feb08, 20.8, Normal range not reported; hepatic

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 343867-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Aug-2008	08-Sep-2008	11	10-Apr-2009	13-Apr-2009	--	WAES0904USA00618	27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Aplastic anaemia, Blood product transfusion, Epistaxis, Fatigue, Gingival bleeding, Headache, Malaise, Nausea, Oropharyngeal pain, Pancytopenia, Petechiae, Pharyngitis, Purpura, Pyrexia, Tachycardia, Transfusion, Upper respiratory tract infection, Vision blurred, Vomiting

Symptom Text: Information has been received from a consumer concerning his 18 year old daughter with no pertinent medical history or no known drug allergies, who on approximately 29-AUG-2008 (reported as last week of August 2008) was vaccinated with the first dose of GARDASIL (Lot not reported). In December 2008 she received the second dose of GARDASIL (Lot not reported). There was no concomitant medication. On approximately 08-SEP-2008 (reported as the second week of September), the patient was diagnosed with aplastic anemia. She was having blood work every week and several other tests were performed. On an unspecified date, the patient stayed in the hospital for 10 days. As of 03-MAR-2009, the patient had not recovered from aplastic anemia. Additional information has been requested. 4/14/09 Received hospital medical records of 2/24-3/5/2009. FINAL DX: very severe aplastic anemia; profound pancytopenia Records reveal patient experienced progressive anemia & fever, HA, blurred vision, sore throat, epistaxis, gum bleeding, nausea, 1 episode of emesis x 1 mo. Developed petechiae & wet purpura, tachycardia, HA. Tx w/IV antibiotics, multiple blood & plt transfusion & immunosuppressive therapy. Gradually improved & d/c to home on oral antibiotics, continued immunosuppresants to be f/u in clinic 4/14/09 Received PCP medical records of 2/21-2/24/2009. FINAL DX: none provided Records reveal pt had been seen in urgent care 2/21 for sore throat, fever, nausea, vomiting, fatigue, malaise. Had been exposed to sick contacts at school. Dx w/pharyngitis & URI.

Other Meds: None

Lab Data: hematology LABS: WBC 1.5(L), ANC 400, H/H 4.7/13.2, plts 3,000. Bone marrow biopsy. Strep & mono c/s neg. CXR WNL.

History: None PMH: asthma, pneumonia x 2 2006 & 2008, oral contraception.

Prex Illness:

Prex Vax Illns:

Vaers Id: 343868-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Jun-2007	01-Jan-2008	201	10-Apr-2009	13-Apr-2009	FR	WAES0904USA00803	13-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Arthralgia, Asthenia, Diarrhoea, Disturbance in attention, Dizziness, Gastrointestinal disorder, General physical health deterioration, Headache, Iron deficiency, Myalgia, Night sweats, No reaction on previous exposure to drug, Reticulocytopenia, Transfusion

Symptom Text: Information has been received from a health authority concerning a 15 year old female patient who was vaccinated with a second dose of GARDASIL (lot #, injection route and site not reported) on 13-DEC-2008. In January 2008 she developed gastrointestinal disorder, dizziness, asthenia, impaired concentration, headache, muscle and joint pain. In June 2008 the symptoms aggravated. Iron deficiency was diagnosed. The patient was treated with iron preparations and developed abdominal cramps and diarrhea (after intake of iron preparations). In September 2008 blood samples showed persisting iron deficiency and reticulocytopenia. The patient received 6 transfusions. In November 2008 the patient was hospitalized. Gastroscopy and colonoscopy showed normal results. In December 2008 the patient recovered from the gastrointestinal disorder, the other events were persisting. In February 2009 the patient received another 6 transfusions. In March 2009 the patient additionally experienced nocturnal perspiration and her general condition was reduced. The patient had not recovered at the time of reporting. D1 of GARDASIL, lot # not reported, administered on 14-JUN-2007 was well tolerated. Other business partner's numbers includes: E2009-02879. No further information is available. The case is closed.

Other Meds: Unknown

Lab Data: iron supplementation, ??Jun08, iron deficiency; diagnostic laboratory test, ??Sep08, persisting iron deficiency and reticulocytopenia; blood transfusion, ??Sep08, persisting iron deficiency and reticulocytopenia; gastroscopy, ??Nov08, norma

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343869-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		10-Apr-2009	13-Apr-2009	--	WAES0904USA01122	13-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a licensed practical nurse (L.P.N.) who was told by a patient's mother that she heard from a school staff member concerning a female child who was vaccinated with doses of GARDASIL on an unspecified date. Subsequently the patient experienced a seizure. At the time of reporting, the outcome was unknown. Upon internal review, seizures was considered to be an other important medical event. Attempts to verify the existence of an identifiable patient have been unsuccessful. This is one of two reports from the same source. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343922-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Mar-2009	23-Mar-2009	0	10-Apr-2009	14-Apr-2009	IL		08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2543AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Arthropathy, Fatigue, Insomnia, Joint swelling, Lethargy, Malaise, Musculoskeletal stiffness, Pain, Polyarthritis, Pyrexia

Symptom Text: within 20 mins of injections, pain, stiffness, extreme fatigue, lethargic . Then experienced cont. pain and soreness, stiffness on and off for next week and 1/2 when became increasingly worse with joints locking up, severe pain and stiffness, fatigue, fever, swelling of joints. Small relief with pain meds. 4/29/009 Received PCP medical records of 8/25/08-4/8/2009. FINAL DX: polyarticular arthralgias Records reveal patient experienced good general health & was on OCP on 3/23/09 for HPV#1 & Menactra. RTC 4/8 & reported malaise since day after vax & then developed progressively worsening joint pain, stiffness & swelling w/difficulty sleeping & generalized body aching x 1 wk. Tx w/NSAIDS & heat.

Other Meds:

Lab Data: Tests done on 4-8-09, show high SED rate and low blood iron levels. LABS: H/H 9.7/29.0(L). ESR 30(H). CMP, TSH, T4, mono WNL. ANA (+). RF neg. Uric acid 3.7(N).

History: PMH: Irregular menses. Juvenile osteoporosis. Heart murmur in childhood. Allergy: suprax. Family hx: CAD, asthma, DM, CVA, colon, cervical & breast cancer.

Prex Illness: none also received TB test/neg

Prex Vax Illns: ALl major reactions to first two pertussis, then stopped pertussis.~DTP (no brand name)~2~0~Patient

Vaers Id: **343934-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	09-Apr-2009	09-Apr-2009	0	10-Apr-2009	16-Apr-2009	SC	SC0910	16-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	GLAXOSMITHKLINE BIOLOGICALS	1536X	0	Right arm	Subcutaneously	
HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2688AA	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	AC52B029AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Incoherent, Loss of consciousness, Nausea, Pallor, Syncope, Vomiting

Symptom Text: After administration of all 4 vaccines, upon departure and standing, client reported feeling dizzy. Assisted client back to chair. Client fainted. Incoherent or unconscious for approximately 30 seconds. Client then nauseated and vomited clear fluid (mucus); pale. BP assessed and cool rag applied to forehead. Given water to drink. Remained in clinic 20-25 minutes. BP assessed and monitored. Stable at departure. Voiced no complaints at departure.

Other Meds: none

Lab Data: none

History: Born with heart murmur

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **343977-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Apr-2009	07-Apr-2009	0	10-Apr-2009	20-Apr-2009	CA		20-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB329CA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	V2820AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3068AA	6	Right arm	Intramuscular	
	HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB518AA	2	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0260X	1	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Pallor

Symptom Text: pass out after the shots, became pale around 5 sec no treatment needed.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344000-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	02-Feb-2009	16-Mar-2009	42	13-Apr-2009	14-Apr-2009	FR	WAES0903USA05577	14-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1477U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Postural orthostatic tachycardia syndrome, Syncope

Symptom Text: Case received from a health care professional on 27-MAR-2009. It was reported by a hospital internist that a 16 year old female who on 02-FEB-2009 was vaccinated with the first dose of GARDASIL (lot #, injection site and route not reported). Approximately 4 weeks post vaccination, the patient developed recurrent syncope. The patient was hospitalized on an unspecified date. Neurological and internal investigations including cranial MRI and Schelling's test showed normal results. The patient had not recovered at the time of reporting. The reporter did not see a causal relation to GARDASIL vaccination. He contacted us on request of the patient's father who had seen a telecast with negative information about GARDASIL vaccines. Previous unspecified vaccinations were well tolerated. Follow-up information received on 01-APR-2009. The reporting form was sent: the patient was vaccinated with a first dose of GARDASIL (lot # 1477U, batch # NH25390), IM into the upper arm. The relapsing syncope occurred approximately since 16-MAR-2009 and lasted "for seconds" each. Postural tachycardia syndrome was evoked. Therapy included "volume therapy" and high sodium diet. The final outcome was unknown to the reporter. File closed. Other business partner numbers include E2009-02696.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, normal; orthostatic hypotension measurement, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344001-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Oct-2008	01-Oct-2008	0	13-Apr-2009	14-Apr-2009	NY	WAES0903USA04563	21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Angioedema, Arthralgia, Fatigue, Gait disturbance, Injection site vesicles, Joint swelling, Musculoskeletal stiffness, Pain, Pruritus, Rash generalised, Serum sickness, Urticaria

Symptom Text: Information has been received from a physician concerning a 24 year old female with allergies to tomatoes and pollen, migraine, rhinitis seasonal, deviated septum and band-aids and a history of GERD who was vaccinated with the first and the second dose of GARDASIL July 2007 and October 2008 respectively at her OB/GYN. Concomitant therapy included ADVIL and ORTHO TRI-CYCLEN. The patient developed some reactions a week or 2 after getting the 2nd dose of GARDASIL. The patient experienced swelling of the joints starting from the left knee and then moving to other areas. The patient had stiffness of her hands, angioedema of the lips and generalized urticaria. The joint conditions subsided somewhat and she still had minor stiffness. The welts were still ongoing and itchy. She treated herself with ADVIL as needed, used 1 dose of BENADRYL, and was given an unspecified NSAID. She was just given a new antihistamine, XYZAL on 24-MAR-2009. Around the same time of these events the patient was given an unspecified antibiotics when she had a wisdom tooth removed. Physician was investigating both serum sickness reactions. The patient was seen by a group of physicians throughout the time period of the symptoms. The patient's C reactive protein was slightly elevated. Other labs were pending: CBC panel, latex and food allergies, thyroid, etc. Follow-up information has been received from a consumer who a few days after receiving the second dose of GARDASIL started to experience swelling in her knee, fatigue, and a blister at the injection site. Then she started to develop swelling and pain in other joints which made it difficult to walk. The consumer reported that she saw her primary care physician a few times and thought it may be Lyme disease or lupus, but after a few months of this going on, the patient realized that she received GARDASIL. The patient then saw a rheumatologist in January 2009 and she had blood work done which showed she had elevated C reactive proteins. Around the time she saw the rheumatologist, the patient deve

Other Meds: Antimicrobial (unspecified); ORTHO TRI-CYCLEN; ADVIL

Lab Data: Serum C-reactive, 01/??/09, slightly elevated

History: Gastrooesophageal reflux disease; Wisdom teeth removal

Prex Illness: Food allergy; Pollen allergy; Nasal septum deviation; Prophylaxis; Adhesive tape allergy; Migraine; Rhinitis seasonal

Prex Vax Illns:

Vaers Id: **344002-1 (S)** **Related reports:** 344002-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	18-Feb-2009	18-Feb-2009	0	13-Apr-2009	14-Apr-2009	--	WAES0904USA00862	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	1	Left arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Injected limb mobility decreased, Musculoskeletal pain, Pain in extremity, Similar reaction on previous exposure to drug, Sleep disorder, Tendon injury, Wrong technique in drug usage process

Symptom Text: Information has been received from a nurse practitioner concerning a 24 year old female who on 18-FEB-2009 was vaccinated with her second dose of GARDASIL (lot number, route and site not reported). On 18-FEB-2009 when she received this vaccination it was noted that the vaccine was "hard to inject". The patient's left arm became "quite sore" and it became hard for her to raise her arm. She had "deep discomfort". On 26-FEB-2009 the patient was seen by the NP continuing symptoms, sleep problems and pain in the front of her shoulder. An X-ray was negative. A magnetic resonance imaging reported reabsorption in the humeral head and a tiny partial thickness tear of the distal tendon. The diagnosis was possible vaccine injection into the bone. Her complete blood count was normal. The patient also reported less intense pain after her first dose vaccination with GARDASIL (lot number, route and site not reported). The patient did not recover at the time of reporting. Possible vaccine injection into the bone, left arm quite sore, sleep problems and pain in the front of her shoulder were considered to be disabling. Additional information has been requested. 5/12/09 PCP records received. In for routine GYN exam 2/18/09 with normal PE. HPV#2 given in L arm. RN reported injection was difficult. RTC 2/26/09 with c/o worsening arm soreness, now difficult to raise. Pain with ROM on exam, otherwise WNL. tx: ice, NSAIDS. RTC 3/16/09 with continued c/o arm pain, now disturbing sleep. Now localized to front of shoulder joint. Sent for X-rays/MRI which showed a partial bursal side thickness tear of the distal supraspinatus tendon and a partial thickness tear of distal infraspinatus tendon. Assess: Pain in Limb.

Other Meds: Unknown

Lab Data: X-ray, ?/?/09, negative; magnetic resonance, ?/?/09, reabsorption in the humeral head and a tiny partial thickness tear of the distal tendon; complete blood cell, ?/?/09, normal. Labs and diagnostics: MRI L shoulder (+) tendon tear). shou

History: Unknown. PMH: condylomata acuminatum. Lumbar disc displacement. Irregular menstruation. On OCs

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344002-2** **Related reports:** 344002-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	19-Feb-2009	19-Feb-2009	0	17-Apr-2009	08-May-2009	--	WAES0903USA05562	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pain in extremity, Wrong technique in drug usage process

Symptom Text: Information has been received from a 24 year old female who in approximately July 2008 (reported as "about 9 months ago", also reported "about 6 months before her second dose"), was vaccinated with a first dose of GARDASIL and on 19-FEB-2009 was vaccinated with a second dose of GARDASIL which was accidentally administered in her bone rather than in her muscle. There was no concomitant medication. On approximately 20-FEB-2009 (about a day after second vaccination) the patient experienced pain in the arm which has increased over time. The MRI was performed. At the time of reporting, the patient's pain in the arm which has increased over time persisted. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **344003-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Mar-2009	18-Mar-2009	2	13-Apr-2009	14-Apr-2009	FR	WAES0904USA01040	14-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1941U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Nausea, Pyrexia

Symptom Text: Information has been received on 05-APR-2009 from a Health Authority (HA ref. DK-DKMA-20090780) concerning an 18 year old female who was vaccinated IM with a first dose of GARDASIL (lot # 1941U, batch # NJ01850) on 16-MAR-2009. On 18-MAR-2009 the patient developed nausea, fever and dizziness. It was reported that the patient experienced consciousness loss on 18-MAR-2009 and 20-MAR-2009. The patient was admitted to hospital (not further specified). It was reported that X-ray of thorax and cerebrum scan revealed no abnormalities. Blood samples were normal, except CRP which was increased (14 mg/L). The patient had during the days before vaccination complained of tiredness. Blood samples taken on the same day as vaccination (16-MAR-2009), but before vaccination, revealed no abnormalities. It was reported that the patient had recovered from all symptoms. Date of recovery was not reported. Other business partner numbers included: E2009-03049. No further information is available.

Other Meds: Unknown

Lab Data: head computed axial tomography, normal; chest X-ray, normal; serum C-reactive protein, 14 mg/L, increased

History: Tiredness

Prex Illness:

Prex Vax Illns:

Vaers Id: **344004-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	28-Aug-2008	17-Nov-2008	81	13-Apr-2009	14-Apr-2009	FR	WAES0904USA01075	14-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1114U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia universalis, No reaction on previous exposure to drug

Symptom Text: Information has been received from a paediatrician concerning a 16 year old female patient who on 13-NOV-2007 was vaccinated with her first dose of GARDASIL (lot number 0482U, batch number NG09910, site and route not reported). On 29-JAN-2008, the patient was vaccinated with her second dose of GARDASIL (lot number 0482U, batch number NG09910, site and route not reported). Both of them were well tolerated. On 28-AUG-2008, the patient was vaccinated IM with her third dose of GARDASIL (batch number NH15190, lot number 1114U) into the deltoid muscle. On 17-NOV-2008 the patient developed alopecia universalis (hair of scalp, eyebrows, eyelashes, hair of arms and legs, pubic hairs). Hormonal examination (thyroid, gonadal hormones, pituitary gland, hypothalamus) showed normal results. The patient was not hospitalized. Dermatological therapy was unsuccessful and the patient had not recovered at the time of reporting. Other business partner numbers included: E2009-02943. Upon medical judgement, the case was considered as serious due to other medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: serum TSH, 17Nov08, normal; serum gonadotropin-releasing hormone, 17Nov08, normal; serum gonadotropin-releasing hormone, 17Nov08, normal; plasma adrenocorticotropic hormone test, 17Nov08, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344010-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	24-Mar-2009	24-Mar-2009	0	13-Apr-2009	14-Apr-2009	FR	WAES0904USA00796	14-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Fall, Head injury, Immediate post-injection reaction

Symptom Text: Information has been received from a pharmacist concerning a 15 year old female patient received her first dose of GARDASIL (batch number not reported), via intramuscular route on 24 or 25-MAR-2009. Immediately after when the patient stood up she had fallen and was hospitalized a few days in pediatrics for an important head trauma. At time reporting the patient had recovered. She had no injection site pain and no problem during the injection. Other business partner numbers include E2009-02930. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344025-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	23-Sep-2008	24-Sep-2008	1	13-Apr-2009	16-Apr-2009	DE		16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus

Symptom Text: Pt. notes truncal pruritis (primarily B/L breasts). Sx occurred 24-48 hours s/p vaccine (GARDASIL) # T and lasted approx. 4 wks. Denies rash/ fever/ chills/ sob.

Other Meds: KEPPRA 500 mg one BID

Lab Data:

History: Seizure Disorder/NKDA

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344038-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Apr-2009	06-Apr-2009	0	13-Apr-2009	16-Apr-2009	NC		27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blood pressure decreased, Syncope

Symptom Text: Approximately 5 minutes post injection, Pt experienced syncopal episode lasting 10 seconds. BP 90/62 at episode. After orientation X 3 was re- established, Pt reported feeling better. BP 96/64 at discharge. Discharged in the care of her mother. No injury noted. Physician aware.

Other Meds: None

Lab Data: Syncopal episode 90/62 (BP reading) : Discharged from clinic 96/64

History: None

Prex Illness: No

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344054-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	20-Mar-2009	21-Mar-2009	1	13-Apr-2009	16-Apr-2009	OR		04-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Cough, Rash

Symptom Text: Pt states rash on face day following administration of GARDASIL. Also a cough.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344089-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	25-Mar-2009	26-Mar-2009	1	13-Apr-2009	16-Apr-2009	IN		28-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Suicidal ideation

Symptom Text: Severe suicidal ideation, ever since vaccination was administered. This has continued to worsen. Before being vaccinated, mental health was at the best it had been in years.

Other Meds: lamotrigine

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **344094-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Apr-2009	04-Apr-2009	2	13-Apr-2009	15-Apr-2009	FL		21-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	0049Y	0	Right arm	Subcutaneously	
TDAP	SANOFI PASTEUR	C3057AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0653XY	1	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB274AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Benign intracranial hypertension, Condition aggravated, Dizziness, Electroencephalogram abnormal, Epilepsy, Erythema, Fall, Headache, Nausea, Oedema peripheral, Pain in extremity, Pyrexia, Vomiting

Symptom Text: Client recieved four vaccines on 4/2/09. The client parent requested all vaccine be given in the same extremity due to a previous injury in the other arm and the client fear of being unable to walk if we used the lower extremities. The parent reports that the Right arm was swollen and became very red and sore on 4/4/09. The client also had reported a headache which began on that date and a low grade fever. Her mother treated her with Motrin. On 4/6/09 the mother called to report that the client began vomiting the night before and that her arm was still swollen but not warm to touch and appered to be improving. The mother was advised to take her daughter to her doctor to be evaluated. The client's mother was contacted on 4/8/09 and informed that the client had been admitted to Hospital. On 4/13 futher follow up revealed that the client was home and has been diagnosed with parietal epliepsy. 4/16/09 MR received for DOS 4/8-10/2009 with D/C DX: Morbid Obesity. Pseudotumor Cerebri. Abnormal EEG. Pt initially presented to PCP with c/o dizziness upon standing, one episode of nausea and vomiting, and worsening of chronic H/A (~9 month hx). Pt recently fell out of a chair but did not have LOC. Pt sent to local hospital and transferred to current facility for neuro w/u. Started on Topamax after abnormal EEG. Pt still reporting mild dizziness and H/A at d/c.

Other Meds: None Known.

Lab Data: Blood work and a spinal tap were performed in the hospital. Labs and Diagnostics: MRI brain WNL except maxillary sinusitis. CSF WNL except increased opening pressure. EEG abnormal.

History: None Known PMH: Chronic H/A x 9 months. Bells Palsy 7/2008. Mono 2009. Strep throat. RAD

Prex Illness: None

Prex Vax Illns:

Vaers Id: **344109-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	09-Apr-2009	10-Apr-2009	1	14-Apr-2009	16-Apr-2009	MI		16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Nausea

Symptom Text: Nausea, fatigue for one week after vaccine administration. Seen in clinic on 04/14/09. Afebrile, WT 150#, BP 130/67. HEENT-negative, abdomen soft, non-tender, no masses. Patient current on depo provera.

Other Meds: depo provera

Lab Data: TSH, CBC, BHCG, mono spot

History: sulfa

Prex Illness: diarrhea

Prex Vax Illns:

Vaers Id: **344122-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Apr-2009	14-Apr-2009	0	14-Apr-2009	16-Apr-2009	RI		16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B029AA	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2826CA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0653X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncopal episode about 5-10 minutes after receiving Menactra and Gardasil in L arm and TDaP in R.

Other Meds: none

Lab Data: none

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344124-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Mar-2009	25-Mar-2009	5	14-Apr-2009	16-Apr-2009	MD		16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Unintended pregnancy

Symptom Text: UNPLANNED PREGNANCY

Other Meds:

Lab Data: POS PREG TEST 03/25/09

History: NONE

Prex Illness: NONE KNOWN

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344155-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.5	F	Unknown	01-Apr-2009		14-Apr-2009	20-Apr-2009	--		20-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Chest discomfort, Chest pain, Dyspnoea, Fatigue, Headache, Nausea

Symptom Text: My daughter is 13 yrs old and has received the gardasil vaccine during which before receiving the 3rd vaccine I was notified that there would be some information broadcasted. I did decide not to give her the third vaccine due to her having some of the symptoms which included headaches, abdominal pain, nausea, fatigue, shortness of breath, chest pain or tightness, I have taken her to the emergency room twice this month for those symptoms and the physicians are not sure what is happening and say it could be asthma but I am concerned that it is more than that. Please let me know what else we need to do. Thank you.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **344156-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	18-Feb-2009	18-Feb-2009	0	14-Apr-2009	20-Apr-2009	--		20-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Fear, Headache, Injected limb mobility decreased, Injection site mass, Injection site pain, Myalgia, Nausea, Scar, Syncope, Vision blurred, Vomiting

Symptom Text: After first dose, there was a very sharp, deep pain at injection site. When I went to leave office I felt dizzy, nauseous, and vision started blurring and going black. Nurse brought me back into room and I fainted. I awoke a few minutes later and vomited. My vision and steadiness had still not returned for about 30 minutes. A month later, the arm of the injected site was still sore and a deep muscular ache was constant. A very sharp pain would be felt if tried to raise my arm higher than horizontally in front of me. -Parallel to ground. - After two months, I still have discomfort while raising it or moving it up and down, but the pain is less intense. I feel like after the vaccination, I've had a weaker immune system - more susceptible to illnesses- than I've ever been in the past, and a lack of energy. I've had an increase of headaches that are reoccurring. There is still a scar on my arm and a raised bump from the injection. I don not feel safe getting the second or third dose, because I am afraid more serious side effects may likely occur.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344157-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	10-Apr-2009		14-Apr-2009	17-Apr-2009	--		17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Fatigue, Oropharyngeal pain, Pain in extremity, Pyrexia

Symptom Text: After injection at 2:33 pm on the date above, Rainbow began to experience, dizziness, fever, sore throat, severe arm pain. Today, the next morning, she is weak, tired, and still has sore throat.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344160-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	31-Mar-2009	31-Mar-2009	0	15-Apr-2009	16-Apr-2009	GA	WAES0904USA01011	29-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	SMITHKLINE BEECHAM	AHAVB262A	0	Unknown	Unknown	
HPV4	MERCK & CO. INC.	0570X	0	Unknown	Unknown	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B029AA	0	Left arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2670AA	0	Unknown	Unknown	

Seriousness: DIED, ER VISIT, SERIOUS

MedDRA PT Arthralgia, Death, Pyrexia, Streptococcal bacteraemia

Symptom Text: Information has been received from a physician concerning an 11 year old female who on 30-MAR-2009 (last week) was vaccinated with the first dose of GARDASIL. Concomitant therapy included VAQTA, MENACTRA and DTAP (unspecified) on the same day. Patient complained about sore throat a week prior to vaccination. A week later some kind test was performed and it showed that a group A strep in the blood was found. On approximately 30-MAR-2009, after getting the first dose of GARDASIL the patient experienced fever and pain in the hip after getting the vaccine. The patient died on 03-APR-2009. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: diagnostic laboratory, a group A strep in the blood was found

History:

Prex Illness: Sore throat

Prex Vax Illns:

Vaers Id: **344161-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		15-Apr-2009	16-Apr-2009	--	WAES0904USA00594	16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Meningitis

Symptom Text: Information has been received from a medical assistant concerning a female who on an unspecified date was vaccinated with a dose of GARDASIL (dose, route and lot number not provided). On an unspecified date the patient developed spinal meningitis after vaccination. The medical assistant reported that the patient was not in her practice so no details other than she was hospitalized were known. The reporter stated that she heard of this "second hand" through a person that knew the person that developed the meningitis. She believed this was reported previously. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344162-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Aug-2008	01-Nov-2008	79	15-Apr-2009	16-Apr-2009	FR	WAES0904USA01038	16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1172U	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Headache, Mental disorder, Nausea, Nervousness, Paraesthesia, Syncope

Symptom Text: It was reported by a gynecologist that a 14-year-old female patient was vaccinated with a third dose of GARDASIL (batch number NH13130, lot number 1172U) IM into the upper arm on 14-AUG-2008. In NOV-2008 the patient developed recurrent syncope, tingling of the legs, headache, nervousness and nausea. The patient was hospitalized on an unspecified date for diagnostics. Neurological and internal investigations including cranial magnetic resonance imaging (MRI) showed normal results. A psychogenic cause was evoked by the hospital physicians. The patient not recovered at the time of reporting. Meanwhile the girl's teachers refused to bear the responsibility, so she cannot visit school anymore. D1 (batch number NH04240, lot number 1113U) and D2 (batch number NH06410, lot number 1068U) of GARDASIL, administered on unspecified dates were well tolerated. Other business partner numbers included E200902921. Additional information has been requested.

Other Meds: Unknown

Lab Data: Magnetic resonance imaging, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344174-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Mar-2008	Unknown		15-Apr-2009	16-Apr-2009	FR	WAES0904USA01214	16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Immediate post-injection reaction, Injected limb mobility decreased, Injection site anaesthesia, Migraine

Symptom Text: Information has been received from a pharmacist concerning an adolescent female with no medical history of migraine who in March 2008, was vaccinated with the first dose of GARDASIL in the arm. Concomitant therapy included hormonal contraceptive (unspecified). At the moment of injection, the patient complained of severe headache. Ever since, i.e. for one year, she has developed regular migraines. Furthermore, she also experienced numbness in the arm of the injection site, sometimes to the point where she cannot lift it anymore. She was given an unspecified antimigraine treatment. At the time of reporting, cerebral scanner was planned within one or two weeks. The patient had not yet recovered. According to the patient's mother, the reported "reactions" were linked to the vaccine, but the physician may have assessed the causal relationship between the vaccine and the reactions as doubtful. The pharmacist considered numbness of limbs, injected limb mobility decreased, and headache to be other important medical events. The pharmacist also considered that the migraines for one year were significant event because disabling for the patient. Additional information has been requested.

Other Meds: Hormonal contraceptives (unspecified)

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344175-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	29-Nov-2008		15-Apr-2009	16-Apr-2009	MI	WAES0904USA01164	16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Drug exposure during pregnancy, Vaginal haemorrhage

Symptom Text: Information has been received from a medical assistant, for the Pregnancy Registry for GARDASIL, concerning an 18 year old female with sulfa allergy and no pertinent medical history who was vaccinated IM with the first and second 0.5 ml doses of GARDASIL by different provider and was vaccinated IM with the third 0.5ml dose of GARDASIL (lot #: 659962/1740U) on 01-DEC-2008. Concomitant therapy included loratadine. The patient who received the three doses of GARDASIL was pregnant. The patient's last menstrual period was 29-NOV-2008 and estimated delivery date was 05-SEP-2009. The patient experienced vaginal bleeding and was hospitalized at an unspecified time period. Additional information has been requested.

Other Meds: LORATADINE

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 11/29/2008); Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **344176-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Feb-2008	21-Feb-2009	370	15-Apr-2009	16-Apr-2009	FR	WAES0904USA01078	16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Hypoaesthesia, Nuclear magnetic resonance imaging, Nuclear magnetic resonance imaging brain

Symptom Text: Information has been received from a Health Authority (case # 96982, local case # IT140/09). A 13 year old female on 17-FEB-2008 was vaccinated with a third dose of GARDASIL (Batch# not reported). On 21-FEB-2009 the patient presented with hypoaesthesia of right limb with D6-D8 (dorsal spine) involvement. The patient was hospitalized. A brain and dorsal-cervical MRI (magnetic resonance imaging) was performed (results not reported). The reported outcome was recovered with sequelae. There is no previous medical history reported. The patient was vaccinated with the first dose of GARDASIL (lot # 1466F, batch # NF22880) on 27-NOV-2007 and with the second dose (batch # not reported) on 29-JAN-2008. Other business partner numbers included E2009-03060. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344177-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	15-Nov-2007	15-Dec-2008	396	15-Apr-2009	16-Apr-2009	FR	WAES0811USA03012	16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0482U	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Back pain, Condition aggravated, Fatigue, Headache, Post lumbar puncture syndrome, Vaccine positive rechallenge

Symptom Text: Information has been initially received from a gynaecologist on 17-NOV-2008. It was reported by a gynaecologist that a 16 year old female patient was vaccinated with a third dose of GARDASIL (lot #1427U, batch #NH15200) into the deltoid muscle on 16-OCT-2008. Four weeks post vaccination, the patient developed headache, tiredness and fatigue. The patient was hospitalized on an unspecified date. The events were still persisting for months at the time of reporting and the patient had not yet recovered. Dose one of GARDASIL, (lot #0278U, batch #NF56940) administered on 15-NOV-2007 was well tolerated. The second dose of GARDASIL, (lot #0482U, batch # NG09920) administered on 24-JAN-2008. After the second dose the patient developed headache, tiredness and fatigue 4 weeks post vaccination. Follow up information was received on 06-APR-2009: The hospital report was provided: The patient was hospitalized from 03-DEC-2008 until 10-DEC-2008. One year prior to hospitalization the patient complained of recurrent headache, mainly in the occipital and temporal area. Additionally, she suffered from back pain and upper abdominal pain for 10 weeks. She was treated with omeprazole before admission. On 26-NOV-2008 a cranial MRI in an outpatient department had shown normal findings. In hospital several investigations (physical, laboratory findings, wake EEG, ECG, gastroscopy, ophthalmological and psychological examinations) showed normal results. A lactose and fructose test showed a suspicion of intolerance of lactose and no indication of fructose intolerance. A nutritional advice was performed. CSF puncture showed an increased CSF pressure whereas ophthalmological examination showed no papilledema so that the diagnosis of cerebral pseudotumor could not be established. A further ophthalmolgoical examination control was recommended. The patient was discharged with persisting relapsing headache. On 17-DEC-2008 the patient was hospitalized again. All extended preceding diagnostical investigation did not result in a leading diagnosis. Cur

Other Meds: Omeprazole

Lab Data: Magnetic resonance imaging, 26NOv08, cranial MRI showed normal findings; Electroencephalography, ??Dec08, wake EEG showed normal result; Electrocardiogram, ??Dec08, wake EEG showed normal result; Ophthalmological exam, ??Dec08, normal resul

History: Headache; Tiredness; Fatigue; Back pain; Abdominal pain upper

Prex Illness:

Prex Vax Illns:

Vaers Id: **344178-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	25-Jun-2008	01-Jan-2009	190	15-Apr-2009	16-Apr-2009	FR	WAES0904CAN00026	16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Thyroid cancer

Symptom Text: Information has been received from a physician concerning a female who on 25-JUN-2008 was vaccinated with the first dose of GARDASIL (lot# not available). On 06-OCT-2008, the patient was vaccinated with the second dose of GARDASIL (lot# not available). On 19-MAR-2009, the patient was vaccinated with the third dose of GARDASIL (lot# not available). In January 2009, the patient was diagnosed with thyroid cancer. Upon internal review, thyroid cancer was considered to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic procedure, ??Jan09, thyroid cancer

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344179-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	13-Oct-2008	13-Oct-2008	0	15-Apr-2009	16-Apr-2009	FR	WAES0904USA01453	16-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1282U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness, Skin injury, Suture insertion

Symptom Text: Case received from health authority on 31-MAR-2009 under reference 2009-01180. Information was received from the health authority concerning a 13 year old female adolescent received the first intramuscular dose of GARDASIL (batch # NH46170, lot #: 1282U, site of administration not reported). Approximately 2 minutes after vaccination, the patient lost consciousness and fell from the chair she was sitting. She got a skin injury on her chin, which had to be sewn. Meanwhile, the patient recovered completely. The adverse events were reported as other medically important condition. Additional information has been requested. Other business partner numbers include E2009-02868.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344181-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	09-Apr-2009	09-Apr-2009	0	15-Apr-2009	21-Apr-2009	NH		21-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AVAVB262AA	0	Left arm	Intramuscular	
TDAP	SANOFI PASTEUR	C3029AA		Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2812AA	0	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0651	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Convulsion, Pallor, Syncope

Symptom Text: Patient left office after getting 4 vaccines. She was standing at window to make another appt. She asked for water then had a syncopal episode with ? of seizure activity. Very pale, weakness. Pt laid in waiting room. Pulse 56, BP 116/38. Was given apple juice & crackers. She had only eaten chocolate and water for breakfast. Moved to exam room. She was monitored for about 30 minutes. Rechecked by MD then left feeling fine.

Other Meds: DEXAMETHASONE 4mg, PROMETHAZINE 23 mg

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344187-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-May-2007	01-Sep-2007	107	15-Apr-2009	20-Apr-2009	CA		20-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Neck pain

Symptom Text: Patient came in for MD visit 4/8/2009, with complaint of on and off neck pain. Patient and pt's mother feels pain started after HPV vaccines, HPV vaccine series given 5/17/2007, 8/31/2007 and 1/17/2008. Neck pain reported first on 12/22/2007 MD visit, stated neck pain for 4 months.

Other Meds: None

Lab Data: 12/28/2007 x-ray cervical spine done. 1/3/2008 MRI cervical spine done. Neurology consult done, seen 12/31/2007.

History: None

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344192-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	31-Mar-2009	31-Mar-2009	0	15-Apr-2009	17-Apr-2009	--		27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Vomiting

Symptom Text: Headache same day lasted 3 days. Throwing up two days after.

Other Meds: None

Lab Data: None

History:

Prex Illness:

Prex Vax Illns: Headache~HPV (Gardasil)~1~0~Patient

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344202-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	03-Apr-2009	03-Apr-2009	0	15-Apr-2009	20-Apr-2009	IL		20-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2823AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0570X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Hyperhidrosis, Pallor

Symptom Text: Child became very pale, lightheaded and felt like she was going to faint. Child was also slightly diaphoretic. Had child lay down and gave water.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344212-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Apr-2009	15-Apr-2009	1	15-Apr-2009	17-Apr-2009	SC		20-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash pruritic

Symptom Text: Patient called our office to inform us that she had "pumps all over her body and they itch really bad." She states that she woke up with the pump and itching this morning. Her mom gave her a Benadryl pill.

Other Meds: NONE

Lab Data: NONE

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **344215-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	08-Jan-2009	20-Jan-2009	12	15-Apr-2009	17-Apr-2009	FL		17-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
TDAP	SANOFI PASTEUR	UF452CA	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB329DA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	1311X	0	Left arm	Intramuscular	
MMR	MERCK & CO. INC.	MSD1255X	0	Right arm	Subcutaneously	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBVB569AA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: AMENORHEA SINCE DECEMBER '08. PREGNANCY TEST NEG. MOTHER REPORTS NEVER HAD A PROBLEM BEFORE GETTING THE GARDASIL VACCINE.

Other Meds:

Lab Data: PREG TEST - NEG

History: NONE

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: **344219-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Jan-2009	22-Jan-2009	2	15-Apr-2009	20-Apr-2009	CA		21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dry skin, Eczema, Erythema, Pruritus, Rash

Symptom Text: States 2-3 days after recieving 1st Gardasil dose in LD, she developed a red, dry, itchy skin rash to left arm, shoulder to knuckles. Also present on knuckles. Self-treated initially with hydrocortisone cream. Seen at health center for same symptoms on 1-27-09. Treated with rx for triamcinolone cream. Diagnosis at that time was eczema. No prior hx of same. Resolved after approx. 2 weeks; student gave this history upon returning for 2nd Gardasil dose on 3-31-09. After discussion with manufacturor and MD, second dose was not given due to the possibility of an allergic reaction and student advised that it would be recommended that she discontinue series at this time. Student given info. sent from Merck as well as CDC and websites for further information.

Other Meds: lutera

Lab Data: N/A

History: N/A

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344255-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	Unknown	27-Jan-2009		16-Apr-2009	17-Apr-2009	WI	WAES0903USA02289	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse, for the Pregnancy Registry for GARDASIL, concerning a 19 year old female who on 21-AUG-2008 and 03-MAR-2009 was vaccinated with her second and third dose of GARDASIL (lot number of the 2nd and 3rd dose was 661952/1129X, the lot number of the 1st dose was 659184/0843X) 0.5ml IM. There was no concomitant medication. The patient had a pregnancy test and was now pregnant. The last menstrual period was 27-JAN-2009. The estimated delivery date was 03-Nov-2009. The patient had not experienced any known symptoms. The patient sought medical attention. Follow-up information has been received from the nurse via a pregnancy questionnaire. The patient with a questionable no previous pregnancies and a questionable history of rheumatoid arthritis on 20-MAR-2009 underwent elective termination (methotrexate). Products of conception were not examined. No further information is available.

Other Meds: Unknown

Lab Data: Beta-human chorionic, ?/?/09, pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 1/27/2009)

Prex Vax Illns:

Vaers Id: **344256-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Feb-2009	16-Feb-2009	0	16-Apr-2009	17-Apr-2009	--	WAES0904USA01356	17-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Chest pain, Computerised tomogram, Convulsion, Dizziness, Dyspnoea, Electroencephalogram, Fatigue, Laboratory test, Nausea, Nuclear magnetic resonance imaging

Symptom Text: Information has been received from a consumer concerning her 17 year old daughter with no pertinent medical history and no known drug allergies/drug reactions who on 16-FEB-2009 was vaccinated with the first dose of GARDASIL. Concomitant therapy included meningococcal vaccine (manufacturer unknown). It was reported that "2 hours after getting the vaccine" the patient started having trouble breathing and feeling chest pains. The patient was taken to the emergency room but was not admitted overnight. "A full work up was performed at the emergency room (results not provided), also a computed axial tomography scan, electroencephalography and magnetic resonance imaging were performed (results not provided). It was reported that she had couple more breathing episodes since. The patient also experienced seizure like activity starting on 11-MAR-2009. It was reported that the first seizure was pretty severe and the patient did not calm down until she was given ATIVAN. It was reported that the patient overall was experiencing tiredness, weakness, chest pains, dizziness and nausea. The patient was seen at the practice. It was reported that the patient had not recovered at the time of the report. Upon internal review, seizure-like activity was determined to be other important medical event. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344285-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Mar-2009	15-Mar-2009	3	16-Apr-2009	21-Apr-2009	WA		13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Asthenia, Fatigue, Hyporeflexia, Immunisation reaction, Lymph node palpable, Muscular weakness, Musculoskeletal chest pain, Myalgia, Oropharyngeal pain, Pain in extremity, Pharyngeal erythema, Rash pruritic, Sensation of heaviness, Upper respiratory tract infection, Urticaria

Symptom Text: 3 days post vaccination, patient had eruption of hives and developed extreme fatigue, arm and leg pain, and muscle weakness, severe enough that she had to discontinue participation in track. Symptoms are slowly resolving, but lower extremity weakness complaint persists. 4/24/09 MR received from PCP. OV 3/17/09 with c/o pruritic rash, fatigue and heaviness and aches in the legs. Sore throat last week. PE (+) for nasal mucosa and throat erythematous, increased anterior nodes, erythematous, hive-like lesions on the arms, legs and back. Assess: Urticaria. URI. Constipation. Office note 4/14/09 states pt still c/o leg heaviness, rib pain, stomach pain, muscle aches and fatigue. RTC 4/16/09 with c/o fatigue, extremity pain and weakness. Had to quit track 2' lower extremity weakness. PE (+) for 1+ patellar DTRs and able to get out of chair using arms. Assess: ? myalgias and lower extremity weakness 2' to Gardasil.

Other Meds: N/A

Lab Data: CBC, CK-muscle, ESR, ANA pending Labs: WBC 4.2. CK 91 (WNL). ANA (-). (no ESR done)

History: History of thyroid nodule; Raynaud's syndrome. PMH: H/A. thyroid nodule with surgery. acne. Raynaud's. folliculitis. herpes zoster 8/07, abnormal brain MRI, ear tubes, arm fx, nasal fx./

Prex Illness: N/A

Prex Vax Illns:

Vaers Id: **344295-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Apr-2009	16-Apr-2009	0	16-Apr-2009	20-Apr-2009	CA		20-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1708X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fall, Gaze palsy, Loss of consciousness, Tremor

Symptom Text: Patient was given the GARDASIL # 1 vaccination in her right deltoid muscle. Pt. was advice to sit for the injection but refused. Very shortly after the injection pt. fell to the floor, loss of consciousness approx 6 second with rolling up of eyes and body shaking. taking to extended care dept. for evaluation

Other Meds: ACYCLOVIR 400mg

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: None~ ()~~0~Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344298-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	02-Apr-2009	03-Apr-2009	1	16-Apr-2009	20-Apr-2009	UT		20-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	SANOFI PASTEUR	C3070AA	0	Left arm	Intramuscular	
	MMR	MERCK & CO. INC.	1579X		Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0653X	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1740X	0	Left arm	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain, Pruritus, Pyrexia, Rash, Rhinorrhoea, Varicella

Symptom Text: Fever, runny nose, itching started evening of 4-3-09 along with start of rash. Diagnosed with chicken pox on 4-6-09 by family physician Rash mainly on trunk, arms & face. Rx for pain Rx for antihistamine.

Other Meds: PROZAC; ATIVAN

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344307-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.4	F	07-Apr-2009	07-Apr-2009	0	16-Apr-2009	21-Apr-2009	FL		29-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548Y	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea

Symptom Text: After receiving shot in AM of 4-7-09 pt c/o shortness of breath in the afternoon at home with mother - *Nurse informed mom to watch patient closely for x24 hrs. ER in rescue if needed. Our f/u call next AM 4-8-09 pt fine now.

Other Meds:

Lab Data:

History: None told.

Prex Illness: Gastroesophageal Reflux (GER)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344313-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Apr-2009	15-Apr-2009	0	16-Apr-2009	21-Apr-2009	KY		22-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amnesia, Chest pain, Dyspnoea, Influenza like illness, Pain, Presyncope

Symptom Text: Chest pain, slight shortness of breath. Amnesia during and half an hour after receiving vaccination. "Almost" passed out during vaccination. Flu like symptoms including body aches the next day.

Other Meds: None

Lab Data:

History: Allergies: AMOXICILLIN; hx: Asthma and seasonal allergies

Prex Illness: None

Prex Vax Illns:

Vaers Id: **344320-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		17-Apr-2009	20-Apr-2009	FR	WAES0904USA01460	20-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia, Autoimmune thyroiditis, Hypothyroidism

Symptom Text: Case received from a physician on 07-APR-2009: A 16-year-old female patient received a dose of GARDASIL (batch # not reported) on a date not reported. On an unspecified onset of time, the patient experienced a loss of hair. A blood work-up revealed hypothyroidism. Autoimmune thyroiditis was suspected. At the time of reporting, the outcome was not provided. Autoimmune thyroiditis was reported as other medically important condition. Additional information has been requested. Other business partner numbers include E2009-03193.

Other Meds: Unknown

Lab Data: Diagnostic laboratory test, hypothyroidism

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344321-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Apr-2007	01-Apr-2007	0	17-Apr-2009	20-Apr-2009	--	WAES0904USA01551	20-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from an 18 year old female with migraine and no allergies for GARDASIL, a Pregnancy Registry product, who in February 2007, was vaccinated with the first dose of GARDASIL (lot# not reported). Concomitant therapy included vitamins (unspecified). In April 2007, the the patient received her second dose of GARDASIL (lot# not reported) 0.5 mL when she was 2 weeks pregnant. The patient requested a pregnancy test before receiving the shot of second dose however it was never given to her. On 13-FEB-2008, the patient delivered a baby. It was reported that the baby experienced unexplained fever almost every other day as well as seizures. The baby was also congested all the time and was diagnosed with asthma. The reporter felt that the baby's unexplained fever, seizures and asthma were related to therapy with GARDASIL. Unspecified medical attention was sought. Upon internal review, seizure was considered to be an other important medical event. No further information is available.

Other Meds: Vitamins (unspecified)

Lab Data: Beta-human chorionic, ?/?/07, pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 5/9/2007); Migraine

Prex Vax Illns:

Vaers Id: **344330-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	20-Mar-2009	Unknown		17-Apr-2009	21-Apr-2009	PA		30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Auricular swelling, Erythema, Rash generalised, Swelling face

Symptom Text: 3/20/09 had GARDASIL #2 at approx. 4:15 pm. Took CLARITIN in AM for allergies. Also takes CONCERTA and ORTHO TRICYCLEN low dose. Used tanning bed and Pomegranate lotion. 3/22/09 had rash behind ears. Used hot tub. 2/23/09 Had rash on chest face and back - "red, bumpy, tiny dots." Went to school nurse at 10 AM and was given BENADRYL and Hydrocortisone cream. Mon. night has rash on inner thighs. 3/24/09 returned to nurse - ears and nose were red and swollen. Nurse called Dr. who wanted her seen at ER. At ER was given steroid shot and Prednisone bid x 4d. Rash was no longer spreading. Was told no to get third GARDASIL. To see regular Dr. 3/27/09.

Other Meds: CONCERTA; CLARITIN; ORTHO TRICYCLEN low dose

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **344332-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Mar-2009	17-Mar-2009	0	17-Apr-2009	21-Apr-2009	OR		21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	1258U	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0653X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2843A	0	Right arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1751X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Dizziness, Pain in extremity, Paraesthesia, Vomiting

Symptom Text: Pt. had acute onset of severe vomiting and dizziness. Lasted into next day. Also began to have leg pain & perceived weakness, tingling. The leg symptoms lasted >/wk. Pt totally normal on 4/8/09

Other Meds:

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344336-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	09-Apr-2009	10-Apr-2009	1	17-Apr-2009	21-Apr-2009	NY		21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea, Pain

Symptom Text: Headache, bodyache, some nausea. 4/10/09. Advised TYLENOL 500 mg 2 tabs P.O. Q6 PRN.

Other Meds: None

Lab Data: None

History: 2004 Hodgkins Lymphoma

Prex Illness: None

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344338-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	06-Apr-2009	Unknown		17-Apr-2009	21-Apr-2009	OH		21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash generalised

Symptom Text: Rash on stomach, chest, genitals

Other Meds:

Lab Data:

History: Herpes

Prex Illness: Leg pain

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344345-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	12-Jul-2007	26-Sep-2007	76	17-Apr-2009	20-Apr-2009	OH		27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0522U	0	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Disturbance in attention, Dizziness, Fatigue, Headache, Hyperacusis, Hyperaesthesia, Muscle spasms, Myalgia, Pain, Paraesthesia, Parosmia, Photophobia

Symptom Text: Initial fatigue, headaches, muscle cramps, muscle pain, sound sensitivityafter 1st shot. Increased in severity of all symptons. After 3 rd shot signficant increase in pain. Hip pain. Light,touch,smell sensitivity, chronic fatigue, tingling in hands, feet, sometimes all over body, faintness, joint spasmas. Poor, limited conentration.

Other Meds: Mircette,multi vitamin, zantac

Lab Data: Positive sacroilitis 10-08.MRI 12-08 Diagnosed migrains, chronic fatigue, depression 4-09

History: acne, GERD, Allergic ceftin, dioxicillian

Prex Illness: Seasonal allergies, acne

Prex Vax Illns:

Vaers Id: **344363-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Oct-2007	01-Jun-2008	226	17-Apr-2009	21-Apr-2009	LA		08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2392BA.	0	Unknown	Unknown	MEN
	HPV4	MERCK & CO. INC.	1265U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, LIFE THREATENING, SERIOUS

MedDRA PT Abdominal pain upper, Anxiety, Back pain, Confusional state, Cough, Croup infectious, Dizziness, Dysphonia, Fatigue, Flank pain, Flatulence, Fluid retention, Gait disturbance, Headache, Hyperpallaesthesia, Hypoaesthesia, Joint swelling, Laryngitis, Malaise, Mobility decreased, Myalgia, Nasal congestion, Neck pain, Oropharyngeal pain, Paraesthesia, Pharyngitis streptococcal, Polymyositis, Pyrexia, Swelling face, Tonsillitis, Viral upper respiratory tract infection, Weight increased

Symptom Text: During summer of 2008, patient had many episodes of anxiety which she never had before, she also is more easily confused; 9/30/08 Dr visit for side pains, and sore neck, 2nd dose of gardasil given at this visit; 10/28/08 Dr visit for dizziness, headaches and stomach pain, Dr attributed to gas, and rec increase fluids, and tylenol; 11/11/08 Dr visit for muscle pain, near inability to walk, inability to raise arms, stomach pain, back pain, tingling, vibrating sensation of extremities, Dr rec continue Ibuprofen or aleve daily; symptoms slightly resolved for a short time; 3/26/09 Dr visit with another doctor in practice- gained 10 lbs in fluids, severe ankle swelling numbness and tingling of feet, had been having nightly fevers for 10 days prior, legs and arms go numb when "crossed" for a few seconds, these symptoms have gotten better for now, she does still have headaches, dizziness and lightheadedness. 5/4/09 Received PCP medical records of 10/19/07-3/26/2009. FINAL DX: polymyositis Records reveal patient experienced usual state of good health on 10/19/07 when received HPV & Menactra. RTC 2/9/08 w/sore throat x 2 days, fever x 1 day, nasal congestion & fatigue. Dx w/strep throat & tx w/IM antibiotics. RTC 4/18/08 w/fever & sore throat x 2 days. Dx w/laryngitis/croup. RTC 10/28/08 w/dizziness, HA, stomach pains, low grade fever, hoarseness & cough x 2-3 days. Dx viral laryngitis & URI. RTC 11/11 w/muscle pain & tingling x 2-3 wks. Dx w/myalgias & paresthesias. Referred to Neuro. RTC 1/14/09 w/resolved polymyositis. RTC 3/16/09 w/pharyngitis. RTC w/ bilateral ankle swelling, possible facial edema, malaise, tonsillitis. Labs done but were unrevealing.

Other Meds:

Lab Data: elevated liver enzymes, elevated wbc, decreased rbc, lowered hct, 16.8 rdw, lowered segs, raised lymphs, raised metas and aniso, elevated esr, ast was raised, alkaline phosphatase and ALT were severely raised; her blood pressure is also hig

History: seasonal allergies PMH: chickenpox, seasonal allergic rhinitis, keratosis pilaris, mild scoliosis, anemia.

Prex Illness: no

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344374-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	13-Apr-2009	14-Apr-2009	1	18-Apr-2009	22-Apr-2009	NJ		12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0074Y	1	Left arm	Intramuscular	HPV4

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain lower, Anxiety, Condition aggravated, Confusional state, Cough, Depression, Diarrhoea, Dizziness, Fatigue, Haemorrhoids, Hypersomnia, Pain, Pharyngitis, Pyrexia, Rhinorrhoea, Sinusitis, Upper respiratory tract congestion, Weight increased

Symptom Text: Extreme fatigue (20 hours of sleep for five days)Extreme body ache, confusion, dizziness 4/20/09 Received PCP medical records of 4/13/2009. FINAL DX: none provided Records reveal pt seen for HPV #2 & breakthrough bleeding on BCP. Reported no AE to HPV #1 other than pain at injection site. t/c to office on 4/17 to c/o fatigue, achy muscles & fever since 4/14. 4/29/09 Received additional PCP medical records of 1/30/08-1/16/2009. FINAL DX: none provided. Records reveal patient experienced lower abdominal pain & diarrhea 7/08. Colonoscopy done 8/22 abnormal w/congested mucosa left colon, redundant colon & internal hemorrhoids. Tx w/diet & meds. RTC 1/09 w/runny nose, achy, cough, fever & head congestion. Dx w/sinusitis & URI & tx w/antibiotics. RTC 5/08 w/weight gain, psych meds ineffective & pharyngitis.

Other Meds:

Lab Data: LABS: intestinal biopsy. CBC WNL. Lipid profile(H). Amylase/lipase WNL. US of abdomen WNL.

History: PMH: depression/anxiety.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344378-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-Mar-2009	06-Mar-2009	0	17-Apr-2009	21-Apr-2009	WY		22-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea, Oxygen supplementation

Symptom Text: After immunization was given pt went to the waiting where she stated she was "feeling like she is going to throw up". Pt was given .30 Epi pen in left thigh, 6L 02, notified Dr. Pt was treated over 3 hrs.

Other Meds:

Lab Data:

History: UNK

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344384-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	15-May-2007	Unknown		17-Apr-2009	21-Apr-2009	IL		22-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Petit mal epilepsy

Symptom Text: Patient started on GARDASIL series 5/15/2007- 2nd given 7/16/2007. Mom noticed in fall of 2007 that absence type seizures began.

Other Meds: ADDERALL XR 25 mg

Lab Data: CBC & Chem 7, nl; EEG, 9/08, nl for age but 1-2 spike-wave d/c that suggest predisposition to seizures

History: ADHD

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344385-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		20-Apr-2009	21-Apr-2009	CA	WAES0904USA02014	21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received from an office manager that the physician heard from the physician's colleague that a 16 year old female colleague's patient was given an unspecified dose of GARDASIL (Lot not reported) on a Friday and on Monday the patient passed away (specific dates were unknown). The reporter considered the event as disabling and life threatening. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344392-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	01-Feb-2008	01-Feb-2008	0	20-Apr-2009	21-Apr-2009	--	WAES0904USA01867	21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy

Symptom Text: Information has been received from a 26 year old female for GARDASIL, a pregnancy registry product, concerning herself with no pertinent medical history or no allergies who in December 2007, was vaccinated with the first dose of GARDASIL. In February 2008 the patient was vaccinated with the second dose of GARDASIL. There was no concomitant medication. In March 2008 she found out she was one month pregnant by doing many pregnancy test which all came out positive. The patient reported that all the sonograms that she had during the pregnancy were normal, and at the time of delivery the babies head was turned in the cervix and the umbilical cord was caught so the patient had a c-section. The patient was at hospital for three days. The patient reported that the baby was delivered on 26-DEC-2008 and the baby was healthy. On 10-APR-2009 the patient was vaccinated with the third dose of GARDASIL. Additional information has been requested.

Other Meds: None

Lab Data: ultrasound, ?/?/08, normal; beta-human chorionic, 03?/??/08, positive

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344393-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	17-Jul-2008	09-Feb-2009	207	20-Apr-2009	21-Apr-2009	CA	WAES0904USA02046	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1758U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Similar reaction on previous exposure to drug, Syncope, Vaccine positive rechallenge

Symptom Text: Information has been received from a nurse concerning a 11 year old female patient who on an unspecified date was vaccinated with the first dose of GARDASIL and experienced fainting. When the patient received the second dose of GARDASIL, she experienced mild seizure. On 09-FEB-2009 the patient received the third dose of GARDASIL and again, experienced mild seizure (Lot number not provided). The reporter added that when the patient rested she improved that same day and they even called the patient a week later to check how she was doing and she recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344394-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	11-Jan-2008	11-Jan-2008	0	20-Apr-2009	21-Apr-2009	--	WAES0801USA05068	21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Caesarean section, Drug exposure during pregnancy, Herpes simplex

Symptom Text: Information has been received from a nurse practitioner, for the Pregnancy Registry for GARDASIL, concerning a 22 year old female with no medical history and no drug allergies, who on 13-NOV-2007 was vaccinated with a first dose of GARDASIL. On 11-JAN-2008 the patient was vaccinated with a second dose of GARDASIL. There was no concomitant medication. Subsequently, the patient was approximately four or five weeks pregnant. The patient's last menstrual period was 24-DEC-2007 and her estimated delivery date was 29-SEP-2008. It was reported that the patient had not seen a physician but would be seeing a nurse practitioner. No laboratory diagnostics were performed. At the time of the report, the outcome of the patient was unknown. No product quality complaint was involved. Follow-up information was received from the nurse practitioner regarding the outcome of the patient. It was reported that the patient had a primary cesarean section at 37+6/7 weeks secondary to an active outbreak of HSV (herpes simplex virus). The baby weight 2785 grams and had Apgar scores of 9&10. The reporter also stated the baby was fine without any problems. There were no reported complications for the mother or baby. Upon internal review, active outbreak of HSV (herpes simplex virus) was determined to be an other important event. No further information is available.

Other Meds: None

Lab Data: Apgar score, 09/14?/08, 9&10 (BABY); body weight measurement, 09/14?/08, 2785 gram (BABY)

History:

Prex Illness: Pregnancy NOS (LMP = 12/24/2007)

Prex Vax Illns:

Vaers Id: **344398-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	30-Apr-2008	03-May-2008	3	20-Apr-2009	21-Apr-2009	FR	WAES0904USA02133	21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1068U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anorexia, Autoimmune thyroiditis, Goitre, Hypochromic anaemia, Malaise, Muscle spasms, Muscle swelling, Myositis, Oedema, Pain in extremity, Pyrexia, Splenomegaly, Weight decreased

Symptom Text: Information has been received from a pharmacist. It was reported that a female patient (age not reported) was vaccinated with a dose of GARDASIL (lot # not reported) on an unspecified date. Subsequently, the patient developed lymphoma (date not reported). No further information on the outcome etc has not been made available at the time of reporting. Further information was requested. Follow up information received on 07-APR-2009. The hospital report, the reporting form and a doctor's letter was provided. It was confirmed that the patient did not develop a lymphoma, this was reported by mistake by the pharmacist. It was reported that the 17 year old female patient was vaccinated IM with a first dose of GARDASIL (batch # NH06410, lot #1068U, injection site illegible) on 30-APR-2008. On 03-MAY-2008 to 31-MAY-2008 and on 03-JUN-2008 to 04-JUN-2008 the patient developed increasing gain and cramps of the calves on effort. Due to these symptoms she was hospitalized from 08-JUN-2008 until 10-JUN-2008. Vein thrombosis was excluded by a specialist. The patient was treated with ibuprofen. After discharged the complaints were persisting. On 20-JUN-2008 the patient was hospitalized again in a pediatric hospital. She had fever and CRP increase of 140 mg/l. Antibiotic therapy with cefuroxime, clindamycin and Vancomycin was initiated. Purulent myositis was suspected. MRI showed an enhancement of the calf muscles. Sonography showed edema of several calf muscle. As the antibiotic therapy was not sufficient enough the patient was transferred to another hospital to clarify by a muscle biopsy the suspicion of an autoimmunologic or vascular disease on 02-JUL-2008. At that time the patient complained of malaise, feeling swollen of the calves, appetite lost and weight loss (6kg) during the last 4 weeks. On 02-JUL-2008 CRP was increased (8.48 mg/dl), Hb was decreased 9.0 g/dl. Autoimmune diagnostic showed ANA slightly increased (1:160), thyreogolobulin and anti-TPO antibodies were increased (478U/ml and 2900U/ml). Serology for enteroviru

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 02Jul08, anti-proteasome antibody: positive; abdominal ultrasound, 02Jul08, mild splenomagaly; ultrasound, 02Jul08, total volume of thyroid gland above the normal range, unusual for HASHIMOTO's thyroiditis; ultra

History:

Prex Illness: Upper respiratory tract infection

Prex Vax Illns:

Vaers Id: **344413-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	18-Nov-2008		20-Apr-2009	21-Apr-2009	FR	WAES0904RUS00002	21-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Uterine haemorrhage

Symptom Text: Information has been received from a physician concerning a 16 year old female who was vaccinated with GARDASIL. On 18-NOV-2008 the patient experienced uterine bleeding and was hospitalized. Therapy with GARDASIL was discontinued. The reporter felt that uterine bleeding was related to therapy with GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344438-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	08-Apr-2009	09-Apr-2009	1	20-Apr-2009	24-Apr-2009	SD		24-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2549AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2966AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pyrexia, Rash, Swelling face

Symptom Text: Fever 1 day after vaccinations, Face Swelling 2 days after, by day 3-4 rash on face

Other Meds: Zyrtec Prn

Lab Data:

History: Seasonal allergies

Prex Illness:

Prex Vax Illns:

Vaers Id: **344440-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Aug-2007	01-Sep-2007	9	20-Apr-2009	21-Apr-2009	WI		01-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	UNKNOWN MANUFACTURER	0780U	1	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	0012U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Adhesiolysis, Cholecystectomy, Colectomy, Colitis ulcerative, Cough, Crohns disease, Diarrhoea, Explorative laparotomy, Gastroenteritis, Gastrointestinal haemorrhage, Haematochezia, Ileostomy, Inflammatory bowel disease, Intestinal anastomosis, Intestinal obstruction, Oropharyngeal pain, Pancreatitis, Rectal haemorrhage, Transfusion, Urinary tract infection

Symptom Text: After recieving vaccine, Mariah started having bouts of rectal bleeding and diareah. In additin to this she had a very loud barking "chronic" cough. Months and months of her PMD telling us not to worry, she finally diagnosed with Ulcerative Colitis. She has had to have a total colectomy resulting with an ostomy and several blood transfusions. 4/28/09 Extensive MR received for multiple hospital admissions and ER visits from 5/2008-4/2009 with the following D/C DX: DOS: 10/3-5/2008- Inflammatory Bowel Disease. Anemia s/p PRBC transfusions DOS: 10/8-31/2008- Ulcerative Colitis. Pancreatitis. S/P Lap Colectomy with Ileostomy. Ex lap, ahesiolysis, wash out. DOS 1/5-8/2009- Ulcerative Colitis s/p Colectomy. Acute pancreatitis. Pancreas divisum. UTI. DOS 2/16-22/2009- Lap Cholecystectomy. Lap-assisted J-pouch ileorectal anastomosis. Anorectal pull through. Loop ileostomy. DOS 4/3-6/2009- Ulcerative Colitis, Pancreatitis. Bowel Obstruction. Multiple ER visits with DX: 4/25/08 Cough. hematochezia 5/4/08 GI bleed. Abdominal cramping 5/22/08 Crohn's exacerbation 6/8/08 Rectal bleeding. 7/26/08, 7/27/08, 9/8/08 Crohn's Flare. 10/8/08 IBD and drug induced pancreatitis. 11/17/08 Gastroenteritis as well as multiple episodes of abdominal pain. Otolaryngology consult 9/8/08 for 9 month hx of chronic cough. Seen in Pulmonary Clinic 3/26/09 for f/u of chronic cough 2' to ulcerative colitis.` Pt initially presented 4/25/08 with c/o 4 wk hx of chronic cough, sore throat and 2 week hx of rectal bleeding. PE WNL. Returned 5/2/08 with c/o rectal bleeding and abdominal pain-frank blood and diarrhea. Frequent hospitalizations and Er visits as above continue to present with multiple surgeries and procedures (above).

Other Meds:

Lab Data: Labs: Hgb 9.7. KUB WNL. WBC 19.8. ESR and CRP elevated. Platelets 583. CT (+) for bowel obstruction. US GB (+) for thickening. Pancreatic enzymes increased. LDH 540 (H). Lipase 1279-8249 (H).

History: none PMH: Env allergies. PCN. Tonsillectomy.

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344442-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	16-Apr-2009	16-Apr-2009	0	20-Apr-2009	24-Apr-2009	VA		24-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2633AA	0	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB264AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0575X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Injection site warmth

Symptom Text: Localized swelling at injection site. Red and warm to upper arm .

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vaers Id: **344443-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	13-Jan-2009	Unknown		20-Apr-2009	24-Apr-2009	OK		24-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0381X		Unknown	Intramuscular	
	MNQ	SANOFI PASTEUR	42659AA		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: No complaints-screened Jan 13, 2009 denied being pregnant-Her informed choice HPV#1 and Menactra given, states due Hept A #2 due after 12 February; Returned April 06, 2009 seen by different nurse- screened pregnant-Rx from Dr for Hep A/B; later, when RN informed possibly pregnant on Jan 13? Due date was not asked by RN? tried to call several days (no answer) to ask if possibly pregnant on Jan 13, 2009? VAERS done-for follow-up and if pregnant needs to be on HPV and Menactra watch list-thanks

Other Meds: none known

Lab Data: none here

History: none known-screening all NO

Prex Illness: none known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344444-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	06-Apr-2009	07-Apr-2009	1	20-Apr-2009	24-Apr-2009	OR		24-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Erythema, Pruritus, Swelling

Symptom Text: Left sided facial redness, itching and swelling 1 day after vaccine administered into left deltoid. Also felt lightheaded day of vaccine.

Other Meds: citalopram, implanon

Lab Data:

History: depression

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344447-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	14-Nov-2007	14-Nov-2007	0	20-Apr-2009	21-Apr-2009	FL		11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0389U	0	Left arm	Intramuscular	UNK
	FLU	UNKNOWN MANUFACTURER	U24767GA	2	Right arm	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Amenorrhoea, Back pain, Carpal tunnel syndrome, Chest pain, Cold sweat, Condition aggravated, Depression, Dysarthria, Fall, Fatigue, Gastritis, Gastroenteritis viral, Haematochezia, Headache, Immediate post-injection reaction, Insomnia, Malaise, Migraine, Mobility decreased, Monoplegia, Muscular weakness, Neuropathy peripheral, Pallor, Paraesthesia, Plantar fasciitis, Pyrexia, Rhinitis allergic, Similar reaction on previous exposure to drug, Sinus tachycardia, Sinusitis, Sleep apnoea syndrome, Syncope, Tonsillitis, Upper respiratory tract infection, Vomiting

Symptom Text: fever, vomiting,malise, headache could not get out of bed for 2 weeks after 1st shot. Developed periphreal neurapathy within 30 days of 1st shot. However it took 3 months to diagnose. Gastritis several times. Migraines constantly, fainting with muscle weakness...can not use legs for hours after faintinf, bloody stools, paralysis in right arm immediately after third vaccine. Pallor, clamminess, amennorhea no period since first vaccine. fatigue, insomnia, sleep apnea, chest pain, pins and needle sensations throughout extremities, sinusitis several times, pins and needles feelings in stomach, fevers on and off, slurred speech. She has been very ill since first vaccine and in a lot of pain. 5/1/09 Received vaccine & PCP medical records of 11/14/06-1/9/2009. FINAL DX: none provided Records reveal patient experienced shooting paine & numbness of extremities 2 wks prior to HPV #1 & flu shot. RTC w/recurrent depression, left plantar fasciitis, migraine HAs. Seen in ER 3/13/08 for HA & dx w/ethmoid sinusitis, tonsillitis & URI. RTC w/viral gastroenteritis, right CTS, recurrent allergic rhinitis. 8/18/08 w/spells x 3-4 yrs which had increased in frequency x 3 wks; dx w/presyncopal episodes. Seen in ER w/dx gastroenteritis. Referred to Neuro for syncope. Missed several days of school. RTC for LBP s/p fall, gastritis w/bloody stools

Other Meds: lo-ogesterl, vitamins, metanx, glucophase, prozac, trazadone, spironlactone

Lab Data: EKG, Holter Monitor, EEG, Sleep Studies, Heavy Metal test, CBC, Urinalysis, Upper GI, Stool sample, Hepatitis test, CBC, metobolic study, Cat Scans, MRI, Has seen neurologist, pulmonary doctor, podiatrist, endocrinologist, tons on blood wor

History: mold, cockroaches, smoke, dust, dust mites, trees, grass,perfume allergies PCOS, blounts, hypoglycemia, PMH: exudative pharyngitis, metabolic syndrome w/hirsutism, Type II DM w/peripheral neuropathy, metromenorrhagia, morbid obesity, Blount's disease w/left tibial lengthenins & reshaping via cage, left gastrocnemius contracture, bronchitis, URI, sleep apnea, restless leg syndrom

Prex Illness: hypoglycemia, PCOS, depression

Prex Vax Illns:

Vaers Id: **344486-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Apr-2009	17-Apr-2009	0	20-Apr-2009	23-Apr-2009	RI		24-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2877AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1312X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Facial bones fracture, Fall, Syncope

Symptom Text: Syncope post GARDASIL and MENACTRA administration. Patient fractured nose during syncope event (hit office counter during fall).

Other Meds:

Lab Data: Xray of nasal bones

History:

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344503-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Jan-2008	Unknown		21-Apr-2009	27-Apr-2009	CA		27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	2	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Joint stiffness, Musculoskeletal pain

Symptom Text: After Gardasil #3 woke up with shoulder pain L now hands fingers hard to work. Tests for lupus & arthritis - neg. Now very stiff joints hands & knees. Vague history when sym started.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344504-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Apr-2009	15-Apr-2009	0	21-Apr-2009	27-Apr-2009	NC		12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0049Y	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2688AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pruritus, Urticaria

Symptom Text: Hives on face and trunk extremities. Intense itching.

Other Meds: DEPO MEDROL, 40mg IM at 12:25pm; DECADRON, 4mg, DM at 12:25pm; ALBUTEROL; DEPO PROVERA, 150mg, IM, left hip; ALLEGRA

Lab Data: No testing only injections given

History: NKDA; H/O hay fever; asthma; seasonal allergies

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344512-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	11-Mar-2009	11-Mar-2009	0	21-Apr-2009	22-Apr-2009	FR	WAES0904NZL00005	22-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1283U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Gaze palsy, Immediate post-injection reaction, Syncope

Symptom Text: Information has been received from an agency, via agency, as part of a business agreement, concerning a 14 year old female who on 11-MAR-2009 was vaccinated with GARDASIL (Lot No. 1283U, Batch No. NJ11440), 0.5 ml, intramuscularly, as prophylaxis. On 11-MAR-2009, instantly after vaccination with GARDASIL, the patient experienced eyes rolling, convulsions and syncope, all of which were reported as not severe. At the time of reporting to the agency in March 2009, the patient had recovered without sequelae from eyes rolling, convulsions and syncope. The agency considered that eyes rolling, convulsions and syncope were probably related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review, convulsions was considered to be an Other Important Medical Event.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344513-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	06-Dec-2008	06-Dec-2008	0	21-Apr-2009	22-Apr-2009	--	WAES0904USA01725	22-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Incorrect route of drug administration

Symptom Text: Information has been received from a registered nurse concerning a 20 year old female with no past drug history, who on 06-DEC-2008 was vaccinated with a 0.5 mL second dose of GARDASIL (lot # 661703/0651X), subcutaneously. There was no concomitant medication. It was reported that in January 2009 the patient had a pregnancy. On 23-MAR-2009 the patient had a spontaneous abortion. There were no laboratory studies performed. On 11-APR-2009 the patient received her third dose of GARDASIL. Follow up information received on 16-APR-2009 from a registered nurse stated that the patient received the first dose of GARDASIL on 03-AUG-2008; second dose on 06-DEC-2008 (lot # 661703/0651X) and third dose on 11-APR-2009 (lot # 661846/1312X). There was no mention of pregnancy at the time of the 06-DEC-2008 dose (second dose). The LMP date was not indicated in the chart, nor was the # of weeks from LMP to the time of the spontaneous abortion (not an elective termination). Also not indicated in the notes was whether or not the products of conception were examined. This was the patient's first pregnancy. Upon internal review spontaneous abortion was determined to be an other important medical event. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 1/1/2009)

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344514-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	14-Oct-2008	20-Oct-2008	6	21-Apr-2009	22-Apr-2009	FR	WAES0904USA02150	22-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1647U		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Dyskinesia

Symptom Text: Information has been received from a Health care professional and Health authority concerning a 12 year old female with no medical history who on 14-OCT-2008 was vaccinated with one dose of GARDASIL (lot number; batch number NH55590). On 20-OCT-2008, the patient presented with abdominal pain that resolved spontaneously. On 25-MAR-2009 she was admitted to the hospital for dyskinesia of the upper left limb. Laboratory work performed in NOV-2008: Activated partial thromboplastin time (APTT) and partial thromboplastin time (ptt) not dosable, in DEC-2008: Lupus anticoagulant: positive, factor VIII 8%, in JAN-2009: Lupus anticoagulant: positive, factor VIII 8%, antinuclear antibodies: positive, in MAR-2009 antinuclear antibodies: negative, extractable nuclear antigens: positive, factor VIII 90% anti DNA antibodies: positive. During admission an electrocardiogram (ECG) and computed axial tomography (CT scan) (NOS) were performed and were negative. The final outcome was not reported. Other business partner numbers include E2009-03157. Additional information has been requested.

Other Meds: Unknown

Lab Data: electrocardiogram, ??Mar09, Negative; computed axial tomography, ??Mar09, (NOS) Negative; APTT, ??Nov08, No dosable; APTT, ??Nov08, No dosable; lupus anticoagulant test, ??Dec08, Positive; factor VIII activity test, ??Dec08, 8%; serum ANA,

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344523-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	24-Mar-2009	24-Mar-2009	0	21-Apr-2009	22-Apr-2009	FR	WAES0904USA02108	22-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0153X	2	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Headache, Hypotension, Vomiting

Symptom Text: Information has been received from a health authority (HA reference number 97311) concerning a 12 year old female with no previous medical history reported who on 24-MAR-2009 was vaccinated with third dose of GARDASIL (dose and route not reported, lot number 0153X, batch number NJ29300). On 24-MAR-2009 the patient presented with headache (right temporal region), vomiting and arterial hypotension. She was hospitalized and treated with analgesics. The outcome was recovered on 30-MAR-2009. Other business partner numbers included: E2009-03237, IT156/08. No further information is available. The case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344527-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	15-Apr-2009	15-Apr-2009	0	21-Apr-2009	27-Apr-2009	CA		27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	0190Y	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2820AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2865AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Gaze palsy, Musculoskeletal stiffness, Respiratory rate increased, Skin discolouration, Staring, Tremor, Urinary incontinence

Symptom Text: About 5-10 min after vaccination given, the patient had a blank stare, turned gray, rapid breathing, got stiff eyes, eyes rolled back, arm and legs stiff and shook some, + urinary incontinence. No h/o seizures in the past.

Other Meds: ADDERALL, 30mg, po, QD

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344549-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	21-Apr-2009	Unknown		21-Apr-2009	27-Apr-2009	CT		27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B029AA	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2733AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0279X		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Syncopal episode fainted

Other Meds: None

Lab Data: none

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344555-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.4	F	20-Apr-2009	20-Apr-2009	0	21-Apr-2009	27-Apr-2009	CA		27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Headache, Immediate post-injection reaction, Malaise, Nausea

Symptom Text: Given HPV injection approx. 8:20 a.m., Immediately felt sick and dizzy, thought she was going to vomit. There were two more incidents during day one; she said she felt more fatigued than usual and after waking up the second time after the vaccination had severe frontal head pain accompanied with dizziness. This is being reported on day two, patient says she continues to be dizzy and in general feels ill.

Other Meds: Seasonique (sp)? A birth control medicine

Lab Data: This is the second day so there have not been any tests.

History: Penicillin, no birth defects. Multiple ear infections, tubes in ears, Anxiety, encopresis, depression, seizures.

Prex Illness: No

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344556-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	20-Sep-2007	01-Oct-2007	11	21-Apr-2009	22-Apr-2009	NY		13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1063U	2	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Activities of daily living impaired, Akathisia, Anxiety, Anxiety disorder, Asthenia, Bipolar disorder, Condition aggravated, Depression, Discomfort, Exercise tolerance decreased, Fatigue, Muscular weakness, Obsessive-compulsive disorder, Restless legs syndrome, Restlessness, Self injurious behaviour, Suicidal ideation, Tic, Tourettes disorder

Symptom Text: Previous diagnosis to vaccine-Hypothyroidism, Hashimotos,Acid Reflux, Anxiety, Depression, OCD and had occassional eye tics. Exacerbation of previous symtoms such as reslessness, restless legs, fatigue, weakness, eye and neck tics, anxiety, OCD and depression escalated after receiving vaccines. At time of 1st vaccine, pt was on Zoloft for 2 yrs, Synthroid and Nexium. After vaccines, different meds were prescribed by psychiatrist to treat pts symptoms. Beg Oct, it seemed as if everything got worse. Attendance in school affected beg Nov 07 she was barely attending in Dec 07 and officialy diagnosed with mild Tourettes. Everything was atributed to medication/akathasia, as any medical professional who was asked said "no side effects" with the vaccine, since she has a hx of anxiety, everything's assumed to be anxiety,so she was treated purely psychologically. The discomfort was unbearable for her leading to suicidal thoughts. Pt ended up in ER 2x, 1/22/08 admitted to adolescent inpt psych unit for almost 3 weeks, then partial hospitalization completed 4/11/08. After hospital-pt on 8 medications (6 psych). Never fully recovered, previous to vaccines, pt exercised daily for 2 hrs/day-still unable to exercise. Pt returned to school 9/08 with accommodations. Pt again experienced worsening of tics eye/neck and restlessness, muscle weakness and fatigue end of Feb 08. Attendance affected in school and unable to attend for 6 weeks beginning of March-home tutored. I believe that previous ailments were escalated by the vaccine. Still being treated for restlessness, muscle weakness, fatigue...gave #2 on 11-20-07 and #3 on 3-28-08. 5/13/09 Received hospital discharge summary DOS 1/22/08-2/8/08. FINAL DIAGNOSIS: Bipolar Affective Disorder, Generalized Anxiety Disorder, Tourette's Disorder Records reveal restlessness, aggression, suicidal ideation, self-injurious behaviors. Neurological tics. Hashimoto's thyroiditis, esophageal reflux. 5/1/09 Received vaccine & PCP medical records of 11/07-1/09. FINAL DX: none provided R

Other Meds: Synthroid, Zoloft, Nexium at time of vaccine

Lab Data: Brain MRI, EEG-normal; bloodwork done 5/13/09 Received hospital discharge summary DOS 1/22/08-2/8/08. LABS and DIAGNOSTICS: Metabolic panel WNL. TSH WNL. Pregnancy (-). Prealbumin WNL. Hematology, CBC, urinalysis WNL. Blood Mercury WNL.

History: Hypothyroidim, Acid Reflux, Hashimotos, Anxiety, Depression, OCD, eye tics Varicella(Merck) #2 Lot # 1182U given 10/26/07, LA; HPV #2, Lot # 1267U given 11/20/07, IM/LA; HPV #3, Lot #1978U given 3/28/08, IM/LA. 5/1/09 Received vaccine & PCP medical records of 11/07-1/09. Hypothyroidism, 23# weight loss, anxiety, depression, HAs, dizziness. Family hx: parent w/MS, tics, OCD.

Prex Illness: no

Prex Vax Illns:

Vaers Id: 344575-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	07-Apr-2009	18-Apr-2009	11	21-Apr-2009	27-Apr-2009	OH		28-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	2	Left leg	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Pruritus, Rash, Rash erythematous, Rash papular, Skin plaque, Vaccine positive rechallenge

Symptom Text: Erythematous papular and plaque like lesions - very pruritic on extensor surface of upper and lower extremities. This rash developed 2 weeks after 2nd and 3rd GARDASIL vaccine

Other Meds:

Lab Data: Skin biopsy: 12/3/09 Spongiotic dermatitis with eosinophils - done after first rash/2nd HPV vaccine

History: None

Prex Illness:

Prex Vax Illns: Skin rash~HPV (Gardasil)~2~12~Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344576-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	31-Mar-2009	01-Apr-2009	1	21-Apr-2009	27-Apr-2009	NC		27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0012U	2	Right leg	Unknown	
	SMALL	ACAMBIS, INC.	W04003A	1	Right leg	Unknown	
	ANTH	EMERGENT BIOSOLUTIONS	FAV148	1	Right leg	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Tenderness

Symptom Text: Received smallpox 31 Mar 09 Lt upper arm, which was followed by swelling, redness, and increasing tenderness, no fever, Pt stated she was vaccinated with Smallpox previously on 28 Nov 2007, but no desired effect and it did not take.

Other Meds:

Lab Data:

History: Negative

Prex Illness: Negative

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344581-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	16-Mar-2009	16-Mar-2009	0	21-Apr-2009	27-Apr-2009	CA		27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2827CA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0940X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anger, Blood pressure normal, Cyanosis, Fall, Fear, Heart rate normal, Muscle rigidity, Tonic clonic movements, Unresponsive to stimuli

Symptom Text: After vaccines were given the patient hopped off the exam table (she was sitting on it) & fell to the floor and became rigid and looked blue and unresponsive but not flaccid with then tonic - clonic movements upon awakening after about 1-1 1/2 minutes and felt scared and angry after episode. HR/BP okay X

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **344584-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	22-Jul-2008	05-Aug-2008	14	22-Apr-2009	27-Apr-2009	NY		27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	1	Left arm	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Back pain, Fatigue, Sacroiliitis

Symptom Text: Since 8/5/08, 2 wks after her 2nd GARDASIL shot, this girl has had severe back pain with diagnosis of Sacroileitis, pain Amplification syndrome. Pain 7/10, fatigued. Her best friend developed severity arthritis too after vaccine recently has missed 35 d of school 2008-9

Other Meds: FOLIC ACID; METHOTREXATE; PREVACID; TRAUIADOL; ENBRIL

Lab Data: Negative HLA-B27; 9-11-08 Hg 12.5, Wbc5 100; Normal LFTS; U/A; IgG, A, ME, C3 C4; ANA; DNAA; RF ASO; Aule SSA & B; acute DNA SE, TY, TSH

History: H/O "Burning" sensation of feet

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344588-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Apr-2009	17-Apr-2009	0	22-Apr-2009	27-Apr-2009	WA		27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	1	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1311X	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Syncope, Tremor

Symptom Text: Immediately after receiving 2nd GARDASIL vaccine along with DTap vaccine, patient fainted. She was unconscious for 2-3 seconds. Awoke with shaking, examined by provider, lied down, legs elevated and drank some juice. Held in office for 20 minutes

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344590-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Apr-2009	17-Apr-2009	0	22-Apr-2009	27-Apr-2009	TX		27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	0933X	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0548X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Balance disorder, Convulsion, Pallor, Syncope

Symptom Text: Patient was given Hep A 1st, then HPV. After HPV was administered pt tensed up and began to loose her color, she then began to lean backwards and started to have a seizure. Seizure only lasted for 10 seconds. Vasovagal Syncope.

Other Meds:

Lab Data: EKG; O2 Saturation; BP; Blood sugar

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **344607-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		22-Apr-2009	23-Apr-2009	FR	WAES0904AUS00010	23-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthritis, Fatigue, Lupus-like syndrome, Myalgia, Vaccine positive rechallenge

Symptom Text: Information was obtained on request by the Company from the agency via a Public Case Detail Form concerning a 22 year old female who was vaccinated with GARDASIL. Concomitant therapy included oral contraceptives (unspecified). Subsequently the patient experienced Lupus-like syndrome, arthritis, fatigue and myalgia which required a visit to the physician. It was described that the patient developed arthritis typical of Lupus, myalgia and fatigue after the first dose of GARDASIL. The patient saw her physician after the second dose of GARDASIL when the symptoms markedly worsened within 2 weeks of the injection. The patient was found to be "seropositive anti-ana + ana". The patient was treated with high dose of oral steroids. At the time of reporting to the agency on 08-JAN-2009, the outcome of Lupus-like syndrome, arthritis, fatigue and myalgia was unknown. It was also reported that the immunologist thought that GARDASIL triggered the Lupus and certainly worsened it. The agency considered that Lupus-like syndrome, arthritis, fatigue and myalgia were possibly related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review, Lupus-like syndrome was considered an other important medical event. Additional information is not expected.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: serum ANA, seropositive anti-ana + ana

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344608-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	27-Mar-2009	02-Apr-2009	6	22-Apr-2009	23-Apr-2009	FR	WAES0904USA02100	27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0779X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Facial paresis, Vestibular disorder

Symptom Text: Information has been received from a Health Authority (case n. 97302) concerning a 11 year old female patient who underwent surgery (NOS) in November 2008, who on 27-MAR-2009 was vaccinated with the first dose of GARDASIL (Lot # 0779X and Batch # NJ36070) intramuscularly. On 02-APR-2009 the patient presented with right facial hemiplegia, grade II-III on the HOUSE-BRACKMANN scale. She was prescribed rest, prednisone, vitamin B and an antibiotic cream for the right eye. Blood work performed (NOS) within normal limits. ENT consultation: negative. Impendenzometry and audiometry: slight sufference right vestibule. Neuropsychiatric evaluation: right facial hemiparesis. At the time of reporting the patient had not yet recovered. The reporter determined that Hemiplegia (right) was other important medical event. Other business partner numbers include: E2009-03236 and IT155/09. No further information is available. The case was closed.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, blood work (NOS); within normal limits; ears, nose, and throat examination, negative; diagnostic laboratory test, impendenzometry; slight sufference right vestibule; auditory evoked potential, audiometry; slight

History: Surgery

Prex Illness:

Prex Vax Illns:

Vaers Id: **344609-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Oct-2006	01-Feb-2007	107	22-Apr-2009	23-Apr-2009	AZ	WAES0904USA02303	23-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0688F	0	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Juvenile arthritis, Musculoskeletal pain, Neck pain

Symptom Text: Initial and additional information has been received from a nurse practitioner concerning a 14 year old female who on 17-OCT-2006 was vaccinated with the first 0.5 ml dose of GARDASIL (lot #: 653735/0688) into the left shoulder. Concomitant therapy included ZYRTEC. In February 2007, the patient developed neck and right shoulder pain, later the patient was diagnosed with juvenile rheumatoid arthritis. The patient was seen by a rheumatologist. On 18-APR-2007, the patient's laboratory test revealed homogeneous antinuclear antibody (ANA) pattern 1 per 80. On 24-APR-2007, the patient's laboratory revealed rheumatoid factor 24.7 and C-reactive protein (CRP) 2.7. On 25-SEP-2007 the patient was seen by another rheumatologist. The patient also saw another physician and a homeopathic physician. On 21-APR-2008, the patient was seen by an orthopedist. On 09-APR-2009, the patient was seen by the physician in the reporter's office. The reporter stated that while the patient was waiting to see the physician, she was seated in a cross-legged position. It was reported the patient's mother request the patient to receive a whole body MRI. The physician was unable to examine the patient due to the patient's pain. The whole body was not ordered by the physician. The reporter stated that she thought the patient's mother was relating the patient's condition to the GARDASIL. Follow-up information was received from a medical assistant in a rheumatologist's office. The medical assistant stated that the patient was first seen the rheumatologist on 18-APR-2007. The patient's laboratory tests revealed a positive rheumatoid factor and a positive anti-CCP (anti-cyclic citrullinated peptide) test. The patient was diagnosed with juvenile rheumatoid arthritis. The medical assistant stated that there was no mention of the patient receiving the GARDASIL vaccine in the physician's notes. The patient was no longer a patient of the rheumatologist. Juvenile rheumatoid arthritis was considered to be disabling. Additional information has been requested.

Other Meds: ZYRTEC

Lab Data: serum ANA protein, 04/18/07, 1/80; serum rheumatoid factor, 04/24/07, 24.7; serum C-reactive, 04/24/07, 2.7; serum cyclic citrulline, 04/18/07, positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344610-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Feb-2007	01-Feb-2009	731	22-Apr-2009	23-Apr-2009	FR	WAES0904USA02350	23-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1427U		Left arm	Intramuscular	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Cervical dysplasia, Smear cervix abnormal

Symptom Text: Information has been received from a health authority on 14-APR-2009 under HA reference no. PEI2009007080. It was reported that a 25 year old female patient was vaccinated with a dose of GARDASIL (batch number NH15200, lot number 1427U) IM into the left upper arm in February 2007, In February 2009 a cervical PAP smear showed PAP IIID. The reporter assessed the event as "life-threatening" (as documented), but the patient was not hospitalized. Previous vaccination with GARDASIL, lot number not reported, was administered on an unspecified date. Toleration was not reported. Final outcome was unknown. Case closed. Other business partner numbers included E200903271. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344611-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Jan-2009	01-Jan-2009	0	22-Apr-2009	23-Apr-2009	FR	WAES0904USA02355	23-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Leukocytoclastic vasculitis, Pain, Palpable purpura, Proteinuria, Prurigo, Pruritus, Purpura

Symptom Text: Initial information received from on the 06-APR-2009 by the foreign Health Authority (reference number ES-AGEMED-224776332) regarding a 14 year old female who was administered on JAN-2009, exact date not reported, a dose of GARDASIL (batch number not reported) route and site not reported. Two days after vaccination the patient began with pruriginous and painful purpuric lesions on lower limbs. No abdominal pain, no hematuria, no rectorrhagia, the patient presents a catarrhal clinical picture. It is reported that 10 days before the patient presented a catarrhal clinical picture with pharyngeal pain, cough and expectoration which had been treated with PARACETAMOL, IBUPROFEN and ANTITUSSIVES. Blood work performed on the 14-JAN-2009: normal hemogram with normal biochemistry and coagulation, complement normal and Antinuclear antibodies negative. Proteinuria 15.7mgl/dl (normal value <12). On the 20-FEB-2009 she was asymptomatic without skin lesions, acute-phase reactants were normal, hepatic serology was negative. Palpable purpura, proteinuria, pruritis and pain were considered by the reporting business partner to be symptoms of leukocytoclastic vasculitis and were not reported as adverse events, although it was noted that the health authority report included leukocytoclastic vasculitis, palpable pupura and proteinuria as coded adverse events. The Health Authorities did comments of this case: vasculitis is not included in GARDASIL SmPC. Schonlein Henoch are described for other vaccines. A second alternative cause is the catharral clinical picture. Case reported as serious by the HA with other medically important condition as criteria. No further information was received. Case is closed. Other business partner numbers included E20090387. No further information is available.

Other Meds: Unknown

Lab Data: serum ANA, 14Jan09, negative; urine protein (quant), 14Jan09, 15.7 mg/dl, Normal Range: - 12; serum hepatitis B surface antigen test, 20Feb09, negative; urine protein, 20Feb09, 0.16 gr/day

History: Catarrh; Throat pain; Cough; Expectoration

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344612-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		22-Apr-2009	23-Apr-2009	--	WAES0904USA02789	23-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician assistant and a licensed practical nurse concerning a female who was vaccinated with the first dose of GARDASIL (lot# not reported) 0.5 ml. The patient experienced seizure like symptoms after receiving her first dose. Series was discontinued and the patient did not receive any further doses of GARDASIL. The patient sought unspecified medical attention. Upon internal review, seizure like symptoms was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344613-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	15-Aug-2007	01-Aug-2008	352	22-Apr-2009	23-Apr-2009	--	WAES0904USA02794	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1060U	2	Left arm	Intramuscular	HPV4
							HPV4

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Hypothyroidism, Rheumatoid arthritis

Symptom Text: Information has been received from a physician assistant concerning a 20 year old female with migraine, penicillin allergy and VICODIN allergy and a history of pneumonia (in November 2006) who on 15-AUG-2007 was intramuscularly vaccinated with the 3rd 0.5 ml dose of GARDASIL (lot #658556/1060U) into the left arm deltoid. The dates of the first two doses of GARDASIL were not available. Concomitant therapy included multivitamins (unspecified), ascorbic acid, vitamin E and unspecified over the counter medication for migraines. In August 2008, the patient experienced hypothyroidism and rheumatoid arthritis. The patient initially treated with prednisone. At the time of reporting, the patient did not recover. The patient had an office visit for medical attention. Hypothyroidism and rheumatoid arthritis were considered to be disabling. Additional information has been requested.

Other Meds: ascorbic acid; vitamin E; vitamins (unspecified)

Lab Data: Unknown

History: Pneumonia

Prex Illness: Migraine; Penicillin allergy; Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **344614-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Mar-2009	16-Mar-2009	0	22-Apr-2009	23-Apr-2009	FR	WAES0904NZL00011	23-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1694U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Hyperhidrosis, Pallor, Presyncope, Tinnitus

Symptom Text: Information has been received from an agency, via CSL, as part of a business agreement, concerning a 16 year old female who on 16-MAR-2009 was vaccinated with GARDASIL (Lot # 1694U, Batch # NJ21420). On 16-MAR-2009, within an hour after vaccination, the patient experienced tinnitus, pallor, sweating increased, vasovagal reaction and convulsions which were reported as not severe. At the time of reporting to the agency in March 2009, the patient had recovered without sequelae from tinnitus, pallor, sweating increased, vasovagal reaction and convulsions. The agency considered that tinnitus, pallor, sweating increased, vasovagal reaction and convulsions were probably related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review, convulsions was considered an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344615-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		22-Apr-2009	23-Apr-2009	FR	WAES0904AUS00012	23-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Multiple sclerosis

Symptom Text: Information has been received from a physician via CSL as part of a business agreement concerning a female patient who was vaccinated with GARDASIL. Subsequently after vaccination, the patient experienced neurological reaction (MS-like) and was hospitalised. The patient's neurological reaction (MS-like) persisted. At the time of reporting, the patient was still in hospital. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344616-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	08-Apr-2009	12-Apr-2009	4	22-Apr-2009	27-Apr-2009	MO		28-Apr-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	0279X	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB274AA	0	Right arm	Intramuscular	
TDAP	SANOFI PASTEUR	C2773BA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Hypersensitivity, Lymphadenopathy, Malaise, Oropharyngeal pain, Pain, Viral infection

Symptom Text: Mother reports child woke up "Sunday night at 1:30" (April 12) with c/o not feeling well, sore throat and swollen glands on side of neck. Reports c/o headache and aching "all over". Reports child was seen by Dr 4/13/09 and diagnosed with "allergies". On 4/14/09 was seen at ED with diagnosis of "virus".

Other Meds: Singular for Asthma

Lab Data: 4/13/09--negative strep test; 4/14/2009 Negative Mono test and Negative Mumps

History: Asthma

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344624-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Apr-2009	22-Apr-2009	0	22-Apr-2009	27-Apr-2009	IA		28-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0940X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Crying, Hyperhidrosis, Immediate post-injection reaction, Nervousness, Pallor, Presyncope

Symptom Text: Patient turned pale and diphoretic after administration of first Gardasil vaccine. Patient complained of feeling like she was going to pass out. Patient was told to lie down, feet were put up, patient was fanned. Recovered with in 1 to 2 minutes, did not pass out. Patient stated that she has passed out before with injections and when her umbilicus was pierced. Was very nervous prior to injection and started crying. Blood pressure after recovery was 90/68. Patient stated that she had not eaten yet today, time was around 1030am.

Other Meds: nuvaring

Lab Data:

History: previously has had syncopal episodes with injections and umbilicus piercing.

Prex Illness: na

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344646-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	16-Apr-2009	19-Apr-2009	3	22-Apr-2009	27-Apr-2009	NC		27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF452CA	5	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Patient had hives 3 days after getting HPV vaccine for the 1st time.

Other Meds: Medroxyprogesterone

Lab Data:

History:

Prex Illness: Amenorrhea

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344647-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	14-Feb-2009	15-Feb-2009	1	23-Apr-2009	24-Apr-2009	FR		24-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0946X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, EXTENDED HOSPITAL STAY, HOSPITALIZED, SERIOUS

MedDRA PT Crying, Depression, Dizziness, Headache, Mood altered, Muscular weakness, Psychotic disorder, Sensory loss, Syncope

Symptom Text: Acute psychotic reaction, headache severe, dizziness, loss of sensory input, fainting, depression, mood change, crying, weakness in leg muscles. 21 days hospitalization - Maldol, Ativan, Xyprexa.

Other Meds:

Lab Data: Will collect from hospital emergency and send later.

History: ADHD type inattentive; learning disability; irregular menstruation

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344659-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	01-Feb-2009	01-Mar-2009	28	23-Apr-2009	24-Apr-2009	FR	WAES0904NZL00003	24-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Inappropriate schedule of drug administration, Inflammation, Lethargy, Monoplegia, Nausea, Pain in extremity

Symptom Text: Information has been received from CSL as part of a business agreement. It was reported in a newspaper article dated 31-MAR-2009 that a 17 year old female was vaccinated with her first dose of GARDASIL as prophylaxis. It was reported in the newspaper article that the patient "had been vaccinated twice since the introduction of treatment a month ago". After her first vaccination, the patient experienced a sore arm. After her second vaccination with GARDASIL in approximately March 2009, the patient experienced nausea and a paralysed left arm. Blood tests (not specified) revealed "inflamed, elevated markers". It was reported that the patient stated that she "didn't link the vaccine with the pain I was feeling until after the second shot as side effects can kick in a month after the vaccination." Subsequently, the patient was unable to go to school for one week. The patient consulted a naturopath and her symptoms were treated with a cleansing of her system. At the time of reporting in the newspaper article dated 31-MAR-2009, the patient hoped to return to school that week, despite prolonged lethargy and a "dead" arm. The reporter felt that sore arm, paralysed left arm, prolonged lethargy, nausea and inflamed elevated markers were possibly related to therapy with GARDASIL. Upon internal medical review, the patient's arm paralysis was considered to be an Other Important Medical Event. Additional information is not expected.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, ??Mar?09, blood test (unspecified) revealed "inflamed elevated markers"

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344661-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		23-Apr-2009	24-Apr-2009	FR	WAES0904USA02824	24-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Encephalitis

Symptom Text: Information has been received from a gynaecologist of a university hospital that a young female patient, exact age not reported, was vaccinated with a dose of GARDASIL (lot #, number in series, injection route and site not reported) on an unspecified date. Subsequently the patient developed encephalitis-like symptoms (not specified). The patient was hospitalized on an unspecified date. Further information was not available. The final outcome was not reported. The reporter was contacted by his colleagues from the neurological department to request whether there were any GARDASIL specific tests for blood or CSF analysis. Other business partner numbers include E200903259.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344663-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	10-Mar-2009	10-Mar-2009	0	23-Apr-2009	24-Apr-2009	FR	WAES0904NZL00017	24-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1283U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Petit mal epilepsy

Symptom Text: Information has been received from an agency, via CSL, as part of a business agreement, concerning a 17 year old female with unspecified epilepsy who on 10-MAR-2009 was vaccinated with GARDASIL (Batch # NJ11440, Lot # 1283U). On 10-MAR-2009 within one hour after vaccination, the patient experienced absences which was reported as not severe. At the time of reporting to the agency in March 2009, the patient had recovered without sequelae from absences. The agency considered that absences was probably related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review, absences was considered an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Epilepsy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344664-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
29.0	F	24-Mar-2009	24-Mar-2009	0	23-Apr-2009	24-Apr-2009	FR	WAES0904USA02361	24-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0773X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a health authority concerning a 29 year old female with no previous reactions to drugs who received the first dose of GARDASIL (batch number NJ46700, lot number 0773X) via intramuscular route on 24-MAR-2009. She should not have received the vaccine at her age. 1 minute later the patient experienced a reaction defined by convulsion during 60 to 90 seconds. At the time of reporting the patient had recovered. Case is closed. Other business partner numbers included E200903281. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344679-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	23-Apr-2009	23-Apr-2009	0	23-Apr-2009	28-Apr-2009	MI		28-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0245U	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B030AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Feeling hot, Hypotonia, Unresponsive to stimuli

Symptom Text: Within 2-3 minutes after second vaccine injection(HPV) client stated that she felt hot,then did not respond to verbal stimuli, eyes open, and body began to become limp and slumped forward while sitting in chair. Client was assisted by two staff to the floor. Client placed on her back and legs were elevated. Client responsive and apple juice and granola bar given. Client tolerated juice and granola without difficulty and held appropriate conversation with staff. B/P 110/70 P-80 Resp-16. Client with this staff for 20 mins after incident and ambulated without difficulty and had no complaints upon leaving the clinic.

Other Meds:

Lab Data:

History:

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344691-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	23-Apr-2009	23-Apr-2009	0	23-Apr-2009	28-Apr-2009	VT		28-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1740U	1	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: After leaving office Pt had a delayed fainting spell - Returned to office - No injury.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **344726-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	22-Jan-2008	22-Jan-2008	0	17-Apr-2009	07-May-2009	CA	WAES0802USA04952	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0928U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received through the Merck pregnancy registry from a Physician's Assistant concerning a female who is social alcohol drinker and smoker who on 11-MAY-2007 was vaccinated IM in the left arm with the first 0.5 mL dose of GARDASIL (Lot #655503/0012U). There was no concomitant medication. The patient received the second 0.5 mL dose via IM of GARDASIL (Lot #658554/0928U) on 22-JAN-2008. The patient reported that she became pregnant. Her LMP is December 2007. Follow up information was received. The patient a female had her last menstrual period on 01-DEC-2007. Her estimated delivery date was reported as 06-SEP-2008. The patient had no previous pregnancies. Follow-up information was received from the 18 year old mother who on 15-SEP-2008 delivered a full-term, health and normal girl, weighing 9LBS 7 OZ. She had an uncomplicated, spontaneous vaginal delivery. She said her pregnancy was fine-there were no complications. The baby was doing well, and was diagnosed at 3 month with "some eczema". The baby had gotten treatment (not specified) for the eczema and was ok with no problems. The mother stated that she was also well and had recovered from the pregnancy without any complications. No further information is available.

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 12/1/2007); Social alcohol drinker; Smoker

Prex Vax Illns:

Vaers Id: **344730-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Mar-2008	03-Mar-2008	0	17-Apr-2009	07-May-2009	PA	WAES0803USA00880	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received via the Merck pregnancy registry, from a registered nurse, concerning a 15 year old female patient, who on 03-MAR-2008 was vaccinated with a dose of GARDASIL (lot # not reported). During the appointment, the patient mentioned that her period began on 02-MAR-2008. However, after the physical exam, the physician ordered a pregnancy test, and the results were positive (date of LMP and gestation details were not provided). On 03-MAR-2008, a physical exam and urine pregnancy test were positive. No systems have been reported. Information has been received from a physician concerning a 14 year old female with eczema, asthma, left clubfoot and refractive error with a history of 0 pregnancies and 0 live births and a history of bacterial infection due to streptococcus, group b and positive for Chlamydia trachomatis and gonococcus, who on 03-MAR-2008 was vaccinated with first dose of GARDASIL (dose, route not reported, lot number 659657/1487U). Concomitant therapy included FLOVENT and albuterol. The physician reported that on 05-JUN-08, the patient delivered a normal, healthy female baby weighing 7 pounds 8 ounces. A hearing test was performed on 05-JUN-2008 and 06-JUN-2008 and failed for right ear both times. Apgar score was 8/9. Hearing test was performed again on 24-FEB-2009 and the patient passed the test for both ears. No further information is available.

Other Meds: albuterol; FLOVENT, 110 microgm

Lab Data: hearing test, 06/05/08, failed right hearing test; hearing test, 06/06/08, failed right hearing test; hearing test, 02/24/2009, passed right and left hearing test; beta-human chorionic, 03/03/08, positive; Apgar score, 06/05/08, 8/9

History: Bacterial infection due to streptococcus, group B; Vaginal infection

Prex Illness: Pregnancy NOS (LMP = Unknown); Eczema; Asthma; Congenital clubfoot; Error

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344732-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	15-Feb-2008	15-Feb-2008	0	17-Apr-2009	07-May-2009	VA	WAES0803USA01292	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1486U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Herpes simplex

Symptom Text: Information and follow up information have been received from a nurse practitioner for the Pregnancy Registry for GARDASIL concerning 23 year old female who on 15-FEB-2008 was vaccinated intramuscularly with her first dose of GARDASIL (lot# 659655/1486U) and was pregnant. Other medications used during pregnancy included PRENATE ELITE taken daily during entire pregnancy and VALTREX which was from 20-MAR-2008 to 23-MAR-2008 for the treatment of herpes simplex. The patient's LMP was 19-JAN-2008 with an estimated due date of 25-OCT-2008. She had a positive pregnancy test and on 06-MAR-2008 a fetal ultrasound for dating (results were within normal limits). The patient was seen in the doctors office. Follow up information has been received from a nurse practitioner concerning the now 24 year old female patient who on 03-NOV-2008, 42 weeks after her last menstrual period delivered a healthy and normal baby female, weight: 8 pounds 5.2 ounces, and height: 20.08 inches. Apgar score 8/9. There were no congenital anomalies, complications or abnormalities. Additional information is not expected.

Other Meds: PRENATE ELITE

Lab Data: ultrasound, 03/06/08, wnl; ultrasound; beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/19/2008)

Prex Vax Illns:

Vaers Id: **344733-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	27-Feb-2008	27-Feb-2008	0	17-Apr-2009	06-May-2009	KS	WAES0803USA01406	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Labour complication, Urinary tract infection

Symptom Text: Information has been received from a certified medical assistant concerning a 16 year old female who on 27-FEB-2008 was vaccinated with her first dose of GARDASIL (658094/0524U) and is now pregnant. Concomitant medication included DOXYCYCLINE from 03-MAR-2008 to 05-MAR-2008 and ZITHROMAX on 06-MAR-2008 for the treatment of Chlamydia and ORTHO TRI-CYCLEN. The patient's LMP was 25-JAN-2008 with an EDD of 01-NOV-2008. The patient sought medical attention in the office. Follow up information has been received from a complete questionnaire for the pregnancy Registry for GARDASIL from a Physician concerning a 16 year old female with cervical dysplasia. During the second trimester of pregnancy in approximately April 2008, the patient experienced a UTI (urinary tract infection) and treated on 16-APR-2008 with ROCEPHIN. On 04-NOV-2008 there was an occiput posterior (OP) position of the infant and a vacuum assisted delivery was necessary. The patient delivered a normal, healthy female baby weighting 7 pounds 2.3 ounces. Additional information was received on 27-MAR-2009, from a certified medical assistant who stated that the patient delivered the baby and the outcome was "fine/normal". Additional information is not expected.

Other Meds: ZITHROMAX 1 gm; DOXYCYCLINE; ORTHO TRI-CYCLEN

Lab Data: beta-human chorionic - positive

History:

Prex Illness: Pregnancy NOS (LMP = 1/25/2008) Cervical dysplasia

Prex Vax Illns:

Vaers Id: **344736-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	07-Apr-2008	07-Apr-2008	0	17-Apr-2009	07-May-2009	--	WAES0805USA04750	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL	0	Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1978U	0	Unknown	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received through the Merck pregnancy registry, for GARDASIL, concerning a 14 year old female patient with attention deficit disorder and no drug allergies reported, who on 07-APR-2008 was vaccinated with the first dose of GARDASIL (Lot # 659964/1978U). Concomitant therapy included a dose of HAVRIX, a dose of MENACTRA and RITALIN. Subsequently, it was reported that the patient was pregnant at the time she received the GARDASIL. At the time of this report, the patient is presently fourteen weeks pregnant. The patient did not have any adverse experiences as a result of the vaccine. The patient sought unspecified medial attention. A pregnancy test was performed. At the time of this report the patient's outcome was unknown. No product quality complaint was involved. Follow up information indicated that the patient delivered a 6.8 pound normal baby boy on 03-NOV-2008 at 39 weeks. There were no complications, abnormalities or congenital anomalies. The patient also used vitamins and calcium during pregnancy. Pediatric medical records were received. On 12-NOV-2008 the 9 day old baby went in for a pediatric visit. The newborn screen results were normal. The birth history included the baby being induced due to possible leakage. The Apgar score was 8/9.5. The physician commented the baby was alert and looking about. The assessment was the baby was back to the birth weight. The plan was feeding and G&D was discussed. Weight check was in 3 weeks. On 26-NOV-2008 at the age of 3 weeks the baby came in for a well child visit for weight check and growth. There was occasional spitting. The baby was having bowel movements daily; does grunt/cry with stooling. Diluted juice was used if needed. There were no hard stools now but did have. The baby was waking up 2 to 3 times a night. Impression was a 3 week infant with excellent growth. Discussed stools - normal versus constipation. Discussed fever and illness again. Call if any concerns. On 17-DEC-2008 at the age of 6 weeks. There was no spitting. Bowel Movement was

Other Meds: RITALIN

Lab Data: ultrasound, 06/02/08, normal; diagnostic laboratory, 11/05/08, normal; beta-human chorionic, results not reported

History:

Prex Illness: Pregnancy NOS (LMP = 2/6/2008); Attention deficit disorder

Prex Vax Illns:

Vaers Id: **344737-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	26-Mar-2008	18-Apr-2008	23	17-Apr-2009	07-May-2009	GA	WAES0806USA02242	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a certified medical assistant for the Pregnancy Registry for GARDASIL concerning a female who on 26-MAR-2008 was vaccinated intramuscularly with her first dose of GARDASIL (lot# not reported). There was no concomitant medication. On 28-MAY-2008 the patient was vaccinated intramuscularly with her second dose of GARDASIL (lot# not reported) and was pregnant. The patient's LMP was approximately 15-APR-2008. Subsequently the patient experienced no known symptoms. The patient has a positive pregnancy test on 10-JUN-2008. The patient's outcome was not reported. Follow-up information has been received from a physician for the Pregnancy Registry for GARDASIL concerning the 25 year old female with asthma and anxiety, a history of 1 pregnancy and 1 normal delivery and a history of vaginal disorder and some complication on 26-MAR-2008 was vaccinated IM with the first dose GARDASIL, on 28-MAY-2008 was vaccinated with the second dose and on 11-MAR-2009 was vaccinated with the third dose (lot #: 660553/0070X). The patient became pregnant in April 2008, the date of last menstrual period was 18-APR-2008, estimated delivery date was 25-JAN-2009. On 22-JAN-2009 the patient delivered a normal, female infant with no congenital anomalies. The baby's weight was 7 LB 14.5 ounce, length was 21.75 inch, head circumference was 14.25 inch. Apgar test score was 8/9. On an unspecified date, group B strep test of the infant was positive. Initial complete blood count secondary to group B strep positive was 9 band. C-reactive protein test was negative and blood culture was negative. At the time of this report, bandemia resolved. No further information is available.

Other Meds: None

Lab Data: diagnostic laboratory, group B strep positive (baby); beta-human chorionic, 06/10/08, positive; Apgar score, 8/9, baby; complete blood cell, 9 bands;bandemia (baby); serum C-reactive protein, negative (baby); blood culture, negative (baby)

History: Normal delivery; Vaginal disorder; Disease complication

Prex Illness: Pregnancy NOS (LMP = 4/18/2008); Asthma; Anxiety

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344738-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	31-Oct-2007	31-Oct-2007	0	17-Apr-2009	07-May-2009	IL	WAES0807USA03038	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a medical assistant for the pregnancy registry for GARDASIL concerning an 18 year old female with no known allergies or pertinent medical history who on 31-OCT-2007 was vaccinated IM with the first dose of GARDASIL 0.5 ml. There was no concomitant medication. The medical assistant reported that on 31-OCT-2007 the patient received her first dose of GARDASIL and was subsequently determined to be pregnant. On 18-JAN-2008 Urine pregnancy test was performed (result:positive). Last menstrual period was reported as October 2007. The patient sought medical attention, "office visit". There was no product quality complaint. The patient has not received her second or third dose of GARDASIL. Follow-up information has been received from a physician concerning the patient. It was reported that the patient had a spontaneous vaginal delivery of a healthy normal-appearing male on 16-JUL-2008, at term. The baby's APGARS were 8 and 9. The mother had a normal prenatal course, with normal fetal anatomy survey at 20 weeks estimated gestational age, though the spine was not fully visualized due to the fetal positioning. The mother was treated with antibiotics in labor as she was found to be group beta strep positive in her urine prenatally. The mother was seen again for a postpartum visit in August 2008: she was doing well and reported that the baby was also doing well. No further information is available.

Other Meds: None

Lab Data: fetal monitoring tests, normal anatomy survey: 20 weeks EGA; urine beta-human, 01/18/08, positive; urinalysis, GBS +

History:

Prex Illness: Pregnancy NOS (LPM = 10/1/2007)

Prex Vax Illns:

Vaers Id: **344739-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		17-Apr-2009	07-May-2009	--	WAES0807USA03843	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Induced labour

Symptom Text: Initial and follow-up information has been received from a nurse practitioner concerning her daughter a 14 year old female with scoliosis and no previous pregnancies who in 2007 was vaccinated with the first dose of GARDASIL 0.5ml IM when she was 17 weeks pregnant. On 25-JUL-2007 the patient was vaccinated with the second dose of GARDASIL (lot # 656050/0245U). Concomitant vaccine on 25-JUL-2007 included DTAP (unspecified) and meningococcal vaccine (unspecified). The male baby was born healthy on 04-JAN-2008. There were no congenital anomalies or other complications. The baby weighed 7 pounds, 3.8 ounces and was 21 inches long. APGAR scores were 9/9 the patient sought medical attention. Additional information is not expected. In follow up medical records were received. It was reported that the patient had had induced vaginal delivery with no complications, mild decelerations during delivery. Subsequently, the baby developed rash after receiving ROTATEQ (WAES #0903USA03600).

Other Meds:

Lab Data: Apgar score, 9/9

History:

Prex Illness: Pregnancy NOS (LMP = Unknown); Scoliosis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344740-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	11-Mar-2008	02-Jun-2008	83	17-Apr-2009	07-May-2009	--	WAES0808USA04369	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Gestational diabetes

Symptom Text: Information has been received for the pregnancy registry for GARDASIL from a nurse practitioner concerning a 21 year old female with no pertinent medical history, no previous history of pregnancy and no drug reactions/allergies who on 11-JAN-2008 was vaccinated with the first dose of GARDASIL, on 11-MAR-2008 was vaccinated with the second dose of GARDASIL and on 19-JUL-2008 was vaccinated with the third dose of GARDASIL. Concomitant therapy included PHENERGAN 25mg, Q6H for the treatment of nausea, given on 25-JUL-2008. The patient received the complete series of GARDASIL and was pregnant. The patient sought medical attention, in office. The last menstrual period was on 02-JUN-2008. Estimated date of delivery on 09-MAR-2009. Pregnancy was normal to date. Follow-up information has been received which reported that the patient was taking prenatal vitamins as concomitant therapy. The patient experienced gestational diabetes on an unspecified date, as complication during pregnancy. There were no any complications during labor/pregnancy. On 05-MAR-2009, the patient gave birth a healthy baby female at 38 weeks from the last menstrual period, without congenital anomalies or complications. The baby weighted 7 pounds, the length was 19.5 inches and the apgar score was 8/9. No additional information is expected.

Other Meds: PHENERGAN; vitamins (unspecified)

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 6/2/2008); Nausea

Prex Vax Illns:

Vaers Id: 344741-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-Apr-2008	05-Nov-2008	198	17-Apr-2009	13-May-2009	TN	WAES0808USA04377	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Inappropriate schedule of drug administration

Symptom Text: Initial and follow-up information has been received from a pediatrician, a physician and a registered nurse for the pregnancy registry for GARDASIL concerning a 15 year old female patient who in September 2007 was vaccinated with her first dose of GARDASIL (Lot # 658094/0524U). On 21-APR-2008, was vaccinated with her second dose of GARDASIL (Lot # 659657/1487U). The patient became pregnant during her series of vaccination. No adverse events were reported. As of 22-AUG-2008 she was at 27 weeks gestation. In follow-up information the registered nurse reported that the patient with a history of 0 pregnancies and 0 live births who was vaccinated on 18-SEP-2007 with the first dose of GARDASIL (Lot # 658094/0524U) became pregnant on 29-OCT-2008 (EDD 31-OCT-2008 also reported 01-NOV-2008) and on 29-OCT-2008 delivered a normal, healthy male baby weighing 7 pounds 11 ounces. Follow-up information was received from a health professional who reported that the baby with no known drug allergies was seen at the doctor's office on 05-NOV-2008. The baby weighted 6 lbs, 15 oz, the length was 20 inches, the head circumference was 31.5 inches and the temperature was 97.2F. The baby was fed with formula received 2-3 times a day. The baby did not present any problem with exception that was spitting up a little. The diagnostic impression indicated a well newborn. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 1/25/2008

Prex Vax Illns:

Vaers Id: **344742-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Jun-2008	03-Jun-2008	0	17-Apr-2009	13-May-2009	DC	WAES0809USA01360	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1522U		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a certified nurse midwife, for the Pregnancy Registry for GARDASIL, concerning a 17 year old female with asthma, hypersensitivity and no known drug allergies who on 03-JUN-2008 was vaccinated a 0.5 ml dose GARDASIL intramuscularly (lot number and injection route not reported). There was no concomitant medication. Subsequently the patient was found to be pregnant. Unspecified medical attention was sought. The patient's LMP was 30-MAR-2008, and the estimated delivery date is 04-JAN-2009. Follow-up information was received from a registered nurse concerning the 17 year old black female with asthma and obesity who on 03-JUN-2008 was vaccinated with the first dose of GARDASIL (lot number 659005/1522U). Concomitant medications included albuterol and Nasalcrom. On 11-SEP-2008, an ultrasound was performed (result unspecified). On an unspecified date, the patient had a CT culture which was positive. The patient was given Zithromax 1 g xl. On 10-JAN-2009, the patient delivered a female baby, weight 6 lb, 8.5 oz. The nurse reported that the baby was normal with no congenital anomalies and not other complications or abnormalities. No further information is available.

Other Meds: Albuterol; Nasalcrom

Lab Data: Diagnostic laboratory, prenatal labs; Diagnostic laboratory, 12/??/08, CT culture positive

History:

Prex Illness: Pregnancy NOS (LMP = 3/30/2008); Asthma; Hypersensitivity; Obesity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344744-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	22-Jan-2009	12-Dec-2008	-41	17-Apr-2009	13-May-2009	--	WAES0902USA01505	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Headache, Muscle spasms, Pollakiuria

Symptom Text: Information has been received from a registered nurse (R.N.) for the pregnancy registry for GARDASIL concerning a female patient who on an unspecified date was vaccinated with the second dose of GARDASIL (Lot #, date and route not reported). It was reported that the patient received the second dose of GARDASIL just before finding out she was pregnant. The patient sought medical attention at the office. Follow up information was received from a Registered Nurse (R.N.) concerning a 16 year old white primigravida female patient with history of chickenpox, no known drug allergies and with allergy to dogs and birds, who on 24-NOV-2008 was vaccinated with the first dose of GARDASIL. On 22-JAN-2009 the patient received the second 0.5 ml dose of GARDASIL intramuscularly into the upper right arm. It was reported that the patient received the second dose of GARDASIL when she was pregnancy. Concomitant therapy on 24-NOV-2008 included a 0.5 ml dose of DTP (+) Poliovirus vaccine inactivated (+) Tetanus toxoid intramuscularly into the upper left arm. It was reported that the patient was taking contraceptives pills (unspecified). It was reported that the interval of the menstrual period was 28 days, the duration was normal and the patient had experienced cramps in the past. It was reported that on unspecified date (present pregnancy) the patient experienced cramps, headache and urinary was high frequency. The blood pressure was measured and the result was 102/58. The last menstrual period was on 12-DEC-2008 and the estimated delivery date was on 18-SEP-2008. Family history was reported, hypertension and diabetes (grand mother and grand father), multiple pregnancy (mom). Additional information has been requested.

Other Meds: DTP

Lab Data: Ultrasound, 03/09/09; Blood pressure, 102/58

History: Chickenpox

Prex Illness: Pregnancy NOS (LMP = 12/12/2008); Cramp; Allergic to dogs; Allergic to birds

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344747-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
9.0	F	24-Feb-2009	24-Feb-2009	0	17-Apr-2009	13-May-2009	OR	WAES0902USA04263	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Right arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect route of drug administration, Injection site pain

Symptom Text: Information has been received from a nurse concerning a 9 year old female patient with a history of migraine headaches and no known drug allergies who on 24-FEB-2009 was vaccinated with her first dose of GARDASIL (lot number 661766/0652X, site not reported) by subcutaneous route for prevention of the human papilloma virus. There was no concomitant mediations or past drug history. The nurse reported that the patient was fine, no syncope, and the injection site looked fine. There was no relevant laboratory date. As of 24-FEB-2009, it was unknown if the patient would continue to get GARDASIL injections and the patient was fine. Follow-up information was received from the nurse indicating that the patient was given GARDASIL Subcutaneous in her right arm in error and the patient experienced pain at the injection site which lasted for 2 days. There were no further problems. No further information was available.

Other Meds: Unknown

Lab Data: Unknown

History: Migraine

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344750-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Apr-2009	06-May-2009	TX	WAES0903USA01086	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper

Symptom Text: Information has been received from a radiologist reported that a gastroenterologist said he had some patients experience stomach pain after receiving a dose of GARDASIL. No specific patient information was provided. Follow up information was received from a radiologist by phone on 19-MAR-2009 providing the name and telephone number of the gastroenterologist. This is one of several reports from the same source. Attempts are being made to obtain additional identifying information to distinguish the individual patients mentioned in this report. Additional information will be provided if available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344751-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Feb-2009	06-Mar-2009	11	17-Apr-2009	06-May-2009	--	WAES0903USA01403	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Musculoskeletal stiffness, Pyrexia, Rash

Symptom Text: Information has been received from a consumer concerning her daughter an 18 year old female with allergy to (unspecified medication) who on 23-FEB-2009 was vaccinated with a "third dose" of GARDASIL. Lot number was not available. Concomitant therapy included MENACTRA. The patient's mother reported her daughter experienced rash, fever, headache and stiffness in her neck on 06-MAR-2009 after receiving her third dose of the vaccine. Additional information is not expected.

Other Meds:

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **344767-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	14-Apr-2009	14-Apr-2009	0	24-Apr-2009	27-Apr-2009	WA	WAES0904USA02392	27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Convulsion, Fatigue, Gaze palsy, Myalgia, Mydriasis, Syncope, Unresponsive to stimuli

Symptom Text: Initial information has been received from a physician and follow up information has been received from a registered nurse concerning a 15 year old female with no medical history, who on 14-APR-2009 was vaccinated with a first dose of GARDASIL (lot # 661846/1312X). There was no concomitant medication. The patient had blood work drawn a few minutes after receiving the vaccination. After the blood work was drawn. The patient fainted for approximately 15 seconds and may have had a minor seizure. The patient's eyes rolled to the back of her head and she became unresponsive for about 15 seconds. It was reported that her pupils were dilated and she was out for about 15 seconds. The patient regained consciousness and was given juice to drink. No medications or treatment were given to the patient. The patient stated that she did not have much to drink prior to the physician's visit. The patient was not hospitalized. The patient was observed for a little while and then was sent home with her mother. It was reported that the patient stayed home from school the next day and reported she was tired and had some muscle aches. On 15-APR-2009 the patient's mother was instructed to call the physician back if the patient continued with any problems. The physician advised the patient not to receive the remaining doses of GARDASIL. The patient did not receive any other vaccinations other than GARDASIL on 14-APR-2009. The patient had an appointment to see the physician on 07-MAY-2009. Upon internal review seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory, 04/14/09, blood drawn

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344768-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	08-Jan-2009	10-Feb-2009	33	24-Apr-2009	27-Apr-2009	FR	WAES0904USA02826	27-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1475F	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Demyelination, Diagnostic procedure, Encephalomyelitis, Nuclear magnetic resonance imaging, Nuclear magnetic resonance imaging brain, Paraesthesia

Symptom Text: Case reported by health authority (case n. 97347) through a foreign health authority (local case n. IT157/09). Initial report received on 14-APR-2009. An 18 year old female was vaccinated on 08-JAN-2009 with the first dose of GARDASIL (Lot # 1475F, batch n. NF35170). On 10-FEB-2009 she presented with paresthesia of the lower left limb and of the IV and V finger of the left hand, demyelinating encephalomyelitis was hypothesized. She was hospitalized and treated with steroid i.v. It was also reported that the patient was vaccinated with the second dose of GARDASIL (batch n. reported as NG22820 which was valid for montelukast sodium (MSD) 4 mg tablet) on 12-MAR-2009. During admission a brain and bone marrow Magnetic Resonance Imaging (MRI), evoked potential and rachicentesis were performed (results not reported). The final outcome was not reported. Other business partner numbers include E200903277.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 344793-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	07-Nov-2008	07-Jan-2009	61	24-Apr-2009	27-Apr-2009	NV		28-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1061U	1	Right arm	Intramuscular	HEPA HPV4

Seriousness: ER VISIT, HOSPITALIZED, PERMANENT DISABILITY, SERIOUS

MedDRA PT Alopecia, Amnesia, Arthralgia, Back pain, Convulsion, Fatigue, Headache, Loss of consciousness, Muscle twitching, Nausea, Neck pain, Pain, Pharyngitis streptococcal, Vomiting

Symptom Text: Symptoms started exactly 2 months after her 2nd shot. Started with headaches, nausea, vomiting, strep throat and body aches. Continues on with non-epileptic seizures, twitches, unconsciousness, long and short term memory loss, hair loss, fatigue, joint pain and neck and back pain. Continues on after 3 1/2 months.

Other Meds: None

Lab Data: blood work, head CT scan, lumbar CT scan, chest x-ray, head MRI, spinal tap

History: None

Prex Illness: None

Prex Vax Illns: None~ ()~~0~Patient

Vaers Id: **344799-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	17-Apr-2009	17-Apr-2009	0	24-Apr-2009	28-Apr-2009	MI		28-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1130X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Within 10 minutes of receiving her first Gardasil injection the patient blacked out. SHe was treated with smelling salts to try and rouse her and was placed in an exam room where her vital signs were measured over a 45 minute period. Her father was then called to come and picke her up as doctor did not want her to drive.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344804-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Apr-2009	22-Apr-2009	2	25-Apr-2009	28-Apr-2009	OR		28-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oropharyngeal pain, Pyrexia

Symptom Text: Pt developed a sore throat and fever 2 days after receiving the vaccine. Fever resolved after 1 day, but sore throat persisted for several days.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **344820-1 (S)** **Related reports:** 344820-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-Apr-2009	21-Apr-2009	0	24-Apr-2009	27-Apr-2009	NJ		11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	1	Unknown	Intramuscular	HPV4 MNQ TDAP

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Apraxia, Condition aggravated, Convulsion, Disorientation, Headache, Hypoaesthesia, Hypokinesia, Malaise, Muscle twitching, Mydriasis, Pallor

Symptom Text: My daughter received her second GARDASIL vaccine and had 2 30-45 second seizure 15 minutes after the injection in the doctors office on the floor. She became pale, disoriented, her pupils were dilated and she kept saying she doesn't feel good thereafter the whole night long. She experienced a glaze for hour after, slow movement numbness to both legs and a headache and has twitching in her left arm still at the present time. I took her to the ER on my own judgement because the pediatrician said there was no need this was normal following this vaccine and she had bloodwork drawn and now has to have an EEG today. Something has to be said to this company. 5/5/09 Received medical records DOS 1/2/09 to 4/23/09. Includes imminzation records. FINAL DX: Seizures Two 'quick seizures' post vaccination. Also several episodes of eyes rolling, and twitching.

Other Meds:

Lab Data: A neurologist had received her results today I have to go see him in the office to find out where we go from here. We left the er after 5 hours and were exhausted so they said I didn't have to wait for the results she was negative the neur

History: She is learning disabled, she has apraxia, sensory integration dysfunction, and had a run of myoclonic seizures 5 years ago.

Prex Illness:

Prex Vax Illns:

Vaers Id: **344820-2** **Related reports:** 344820-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-Apr-2009	21-Apr-2009	0	30-Apr-2009	01-May-2009	NJ	WAES0904USA03569	01-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Convulsion, Gaze palsy, No reaction on previous exposure to drug, Pallor, Tremor

Symptom Text: Information has been received from a nurse concerning a female with no known drug allergies, asthma, verbal aphasia, sensory integration disturbance, developmental delay and myoclonus and a history of seizure (but the last one was in 2005) who on 21-Apr-2009 at 16:15 was vaccinated with the second dose of GARDASIL (lot# not reported) (lot# 661846/1312X). 0.5ml IM. The nurse reported that there was no adverse event after the patient was vaccinated with the first dose of GARDASIL (lot# not reported). On 21-Apr-2009 at 16:15 the patient experienced mild seizure which lasted about 15 seconds after she was vaccinated with the second dose of GARDASIL. The patient went to a Hospital for a follow up. It was unspecified if she was admitted to the Hospital. Additional information was received from the physician's nurse manager (a registered nurse) reported that this event was probably already reported by the patient's mother (a nurse) or by pharmacist friend of the mother. In follow up the physician reported on 21-Apr-2009 at 16:15 the patient experienced mild seizure. The patient was waiting in the room for 5 minutes. The mother of the patient stated the patient was fine. The patient had no known reaction to the first dose of the vaccine. After her second dose, she went down when nurse got to side and noticed shaking event, eyes rolled back and patient sat up immediately. The patient was responsive to her name. The patient was made to lay down for 15 minutes, secondary to weakness and pallor. The patient wakened sitting up for 10 minutes. The patient required emergency room visit and recovered. Upon internal review, mild seizure was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Convulsion

Prex Illness: Asthma; Developmental delay; Myoclonus; Unresponsive to verbal stimuli; Sensory disturbance

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344828-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	23-Apr-2009	23-Apr-2009	0	24-Apr-2009	28-Apr-2009	AR		12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0339Y	1	Right arm	Subcutaneously	
	MNQ	SANOFI PASTEUR	U2877AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1312X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling, Injection site warmth

Symptom Text: Localized swelling, redness, and warmth to immunization site (right posterior upper arm).

Other Meds:

Lab Data:

History: No

Prex Illness: No

Prex Vax Illns:

Vaers Id: **344848-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	16-Apr-2009	16-Apr-2009	0	24-Apr-2009	28-Apr-2009	WA		28-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Muscle contractions involuntary, Muscle rigidity, Mydriasis

Symptom Text: Received GARDASIL shot. Approx 3-5 min. later had several vials of blood drawn. After last vial pt. became "rigid", had muscle contractions, eyes were open, pupils were "dilated" and she mad some noises - per mother. Lasted 15-20 seconds. Examined by provider. Next day tired, but "better" per mother.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344903-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.0	F	01-Oct-2008	01-Oct-2008	0	27-Apr-2009	28-Apr-2009	FR	WAES0904COL00007	28-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a physician concerning a 10 year old female who on 18-JUL-2008 was vaccinated with GARDASIL. In October 2008, the patient was vaccinated with the second dose of GARDASIL. Two minutes after the vaccination the patient experienced convulsion. The patient was hospitalized for 1 day. During the hospitalization an electrocardiogram and brain computed axial tomography were performed, the both exams were normal. After one day the patient was discharged. Subsequently the patient recovered. The reporter felt that convulsion was related to therapy with GARDASIL. Additional information is not expected.

Other Meds: Unknown

Lab Data: electrocardiogram, ??Oct08, Normal; computed axial tomography, ??Oct08, Normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344908-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		22-Apr-2009	06-May-2009	NJ	WAES0901USA03372	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect route of drug administration, Injection site swelling

Symptom Text: Information has been received from a 22 year old medical assistant who was given the second dose of GARDASIL "subcutaneously instead of intramuscularly" by a worker in their office. The medical assistant reported she had a "plump" area under her skin after it was given since it was given wrong. At the time of this report, the patient was recovering. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344909-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	13-Feb-2009	13-Feb-2009	0	22-Apr-2009	06-May-2009	--	WAES0902USA02446	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Device leakage, Underdose

Symptom Text: Information has been received from a Nurse Practitioner concerning a patient who on 13-FEB-2009 was vaccinated with an inadequate dose of GARDASIL, which was partially lost during vaccination. The patient has not experienced any known symptoms. Follow-up information was received from the Nurse Practitioner concerning the 25 year old patient who on 13-FEB-2009 received her second dose of GARDASIL (lot # 661951/1129X) in her right arm. The patient only received partial dose due to needle separating from syringe. The patient was unharmed. No diagnostic test were preformed. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344910-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	12-Jan-2009	Unknown		22-Apr-2009	06-May-2009	SC	WAES0903USA00415	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site swelling, Injection site urticaria, Rash

Symptom Text: Information has been received from a physician concerning a 16 year old female who on 12-JAN-2009 was vaccinated with the second dose of GARDASIL (Lot # not reported). After receiving the second dose of GARDASIL, the patient broke out in a rash and hives on her legs, and she also had swelling and hives at the injection site. The outcome of adverse event was unknown. It was reported that the patient sought medical attention: called the physician. Additional information has been received from the medical assistant who was inquiring if the patient should received her third dose of GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344911-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	26-Feb-2009	26-Feb-2009	0	22-Apr-2009	06-May-2009	MI	WAES0903USA00427	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Nausea, Pharyngitis streptococcal, Vomiting

Symptom Text: Information has been received from a medical assistant concerning a 11 year old female with a history of pharyngitis streptococcal who on 26-FEB-2009 was vaccinated with her first and only dose of GARDASIL (lot # 661952/1129X) IM. On 26-FEB-2009, "2 to 3 hours after the vaccination" the patient experienced abdominal pain, nausea and vomiting. The patient was diagnosed with "strep throat". The patient was prescribed AMOXIL. The patient's mother called the physician for medical attention. On an unspecified date the patient recovered from abdominal pain, nausea, vomiting and strep throat. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Pharyngitis streptococcal

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344912-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		22-Apr-2009	06-May-2009	--	WAES0903USA00454	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash, Rash macular

Symptom Text: Information has been received from a Registered Nurse concerning a 16 year old female who was vaccinated intramuscularly with her third dose of GARDASIL. Subsequently the patient developed a rash on her arm and a blotchy rash on her nose shortly after receiving the vaccine. Lot numbers not available. The patient sought unspecified medial attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344913-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	19-Feb-2009	19-Feb-2009	0	22-Apr-2009	06-May-2009	CA	WAES0903USA00457	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Hypoaesthesia, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 19 year old female with penicillin allergy who on 19-FEB-2009 was vaccinated IM into the left arm with a first 0.5 ml dose of GARDASIL (661046/0546X). Concomitant therapy included hormonal contraceptives (unspecified). On 19-FEB-2009 the patient experienced pain and numbness in left arm and forearm. The patient sought medical attention at physician's office on 26-FEB-2009. No lab test were performed. The patient was told to take ADVIL and to call the office if her symptoms did not improve within a week. The physician has not heard from the patient. As of 2-MAR-2009, the patient's outcome was unknown. It was reported that the patient did not want to continue the series. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vaers Id: **344914-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	27-Feb-2009	27-Feb-2009	0	22-Apr-2009	06-May-2009	--	WAES0903USA00536	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest pain, Dizziness, Nausea, Pyrexia

Symptom Text: Information has been received from a physician assistant concerning a 15 year old female who on 27-FEB-2009 was vaccinated with a first dose of GARDASIL 0.5 ml IM. That same day, 6 hours later the patient experienced fever, chest pains, nausea and dizziness. The patient sought unspecified medical attention. No further information is available. Additional information is available. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344915-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	18-Feb-2009	Unknown		22-Apr-2009	06-May-2009	--	WAES0903USA00539	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspepsia, Pain in extremity

Symptom Text: Information has been received from a 25 year old female who on 18-FEB-2009 was vaccinated with her first dose of GARDASIL and the patient had not had her period although she was due on 27-FEB-2009. A pregnancy test was negative. She also experienced on 18-FEB-2009, heartburn since vaccination and stated her arm was sore after vaccination. The patient's symptoms still persisted. The patient sought unspecified medical attention. Additional information is not expected.

Other Meds: Unknown

Lab Data: beta-human chorionic, Negative

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344916-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	02-Nov-2008	01-Dec-2008	29	22-Apr-2009	06-May-2009	NY	WAES0903USA00547	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Amenorrhoea

Symptom Text: Information has been received from a nurse concerning a 13 year old female who on 26-AUG-2008 was vaccinated with her first dose of GARDASIL 0.5 ml, IM. The patient received her second dose of GARDASIL 0.5 ml, IM on 2-NOV-2008 and her third dose of GARDASIL 0.5 ml, IM on 3-MAR-2009. She mentioned she had not had a menstrual period "since my last dose of vaccine". Her last menstrual period was "at the end of November 2008". A urine pregnancy test performed in the office on 3-MAR-2009 was negative. A serum pregnancy test had been ordered but the results were pending. The patient's absence of period persisted. Additional information has been requested.

Other Meds: None

Lab Data: urine beta-human, 3/3/09, negative; serum beta-human, 3/3/09, pending

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344917-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	12-Feb-2009	17-Feb-2009	5	22-Apr-2009	06-May-2009	NY	WAES0903USA00572	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0546X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Mobility decreased, Pain, Pain in extremity

Symptom Text: Information has been received from a physician concerning a 14 year old female patient with no pertinent medical history and no known drug allergies, who on 12-FEB-2009 was vaccinated with the first dose of GARDASIL (lot # 661046/0546X) 0.5ml intramuscularly. There was no concomitant medication. On approximately 17-FEB-2009, "within the last week or two, the patient developed generalized joint pain that was migratory, and pain at the unspecified arm and was not able to lift that arm, which has improved. Patient also developed generalized body pain and leg pain.; Patient sought medical attention by calling the office. No lab diagnostic studies were performed. At the time of this report the patient had not yet recovered. Additional information has been requested

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **344918-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		22-Apr-2009	06-May-2009	--	WAES0903USA00589	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lichen nitidus, No reaction on previous exposure to drug, Rash generalised

Symptom Text: Information has been received from a physician assistant concerning a female under 18 year old who on unspecified date was vaccinated with her third dose of GARDASIL (lot number, route and site not reported) About 6 weeks after the third dose of GARDASIL the patient broke out in a rash all over her body. The patient had gone to a dermatologist who diagnosed the patient with lichen nitidus. The physician assistant was not sure if it was from the GARDASIL since the patient had no reaction with the first and second dose of GARDASIL, but the dermatologist believed it was from GARDASIL. Subsequently, the patient recovered from lichen nitidus. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344919-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Dec-2008	29-Dec-2008	0	22-Apr-2009	06-May-2009	--	WAES0903USA00747	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fatigue, Medical device complication, Mobility decreased, Pain in extremity, Underdose

Symptom Text: Information has been received from a registered nurse concerning her 16 year old with no pertinent medical history and no drug reactions/allergies who on 29-DEC-2008 was vaccinated with the second dose of GARDASIL. No concomitant medications. On 29-DEC-2008, during the injection, the needle broke apart. It was reported that the patient only received part of the vaccine. On 20-MAR-2009 the patient has been a little tired and her arm was sore and she was having trouble lifting her arm. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **344920-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	01-Sep-2008		22-Apr-2009	06-May-2009	--	WAES0903USA00761	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a consumer concerning her daughter (approximately 17 year old) with codeine allergy who had been experiencing headaches 6 month ago (approximately September 2008) after receiving a dose of GARDASIL. The patient received the third dose last month. She had been receiving the vaccine at a Healthcare Center. At the time of reporting the patient had not recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vaers Id: **344938-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	07-Jan-2009	Unknown		27-Apr-2009	28-Apr-2009	MI		28-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Right arm	Unknown	

Seriousness: ER VISIT, LIFE THREATENING, PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Alopecia, Amnesia, Anxiety, Asthenia, Autoimmune disorder, Condition aggravated, Disturbance in attention, Dizziness, Dyspnoea, Fatigue, Fibromyalgia, Flushing, Headache, Hyperhidrosis, Hypoaesthesia, Insomnia, Musculoskeletal stiffness, Myalgia, Pain, Presyncope, Raynauds phenomenon, Vision blurred, Visual impairment

Symptom Text: autoimmune disease fibromyalgia, raynods, numbness, flushing/sweats, anxiety,headaches, exhaustion to the point where its impossible to work, total body pain constantly,hair loss, vision problems,stiff and sore muscles,insomnia, trouble focusing and concentrating, memory loss, weakness, trouble breathing,and dizziness near syncope. All the side effects happened and intensified during December through January so I had an anti nuclear antibody blood test that was positive revealing the autoimmune disease fibromyalgia and raynods. My ANA blood test has come back positive several times. The doctors put me through a ridiculous amount of tests to try to figure out a diagnosis and why this had come out of nowhere. They thought I had at one point every different type of autoimmune disease including lupus but settled on FIbromyalgia with raynods and the possible beginnings of Lupus. I have to frequent a rheumatologist, neurologist,and primary care doctor several times a month. The side effects have made me very weak and unable to live my life normally, its hard for me to work. I teach children which take a lot of energy when I have none what so ever. I used to be strong and able to work out and ride horses and live a healthy active lifestyle, now I cannot enjoy any of it. My body is in such pain all the time that its impossible for me to have a normal life. I wanted this vaccine to help prevent problems, when all it did was destroy my life.

Other Meds: pentoxifllyne,

Lab Data: positive anti nuclear antibody blood test.

History: Fibromyalgia, raynods, beginnings of lupus.

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344955-1** **Related reports:** 344955-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Apr-2009	15-Apr-2009	8	27-Apr-2009	28-Apr-2009	NY		11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Convulsion, Foaming at mouth, Headache, Nausea, Unresponsive to stimuli

Symptom Text: Pt's mom called doctors office 4/16/09 @ 1424 and left message for doctors office that pt was in ER on 4/15/09 for seizure episode. Records received 05/06/09 for ED 04/15/2009 to 04/17/09. Parents witnessed seizure. Was foaming at the mouth, unresponsive, seizure resolved on its own. Initially very confused, confusion gradually decreased, patient was able to converse and was aware of date. Complained of mild to moderate headache and nausea. Discharged alert and oriented. To be followed by neurologist as needed. As of 5/11/09 no more seizures per PCP. DX: First-time seizure

Other Meds:

Lab Data: Brain CT/MRI/LABS Records recieved 05/06/09 - LAB: WNL. ECG, EEG, WNL.

History: Dust/pollens/molds Records received 05/06/09 PMH: Recent workup for dizziness

Prex Illness:

Prex Vax Illns:

Vaers Id: **344955-2** **Related reports:** 344955-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	07-Apr-2009	15-Apr-2009	8	28-Apr-2009	29-Apr-2009	NY	WAES0904USA02798	30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Confusional state, Dizziness, Dyspnoea, Foaming at mouth, Grand mal convulsion, Headache, Mitral valve incompetence, Nasal congestion, Nausea, Salivary hypersecretion, Tricuspid valve incompetence, Unresponsive to stimuli

Symptom Text: Initial and follow up information has been received from a consumer, a certified medical assistant and medical records concerning the consumer's 18 year old female daughter with no pertinent medical history and no drug reactions or allergies. The patient did not smoke or drink. There was no related family history and no history of seizure disorder in the family. On 02-FEB-2009 she was vaccinated with the first dose of GARDASIL (lot # 661766/0652X) and seemed fine. On 07-APR-2009 the patient was vaccinated with second dose of GARDASIL (lot # 661766/0652X). There was no concomitant medication. On 15-APR-2009 the patient stated that the first thing she remembered before having an apparent seizure witnessed by her parents was waking up feeling that she had a lot of saliva in her mouth, so she went to the bathroom to wash her mouth out and then her parents were in another room and heard a sound. They walked into the bathroom and found her having a tonic/clonic seizure that, in their estimation, lasted 5 minutes. She was foaming at the mouth was unresponsive initially and the seizure resolved on its own. Initially, after the seizure ended, she was quite confused, and gradually, since being brought in by ambulance, she had become less and less confused and was able to converse and now knew the date. She initially only knew the President's name. The patient complained of headache that was mild to moderate. She denied any weakness. She had been getting a workup done recently for dizziness. She had no other associated symptoms. She was slightly nauseous. She was treated with Zofran and morphine. She had an echo, which showed some abnormalities with mitral and tricuspid regurgitation, which seemed mild. An EKG was done, which showed sinus rhythm with a rate of 75. No ischemic changes. CBC showed a positive normal CBC, negative UA, normal comprehensive metabolic panel, negative beta HCG. A urine toxicology screen was only positive for opiates. She was given morphine in the emergency department for her headache. CT of head wa

Other Meds: None

Lab Data: Head computed axial, 04/15/09, see narrative; Magnetic resonance, 04/15/09, see narrative; Echocardiography, 04/15/09, see narrative; Electrocardiogram, 04/15/09, see narrative; Diagnostic urinalysis, 04/15/09, toxicology positive for opiat

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344963-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	10-Apr-2009	12-Apr-2009	2	27-Apr-2009	28-Apr-2009	VT		29-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	0	Left leg	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Axillary pain, Lymph node pain

Symptom Text: Pt received first GARDASIL injection 4/10/09. On 4/12/09, noted 1cm round tender axillary node.

Other Meds: Depo Provera

Lab Data: None

History: Beta Blockers, asthma, migraine with auva

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344967-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	17-Apr-2009	17-Apr-2009	0	27-Apr-2009	29-Apr-2009	MI		11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	1	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Body temperature increased, Dizziness, Dyskinesia, Gaze palsy, Mental status changes, Presyncope, Unresponsive to stimuli

Symptom Text: HPV# 2 4 1/2 hours after patient got the vaccine she felt light headed + dizzy and then became unresponsive, eyes deviated upwards, slight jerking for 40 seconds HPV#1 Pt had temp of 104 X 1 night after receiving HPV #1. 5/8/09 ER records received for DOS 4/17/09 with dx: Altered mental status, near syncope-etiology unclear. Pt presented after episode of altered mental mental status lasting ~ 40 secs. Onset abrupt but had resolved by arrival in ED.

Other Meds: BCP- YAZ

Lab Data: Ct Scan head, CXR, EKG, Labs- normal Labs and Diagnostics: Glucose 166. ALT 29 (L). Head CT (-). Drug screen (-). CXR WNL. ECG NSR.

History: Being worked up for Neurofibromatosis . PMH: none noted

Prex Illness: None

Prex Vax Illns: Temp 104~HPV (no brand name)~1~0~Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344969-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
41.0	F	02-Mar-2009	02-Mar-2009	0	22-Apr-2009	06-May-2009	CO	WAES0903USA00792	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Wrong drug administered

Symptom Text: Information has been received from a 41 year old female patient with an allergy to "cloricidin" and a history of bleeding during pregnancy who on 2-MAR-2009 was accidentally vaccinated with a first dose of GARDASIL (lot number and route not reported) in the arm while she was 10 weeks pregnant. She was supposed to be receiving globulin, RHOGAM. Concomitant therapy included levothyroxine Na. Pregnancy test and ultrasound were performed on an unspecified date (no results reported). The patient saw the physician. It was reported that the patient was 10 1/2 weeks pregnant at the time of this report. Additional information has been requested.

Other Meds: levothyroxine sodium

Lab Data: Unknown

History: Hemorrhage in pregnancy

Prex Illness: Pregnancy NOS (LMP=12/22/2008); Hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344970-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		22-Apr-2009	06-May-2009	--	WAES0903USA00860	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Infertility

Symptom Text: Information has been received from a female who was vaccinated with a first and second doses of GARDASIL on an unspecified date, respectively. The patient and her husband had been trying to get pregnant since November but no luck. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344971-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	02-Mar-2009		22-Apr-2009	06-May-2009	--	WAES0903USA00891	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who was vaccinated with a dose of GARDASIL. On 2-MAR-2009 the patient developed a reaction similar to hives. The patient was fine within 24 hours. It is unknown if the patient sought medical attention. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344973-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	01-Feb-2009	01-Feb-2009	0	22-Apr-2009	06-May-2009	VA	WAES0903USA00901	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a registered nurse concerning a 24 year old female who in approximately February 2009, about 1 month ago, was vaccinated IM with the first 0.5 ml dose of GARDASIL into the arm. On an unspecified date, following vaccination, the patient developed a headache that lasted 3 days. At the time of this report, the patient was in the office to receive her second dose. The physician was considering whether to continue the series. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344976-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	25-Sep-2007	24-Feb-2009	518	22-Apr-2009	06-May-2009	--	WAES0903USA00904	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1062U	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cervical dysplasia, Papilloma viral infection

Symptom Text: Information has been received from a nurse practitioner concerning a 20 year old female with no pertinent medical history or drug reaction/allergies who on 23-MAR-2007 was vaccinated IM with the first 0.5ml dose of GARDASIL, on 23-MAY-2007 was vaccinated IM with the second 0.5ml dose of GARDASIL and on 25-SEP-2007 was vaccinated IM with the third dose of GARDASIL. There was no concomitant medication. It was reported the patient had a positive DNA test for high risk Human Papilloma Virus (HPV) on 24-FEB-2009. The patient was seen by physician. Additional information has been requested.

Other Meds: None

Lab Data: diagnostic laboratory, 2/24/09, positive HPV test

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **344979-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	25-Feb-2009	26-Feb-2009	1	22-Apr-2009	06-May-2009	OH	WAES0903USA00914	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning a 14 year old female who 25-FEB-20009 was vaccinated with a dose of GARDASIL (lot # not reported). 1-2 days post vaccination, on approximately 26-FEB-2009 the patient experienced prolonged dizziness. The patient received an ear exam to check for inner ear problems and a neurological exam (results unknown). Unspecified medical attention was sought. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344988-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		22-Apr-2009	06-May-2009	--	WAES0903USA00928	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea

Symptom Text: Information has been received from a Nurse Practitioner (N.P.) concerning a female who was vaccinated with 0.5 ml dose of GARDASIL. The patient experienced shortness of breath after getting the vaccine and had got worse. Lot # was not provided. At the time of reporting (05-MAR-2009) the patient was not recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344990-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	23-Apr-2009	23-Apr-2009	0	27-Apr-2009	29-Apr-2009	MD		29-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0575X	2	Left arm	Unknown	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB330BA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Laboratory test, Syncope

Symptom Text: Syncope following vaccinations, then labwork (Had vaccines, then labs, then syncope occurred - Nothing to eat today).

Other Meds: None

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344991-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		22-Apr-2009	06-May-2009	--	WAES0903USA00936	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Metal poisoning

Symptom Text: Information has been received from a registered nurse (R. N.) concerning a female patient at one of the local schools who had an aluminum poisoning. The patient received a dose of GARDASIL at an unspecified date. The patient sought medical attention and was seen by a doctor. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **344993-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		22-Apr-2009	06-May-2009	NJ	WAES0903USA00937	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Oedema peripheral, Pyrexia

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated intramuscularly with 0.5 ml dose of GARDASIL. Concomitant therapy included HAVRIX. The patient developed a fever 2 days after she received the vaccine. The fever lasted 2 days. After the fever went back down, she had "swelling in her legs". The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **344996-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		22-Apr-2009	06-May-2009	--	WAES0903USA00956	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a mother concerning her daughter who on unspecified dates was vaccinated with all the three doses of GARDASIL (lot number, route and site not reported). On an unspecified date, the patient developed HPV. The outcome of the event was not reported. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345001-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	28-Feb-2009	28-Feb-2009	0	22-Apr-2009	06-May-2009	OH	WAES0903USA00966	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Injection site erythema, Injection site papule, Tinnitus

Symptom Text: Information has been received from a nurse concerning a 17 year old female patient who on 28-FEB-2009 was vaccinated with the first dose of GARDASIL (lot number and route not reported) in her arm. After receiving the vaccination, the patient felt dizzy and had ringing in her ears. So the office had the patient lay down for 10 minutes with an ice pack on her head and then she was "ok" to leave the office. The nurse stated that on 5-MAR-2009 the patient called the office and stated that she woke up with a red bump on her arm near the injection site. The patient was told to put ice on the bump and if the bump would not go away or get worse by the weekend then she should call the office back. The red bump on her arm persisted at the time of this report. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345003-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-Dec-2008	23-Feb-2009	63	22-Apr-2009	06-May-2009	TX	WAES0903USA01098	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 13 year old female who on 22-DEC-2008 was vaccinated with her first dose of GARDASIL (lot number, route and site not reported). On 22-DEC-2008 the patient was vaccinated with her second dose of GARDASIL (lot number 661766/0652X, route and site not reported) 0.5 ml. There was no concomitant medication. On 23-FEB-2009 after receiving the second dose, the patient fainted. On 23-FEB-2009 the patient recovered from fainting. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **345004-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		22-Apr-2009	06-May-2009	CO	WAES0903USA01124	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Asthenia, Headache, Lethargy

Symptom Text: Information has been received from a physician concerning a 15 or 16 year old female who was vaccinated with the second dose of GARDASIL. On an unspecified date, 2 months after receiving the second dose of GARDASIL, the patient had a terrible headache, severe lack of energy and was very lethargic. The patient sought unspecified medical attention from physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345006-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Aug-2008	01-Aug-2008	0	22-Apr-2009	06-May-2009	--	WAES0903USA01155	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nausea

Symptom Text: Information has been received from a consumer concerning her 23 year old daughter with no pertinent medical history and no known drug allergies or reactions who in August 2008, was vaccinated with the first dose of GARDASIL (lot # not provided). There was no concomitant medication. In August 2008, the patient experienced nauseous constantly. No lab diagnostics studies were performed. The patient had not gotten the second dose of GARDASIL and did not plan on receiving it. At the time of reporting, the patient's nausea persisted. The patient did not seek medical attention. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345007-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		22-Apr-2009	06-May-2009	AZ	WAES0903USA01367	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a physician concerning a female who on an unspecified dates was vaccinated with first and second doses of GARDASIL (dose, route and lot number not provided). The physician reported that after receiving the two doses the patient was diagnosed with human papilloma virus (HPV). The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345008-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	31-Jul-2007	Unknown		22-Apr-2009	06-May-2009	--	WAES0903USA01378	11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0524U	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain, Gastrooesophageal reflux disease, Nausea, Pharyngitis streptococcal

Symptom Text: Information has been received from a school nurse (registered nurse concerning a high school aged female who was vaccinated with a dose of GARDASIL. On an unspecified date, after receiving GARDASIL, the patient developed aluminum poisoning. The patient sought unspecified medical attention. Additional information was received from the school nurse and an office manager concerning the 15 year old high school female who on 31-JUL-2007 was vaccinated with the first dose of GARDASIL (lot #: 658094/0524U), on 5-OCT-2008 was vaccinated with the second dose (lot # : 658282/0929U) and on 6-FEB-2008 was vaccinated with the third dose (lot #: 659657/1487U). It was reported that the patient did not have poisoning but had a reaction to GARDASIL. This is one of several report received from the same source. Additional information has been requested. 5/1/09 Received PCP vaccine & medical records of 7/31/07-11/24/08 FINAL DX: none provided Records reveal patient experienced good health on 7/31/07 & 8/5/08. RTC 9/26/08 & 11/14/08 w/abdominal pain & nausea. Dx w/GERD. RTC 11/24 w/strep pharyngitis

Other Meds: Unknown

Lab Data: Unknown LABS: CBC, CMP & US of abdomen WNL. Strep ID test (+).

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 345018-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	17-Jun-2008	17-Jun-2008	0	28-Apr-2009	29-Apr-2009	PA	WAES0901USA00777	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067X	0	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain upper, Activities of daily living impaired, Anorexia, Asthenia, Back pain, Chest discomfort, Chest pain, Condition aggravated, Constipation, Diarrhoea, Dizziness, Dysmenorrhoea, Dyspnoea, Ear discomfort, Eructation, Eustachian tube dysfunction, Fatigue, Gastrooesophageal reflux disease, Haemorrhage, Headache, Influenza like illness, Initial insomnia, Malaise, Nausea, Pyrexia, Rash, Sinusitis, Somnolence, Stress, Throat tightness, Upper respiratory tract infection, Vomiting, Weight decreased

Symptom Text: Information has been received from a consumer concerning a her daughter 21 year old with penicillin allergy and no pertinent medical history who in June-2008 was vaccinated with first dose of GARDASIL (Lot # not provided) 0.5ml, intramuscularly. After the patient received first dose of vaccine she experienced nausea and recovered from rash. On 20-SEP-2008 the patient received second dose of GARDASIL (Lot # not provided) 0.5ml, intramuscularly. There was no concomitant medication. Then after the patient received second dose of GARDASIL she became nauseous again, developed a fever, and had headaches "all the time". It was reported that she no longer had the fever but she still felt nauseous and had headaches. She also "had no energy", "no appetite" and lost 25 pounds. She received NEXIUM and Omeprazole and "each one worked for a day" and then stopped working. She also received ZITHROMAX for her fever and she developed a rash after she stopped taking it. Blood test was performed to check her stomach and her gall bladder (results not reported). At the time on the report on 07-JAN-2009 the patient was recovering. The patient sought unspecified medical attention. Follow up information was received from doctor's office and medical record. It was reported that the patient had variable bleeding from 02-APR-2008 to 06-MAY-2008 and moderate bleeding 22-MAY-2008 to 17-JUN-2008. On 17-JUN-2008 the female patient with cyst and always bowel problem was vaccinated with a first dose of GARDASIL (Lot # 660393/0067X) 0.5ml, intramuscularly into left deltoid. She was having some menstrual irregularity at the time of her first vaccination. Since she had no bleeding when she was on DMPA. On 14-JUN-2008 her bleeding was very light. At that time she was prescribed FEMCON. The physician's impression was that the patient had abnormal uterine bleeding. On 19-AUG-2008 she was vaccinated with the second dose of GARDASIL lot # 660612/0229X into right deltoid IM. Approximately on 19?AUG-2009 the patient experienced nausea, anorexia, low grade

Other Meds:

Lab Data: Diagnostic laboratory, Blood test checked in her stomach and her gall bladder; Chest X-ray, 03/03/09, slight hyperinflation of lungs (see narrative); Hepatobiliary, 11/28/08, Gall bladder ejection was 44%; Diagnostic laboratory, 12/11/08, H

History:

Prex Illness: Penicillin allergy; Menstruation irregular; Cyst; Bowel discomfort; Diarrhoea; Constipation

Prex Vax Illns:

Vaers Id: **345019-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	20-Feb-2008	01-May-2008	71	28-Apr-2009	29-Apr-2009	FR	WAES0904USA03139	29-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1068U	1	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain, Acute sinusitis, Arthralgia, Arthritis reactive, Bacterial infection, Bacterial pericarditis, Chills, Circulatory collapse, Dehydration, Dizziness, Enterococcal infection, Euthyroid sick syndrome, Fatigue, Gastric ulcer, General physical health deterioration, Headache, Infection, Inflammation, Oesophageal candidiasis, Oropharyngeal pain, Pain, Pericarditis, Pyrexia, Rhinitis, Sinus headache, Sinusitis, Surgery, Urinary tract infection

Symptom Text: Case received from Health Authority in a foreign country on 15-APR-2009 under Health Authority reference No. PEI2009007468. It was reported that a 20 year old female patient with a medical history of nasal septum deviation, pollen and house dust allergy and cachexia was vaccinated with a second dose of GARDASIL (Lot # 1068U, batch # NG42070) IM into the upper arm on 02-MAY-2008. Concomitant treatment included hormonal contraceptives. Several hospital reports and reports of findings were sent by the patient's parent to Health Authority. Short after vaccination the patient experienced rhinitis, dizziness and tiredness. Few dates later she developed fever and "circulatory breakdown" twice. She was admitted to the hospital first time from 15 till 17-MAY-2008. At that time she complained of pain in the area of the ethmoidal sinuses (face) and showed signs of exsiccosis. Examinations (MRI sinuses) revealed diagnosis of polysinusitis. Additionally she suffered from a urinary tract infection and an unspecific inflammation / infection on the left foreleg (possible insect bite). Inflammatory laboratory parameters were increased. Antibiotic treatment with UNACID and inhalations were started. The leg was treated with LAVASEPT bandages. She was discharged in "almost recovered" condition. The patient was hospitalized again from 19-MAY-2008 till 04-JUN-2008. At that time she suffered from a high-feverish infection, acute sinusitis and urinary tract infection. Additionally reactive arthritis and reactive pericarditis was diagnosed as well as euthyroid sick syndrome. The general condition was reduced. The patient complained of abdominal pain, arthralgia, chills, sore throat and headache. Fever raised up to 40 C. Enterococcus faecium was found in nasal secretion and urine. Abdominal sonography, blood culture, electrocardiogram, echocardiography showed initially normal results. Electrocardiogram follow up on 23-MAY-2008 revealed negative T-waves in III, VI - V4. Diagnosed of secondary pericarditis in the scop

Other Meds: hormonal contraceptives (unspecified)

Lab Data: Diagnostic laboratory test, 13May08, FT3: 2.86pmol/l; Electrocardiogram, 23May08, T-negative in III, VI - V4; Diagnostic laboratory test, 26May08, 150 IE/ml, Anti-DNASE B; Diagnostic laboratory test, 26May08, Yersinia agglutination and Y: N

History:

Prex Illness: Deflected nasal septum; Pollen allergy; House dust allergy; Cachexia

Prex Vax Illns:

Vaers Id: 345020-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	06-Apr-2009	07-Apr-2009	1	28-Apr-2009	29-Apr-2009	FR	WAES0904USA03703	04-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NJ0020	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Back pain, Bacteriuria, Chills, Haemangioma, Headache, Malaise, Muscle rigidity, Nervousness, Pyrexia

Symptom Text: Information has been received from a health care professional on 13-APR-2009 concerning a patient who vaccinated with GARDASIL (batch number NJ0020) was in hospital, the reporter was unable to identify a patient or the adverse reaction at the time. On the 14-APR-2009 further information was received. The patient an 18 year-old female was administered on the 06-APR-2009 the second dose of GARDASIL route and site not reported. The reporter was unaware of the patent's adverse event, but confirmed that the patient was hospital admitted. On the 15-APR-2009 the doctor was contacted, who did not want to give any information until he had the report. On the 16-APR-2009 the doctor, who had not yet sent any information regarding the patient, was contacted again. The doctor only informed that the patient was very nervous, he believed that it was due to a lumbar punction. He would send the report. According to the hospital report received on the 17-APR-2009 the patient, a female who was vaccinated on the 06-APR-2009 with the second dose of a GARDASIL route and site not reported. The patient was allergic to pantomicine and Atypical background. She didn't have toxic habits. The patient had ovarian cysts, she is currently being treated with oral contraceptives. She was a smoker, 15 cigarettes per day. The patient has been taken fluoxetine, lorazepam, ketoprofen, DIANE, AUGMENTIN, scopolamine, Itraconazole, ciclopirox, ibuprofen, Hidroxyl b1, b6, b12, INZITAN and TORADOL. After vaccine administration, approximately one hour later, the patient started with an oppressive frontal cephalea that evolved into a hemicraenal cephalea which lasted all night long. On that same night the patient presented with shivers and general malaise. The patient took Paracetamol GELOCATIL to treat adverse effects. The next morning the patient continued to have a headache, which was spreading to the back area, and also presented fever. These symptoms did not cease with GELOCATIL thus the patient was taken to the emergency room. According to the hospital

Other Meds: DIANE

Lab Data: spinal tap; CSF urea, hepatic liquid, clear supernatant, leukocytes 3, red blood cell count 6840, glucose 66, proteins 21; INR, 1.08; adenovirus PCR, 2.40; platelet count, normal; serum procalcitonin, <0.5; complete blood cell count, leukoc

History:

Prex Illness: Hypersensitivity; Ovarian cyst; Smoker

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345026-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	03-Feb-2009	17-Feb-2009	14	28-Apr-2009	29-Apr-2009	FR	WAES0904NZL00009	29-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1283U		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Vaccine positive rechallenge

Symptom Text: Information has been received from an agency as part of a business agreement, concerning a 17 year old female who was vaccinated with a dose of GARDASIL (date not reported). Subsequently the patient experienced convulsions. Subsequently the patient recovered from convulsions. On 03-FEB-2009 she was vaccinated with another dose of GARDASIL (Batch # NJ11440, Lot # 1283U). On 17-FEB-2009, less than one month after vaccination the patient experienced another episode of convulsions and was hospitalised which was reported as severe. At the time of reporting to the agency in March 2009, the patient had recovered without sequelae from convulsions. The agency considered that the second episode of convulsions was possibly related to therapy with GARDASIL. The original reporting source was not provided. Upon internal medical review, the first episode of convulsions was considered an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 345028-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	01-Jun-2008	03-Nov-2008	155	28-Apr-2009	29-Apr-2009	FR	WAES0904USA03127	04-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Haemoptysis, Malaise, Wegeners granulomatosis

Symptom Text: Information has been received from foreign Health Authority (H.A. Ref # 0901268). Additional information was received from the Health Authority on 15-Apr-2009. It was reported that the 15 year old woman was vaccinated with GARDASIL (second dose, batch number not reported) on unspecified date in June-2008. Health Authority reported Wegner's granulomatosis (causality unclassified) with onset 3-NOV-2008. It was reported that a previous healthy patient developed malaise and bloody rheum about 4 months after the second dose of GARDASIL. She was evaluated at the ear-nose-neck department was hospitalized at the rheumatologic clinic. High resolution Computed Tomograhy (HRCT) showed bilateral infiltrate corresponding to the diagnosis Wegener's granulomatosis. Sinus computed tomography indicated a swelling in the nose ventricle with bilateral bone destruction in the bone wall to sinus maxilaris. The clinical picture reminded of vasculitis. Patho-anatomical diagnosis (PAD) indicated a severe inflammatory cell infiltration but there was no suspicion of malignity. After the final result from HRCT the diagnosis was changed from a limited Wegener's granulomatosis to Wegener's with lung affection. The patient started treatment with PREDNISOLON, PFIZER and METHOTREXAT, Onion. A position regarding CYCLOPHOSPHAMIDE, BAYER treatment was planned. Results for lab analysis performed on unspecified date: S-ANA (antinuclear antibodies) via ELISA was negative, S-ANCA (Ig G) (Anti-Neutrophil Cytoplasmic antibodies) was positive, S-P-ANCA (Ig G) was negative, S-PR3-ANCA (Protinase 3) a.b. (Ig G) quantity was 200 E/ml (ref <10), S-ANCA-MPO (Myeloperoxidase) a.b. (Ig G) quantity was <20 E/ml (ref <20), S -cArdiolipin -a.b. (Ig G) was <10 E/ml (ref <10) and S-Cardiolipin -a.b. (Ig M) as <7 E/ml (ref <7). The patient received first dose of GARDASIL in April-2008 and no adverse reaction was reported. The outcome was at the time of reporting not yet recovered. No further information was available. Other business partner include E2009-03255. Case

Other Meds: Unknown

Lab Data: computed axial tomography, Diagnosis Wegener's granulomatosis; diagnostic procedure, Patho-anatomical diagnosis indicated severe inflammatorycell; Anti-MPO Ab, <20 E/ml; serum ANA, Ig G-Negative; serum ANCA, 200 E/ml, Proteinase 3; serum C-

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 345029-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-May-2008	20-May-2008	14	28-Apr-2009	29-Apr-2009	FR	WAES0904USA03552	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1113U	1	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Asthenia, Haematoma, Muscle spasms, Panic attack, Paraesthesia, Syncope

Symptom Text: Information has been received from Health Authority (H.A. Ref # PEI2009007496). This case was linked with serious case E2009-03313 (same patient, different reactions after first dose of the vaccine). (WAES# 0904USA03128). It was reported that a 16 year old female patient was vaccinated with a second dose of GARDASIL (lot number:1113U, batch number:NH04240, injection route not reported) into the left upper arm on 6-MAY-2008. Two weeks post vaccination, the patient experienced paraesthesia, generalised muscle cramps, asthenia, panic attacks. Six weeks post vaccination, the patient developed hematoma at the right thigh medial and the crook of the right arm. Ten months post vaccination, the patient developed syncope of unknown origin. The patient was admitted to hospital for diagnostics 3 times in total. Diagnostics include cranial MRI, ophtalmological and ENT examination, EEG, ECG and lumbal puncture, results were not reported. The patient recovered from haematoma after one week, all other symptoms were ongoing at the time of reporting to Health Authority 7-APR-2009. The patient received her first dose of GARDASIL, lot number:0253U, batch number:NF58540 on 4-MAR-2008 and experienced recurrent headache, dizziness and staggering, nausea and diarrhoea two weeks post vaccination (see case E2009-03313). The patient had also not recovered from these symptoms at the time of reporting to HA (7-Apr-2007). Other business partner include E2009-03313, E2009-03314.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, Cranial MRI-results not reported; ophthalmological exam, Results not reported; spinal tap, Results not reported; otorhinolaryngologic surgery, Results not reported; electroencephalography, Results not reported; e

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 345031-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	04-Mar-2008	18-Mar-2008	14	28-Apr-2009	29-Apr-2009	FR	WAES0904USA03128	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0253U	0	Left arm	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Diarrhoea, Dizziness, Gait disturbance, Headache, Nausea

Symptom Text: Information has been received from Health Authority (H.A. Ref # PEI2009007496). This case was linked with serious case E2009-03314 (same patient, different reactions after second dose of the vaccine (WAES#0904USA03552). It was reported that a 16 year old female patient was vaccinated with a first dose of GARDASIL (lot number: 0253U, batch number: NF58540, injection route not reported) into the left upper arm on 4-MAR-2008. Two weeks post vaccination the patient experienced recurrent headache, dizziness and staggering, nausea and diarrhoea. The patient was admitted to hospital for diagnostic 3 times in total. Diagnostics included cranial MRI, ophthalmological and ENT examination, EEG, ECG and lumbal puncture, results were not reported. At the time of reporting to HA (7-APR-2009) symptoms were still ongoing. The patient experienced paraesthesia, generalized muscle cramps, asthenia, panic attacks, hematoma of arms and legs and syncope after second dose of GARDASIL (see case E2009-03314). Other business partner include E2009-03313, E2009-03314.

Other Meds: Unknown

Lab Data: magnetic resonance imaging, Cranial MRI-Results not reported; spinal tap, Results not reported; ophthalmological exam, Results not reported; ears, nose, and throat examination, Results not reported; electroencephalography, Results not repor

History: No reaction on previous exposure to vaccine.

Prex Illness:

Prex Vax Illns:

Vaers Id: **345032-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	17-Jan-2008	22-Mar-2008	65	28-Apr-2009	29-Apr-2009	FR	WAES0904USA03492	29-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0352U	1	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Epilepsy, No reaction on previous exposure to drug

Symptom Text: Information has been received from a general practitioner concerning a 16 year old female who was administered her first dose of GARDASIL (Lot# not reported) on an unspecified date was well tolerated. On 17-JAN-2008 she was vaccinated with a second dose of GARDASIL (lot# 0352U; batch # NG00320) IM into the left upper arm. On 22-MAR-2008 the patient experienced three epileptic fits and was hospitalized on the same day. She was treated with antiepileptics (not otherwise specified). The patient recovered after 1 day. A neurologist assessed a possible relationship to therapy with GARDASIL. Other company numbers included: E2009-03323. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345033-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	08-Apr-2009	11-Apr-2009	3	28-Apr-2009	29-Apr-2009	FR	WAES0904USA03676	29-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Tonic clonic movements

Symptom Text: Information has been received from a health care professional via SPMSD concerning a 14 year-old girl who was vaccinated on 08-APR-2009 with the second dose of GARDASIL (batch number not reported, route and site of administration not reported). It is reported that on the 11-APR-2009, the patient presented with loss of consciousness and tonic clonic movements events ceased after a few minutes. It is reported that the patient was at the beach when the events occurred. The patient was taken to the emergency room for a check-up. The patient was in perfect condition, she did not require any assistance or treatment. The case has been sent by the reporter to the Health Authorities, with other medically important condition as criteria. Loss of consciousness and tonic clonic movements were determined to be an other important medical event. This case is linked to case E2009-03320 (WAES # 0904USA03476, same reporter, same product, same adverse event). Other business partner numbers include E2009-03321. No further information is reported. Case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345034-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	24-Mar-2009	25-Mar-2009	1	28-Apr-2009	29-Apr-2009	FR	WAES0904USA03494	29-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1535U		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dyskinesia, Pyrexia, Rash maculo-papular

Symptom Text: Information has been received from the Health Authority concerning a 20 year old female with depression and contraception use who on 24-MAR-2009 was vaccinated with GARDASIL (Lot #1535U and batch#NH41820), intramuscularly (site not reported). The patient's medical history included depression for which on 17-OCT-2008 the patient was receiving treatment with FLUOXETIN, 20mg, orally. On 30-JAN-2008, the patient was also receiving YASMIN for contraception, orally. On 25-MAR-2009, one day past immunization, the patient was hospitalized with fever and protraction. A few days later the patient also developed a small maculopapular rash on the chest. The patient was recovering at the time of reporting to the agency. Both the agency and the reporter considered the events to be serious. Other company numbers included: E2009-03366. No further information is available.

Other Meds: FLUOXETIN; YASMIN

Lab Data: Unknown

History:

Prex Illness: Contraception; Depression

Prex Vax Illns:

Vaers Id: **345035-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	15-Jan-2009	24-Jan-2009	9	28-Apr-2009	29-Apr-2009	FR	WAES0904USA03600	29-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Dizziness, Dyspnoea, Gastrooesophageal reflux disease, Hyperhidrosis, Pallor, Tachycardia

Symptom Text: Information has been received from a Health Authority (reference number ES-AGEMED-520845241) concerning a 14 year old female who on 15-JAN-2009 was vaccinated with a dose of GARDASIL (batch # not reported) by intramuscular route (site of administration not reported). It was reported that on 24-JAN-2009 the patient presented with gastroesophageal reflux, pallor, dizziness, dyspnea, shivers, tachycardia and sweating. The patient recovered on the 03-MAR-2009. Case reported as serious by the HA with other medically important condition as criteria. No further information has been given. Case was closed. Other business partner numbers include E2009-03485.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345036-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	30-Dec-2008	30-Dec-2008	0	28-Apr-2009	29-Apr-2009	FR	WAES0904USA03604	29-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a Health Authority (reference number ES-AGEMED-720847241) concerning a 14 year old female who on 30-DEC-2008 was vaccinated with a dose of GARDASIL (batch # not reported) by intramuscular route (site of administration not reported). It was reported that on the day of vaccination, the patient suffered a loss of consciousness, she recovered in 2 or 3 minutes, and fully recovered after a 30 minute period on a high pelvic position (trendelenburg). No further information reported. Case reported as serious by the HA with other medically important condition as criteria. Case was closed. Other business partner numbers include E2009-03463.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345050-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Nov-2008	20-Nov-2008	1	28-Apr-2009	06-May-2009	IN		13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB289AA	1	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	0650X	0	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2729AA	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion, Crying, Headache, Postictal state, Tachycardia, Tremor, Unresponsive to stimuli

Symptom Text: seizure activity taken by ambulance to hospital 18 hours after vaccine given. Patient has no previous events of seizures ever. 5/4/09 MR received for 2 ER visits 11/20/08 and 11/21/08 with DX: Seizure. Pt with no PMH found unresponsive at school with seizure activity. Initially found to be post-ictal on arrival by EMS andransported. Continued seizure activity of shaking all over in EMS. Pt unresponsive to painful stim. Upon arrival to ER pt crying and yelling, tachycardic, now drawing back from pain. Later to baseline and d/c. Returned 11/21/08 with c/o multiple episodes of seizure at home. Also c/o h/a. PE WNL by arrival. D/C for outpt f/u.

Other Meds: none

Lab Data: eeg, cat scans, mri of brain. To have eeg repeated at vanderbilt university in June Labs and diagnostics: CBC and Chem WNL. Drug screen (-). Head CT (+) for chronic R mastoiditis.

History: none. PMH: diarrhea x 1 week. Appy. On birth control

Prex Illness: none

Prex Vax Illns:

Vaers Id: **345052-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Apr-2009	20-Apr-2009	0	28-Apr-2009	04-May-2009	MN		04-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2688AA	0	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0588X	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	UF456CA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyskinesia, Feeling cold, Gaze palsy, Pain in extremity, Pallor, Skin discolouration, Unresponsive to stimuli

Symptom Text: Patient seated on a chair in exam room one with mother and younger brother present. Patient given HPV, Tdap, and Menactra vaccines at 4 pm by RNs. Patient chatted following the vaccine, said her arms really hurt, and was encouraged to move her arms using a small stacking toy, which she did. I discussed with patient's mom the vaccines and providing Tylenol/Advil to patient as needed. Toy suddenly fell onto the floor; patient's head leaned back against the wall, and patient's eyes rolled back into her head. Patient's mother shook her and spoke her name loudly several times with no response. Patient's color was becoming pale and slightly green. Patient's right hand briefly clenched into a fist and flexed at the wrist. I asked support staff to call 911 and ambulance was requested. Patient's mother and I lowered patient to floor and placed head onto floor and elevated legs onto chair. Patient opened eyes and eyes focused on us. Pulse and BP taken by RN and results were normal. RN made ready and available anaphylactic reaction medical protocol supplies. Patient covered with blanket and cool compress applied to forehead. Supervisor RN observed patient and noted that patient was now responding verbally and respirations were normal; ambulance request cancelled. Patient stated she was cold. Patient said she had not eaten much for lunch. Patient's coloring returned to normal. Patient's pulse continued to be normal. Patient assisted to a sitting position on the floor, given sweatshirt to wear, and drank 8 oz water. Patient assisted to standing position at 4:45 pm. Mother instructed to monitor patient's breathing and to take patient to ER immediately if breathing problems developed. Patient said she felt well enough to walk. Patient left to return home with mother and brother.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345082-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	28-Apr-2009	28-Apr-2009	0	28-Apr-2009	29-Apr-2009	FL		30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2872AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0558X	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dyspnoea, Hyperhidrosis, Paraesthesia

Symptom Text: Shortness of breath, tingling, sweating.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345105-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Aug-2008	15-Mar-2009	226	28-Apr-2009	30-Apr-2009	--		01-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Alopecia

Symptom Text: Excessive rapid hair loss a month after administration of GARDASIL vaccine

Other Meds:

Lab Data: Normal physical examination 03/01/2009.

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345138-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
37.0	F	14-Apr-2008	02-Oct-2008	171	29-Apr-2009	30-Apr-2009	FR	WAES0904USA03900	30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Inappropriate schedule of drug administration

Symptom Text: Information has been received from Health Authorities (reference number ES-AGEMED-320844341) regarding a 37 year old female who on 14-APR-2008 was administered the second dose of GARDASIL (batch number not reported) by intramuscular route (site of administration not reported). On 02-OCT-2008 the patient suffered a generalized convulsive crisis. She recovered on the same date (02-OCT-2008). The patient had a demyelinating disease, later on it had been diagnosed as a possible multiple sclerosis. After the first episode no other seizures had been registered, the patient was being treated with KEPPRA anticonvulsive medication 500 every 12 hours. The patient received the first dose of GARDASIL (batch number not reported, route and site of administration not reported) on 14-FEB-2008. It hadn't been reported whether the patient had had any adverse event after this first dose or not. Case reported as serious by the HA with other medically important condition of convulsive seizure as criteria. Other business partner numbers include: E2009-03500. No further information is available. The case is closed.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Multiple sclerosis

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345139-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	19-Dec-2008	30-Dec-2008	11	29-Apr-2009	30-Apr-2009	FR	WAES0904USA03855	30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Petechiae

Symptom Text: Information was obtained on request by the company from the agency, via a Public Case Details forms, concerning a 25 year old female who on 19-DEC-2008 was vaccinated with GARDASIL IM (therapy dose, site and lot # unknown). Concomitant therapy included LEVLEN ED. On 30-DEC-2008 the patient experienced petechial rash on legs and was hospitalized. Laboratory investigations included Hemoglobin of 14.0, "pit" of 1, WCC of 9.1, Neutrophils of 7.76, and viral and immune disease screen non-contributory. The patient was given PREDNISOLONE 50mg daily. Subsequently, on 04-JAN-2009 the patient recovered. The reporter felt that petechial rash on legs was possibly related to therapy with GARDASIL. The original reporting source was not provided. Additional information has been requested.

Other Meds: LEVLEN ED

Lab Data: diagnostic laboratory test, pit:1; diagnostic laboratory test, viral and immune disease screen non-contributory; WBC count, 9.1; hemoglobin, 140; neutrophil count, 7.76

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345140-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	02-Dec-2008	04-Dec-2008	2	29-Apr-2009	30-Apr-2009	FR	WAES0904USA03853	30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Atypical benign partial epilepsy, Convulsion

Symptom Text: Information has been received from a Health Authority (reference number ES-AGEMED-930976340) concerning a 12 year old female with no other relevant history who on 02-DEC-2008 was vaccinated with a dose of GARDASIL (lot # and injection site not reported) by intramuscular route. On 04-DEC-2008 the patient presented with 2 generalized convulsive crisis. It was reported that a benign partial epilepsy of the adolescence was suspected. Convulsion was the only adverse event that had been coded in the Health Authority's report (but not reported in the narrative on the Health Authority's report). It was reported that computed axial tomography (CAT) scan and electroencephalography (EEG) were normal. On 21-APR-2009 a new report from the Health Authority was received where CAT scan and EEG results were not given. Case reported as serious by the HA with other medically important condition as criteria. Other business partner numbers include E2009-03324. No further information is available. Case is closed.

Other Meds: Unknown

Lab Data: Computed axial tomography, normal; Electroencephalography, normal

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345141-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	28-Nov-2008	06-Dec-2008	8	29-Apr-2009	30-Apr-2009	FR	WAES0904USA03843	30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hemiparesis, Migraine with aura

Symptom Text: Information has been received on 20-APR-2009 from the Health Authority (reference number ES-AGEMED-80951337) concerning a 19 year old female with migraine since 2001 who was administered on 28-NOV-2008 the second dose of GARDASIL (batch number, not reported) by intramuscular route (site of administration not reported). 8 to 10 days after vaccination, the patient presented a right side hemiparesis episode. The patient was taken to the emergency room where the neurologist diagnosed the patient with an atypical migraine with aura. Only hemiparesis has been coded in the foreign Health Authority's report. CAT scan was performed on DEC-2008 results normal. The patient recovered with no sequelae. Case reported as serious by the HA with other medically important condition as criteria. Case is closed. Other business partner numbers included: E2009-03506. No further information is available.

Other Meds: Unknown

Lab Data: computed axial tomography, ??Dec08, normal

History: Migraine

Prex Illness:

Prex Vax Illns:

Vaers Id: **345142-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	Unknown		29-Apr-2009	30-Apr-2009	FR	WAES0904USA03841	30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a health care professional concerning a 23 year old female patient. The patient was tested for human papilloma virus (HPV) infection in 2006 and the result was negative. On unreported date, the patient received the first dose of GARDASIL, batch number, route and site not reported. On unreported date, the patient received the second dose of GARDASIL, batch number, route and site not reported. On unreported date, the patient received the third dose of GARDASIL, batch number, route and site not reported. On an unreported date but after completing the course of GARDASIL vaccinations, the patient was tested again for a human papilloma virus (HPV) infection and was found to be positive to several types of high risk HPV infection (type not specified)., The patient outcome is unknown. The reporter considers the event to be serious as the vaccine should have provided protection against the HPV. Other company numbers included: E2009-03372. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Human papilloma virus test negative

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345143-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	01-Dec-2008	01-Dec-2008	0	29-Apr-2009	30-Apr-2009	--	WAES0904USA03689	30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Osteomyelitis, Swelling

Symptom Text: Information has been received from a health care professional concerning an 11 year old female patient who on an unspecified date was vaccinated with a dose of GARDASIL. It was reported that the patient called the next day after receiving GARDASIL with complaints of swelling. It was reported that this adverse event occurred four to five months ago (approximately in December 2008). It was reported that two weeks later the patient was at the office and was referred to the Emergency Room and was provided antibiotics. The patient was identified with osteomyelitis and was hospitalized for three to four days. It was reported that the patient had recovered at the time of the report. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345144-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-Feb-2009	28-Feb-2009	1	29-Apr-2009	30-Apr-2009	FR	WAES0904USA03680	30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Influenza like illness, Pyrexia

Symptom Text: Information has been received via a Health Authority from a pharmacist who was informed by the patient's mother that her adult daughter (18 to 20 years old) received an injection of GARDASIL (lot # not reported and number in series of the dose were unknown) via intramuscular route on 27-FEB-2009. On 28-FEB-2009 the patient presented with important fever and flu-like syndrome qualified as resistant to antibiotics. At time of reporting the outcome was unknown. Very few information, the case was reported to the pharmacist by the patient's mother. The patient was lost to follow up, no more information could be obtained. Case reported as serious due to the necessity of consultation and treatment. The health Authorities assessed the causal relationship between the reported reaction(s) and vaccination as "doubtful" according to the method of assessment. The case is closed. Additional information is not expected. Other business partner numbers include E2009-03502, NT20090221 and NT0900233.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345145-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Feb-2009	01-Feb-2009	0	29-Apr-2009	30-Apr-2009	FR	WAES0904USA03678	30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Subcutaneously	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Cheilitis, Cytomegalovirus test negative, Echocardiogram normal, Hypotonia, Incorrect route of drug administration, Inflammation, Mononucleosis heterophile test negative, Myalgia, Pain, Palmar-plantar erythrodysaesthesia syndrome, Pyrexia, Rash vesicular, Skin exfoliation, Strawberry tongue, Toxoplasma serology negative

Symptom Text: Information has been received from the health authorities under the reference number NY20090213 NY0919283 concerning a 16 year old female who in February 2009, was vaccinated with the second dose of GARDASIL (batch number not reported) via subcutaneous route instead of intramuscular route (exact date not provided). 15 days after vaccination, the patient experienced an abrupt bout of fever at 40.7 centigrade degree, associated with a palmoplantar erythema, a cheilitis with strawberry tongue, myalgias and a decrease of muscle tone in the hands associated with pain when bending fingers. It was noteworthy that the patient also complained of a microvesicular eruption of both trunk and abdomen on an unspecified date. There was no adenopathy nor organomegaly. Cardiopulmonary auscultation revealed normal and cardiac ultrasonography without any particularity. Biological work-up showed an inflammatory syndrome with C-reactive protein at 200mg/L. Toxoplasma, cytomegalovirus and infectious mononucleosis serologies revealed negative. Antibiotherapy was given as corrective treatment. The inflammatory syndrome resolved, but desquamation at the palm of the hands and decrease of the muscular tone persisted. The patient was hospitalized. The evolution was unknown. The health authorities assessed the causal relationship between the reported reactions and the vaccination as "doubtful" according to the foreign method of assessment. Other business partner numbers include E200903501. No further information is available. The case is closed.

Other Meds: Unknown

Lab Data: serum C-reactive protein, 200 mg/L

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345160-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Mar-2009	09-Apr-2009	17	29-Apr-2009	30-Apr-2009	FR	WAES0904USA03476	30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Tonic clonic movements

Symptom Text: Information has been received from a health professional via a company representative concerning a 14 year old female who on 23-MAR-2009 was vaccinated with the second dose of GARDASIL (batch number not reported, route and site of administration not reported). On 09-APR-2009 the patient experienced tonic clonic movements and loss of consciousness, and these events ceased after a few minutes. The patient was taken to a private clinic for a check-up. The patient was in perfect condition, she did not require any assistance or treatment. Loss of consciousness and tonic clonic movements were considered to be other important medical condition. No further information is available. The case is closed. Other business partner number included: E200903320.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345161-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	02-Jan-2009	15-Jan-2009	13	29-Apr-2009	30-Apr-2009	FR	WAES0904USA03838	30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depersonalisation, Dizziness, Fatigue, Headache

Symptom Text: Information has been received from the foreign Health Authority (reference number ES-AGEMED-414335243) concerning an 18 year old female with no other relevant history who on the 02-JAN-2009 was vaccinated with a dose of GARDASIL (batch number not reported, route and site of administration not reported). On the 15-JAN-2009 the patient experienced tiredness, cephalea, depersonalization and dizziness, according to the reporter the events continue intermittently. Case reported as serious by the HA with other medically important condition as criteria. No further information is available. Other business partner number included: E200903521.

Other Meds: Unknown

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345162-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Nov-2008	01-Dec-2008	1	29-Apr-2009	30-Apr-2009	FR	WAES0904USA03846	30-Apr-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema nodosum

Symptom Text: Information has been received from the Health Authority (reference # ES-AGEMED-824835232) concerning a 15 year old female who was administered on 30-NOV-2008 a dose of GARDASIL (batch number not reported) (route and site not reported). In December 2008, exact date not reported, the patient presented a nodosum erythema. 3 months later, according to the report, the events were still ongoing. Case reported as serious by the HA with other important condition as criteria. Other company numbers included: E2009-03505. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345165-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Apr-2009	29-Apr-2009	0	29-Apr-2009	06-May-2009	NC		06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Right arm	Intramuscular	
	TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B029AA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Musculoskeletal stiffness, Pain in extremity, Pallor, Tremor

Symptom Text: Client received Tdap without any symptoms of concern. Then, immediately after HPV vaccine was given, the client complained that her arm hurt. She turned her head away and when I checked on her(within seconds), her upper body stiffened and her head and arms started shaking. She was very pale. Shaking lasted 15-30 seconds, then her eyes were opened very wide and she seemed to be aware that something had just happened. She did not complain of dizziness, nausea, discomfort other than her right arm, headache or any other symptoms. Vitals lying down - 10:20 am: BP 118/70, pulse 88; 10:23 am BP 122/74, Pulse 64, Resp 14; 10:38 am BP 118/60, pulse 76; 10:46 am BP 108/68, resp. 20,pulse 80, temp 98.4. Vitals sitting upright - 10:53 am BP 110/70; pulse 76; 11:02 BP 118/40, Pulse 68, Resp. 16. Client was given Tylenol, peanut butter crackers and orange juice and reported feeling much better. Telephone messages left for parent.

Other Meds: Given Acetaminophen 650 mgs at 10:58 a.m.

Lab Data:

History: Allergic to Pollens (hayfever-like symptoms) and Tomatoes eaten in large quantity cause rash & hives

Prex Illness: None known

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345177-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	28-Apr-2009	29-Apr-2009	1	29-Apr-2009	06-May-2009	OR		06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2624AA	0	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C3028AA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	0651X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Swelling face

Symptom Text: headache, facial swelling- in pts temples

Other Meds: none

Lab Data:

History: none

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345197-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	29-Apr-2009	29-Apr-2009	0	29-Apr-2009	06-May-2009	AZ		06-May-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HPV4	MERCK & CO. INC.	1062U	1	Right arm	Intramuscular	
MNQ	SANOFI PASTEUR	U2669AA	1	Right arm	Intramuscular	
TDAP	GLAXOSMITHKLINE BIOLOGICALS	AC52B029AA	1	Left arm	Intramuscular	
VARCEL	MERCK & CO. INC.	0047Y	2	Left arm	Subcutaneously	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB268EA	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall

Symptom Text: 950am student in nurses office or immunization clinic. Rec'd 5 vaccines - after several min of sitting looking @ stickers leaned to (L) an fell out of chair = 24 inches hit (L) knee an elbow, eyes open - no sign of injury - sat after an assisted back to chair, water offered, cool cloth applied to neck - no LOC denied pain anywhere assisted to nurses bed to rest - mom called 10:22 arrived informed what to watch for encouraged food/liquids. BP checked 86/62 HR 64. @ 1025 home with mom

Other Meds: None Known

Lab Data: None

History: None Known

Prex Illness: None

Prex Vax Illns:

Vaers Id: **345209-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	Unknown	09-Mar-2009		17-Apr-2009	06-May-2009	--	WAES0903USA05482	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema of eyelid, Eyelid oedema

Symptom Text: Information has been received from a nurse practitioner concerning a 27 year old female with allergy to thimerosal and no medical history who on an unknown date, was vaccinated with GARDASIL (lot # not reported). There was no concomitant medication. "About three weeks ago" (on approximately 9-MAR-2009), the patient developed swollen and slightly red eyelids. An allergy skin test was performed (result unknown). The patient's swollen and slightly red eyelids persisted. The patient sought medical attention by office visit. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Drug hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345210-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	13-May-2009	NY	WAES0903USA05497	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Anaphylactic reaction

Symptom Text: Information has been received from a physician concerning a young adult female who was vaccinated with the first dose of GARDASIL (lot number not available) a year ago (in 2008). One or two weeks after receiving GARDASIL the patient developed systemic allergic reaction in 2008. She was hospitalized for 7 days (hospital demographic unspecified). Subsequently, the patient recovered on an unspecified date. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345211-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	20-Mar-2009	20-Mar-2009	0	17-Apr-2009	06-May-2009	CO	WAES0903USA05499	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site urticaria

Symptom Text: Information has been received from a nurse concerning a 25 year old female who on 20-MAR-2009 was vaccinated with GARDASIL (lot number 659184/0843X) 0.5 ml IM (site not reported). Concomitant therapy included XANAX. On approximately 20-MAR-2009, "a week" ago the patient developed a welt at the injection site. It was unspecified if the patient sought medical attention. The outcome was unknown. Additional information has been requested.

Other Meds: XANAX

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345212-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	08-Aug-2008	08-Aug-2008	0	17-Apr-2009	06-May-2009	OR	WAES0903USA05512	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Myalgia

Symptom Text: Information has been received from a physician concerning a 23 year old female patient with no pertinent medical history and no known drug allergies/reactions who on 8-AUG-2008 (also reported as 8-AUG-2009) was vaccinated with the first 0.5 ml IM dose of GARDASIL (lot # 659184/0843X). There was no concomitant medication. On 8-AUG-2008 the patient experienced muscle aches near the injection site. No lab diagnostics studies were performed. On 10-AUG-2008 (also reported as 10-AUG-2009) the patient recovered. The patient sought medical attention via going to the office. The patient would be getting the second dose of GARDASIL on 30-MAR-2009 which was late. This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 345213-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	03-Mar-2009	17-Mar-2009	14	17-Apr-2009	06-May-2009	--	WAES0903USA05548	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Influenza like illness, Lymphadenopathy, Muscular weakness

Symptom Text: Information has been received from a 21 year old female with hypersensitivity to yeast who on 3-MAR-2009 was vaccinated with the first dose of GARDASIL. Concomitant vaccination included hepatitis A vaccine (unspecified) and typhoid vaccine (unspecified). On 17-MAR-2009 the patient experienced weak, swollen glands, muscle weakness and flu like symptoms. The patient's weak and swollen glands and muscle weakness and flu like symptoms persisted. No lab diagnostics study was performed. At the time of reporting the patient had not recovered from the above events. No further information is available.

Other Meds:

Lab Data: None

History:

Prex Illness: Hypersensitivity

Prex Vax Illns:

Vaers Id: **345214-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Mar-2009	Unknown		17-Apr-2009	06-May-2009	CA	WAES0903USA05559	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: Information has been received from a physician concerning a 14 year old female who on 27-MAR-2009 was vaccinated with a first dose of GARDASIL (lot # not reported). Concomitant therapy included MENACTRA. Subsequently, the patient experienced dizzy. No lab diagnostics studies were performed. The patient sought unspecified medical attention from the physician. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345215-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	08-May-2009	--	WAES0903USA05566	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depression

Symptom Text: Information has been received from a physician assistant concerning a "teenager" female who was vaccinated with GARDASIL 0.5 ml. After getting GARDASIL the patient experienced depression. At the time of reporting, the outcome was not reported. The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345216-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Apr-2009	08-May-2009	--	WAES0904USA00004	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Dizziness, Headache, Wheezing

Symptom Text: Information has been received from an employee at a physician's office concerning a couple of patients who was vaccinated with GARDASIL. The patients experienced "headaches, wheezing, dizziness and joint pains" after vaccination. It was stated that the vaccine was not administered at the office therefore she could not provide additional information. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345217-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	18-Mar-2009	30-Mar-2009	12	17-Apr-2009	08-May-2009	MD	WAES0904USA00014	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed

Symptom Text: Information has been received from an office administrator concerning a 19 year old female who on 12-JAN-2009 and 18-MAR-2009 was vaccinated with the first and second doses of GARDASIL 0.5ml (lot # not reported). The patient reported her period being 2 weeks late on 30-MAR-2009. The patient sought unspecified medical attention from the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 345218-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	12-Mar-2009	12-Mar-2009	0	17-Apr-2009	13-May-2009	FL	WAES0903USA02293	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Injection site pain, Malaise, Syncope

Symptom Text: Information has been received from a physician concerning his 22 year old daughter who on 12-Mar-2009 was vaccinated with her first dose of GARDASIL (lot number and site not reported) 0.5ml IM. There was no concomitant medication. On 12-Mar-2009, after receiving the vaccine the patient experienced pain at the injection site and fainted. The patient also did not "feel well" for a few hours after vaccination. On 12-Mar-2009 the patient recovered from pain at the injection site, fainted and did not feel well. Pain at the injection site, fainted and did not feel well were considered to be disabling. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 345219-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	16-Mar-2009	16-Mar-2009	0	17-Apr-2009	08-May-2009	IL	WAES0904USA00051	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Anxiety

Symptom Text: Information has been received from a RN concerning a 15 year old female patient who on approximately 16-MAR-2009 was vaccinated with the first dose of GARDASIL. It was reported that the patient has been having acute anxiety since. The patient sought unspecified medical attention. It was reported that the patient had not recovered at the time of the report. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345220-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	06-Mar-2009	06-Mar-2009	0	17-Apr-2009	13-May-2009	TX	WAES0903USA02323	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Dizziness

Symptom Text: Information has been received from a physician concerning a 15 year old female who on 06-MAR-2009 was vaccinated with GARDASIL IM 0.5ml. Concomitant therapy included a recent shot of DEPO-PROVERA. The patient experienced dizziness on 06-MAR-2007, 07-MAR-2009 and 09-MAR-2009. The physician did not say if there was any dizziness occurring on 08-MAR-2009. The patient "had to leave school". The patient sought unspecified medical attention. Dizziness was considered to be disabling. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345221-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	08-May-2009	AR	WAES0904USA00085	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Bedridden, Headache, Pyrexia

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with the second dose of GARDASIL (Lot not reported). Subsequently, the patient experienced fever, headache and was bedridden after receiving the second dose of GARDASIL. The mother of the patient called the clinic. The outcome of the patient was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345222-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	20-Dec-2007	Unknown		17-Apr-2009	13-May-2009	VA	WAES0903USA02643	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1267U	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Guillain-Barre syndrome

Symptom Text: Information has been received from an office nurse concerning a female who on an unknown date, was vaccinated with the third dose of GARDASIL (lot# not reported). Subsequently the patient was diagnosed with Guillain Barre by a neurologist. Upon internal review, Guillain Barre was considered to be an other important medical event. In follow-up, the nurse revealed that the approximately 22 year old patient received two doses of GARDASIL on 18-JUL-2007 (lot# 658100/0525U) and 20-DEC-2007 (lot# 659439/1267U). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345223-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	13-May-2009	TX	WAES0904USA00089	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Immediate post-injection reaction, Loss of consciousness, Tooth injury

Symptom Text: Information has been received from a physician concerning a female who in 2008, "within the past year", was vaccinated with a dose of GARDASIL (lot # not reported). Immediately after vaccination the patient passed out, hit her head and broke a tooth. Patient sought medical attention via an office visit. On an unspecified date the patient recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345224-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	13-May-2009	--	WAES0903USA03984	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Hypersensitivity

Symptom Text: Information has been received from a Registered Nurse concerning a female patient who was vaccinated with a dose of GARDASIL (Lot # not reported) 0.5ml. Patient had a "severe allergic reaction" after received the vaccine and was hospitalized. The reporter did not know what the "severe allergic reaction" consisted of. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345225-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		17-Apr-2009	13-May-2009	AZ	WAES0903USA04598	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a 16 year old female who was vaccinated intramuscularly with a 0.5 ml dose of GARDASIL. It was reported that sometime after she got the vaccine the patient had been having "fainting spells." The patient sought unspecified medical attention and went to an emergency room but was not admitted. The doctor reported that since the patient was continuing to faint then it was a significant disability/incapacity. At the time of reporting the patient was not recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 345226-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		17-Apr-2009	13-May-2009	OR	WAES0903USA01645	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT No reaction on previous exposure to drug, Syncope

Symptom Text: Information has been received from a physician concerning a 17 year old female who was vaccinated with the second dose of GARDASIL (Lot # not provided). After getting the second dose of GARDASIL the patient experienced fainting. Subsequently, the patient recovered from fainting on unspecified date. The reporter stated that the patient had no AE after first dose. It was reported that the patient sought unspecified medial attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345227-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Jan-2009	22-Jan-2009	2	17-Apr-2009	13-May-2009	--	WAES0904USA00097	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Rash erythematous

Symptom Text: Information has been received from a nurse concerning an 18 year old female who on 20-JAN-2009 was vaccinated with her first dose of GARDASIL 0.5ml IM, lot number: 661703/0651X. On approximately "2 or 3 days after vaccination" (22-JAN-2009 or 23-JAN-2009), the patient experienced red rash on her arm from shoulder to hand. Subsequently, the patient recovered "2 weeks after the vaccination", on approximately 3-FEB-2009. The patient sought medical attention, she saw the physician. Additional information has been requested.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345228-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	23-Feb-2009	23-Feb-2009	0	17-Apr-2009	08-May-2009	--	WAES0903USA01677	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Drug exposure during pregnancy, Malaise

Symptom Text: Information has been received from a consumer concerning her 18 year old daughter with Nail-patella syndrome who in 2008 was vaccinated with the first and second doses of GARDASIL. On 23-FEB-2009 when she was 7 weeks pregnant, the patient was vaccinated with the third dose of GARDASIL. Concomitant medication included birth control pills for one week. Her EED was 26-OCT-2009. This was her first pregnancy. It was reported that the patient was "pretty sick and kind of weak". No further information is available.

Other Meds: hormonal contraceptives

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP-1/19/2009) Nail-patella syndrome

Prex Vax Illns:

Vaers Id: 345229-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	23-Jan-2009	23-Jan-2009	0	17-Apr-2009	13-May-2009	MI	WAES0903USA01999	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Vaginitis bacterial

Symptom Text: Information has been received for the pregnancy registry for GARDASIL from a certified medical assistant concerning a 15 year old Hispanic female patient who on 23-JAN-2009 received a first dose of GARDASIL and was pregnant. Concomitant therapy included prenatal vitamins. The patient's last menstrual period was on 27-DEC-2008 and the estimated delivery date is on 02-OCT-2009. The patient had no previous pregnancies or full term deliveries. On approximately 03-MAR-2009, the patient experienced a bacterial vaginosis and was treated with METRONIDAZOLE 500 mg twice a day since 03-MAR-2009. Additional information has been requested.

Other Meds: Vitamins (unspecified)

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = 12/27/2008)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345230-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	13-May-2009	CA	WAES0903USA02061	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site discharge, No reaction on previous exposure to drug

Symptom Text: Information has been received from a nurse concerning a female who on an unspecified date was vaccinated with the second dose of GARDASIL. The nurse reported that "right after receiving the second dose" the patient came back to the clinic because she saw a crystallized mass come out from the surface of the injection site. Nurse reported that the patient did not report this kind of issue when she got the first dose of GARDASIL vaccine. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345231-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	Unknown	Unknown		17-Apr-2009	08-May-2009	--	WAES0903USA02101	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Amenorrhoea, Vaginal haemorrhage

Symptom Text: Information has been received from a certified medical assistant concerning her 17 year old female friend with no pertinent medical history who in 2008, "several months ago", was vaccinated with the second dose of GARDASIL. There was no concomitant medication. It was reported that the patient was not pregnant. The patient hadn't had her period since. She had occasional spotting that lasted no more than one day. At the time of this report, the patient's symptoms persisted. No lab test were done. The patient did not seek medical attention. No further information is available.

Other Meds: None

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345232-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	09-Mar-2009	Unknown		17-Apr-2009	08-May-2009	PA	WAES0903USA02285	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site irritation, Injection site pruritus, Injection site reaction

Symptom Text: Information has been received from a registered nurse concerning a 22 year old female with pertinent medical history or drug allergies/reactions who on 7-JAN-2009 was vaccinated IM with the first dose of GARDASIL and on 9-MAR-2009 was vaccinated IM with the second dose of GARDASIL (lot # : 661703/0651X). There was no concomitant medication. In March 2009, after receiving the second dose, the patient experienced injection site reaction. The patient complained of "puffy arm with redness, itching and burning". At the time of this report , the patient was recovering. The patient called the office for medical attention. Additional information has been requested

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345233-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	11-Mar-2009	12-Mar-2009	1	17-Apr-2009	08-May-2009	--	WAES0903USA02333	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Tremor

Symptom Text: Information has been received from a nurse practitioner concerning an approximately 20 year old female with no relevant medical history, no relevant concomitant medications and no relevant past drug history who on 11-MAR-2009 was vaccinated with the third dose of GARDASIL at about 12:00. The patient did not develop any adverse events after 2 doses of GARDASIL. On 12-MAR-2009, at approximately 02:00 am, the patient woke up with uncontrollable shaking and called the nurse practitioner. The nurse practitioner described the patient as being alert and able to talk. She recommended her to take an unknown dose of BENADRYL. As of 12-MAR-2009, the patient's uncontrollable shaking subsided after she took BENADRYL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345234-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	13-Mar-2009	14-Oct-2008	-150	17-Apr-2009	13-May-2009	TX	WAES0903USA02337	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a licensed visiting nurse concerning a 13 year old female patient who on 16-JUL-2007 was vaccinated with the first dose of GARDASIL, on 14-OCT-2008 received the second dose of GARDASIL (lot # 661044/0548X) and on 13-MAR-2009 was administered IM with a 0.5 ml third dose of GARDASIL. On 13-MAR-2009, approximately 12 minutes after receiving the third dose of GARDASIL vaccine, the patient fainted. The patient was seen by the physician at the practice. On 13-MAR-2009 the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345235-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	20-Oct-2008	01-Jan-2009	73	17-Apr-2009	13-May-2009	--	WAES0903USA01421	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Back pain, Influenza, Urinary tract infection

Symptom Text: Information has been received from a nurse practitioner concerning a 16 year old female with not sexually active and a history of meningitis as a baby who in August 2008, was vaccinated with the first dose of GARDASIL (Lot# not reported), on 20-OCT-2008, was vaccinated with the second dose of GARDASIL (Lot# not reported). There was no concomitant medication. And the patient had had an unspecified number of urinary tract infections, frequent lower back pain, abdominal pain and got the flu for the first time. The first dose and second dose were given by another unspecified provider's office. Prior to receiving GARDASIL, the patient had "always been healthy all her life" (as reported by the patient's mother). The patient went to emergency room in January 2009 for the flu. The nurse practitioner assumed urine culture and sensitivity test done by another unspecified provider's office. The reporter nurse mentioned although she did not feel the patient's symptoms were related to the GARDASIL, the third dose of GARDASIL would not be given. Subsequently, the patient recovered from unspecified number of urinary tract infections, frequent lower back pain, abdominal pain and flu on unknown date. It was reported that the patient sought medical attention: office visit. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: Meningitis

Prex Illness: Not sexually active

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345236-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	13-Feb-2009		17-Apr-2009	13-May-2009	OH	WAES0903USA01423	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a nurse practitioner concerning a 23 year old female who was vaccinated with complete GARDASIL series. On 13-FEB-2009, the patient had a PAP test, the result showed positive for HPV and had atypical cells during a recent PAP test. The reporter nurse did not know what types of GARDASIL were positive. The patient was not recovered from the adverse events. It was reported that the patient sought medical attentions: seen in office. Additional information has been requested.

Other Meds: Unknown

Lab Data: cervical smear, 02/13/09, HPV positive, had atypical cells

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345237-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	01-Jan-2008		17-Apr-2009	13-May-2009	OK	WAES0903USA01428	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Skin papilloma

Symptom Text: Information hs been received from a physician concerning a female patient who was on unspecified dates was vaccinated with 0.5 ml doses of GARDASIL (lot number, site and route not reported). In January 2008, the patient developed warts on her feet after getting GARDASIL. She sought unspecified medial attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345238-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	13-May-2009	--	WAES0903USA01434	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cardiac flutter, Cardiac murmur

Symptom Text: Information has been received from a nurse concerning a female who patient who on an unspecified date was vaccinated IM with her second 0.5 ml dose of GARDASIL (lot number and site not reported). The day after she got her second dose of GARDASIL, the patient's "heart fluttered", and it happened again "a month later". Her doctor later verified that she had two heart murmurs. The nurse didn't know if the patient had the murmurs before getting vaccinated. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345239-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		17-Apr-2009	13-May-2009	--	WAES0903USA01443	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest pain, Dizziness, Headache, Insomnia, Pyrexia, Vision blurred, Vomiting

Symptom Text: Information has been received from a consumer concerning her daughter, a 11 year old female patient, with no known drug allergies, joint pain and problems with bones who was vaccinated with her first and second doses of GARDASIL (lot number, site and route not reported) several months ago. There was no concomitant medication. A few months ago, the patient experienced a fever, vomiting, headache, blurred vision, trouble sleeping, chest pain and dizziness. MRI and other unspecified lab work were performed on an unspecified date (no result reported). The events persisted at the time of this report. An unspecified medical attention was sought. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Arthralgia; Bone disorder

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345240-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	05-Mar-2009	06-Mar-2009	1	17-Apr-2009	13-May-2009	FL	WAES0903USA01445	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache, Pain, Pyrexia

Symptom Text: Information has been received from a licensed practical nurse concerning an 18 year old female patient with no pertinent medical history and no known drug allergies who on 5-MAR-2009 was vaccinated with the third dose of GARDASIL (lot # not provided). Concomitant therapy included YAZ. On 6-MAR-2009 the patient experienced a fever of 99.8 F to 101F, achiness and headache. No lab diagnostics studies were performed. The patient was treated with MOTRIN. At the time of reporting, the patient was recovering. The patient sought medical attention via an office visit. Additional information has been requested.

Other Meds: YAZ

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 345241-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
49.0	F	02-Mar-2009	02-Mar-2009	0	17-Apr-2009	08-May-2009	--	WAES0903USA01457	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	
	TTOX	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pain, Swelling, Wrong drug administered

Symptom Text: Information has been received from a nurse practitioner (N.P.) concerning a 49 year old female with hypothyroidism and gastroesophageal reflux disease who on 2-MAR-2009 was inadvertently vaccinated IM with a 0.5 ml first dose of GARDASIL (lot # not reported) due to human error. It was reported that the patient was supposed to received a tetanus toxoid vaccination. There was no product confusion involved. Concomitant therapy included omeprazole (MSD), SYNTHROID and vitamins (unspecified). On 3-MAR-2009 the patient experienced pain and swelling in armpit after the vaccination. The patient sought medical attention at the practice. No lab test performed. As of 9-MAR-2009 the patient was recovering. Additional information has been requested,

Other Meds: SYNTHROID; PRILOSEC; vitamins (unspecified)

Lab Data: None

History:

Prex Illness: Hypothyroidism; Gastroesophageal reflux disease

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345242-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	09-Mar-2009	09-Mar-2009	0	17-Apr-2009	13-May-2009	NE	WAES0903USA01595	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site warmth

Symptom Text: Information has been received from a registered nurse concerning her daughter with eczema and allergies who in June 2008 was vaccinated with the first dose of GARDASIL. On 09-MAR-2009 the patient was vaccinated with her third dose of GARDASIL subcutaneously in the left upper arm. Concomitant therapy included CLARITIN. On 09-MAR-2009 the patient experienced soreness, warmth and redness at the injection site after the vaccination. The reporter added that an unspecified amount of vaccine "run down my daughter's arm" during administration. The patient self treated the injection site reaction with cool compresses and at the time of reporting, 10-MAR-2009, was recovering. Additional information is not expected.

Other Meds: CLARITIN

Lab Data: None

History:

Prex Illness: Eczema; Hypersensitivity

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345243-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	21-Jan-2009	24-Oct-2008	-89	17-Apr-2009	13-May-2009	WI	WAES0903USA01609	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Congenital uterine anomaly, Drug exposure during pregnancy, Ovarian cyst

Symptom Text: Information has been received from a registered nurse for the pregnancy registry for GARDASIL concerning a 23 year old female with asthma and no known drug reactions/allergies, who on 21-JAN-2009 was vaccinated with the first dose of GARDASIL, 0.5ml intramuscularly. Concomitant therapy included albuterol. The registered nurse reported that the patient was pregnant. On an unspecified date, the patient had a positive beta-human chorionic gonadotropin pregnancy test. Date of last menstrual period was on 24-OCT-2008. The estimated delivery date is 31-JUL-2009. The patient sought medical attention and was seen at the practice. Follow-up information was received from a questionnaire completed by a gynecologist indicating that the patient was a female, with cervical dysplasia and with a history of 1 pregnancy, 1 live birth and no pre-term deliveries, spontaneous abortions, elective terminations nor fetal deaths, who on 21-JUN-2009 was vaccinated with the first dose of GARDASIL (Lot # 661703/0651X). Concomitant therapy included albuterol. Medications taken during the pregnancy included folic acid and prenatal vitamins. Routine prenatal testing included a routine ultrasound performed on 06-MAR-2009, which detected bicornuate uterus and fluid filled cyst. Follow-up information was received on 19-MAR-2009 from the licensed practical nurse, clarifying that the bicornuate uterus and fluid filled cyst was in the mother and not in the fetus. She also mentioned that it was a left ovarian ovarian fluid filled cyst. Additional information has been requested.

Other Meds: albuterol

Lab Data: ultrasound, 03/06/09, Bicornuate Uterus and fluid filled cyst; beta-human chorionic, positive

History:

Prex Illness: Pregnancy NOS (LMP = 10/24/2008); Asthma; Cervical dysplasia

Prex Vax Illns:

Vaers Id: **345244-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Nov-2008	31-Dec-2008	60	17-Apr-2009	13-May-2009	MA	WAES0903USA01611	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain upper, Fatigue, Nausea, Vomiting, Weight decreased

Symptom Text: Information has been received from a Registered Nurse (R.N) concerning her 16 year old daughter with juvenile rheumatoid arthritis, and allergies to BACTRIM, ZITHROMAX, CECLOR, potatoes, tree nuts, peaches, pears and apples who in November 2008 was vaccinated with the first dose of GARDASIL. There was no concomitant medication. It was reported that the patient received the first dose of GARDASIL and has been sick for 6-8 weeks. It was reported that the patient was fatigued, nauseous, vomited, stomach hurt and lost 8 pounds. It was reported that the patient's stomach hurting was getting better but she was still fatigued and had not gain the 8 pounds of weight back that was lost. No significant disability was reported however the patient has seen three unspecified physicians and has missed school. A gastrointestinal work up, allergy work and blood work were performed (results not provided). It was reported that the patient saw the pediatrician on 10-MAR-2009. It was reported that the patient took one pill of an unspecified "gastrointestinal medication" that gave the patient a bad stomachache. It was reported that the "gastrointestinal medication may have been PREVACID or pills (MSD). Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Sulfonamide allergy; Allergic reaction to antibiotics; Potato allergy; Allergy to nuts; Fruit allergy; Juvenile rheumatoid arthr

Prex Vax Illns:

Vaers Id: **345245-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	24-Feb-2009	Unknown		17-Apr-2009	13-May-2009	--	WAES0903USA01628	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal distension, Drug exposure during pregnancy, Fatigue, Swelling, Tenderness

Symptom Text: Information has been received from a consumer concerning her 22 year old niece who on approximately 24-FEB-2009 was vaccinated with a dose of GARDASIL (Lot # not reported) 0.5ml, intramuscularly. The patient took an at home pregnancy test a week after she got the vaccine and it was positive. In approximately February 2009, since the patient got the shot, she experienced swelling, tiredness, bloating and tenderness. At the time on the report the patient was not recovered. The patient did not seek medial attention. Additional information is not expected.

Other Meds: Unknown

Lab Data: beta-human chorionic, was positive

History:

Prex Illness: Pregnancy NOS (LMP= unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345246-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	13-May-2009	SC	WAES0903USA01631	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a registered nurse concerning a female patient who was vaccinated with her second dose of GARDSIL (lot # not provided). The patient fainted after getting her second dose of GARDASIL. There was no adverse event after the patient received her first and third dose of GARDASIL. The patient had sought unspecified medical attention. On an unspecified date the patient recovered from an adverse event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345247-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	01-Nov-2008	01-Nov-2008	0	17-Apr-2009	13-May-2009	NJ	WAES0903USA01637	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Nasopharyngitis, Rhinorrhoea

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female with no pertinent medical history or drug reactions/allergies who in November 2008, was vaccinated IM with a 0,5ml dose of GRADASIL (lot #: 659184/0843X). There was no concomitant medication. 3 days after the vaccination, the patient developed a cold. The patient experienced runny nose but no fever. At the time of this report, the patient was recovered. The patient did not seek medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345248-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Jun-2008	01-Jun-2008	0	17-Apr-2009	13-May-2009	NY	WAES0903USA01639	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain, Vaccine positive rechallenge

Symptom Text: Information has been received from a female who in June 2008 and August 2008 was vaccinated with her first and second dose of GARDASIL (lot number, route and site not reported). The patient stated that she experienced injection site soreness each time she was vaccinated with GARDASIL. Each time the pain went away with in 24 hours. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345256-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	02-Dec-2008	02-Dec-2008	0	30-Apr-2009	01-May-2009	FR	WAES0904USA03857	01-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0055X		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Presyncope, Syncope

Symptom Text: Information was obtained on request by the company from the agency, via a Public Case Details forms, concerning a 19 year old female who on 02-DEC-2008 was vaccinated with GARDASIL IM (therapy dose, site unknown) (Lot number 659659/0055X, Batch number K3111). On 02-DEC-2008, within 10 minutes of vaccination, the patient stood and then collapsed with what appeared to be a vaso vagal episode followed by seizure. The patient underwent an electrocardiogram (results not reported) and "EEG report NAO". Subsequently, the patient recovered. The reporter felt that these events were possibly related to therapy with GARDASIL. Upon internal review, convulsion was considered to be an other important medical event. The original reporting source was not provided. Additional information has been requested.

Other Meds: Unknown

Lab Data: electrocardiogram, results not provided; electroencephalography, NAO

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 345257-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	20-Mar-2009	20-Mar-2009	0	30-Apr-2009	01-May-2009	TX	WAES0904USA03645	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Vaginal haemorrhage

Symptom Text: Information has been received from a licensed visiting nurse, for the GARDASIL a Pregnancy Registry concerning a 23 year old female with hypothyroidism and a history of 3 pregnancies: 1 live birth at 39 week from LMP, 2 spontaneous abortions including an ectopic pregnancy in March 2008 (5-6 weeks from LMP), with no birth defects of infant complications in previous pregnancies who on 20-MAR-2009 was vaccinated with the first dose of GARDASIL (lot# 661952/1129X). Concomitant therapy included levothyroxine Na. The nurse reported that the patient was pregnant. Her LMP was 03-MAR-2009 and her EDD was 08-DEC-2009. On 26-MAR-2009 the patient started spotting. The nurse stated that the patient was having heavy bleeding and was in the process of miscarrying. Laboratory tests included urine beta-human chorionic gonadotropin test and progesterone performed on 03-APR-2009. On 06-APR-2009 an ultrasound was performed due to her spotting with result intrauterine pregnancy early vs missed abortion. On the same date an urine beta-human chorionic gonadotropin test was done. Additional ultrasounds performed on 09-APR-2009 due to the patient's spotting revealed fetal cardiac activity as well on 13-APR-2009 there was fetal cardiac activity. On 17-APR-2009 the patient experienced spontaneous abortion (7 weeks from LMP), and she has chosen to wait and see if the fetus will pass on its own. It was reported that the patient has a follow up visit in 2 weeks and will have an ultrasound. If the fetus does not pass the patient will be scheduled for a dilation and curettage. On 21-APR-2009 an ultrasound revealed no fetal cardiac activity, there was no fetal heartbeat. Upon internal review in the process of miscarrying was considered to be an other important medical event. Additional information is not expected.

Other Meds: Levothyroxine sodium, microgm

Lab Data: ultrasound, 04/06/09, IUP early vs MAB. Reason: spotting; ultrasound, 04/09/09, Result: Cardiac activity. Reason: spotting threatened MAB; ultrasound, 04/13/09, Result: Cardiac activity; ultrasound, 04/21/09, Result: No cardiac activity; ur

History: Ectopic pregnancy

Prex Illness: Pregnancy NOS (LMP = 3/3/2009); Hypothyroidism

Prex Vax Illns:

Vaers Id: **345258-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Nov-2008	Unknown		30-Apr-2009	01-May-2009	FR	WAES0904USA03608	01-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a health authority (reference number ES-AGEMED-418781344) regarding a 14 old female who on 17-SEP-2008 was vaccinated with the first dose of GARDASIL IM. It hadn't been reported whether the patient had any adverse event after that first dose or not. On 17-NOV-2008 the patient was vaccinated with the second dose of GARDASIL IM 0.5 ml (batch number not reported). It was reported that, according to the patient's mother, she presented several convulsions some time after the administration of GARDASIL. The patient's case was being taken care of by the hospital's neurology ward. They will send the rest of the information if it's possible. Case reported as serious by the HA with other medically important condition as criteria. Other business partner numbers include E200903462. Case is closed. No further information reported.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345261-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	22-Jul-2008	22-Jul-2008	0	30-Apr-2009	01-May-2009	KS	WAES0808USA00962	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder, Labour complication, Pregnancy induced hypertension

Symptom Text: Information has been received from a nurse, for the Pregnancy Registry for GARDASIL, concerning a 27 year old female with cephalexin allergy and no relevant medical history and no history of prior pregnancies who on an unspecified dates received the first and second doses of GARDASIL and on 22-JUL-2008, was vaccinated with a third dose of GARDASIL (lot number, injection site and route not reported). Concomitant therapy included LEXAPRO and ACIPHEX. On 26-JUL-2008 the patient was found out to be pregnant by urine pregnancy test. Date of last menstrual period 18-JUN-2008, estimated date of delivery 25-MAR-2009. Unspecified medical attention was sought. Follow-up information was received from a physician who reported that patient was on LEXAPRO throughout pregnancy, 10 mg daily for depression. Complications during pregnancy included gestational hypertension. On 09-MAR-2009, patient delivered an 8 pound and 1 ounce male baby, 21 inches tall, 38 weeks from LMP. Apgar score 8-9-10. Complication during labor/delivery included failure to progress. Baby was born with congenital anomaly: no left nipple. No other complications or abnormalities. No further information is available.

Other Meds: LEXAPRO, 10 mg; ACIPHEX

Lab Data: urine beta-human, 07/26/08, pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 6/18/2008); Allergic reaction to antibiotics; Depression

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345262-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	27-Jan-2009	27-Jan-2009	0	30-Apr-2009	01-May-2009	FR	WAES0904USA03470	01-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Convulsion, Migraine, Petit mal epilepsy, Vomiting

Symptom Text: Information has been received from a gynaecologist concerning a 12 year old female with a medical history of migrainous headache sometimes with vomiting who on 27-JAN-2009 was vaccinated with a dose of GARDASIL (Manufacture unknown, lot #, injection site and route not reported). According to the reporter, she experienced short absence with convulsion but without enuresis for about 2 minutes. On 09-APR-2009, the patient was seen by a neurologist. The patient complained about frequent headache sometimes with vomiting. Onset of headache was not reported. Transcranial Doppler revealed pathological flows in anterior and middle cerebral artery. EEG showed diffuse slowing (at the threshold value). Cranial MRI was normal. Migrainous headache was diagnosed. Cerebral seizures could not be definitely ruled out. The reporter considered the events serious due to other important medical event. Other business partner numbers included: E2009-03360. Additional information has been requested.

Other Meds: Unknown

Lab Data: Electroencephalography, 09Apr09, diffuse slowing (at the threshold value); Magnetic resonance imaging, 09Apr09, normal; Transcranial ultrasound, 09Apr09, pathological flows in anterior and middle cerebral artery

History: Vomiting

Prex Illness: Migraine

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345269-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	13-May-2009	--	WAES0903USA02345	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Gluteous maxima	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug administered at inappropriate site, Injection site atrophy, Injection site discolouration, Injection site pain

Symptom Text: Information has been received from a nurse practitioner concerning a female patient who on unspecified dates in 2007 was vaccinated with the first two doses of GARDASIL, o.5ml, intramuscularly in the buttocks and in December, 2007 was vaccinated with the third dose of GARDASIL, o.5ml, intramuscularly in the left arm. The nurse practitioner reported that when the patient was seen in December, 2007, there was an indentation in her buttocks about the size of half dollar and the skin was "caved in". There was no inflammation. The patient was seen again that week. The area on her buttock has increased in severity. The indentation remained. The area was blue-purple in color and tender to touch. At the reporting time, the patient had not recovered. The patient sought medical attention through an office visit. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345270-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Sep-2008	01-Sep-2008	0	17-Apr-2009	13-May-2009	MO	WAES0903USA02346	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	DTAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Feeling hot

Symptom Text: Information has been received from a physician concerning a 14 year old female patient who in approximately September 2008, "4-6 months ago" from the reporting date, was vaccinated with the first dose of GARDASIL, 0.5ml. No lot number was provided. Concomitant therapy included DTAP (unspecified). The physician reported that in approximately September 2008, "4-6 months ago" from the reporting date, the patient experienced warmth and dizziness. At the time of the report, the patient had recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345271-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	06-Mar-2009	06-Mar-2009	0	17-Apr-2009	08-May-2009	MO	WAES0903USA02349	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning an approximately 12 year old female who on approximately 6-MAR-2009, "about a week ago" from the reporting date, was vaccinated with the first dose of GARDASIL, 0.5 ml. No lot number was provided. Concomitant therapy included diphtheria toxoid (+) pertussis acellular vaccine (unspecified) (+) tetanus toxoid. The physician reported that the patient fainted after receiving her first dose of GARDASIL. It was stated that "about a week ago" from the reporting date, on approximately 6-MAR-2009, the patient had recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345272-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	Unknown	Unknown		17-Apr-2009	13-May-2009	MO	WAES0903USA02354	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a "16 years old" female who was vaccinated with a third 0.5 ml dose of GARDASIL (lot # not reported) "4-6 months ago". Subsequently the patient fainted after the vaccination. The patient sought an unspecified medical attention. As of 13-MAR-2009, the patient's outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 345273-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Mar-2008	01-Mar-2008	0	17-Apr-2009	13-May-2009	NJ	WAES0903USA02374	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Muscle spasms, Myalgia

Symptom Text: Information has been received from a consumer concerning her daughter, a 14 year old female with a history of mononucleosis and no drug reaction who in March 2008, was vaccinated with the first dose of GARDASIL. Concomitant therapy included LOESTRIN FE. The patient experienced headache, muscle spasm, muscle pain and muscle aches ever since she received her first dose of GARDASIL. It was noted that the patient had received two doses of GARDASIL. At the time of report the patient was not recovered. The patient did not seek medical attention. Additional information has been requested.

Other Meds: LOESTRIN FE

Lab Data: Unknown

History: Infectious mononucleosis

Prex Illness:

Prex Vax Illns:

Vaers Id: **345274-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	Unknown	Unknown		17-Apr-2009	13-May-2009	--	WAES0903USA02555	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Malaise

Symptom Text: Information has been received from an 18 year old female with no known drug allergies/reactions and no pertinent medical history reported who on an unspecified date was vaccinated with the first dose of GARDASIL. There was no concomitant medication. The patient reported that she felt sick after taking the first dose of GARDASIL. The patient did not seek medical attention. No labs were performed. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **345275-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	11-Mar-2009	13-Mar-2009	2	17-Apr-2009	13-May-2009	FL	WAES0903USA02593	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Groin pain, Local swelling

Symptom Text: Information has been received from a healthcare worker concerning a 21 year old female with no medical history and drug allergies who on 11-MAR-2009 was vaccinated intramuscularly with her second 0.5 ml dose of GARDASIL (660616/0570X). There was no concomitant medication. On 13-MAR-2009 the patient developed groin pain and a lump in her groin. The side of the groin that is affected was unspecified. The patient was seen in the physician's office. Sexually transmitted disease cultures were collected at the same visit that the second dose of vaccine was given. At the time of reporting (16-MAR-2009) the patient was not recovered. The patient was vaccinated intramuscularly with her first 0.5 ml dose of vaccine on 04-DEC-2008 (660616/0570X). This is one of several reports from the same source. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345276-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	13-May-2009	MD	WAES0903USA02852	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hypersensitivity

Symptom Text: Information has been received from a physician concerning a female with latex allergy who was vaccinated with a dose of GARDASIL, IM, 0.5ml. Subsequently the patient experienced "some type of allergic reaction". Symptoms of reaction were unspecified by reporter. The patient sought medical attention, office visit. At time of the report the outcome of the patient was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Latex allergy

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345277-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	26-Jan-2009	26-Jan-2009	0	17-Apr-2009	13-May-2009	NC	WAES0903USA02886	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Fatigue, Headache, Vomiting

Symptom Text: Information has been received from a consumer concerning her 15 year old daughter with allergies to penicillin and other antibiotic and no pertinent medical history who in approximately 2008 ("about a year ago"), in fall 2008, and on 26-JAN-2009 was vaccinated with the first, second and third dose of GARDASIL respectively (lot # not provided). There was no concomitant medication. On approximately 26-JAN-2009 ("right after she received the third dose") the patient experienced extreme fatigue, vomiting and headache that seemed to be getting worse everyday. Blood panel and CAT scan were performed (no results provided). At the time of reporting, the patient's extreme fatigue, vomiting and headache persisted. The patient sought medical attention via visiting primary care physician and pediatrician. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History:

Prex Illness: Penicillin allergy; Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **345278-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	16-Mar-2009	16-Mar-2009	0	17-Apr-2009	13-May-2009	--	WAES0903USA02903	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Information has been received from a nurse practitioner (N.P.) concerning a 24 year old female who on 16-MAR-2009 was vaccinated with a 0.5 ml dose of GARDASIL. When she got home she had a rash on her forearm. Unspecified medical attention was sought. On 17-MAR-2009 the patient recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345279-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	17-Mar-2009	17-Mar-2009	0	17-Apr-2009	13-May-2009	--	WAES0903USA02907	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, Injection site pain

Symptom Text: Information has been received from a nurse concerning a female who was vaccinated intramuscularly with the second 0.5 ml dose of GARDASIL on 17-MAR-2009. On 17-MAR-2009 the patient experienced pain at the injection site immediately after the second dose of vaccine. The patient was vaccinated intramuscularly with her first 0.5 ml dose of GARDASIL "3 months ago" At the time of reporting (17-MAR-2009) the patient was not recovered. The patient sought medical attention by visiting the physician's office. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345280-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	05-Nov-2008	16-Feb-2009	103	17-Apr-2009	13-May-2009	CA	WAES0903USA02927	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Pain

Symptom Text: Information has been received from a 23 year old female with allergy to anything in the "cillin family" and a history of cesarean section and tuberculosis exposure, for the Pregnancy Registry for GARDASIL, who on 05-SEP-2008 was vaccinated with the first dose of GARDASIL. On 05-NOV-2008 the patient was vaccinated with the second dose of GARDASIL. On 16-MAR-2009 the patient was vaccinated with the third dose of GARDASIL. Home pregnancy test was done. The patient was pregnant now. Her LMP was 16-FEB-2009. On approximately 17-MAR-2009, "currently", she was experiencing sharp pains located "4 inches below her belly button and 4 inches to the left of her belly button". She stated the pain might be due to a previous cesarean section. Unspecified medical attention was sought by phone call. Follow-up information was received from the physician via a completed initial pregnancy questionnaire. It was reported that the patient had one previous pregnancy and one full term delivery. There were no birth defects or infant complications in the previous pregnancy. The patient's PPD tuberculin test was positive. The patient was taking isoniazid and vitamin B6 for the positive PPD concurrently. The lot number for the third dose of GARDASIL was provided as 661953/1130X. No other information provided at the this time. Additional information has been requested.

Other Meds: isoniazid; pyridoxine

Lab Data: beta-human chorionic, positive; Mantoux test, positive

History: Cesarean section; TB exposure

Prex Illness: Pregnancy NOS (LMP = 2/16/2009); Penicillin allergy; PPD skin test positive

Prex Vax Illns:

Vaers Id: **345281-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Apr-2009	13-May-2009	--	WAES0903USA02993	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loop electrosurgical excision procedure, Smear cervix abnormal

Symptom Text: Information has been received from a certified medical assistant concerning a patient who in 2007 was vaccinated with a dose of GARDASIL. In 2009 the patient came up with an abnormal pap. In 2007 the patient had a LEEP procedure and in 2008 had a normal pap test. Additional information has been requested.

Other Meds: Unknown

Lab Data: pap test, ?/?/08, normal; pap test, ?/?/09, abnormal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345282-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	13-May-2009	FL	WAES0903USA03188	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Groin pain, Local swelling

Symptom Text: Information has been received from a healthcare worker concerning a female who experienced groin pain and a lump in her groin after receiving a dose of GARDASIL (660616/0570X). The outcome was unknown. This is one of several reports from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345283-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	23-Oct-2008	23-Oct-2008	0	17-Apr-2009	13-May-2009	MO	WAES0903USA03192	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Activities of daily living impaired, Cough, Lymphadenopathy, Musculoskeletal stiffness

Symptom Text: Information has been received from a registered nurse concerning her daughter, an 11 year old female patient with no pertinent medical history and no known drug allergies, who on 23-OCT-2008 was vaccinated with the first dose of GARDASIL (lot# not reported) and 20 minutes later developed a stiff neck while riding home from the doctor's office. There was no concomitant medication. The stiff neck resolved after the ride. On 23-DEC-2008, the daughter had a second dose of GARDASIL (lot# not reported) and within 11 days she developed a "constant cough and an enlarged lymph node at the cervical area". There was no concomitant medication. Patient was seen at the doctor's office. No abnormal labs. The cough lasted all of January and February and impeded in her basketball activity. She was given Z-PACK and TESSALON PEARLS but it did not help. She was also given Hydrocodone and TUSSIONEX that helped some days but made her drowsy. Both the cough and enlarged lymph nodes resolved by March. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345284-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	01-Mar-2009	Unknown		17-Apr-2009	13-May-2009	GA	WAES0903USA03221	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Gastrointestinal disorder, Pyrexia

Symptom Text: Information has been received from a physician concerning a female patient with a history of urinary tract infection who in the last couple of weeks was vaccinated with GARDASIL. Fairly recently, the patient presented with high fever and some gastrointestinal issues after receiving GARDASIL. A blood work was performed with unknown results. The patient's outcome was not reported. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Urinary tract infection

Prex Vax Illns:

Vaers Id: **345285-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	08-May-2009	--	WAES0903USA03230	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a physician concerning a female patient who on an unknown date was vaccinated with the first dose of GARDASIL. The patient experienced syncope after receiving the GARDASIL. It was reported that the patient had a viral illness at the time of injection. The patient sought unspecified medical attention. The patient's outcome was not reported. Additional information has been requested.

Other Meds: HAVRIX

Lab Data: Unknown

History:

Prex Illness: Viral infection

Prex Vax Illns:

Vaers Id: **345286-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	02-Feb-2009	02-Feb-2009	0	17-Apr-2009	13-May-2009	IN	WAES0903USA03231	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	1311X	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Malaise, Vomiting

Symptom Text: Information has been received from a certified medical assistant, for the GARDASIL a Pregnancy Registry, concerning a 14 year old female patient with no pertinent medical history and no drug reactions or allergies who on 02-FEB-2009 was vaccinated with the first dose of GARDASIL (lot # 661531/1311X). Concomitant therapy included HAVRIX. It was reported that the patient received her first dose of GARDASIL while pregnant. LMP was in January 2009, EDD was approximately 08-OCT-2009. The patient was seen at the physician's office for vomiting and feeling ill. Laboratory test performed on an unspecified date included urine pregnancy test. Patient's outcome for vomiting and feeling ill is unknown. Additional information has been requested.

Other Meds:

Lab Data: urine beta-human, pregnant

History:

Prex Illness: Pregnancy NOS (LMP = 1/1/2009)

Prex Vax Illns:

Vaers Id: **345287-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	01-Sep-2008		17-Apr-2009	13-May-2009	FL	WAES0903USA03237	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea

Symptom Text: Information has been received from an emergency medical technician concerning a 15 year old female with asthma who was vaccinated with the complete series of GARDASIL on an unspecified dates in the past. In September 2008, the patient experienced shortness of breath. The shortness of breath occurred when she was stressed or sitting still and not when exercising. She was seen in the office and Echocardiogram was performed but no result was provided. She has been prescribed antibiotics and 2 "puffers" (unknown names and manufacturers for both). At the time of reporting, the patient's shortness of breath persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Asthma

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345288-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	13-May-2009	IL	WAES0903USA03242	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Lymphadenopathy, Pyrexia, Vaccine positive rechallenge

Symptom Text: Information has been received from a physician concerning a registered nurse who was vaccinated with her first dose of GARDASIL. 6 weeks after her first vaccination the patient experienced a fever and swollen cervical lymph nodes. The patient was treated with steroids. The nurse also experienced a fever and swollen cervical lymph nodes after her second dose of GARDASIL. She was treated again with steroids. The physician reported that the nurse approached her while working at the hospital for medical attention. The physician did not have any additional information since the nurse was not her patient. It was also reported that the patient underwent a CT scan (results not reported). No further information is available.

Other Meds: Unknown

Lab Data: computed axial

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 345289-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	17-Mar-2009	17-Mar-2009	0	17-Apr-2009	13-May-2009	--	WAES0903USA03245	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anxiety, Contraception, Dyspnoea, Restlessness

Symptom Text: Information has been received from a nurse practitioner concerning a 15 year old female patient with no pertinent medical history and no known drug allergies/reactions who on 17-MAR-2009 was vaccinated with the first 0.5 ml IM dose of GARDASIL (lot # 0250X). Concomitant therapy included ORTHO-CYCLEN. On 17-MAR-2009 the patient experienced restless, shortness of breath and anxiety around the bedtime. No lab diagnostics studies were performed. At the time of reporting, the outcome was unknown. The patient sought medical attention via calling nurse practitioner. Additional information has been requested.

Other Meds: ORTHO-CYCLEN

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345290-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	06-Nov-2007		17-Apr-2009	08-May-2009	WI	WAES0903USA03247	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope, Vomiting

Symptom Text: Information has been received from a physician concerning a female patient who was vaccinated with the first 0.5 ml dose of GARDASIL. Subsequently the patient experienced fainted. On approximately 6-NOV-2007, the patient received the second 0.5 ml dose of GARDASIL (lot # 658222/0927U). The patient experienced light headed and vomited. Therapy with GARDASIL was discontinued on 6-NOV-2007. On 6-NOV-2007, the patient recovered. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345291-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	11-Mar-2009	11-Mar-2009	0	17-Apr-2009	13-May-2009	--	WAES0903USA03252	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0962F	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Expired drug administered, Pain in extremity

Symptom Text: Information has been received from a registered nurse concerning an 11 year old female with no pertinent medical history or drug reactions or allergies and no pregnant who on 21-AUG-2008 was vaccinated IM with the first 0.5 ml dose of GARDASIL. On 29-OCT-2008 the patient was vaccinated IM with the second 0.5 ml dose of GARDASIL. On 11-MAR-2009 the patient was vaccinated IM with the third 0.5 ml dose of GARDASIL (lot # 654510/0962F). There was no concomitant medication. It was reported that the third dose of GARDASIL was expired at time of administration. The third dose's expiration date was 14-FEB-2009. The nurse also reported that on 12-MAR-2009 the patient developed a sore arm after the third dose. The patient recovered on 13-MAR-2009. No lab tests were done. Unspecified medical attention was sought. This is one of several reports received from the same source. Additional information is not expected.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345292-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		17-Apr-2009	13-May-2009	NJ	WAES0903USA03626	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Herpes zoster

Symptom Text: Information has been received from a physician (OB/GYN) concerning a 21 year old female patient who on an unspecified date was vaccinated with her first dose of GARDASIL (lot number, site and route not reported) at her pediatrician's office and then a short time after she was diagnosed with the shingles. The physician reported that the patient's pediatrician thought she developed the shingles due to GARDASIL and so the patient did not received the rest of the series. The patient sought medical attention in the pediatrician's office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345293-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	19-Jan-2009	19-Jan-2009	0	17-Apr-2009	13-May-2009	FL	WAES0903USA03643	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Feeling abnormal, Headache, Nausea, Vomiting

Symptom Text: Information has been received from a physician concerning a 16 year old female patient with no known drug allergies who on 19-JAN-2009 was vaccinated with her first dose of GARDASIL (lot number 661703/0651X, site and route not reported). Concomitant medication included "LOVLO" which was a birth control pill. On 19-MAR-2009, the patient went in the office for her second dose of GARDASIL (lot number, site and route not reported) and she reported that in the evening of 19-JAN-2009, when she received the first dose, she experienced nausea and vomiting which lasted for two days. The patient sought unspecified medical attention. Follow-up information was received from the physician who reported that the patient got a headache shortly after receiving vaccine on 19JAN2009 whose lot number was reported as 660616/0570X at this time. That evening she complained of nausea and vomited 3 times. She did feel bad for two days after. The patient did not notify office until 19-MAR-2009 when she came for second dose of GARDASIL. It was noted that the patient recovered. The patient and her mother decided to receive the second dose on 19-MAR-2009 with no pressure. No further information was available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345294-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	12-Mar-2009	12-Mar-2009	0	17-Apr-2009	13-May-2009	MN	WAES0903USA03665	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Malaise

Symptom Text: Information has been received from a physician concerning a 24 year old female with no relevant medical history or drug allergy who was vaccinated with a first 0.5 ml dose of GARDASIL (lot # not reported) " a week ago", on approximately 12-MAR-2009. After the vaccination the patient became light headed however did not faint. The patient sought an unspecified medical attention. It was reported that she continued to "not feel well" for 2-3 days. The patient admitted she did not eat before coming to the office. The patient recovered about 2-3 days after administration. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345295-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	25-Nov-2008	25-Nov-2008	0	17-Apr-2009	13-May-2009	--	WAES0903USA03945	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral, Pain in extremity, Paraesthesia

Symptom Text: Information has been received from a registered nurse concerning a 23 year old female with Graves' disease, latex allergy and poppy seeds allergy who on 19-SEP-2008 was vaccinated with the first dose of GARDASIL and on 25-NOV-2008 received the second dose of GARDASIL. It was reported that 4 to 5 hours after the second dose the patient experienced arm pain and swollen, red, tingling hands. The reaction lasted for 1 hour and then resolved with no complications. The nurse stated that the patient will not receive the third dose of GARDASIL. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Graves' disease; Latex allergy; Food allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345296-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	U	Unknown	Unknown		17-Apr-2009	13-May-2009	--	WAES0903USA03970	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Adverse event, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a registered nurse concerning a patient who on unspecified dates was vaccinated with the first and second dose of GARDASIL (lot # not specified). It was reported that the patient was late on getting the second dose of GARDASIL, it was given 4 months after the first dose due to an illness. The nurse indicated that the patient was from a different practice. The patient consulted a nurse. The patient's outcome is unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345307-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Feb-2009	23-Feb-2009	0	30-Apr-2009	06-May-2009	IL		11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129Z	0	Left arm	Intramuscular	
	TD	UNKNOWN MANUFACTURER	C3057AA		Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Abdominal pain upper, Alopecia, Arthralgia, Chest discomfort, Condition aggravated, Diarrhoea, Dyspnoea, Eating disorder, Exercise tolerance decreased, Fatigue, Gastritis, Gastrooesophageal reflux disease, Headache, Immediate post-injection reaction, Injection site pain, Lymph node pain, Myalgia, Oropharyngeal pain, Pain, Pain in extremity, Pharyngitis, Pneumonia, Tonsillar ulcer, Weight decreased

Symptom Text: Immediate severe pain in left arm, 'as though someone just broke it'; headache developed; 24 hours of joint and muscle pain; within weeks, sharp stabbing pain in the stomach that radiates throughout the upper abdomen and shoots toward the back and left shoulder; persistent upset 'sour' stomach that complicates her ability to eat. Now, 2 months later she is losing hair and weight. 5/4/09 Received PCP medical records of 1/5/08-4/30/2009 including GI, Ortho & ENT consults. FINAL DX: acid reflux, inflammatory gastropathy, ulcerative tonsillitis, exercise intolerance, dyspnea Records reveal patient experienced usual state of health on 2/23/09 for HPV#1. RTC 4/29/09 w/c/o of injection site pain, HA & joint pain since 2/23/09. Hx of persistent abdominal pain. GI referral 8/08. Dx w/pneumonia 12/08. RTC 1/09 w/exhaustion, sore throat, loose stool x 2 days. Exam revealed 4+ red exudative throat w/bilateral node tenderness. Strep & mono neg. RTC 2/09 w/chest tightness & difficulty breathing x 2 yr.

Other Meds: Focalin, 10mg/day; aciphex, 10mg/day;

Lab Data: Hyda Scan for suspected gall bladder issues, no problems noted; MRA is scheduled for May 13th for suspected MALS (Median Arcuate Ligament Syndrome); LABS: Upper endoscopy WNL. Gallbladder US neg. Biopsy WNL.

History: Acid Reflux diagnosed in August, 2009; medication helped and all symptoms were gone by October. PMH: ADD, anxitey, exudative pharyngitis, ulcerative tonsillitis, epigastric pain, GERD, HA, fatigue, stiff neck, environmental allergies, vocal cord nodules, right shoulder AC strain.

Prex Illness: had just recovered from the 12 hour stomach flu which she had on Feb 16th.

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345308-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	29-Apr-2009	29-Apr-2009	0	30-Apr-2009	06-May-2009	FL		07-May-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MNQ	SANOFI PASTEUR	U2867AA	0	Left arm	Intramuscular	
HPV4	MERCK & CO. INC.	0653X	0	Left arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB330BA	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Pallor, Syncope

Symptom Text: PATIENT WAS GIVEN ALL THREE VACCINES HEP A#1 (RIGHT ARM), MCV4 AND HPV#1 (LEFT ARM) IN THAT ORDER, WHEN I WAS APPLYING THE LAST BANDAID THE PT STATED SHE FELT DIZZY AND SLUMPED TO HER RIGHT SIDE ON THE EXAM TABLE THIS WAS 3:55 PM. I PULLED HER TOWARDS ME SO SHE WOULD BE FLAT ON HER BACK AND WHEN I DID SHE THEN LOOKED AT ME AND SAID DID I JUST PASS OUT. THIS WAS BRIEF MAYBE 5-10 SECONDS SHE HAD SOME PALLOR AFTER FAINTING SHE WAS GIVEN A COOL WASH CLOTH FOR HER FOREHEAD AND ADVISED TO STAY LAYING FOR A FEW MINUTES DR. WAS NOTIFIED AND BP WAS TAKEN AND @ 3:57 BP WAS 98/60. PATIENT WAS ALERT AND ORIENTED X3 AND JOKING AND REMEMBERS EVERYTHING BEFORE AND AFTER EVENT. BP PRIOR TO FAINTING WHICH WAS TAKEN AT ABOUT 3:45 WAS 100/50. PT WAS MONITORED APPEARED ASYMPTOMATIC COLOR CAME BACK AND LAST BP @ 4:22 WAS 100/60 PT WAS THEN ALLOWED TO LEAVE @ 4:30. SHE WAS ADVISED TO COME BACK TOMM (4/30/09) AND FOLLOW UP WITH DR. APPOINTMENT WAS MADE.

Other Meds: NONE

Lab Data: NONE

History: ALLERGIC RHINNITIS (SEASONAL ALLERGIES) MOM STATED MAY BE ALLERGIC TO PENICILLIN

Prex Illness: NONE

Prex Vax Illns:

Vaers Id: 345322-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Feb-2008	10-Mar-2008	11	30-Apr-2009	04-May-2009	OH		13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	1766U	1	Left arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	9725102	1	Left arm	Intramuscular	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Abdominal pain upper, Cellulitis, Colitis, Crohns disease, Diarrhoea, Gastrointestinal oedema, Gynaecological examination normal, Inflammatory bowel disease, Intestinal anastomosis, Intestinal resection, Laparoscopy, Pollakiuria, Pseudopolyp, Rash, Small intestinal stenosis, Tinea pedis, Vomiting

Symptom Text: Began with stomach pains, rash on the top and bottom of both feet. Stomach pains were intermittent then became constant. 1 year later 2/09 diagnosed with Crohn's. I feel the vaccine initiated the Crohn's. 5/8/09 Received PCP medical records of 2/28/08-4/22/2009. FINAL DX: Crohn's disease w/terminal ileum inflammation & stricture s/p laparoscopic assisted ileocecal resection/anastamosis Records reveal patient experienced good general health on 2/28/09. RTC 4/29/08 w/increasing abdominal pain x 2-3 wks w/1 episode emesis, urinary frequency over past few days. RTC 5/21/08 w/tinea pedis & cellulitis. RTC 5/30/08 w/dermatitis. RTC 6/13 w/continuation of cellulitis of foot & tinea pedis. RTC 10/16/08 & referred to GI for 4-6 mo hx of abdominal pain & diarrhea w/normal GYN exam & no relief from pepcid. GI consult records of 12/30/08-4/16/09 included & reveal intial dx of non specific colitis. Hospitalized 3/11-16/2009 w/Crohn's disease. Did not respond to med treatment & re-hospitalized 4/16-4/22/09 for surgery. No further records available.

Other Meds: None at the time of the vaccine

Lab Data: Crohn's disease; Upper/lower US; Endoscopy/colonoscopy; Abdominal CT Scan LABS: abdominal US w/right ovarian follicle otherwise WNL.. Urine c/s neg. Upper endoscopy WNL. Colonoscopy abnormal w/ileocecal valve edematous & friable w/pse

History: None

Prex Illness: None

Prex Vax Illns: abdominal pain~HPV (Gardasil)~2~15~Patient

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345332-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	21-Apr-2009	22-Apr-2009	1	30-Apr-2009	07-May-2009	TN		07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cellulitis, Erythema, Skin warm, Swelling

Symptom Text: Right upper arm with redness, swelling & warm to touch qcm in size Dx with cellulitis.

Other Meds: ADVIL 200mg

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **345336-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	17-Apr-2009	17-Apr-2009	0	30-Apr-2009	06-May-2009	OH		06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0074Y	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Pt. became slightly lightheaded immediately after receiving GARDASIL. She layed down but continued talking & said she felt fine. She walked out to the waiting room to sit for 15 min as per office policy/protocol. She fainted while sitting & was eased to floor. She was roused to consciousness immediately with 0.3 ml ammonia inhalant BP 126/80 pulse 72 Remained in office X 10-15 min Stated she felt fine & left with her mother.

Other Meds: LOESTRIN 24; FLORINEF

Lab Data:

History:

Prex Illness: No

Prex Vax Illns:

Vaers Id: 345338-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	13-Apr-2009	15-Apr-2009	2	30-Apr-2009	07-May-2009	MI		13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dermatitis bullous, Injection site erythema, Lip swelling, Nausea

Symptom Text: 24 hrs after injection: lip swelling, nausea, red injection site. 48 hrs after injection: larger area of redness with central bullous lesions. Treated for 1 1/2 week with SILVADENE cream. Cultures (viral bacterial) taken from bullous lesions - Results: Negative viral and bacterial cultures. KEFLEX 100 mg bid X 10d started.

Other Meds: ZOLOFT 100mg OD

Lab Data: Viral and bacterial cultures negative

History: None except depression NOS

Prex Illness: None

Prex Vax Illns:

Vaers Id: **345342-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	20-Apr-2009	20-Apr-2009	0	30-Apr-2009	07-May-2009	OH		07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Decreased appetite, Dizziness, Nausea, Odynophagia, Pharyngitis, Vomiting

Symptom Text: Pharyngitis, odynophalgia, nausea, vomiting, decrease appetite, dizziness.

Other Meds: Birth control pill.

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns: dizziness~HPV (Gardasil)~1~18~Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345345-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	13-May-2009	--	WAES0903USA03974	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a registered nurse concerning a female student in her twenties who on an unspecified date was vaccinated with a dose of GARDASIL (lot # not specified). The nurse stated that the patient had received one dose of GARDASIL and now her physician's office had been told her she had papilloma viral infection. The patient sought medical attentions at the physician's office. At the time of reporting, her outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345346-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	16-Jul-2008	16-Jul-2008	0	17-Apr-2009	13-May-2009	--	WAES0903USA03975	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthropod bite, Condition aggravated, Urticaria

Symptom Text: Information has been received from a nurse practitioner concerning an 18 year old female patient with several bug bites who on 18-MAR-2008 was vaccinated with the first dose of GARDASIL (lot # 659655/1486U) 0.5 mL, intramuscular route, and on 16-JUL-2008 was vaccinated with the second dose of GARDASIL (lot # 660555/0279X) 0.5 mL, intramuscular route. There was no concomitant medication. It was reported that on 16-JUL-2008 the patient developed hives several hours after administration of second dose of GARDASIL. The nurse indicated that at the time of the administration the patient had several bug bites and the hives caused the bug bites to intensify in appearance. On approximately 30-JUL-2008 the patient recovered completely from both the hives and bug bites. The patient did not seek medical attention. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Arthropod bite

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345347-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	13-May-2009	PA	WAES0903USA03979	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Chest discomfort, Dyspnoea, Vaccine positive rechallenge

Symptom Text: Information has been received from a medical assistant concerning a female patient who on unspecified dates was vaccinated with the first dose and second dose of GARDASIL (lot # not available). It was reported that the patient experienced shortness of breath and felt like there was a brick sitting on her chest after receiving her first and her second dose of GARDASIL. The patient was seen by her physician. At the time of reporting, the patient had recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345348-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	20-Jan-2009	20-Jan-2009	0	17-Apr-2009	12-May-2009	PA	WAES0903USA03982	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	
	TTOX	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Headache, Influenza like illness, Pyrexia

Symptom Text: Information has been received from a consumer concerning her daughter, who on 20-JAN-2009 was vaccinated with her first dose of GARDASIL. Concomitant therapy included TD and meningitis vaccine, (manufacturer unspecified), given on 20-JAN-2009. The caller stated that after the vaccination, the patient had a fever, flu like symptoms, headache and stomachache. The patient's outcome is unknown. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345349-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	20-Oct-2008	18-Mar-2009	149	17-Apr-2009	13-May-2009	--	WAES0903USA03986	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Papilloma viral infection

Symptom Text: Information has been received from a 19 year old female patient with no pertinent medical history who a few months ago received the first dose of GARDASIL (lot# not reported) and approximately 4 or 5 months ago was vaccinated with the second dose GARDASIL (lot# not reported). There was no concomitant medication. On 18-MAR-2009 the patient visited the nurse practitioner and a pap smear was performed. Patient was told by the nurse practitioner that according to the pap smear results she was positive for HPV (unspecified type). At the time of the report, the patient had not yet recovered. Additional information has been requested.

Other Meds: None

Lab Data: cervical smear, 03/18/09, positive for hpv

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345350-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	Unknown	20-Mar-2009		17-Apr-2009	08-May-2009	NJ	WAES0903USA04004	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a medical assistant concerning a 23 year old female patient with no pertinent medical history and no known drug allergies/drug reactions who on an unspecified date was vaccinated with the third dose of GARDASIL. There was no concomitant medication. It was reported that on 20-MAR-2009 the patient experienced "bad headache". The patient called to the office. It was reported that the patient had not recovered at the time of the report. Additional information has been requested.

Other Meds: None

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345351-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	08-May-2009	--	WAES0903USA04033	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache

Symptom Text: Information has been received from a registered nurse concerning an 11-18 year old female who was vaccinated with her first dose of GARDASIL (lot number, route and site not reported). Subsequently the patient experienced headache. The patient did not receive anymore GARDASIL. This is one of several reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345352-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	08-May-2009	--	WAES0903USA04036	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstrual disorder

Symptom Text: Information has been received from a health professional concerning a female patient between 11-18 years who on an unspecified date was vaccinated with the fist dose of GARDASIL (lot number, site and route not reported). On an unspecified date, the patient's menstrual cycle was interrupted. She stopped the vaccine series because her MD recommended it. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345353-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	16-Mar-2009		17-Apr-2009	08-May-2009	--	WAES0903USA04255	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Condition aggravated, Tension headache

Symptom Text: Information has been received from a nurse practitioner concerning a female with a history of tension headache who was vaccinated with the third 0.5ml dose of GARDASIL. After receiving her third dose, on approximately 16-MAR-2009, "last week", the patient experienced tension headache. The patient recovered from tension headache "last week". The patient sought unspecified medical attention. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Tension headache

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345354-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	04-Mar-2009	04-Mar-2009	0	17-Apr-2009	08-May-2009	--	WAES0903USA04259	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Incorrect product storage

Symptom Text: Information has been received from a health department nurse concerning a patient who on 04-MAR-2009 was vaccinated with a dose of GARDASIL (lot number, site and route not reported) which was stored at 35F for 24 hours on 23-FEB-2009. No details about the patient were known. Also reported as out of range for one day on 04-MAR-2009. The reporter answered and reported that they only had one patient who received a first dose of GARDASIL (lot number 660389/1968U, site and route not reported) on 04-MAR-2009. There was no adverse event was reported. No further information was expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345355-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.8	F	12-Jan-2009	12-Jan-2009	0	17-Apr-2009	13-May-2009	MD	WAES0903USA04271	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse, for GARDASIL, a Pregnancy Registry product, concerning a 20 year old female with no known drug allergies and no medical history who on 12-JAN-2009 was vaccinated with the first dose of GARDASIL (Lot# 661531/1311X), IM. There was no concomitant medication. The patient was subsequently determined to be pregnancy by an unspecified Planned Parenthood clinic. Her last menstrual period was 07-JAN-2009. The patient sought medical attention. There was no lab and diagnostic test performed. No problems were reported. The patient's estimated delivery date was 14-OCT-2009. Additional information has been requested.

Other Meds: None

Lab Data: None

History:

Prex Illness: Pregnancy NOS (LMP = 1/7/2009)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345356-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	20-Mar-2009	21-Mar-2009	1	17-Apr-2009	13-May-2009	KY	WAES0903USA04275	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Eye pruritus, Rash

Symptom Text: Information has been received from a physician assistant concerning a 16 year old female on 20-MAR-2009 was vaccinated with the first dose of GARDASIL (lot number, dose not reported). Concomitant therapy included YAZ as birth control pill. On 21-MAR-2009, the next day the patient experienced rash on her abdomen, arm and shoulders and the patient's eyes were itchy. On unspecified date, the patient sought unspecified medical attention. Additional information has been requested.

Other Meds: YAZ

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345357-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	19-Feb-2009	Unknown		17-Apr-2009	13-May-2009	MD	WAES0903USA04281	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0548X	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Menstruation delayed, Night sweats

Symptom Text: Information has been received from a physician concerning a 20 year old female with a history of human papillomavirus high risk. On 11-FEB-2009, the patient came in the office because she had an upper respiratory infection and was given ALERXPE (manufacturer unspecified) and Azithromycin manufacturer unspecified). On 19-FEB-2009, the patient came into the office and received her first dose of GARDASIL (lot # 661044/0548X) (dose not report). The mother then called the office and said after receiving GARDASIL the patient experienced night sweats and her period was eleven days late. The mother of the patient mentioned that she was unsure if the patient should receive the second dose of GARDAIL. On unspecified date, the patient sought unspecified medical attention. On an unknown date, the physician reported that the patient had recovered but there were still unsure if she could receive the second dose of GARDASIL. Additional information has been requested.

Other Meds: azithromycin

Lab Data: Unknown

History: Upper respiratory tract infection

Prex Illness: Infection susceptibility increased

Prex Vax Illns:

Vaers Id: **345358-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	23-Sep-2008	01-Nov-2008	39	17-Apr-2009	12-May-2009	WI	WAES0903USA04302	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0250X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal discomfort, Abdominal distension, Constipation, Diarrhoea, Dyspepsia

Symptom Text: Information has been received from a certified medical assistant concerning a 21 year old female with dysmenorrhea and no known drug allergies who was intramuscularly vaccinated with 1st, 2nd and 3rd 0.5 ml doses of GARDASIL (1st lot #0250X, 2nd lot #660620/0571X, 3rd lot #661846/1312X) on 23-SEP-2008, 24-NOV-2008 and 23-MAR-2009, respectively. Concomitant therapy included YAZ and FAMVIR. In November 2008, prior to the 2nd dose, the patient experienced sensitivity to wheat. It was reported that bread and pasta products caused severe bloating, a churning feeling in her stomach, and difficult digestion. Then she got either constipation or diarrhea. These symptoms occurred about 15 minutes after any wheat consumption. When she did not not eat those products, she felt much better. At the time of reporting, she did not recover. The patient called the office for medical attention. Additional information has been requested.

Other Meds: YAZ; FAMVIR

Lab Data: None

History: HPV #2 given 11/24/2008, Lot # 0571X HPV #3 given 1/23/2009, Lot # 1312X

Prex Illness: Dysmenorrhea

Prex Vax Illns:

Vaers Id: **345359-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	13-May-2009	--	WAES0903USA04310	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Injection site pain, Malaise, Pain in extremity

Symptom Text: Information has been received from a female who in September 2008, was vaccinated with her first dose of GARDASIL. On an unspecified date, she was vaccinated with the third dose of GARDASIL. She stated that she became ill "week" after the third dose was given. She was experiencing pain at the injection site, pain up and down the arm, and feeling weakness in the legs. She also stated the pain had become painfully worse. She stated that the pain in her arm was a "sharp pain" and had been getting "progressively worse" and hurt "when I move my arm in a certain way." As of 23-MAR-2009, her experience didn't improve. No laboratory diagnostic studies were performed. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345360-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	08-May-2009	--	WAES0903USA04317	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Dizziness, Headache, Wheezing

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with a dose of GARDASIL, 0.5 mL. The patient experienced "headaches, wheezing, dizziness and joint pains" after the vaccination. The physician did not know if this was the patient's first, second or third dose, and did not know if she got any shots of GARDASIL after this experience. Follow-up information was received from an employee at the physician's office who stated that the vaccine was not administered at the office therefore she could not provide additional information. This is one of several reports from the source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345361-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-Feb-2009	13-Feb-2009	7	17-Apr-2009	08-May-2009	TX	WAES0903USA04511	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1978U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, Nausea, Oropharyngeal pain, Pyrexia, Rhinorrhoea, Vomiting

Symptom Text: Information has been received from a registered nurse concerning a 14 year old female patient with no pertinent medical history and no known allergies who in July 2008, was vaccinated with the first dose of GARDASIL (lot# not provided). On 06-FEB-2009 the patient was vaccinated with the second dose of GARDASIL (lot#659964/1978U) 0.5ml intramuscularly. There was no concomitant medication. One week after the second dose the patient developed nausea, vomiting, headache, fever, sore throat and runny nose. The patient has improved but continues with intermittent headaches and fever. Patient sought medical attention via a telephone call. No lab diagnostic studies were performed. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345362-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
42.0	F	09-Feb-2009	09-Feb-2009	0	17-Apr-2009	08-May-2009	--	WAES0903USA04517	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Rash

Symptom Text: Information has been received from a 42 year old female who on 09-FEB-2009 was vaccinated with the first 0.5 ml dose of GARDASIL. After vaccination, the patient developed rash on her left shoulder. The patient sought unspecified medical attention. At the time of reporting, the patient had not recovered. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345363-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	08-Jan-2009	08-Jan-2009	0	17-Apr-2009	08-May-2009	--	WAES0903USA04527	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pruritus, Injection site rash

Symptom Text: Information has been received from a physician assistant concerning a 21 year old female patient who on 08-JAN-2009 was vaccinated with the first dose of GARDASIL (lot# not provided) 0.5ml. Subsequently, on 08-JAN-2009, the patient experienced mild itching at the injection site. On 09-MAR-2009 patient received the second dose of GARDASIL (lot# not provided) and also experienced rash and itching at injection site. Patient sought unspecified medical attention. Subsequently, the patient recovered. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345364-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	24-Mar-2009	Unknown		17-Apr-2009	07-May-2009	PA	WAES0903USA04889	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	0	Unknown	Intramuscular	
	MEN	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pain, Injection site swelling

Symptom Text: Information has been received from a medical assistant concerning a 20 year old female with no medical history or drug allergy who on 24-MAR-2009 was intramuscularly vaccinated with her first 0.5 ml dose of GARDASIL (lot #661952/1129X). She was also vaccinated with a dose of meningitis vaccine on the same day. Subsequently the patient developed an injection site reaction after receiving GARDASIL. The patient complained that the injected site was red, swollen, and painful. She did not recover at time of reporting. The patient called the office for medical attention. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

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VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345365-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	17-Nov-2008	27-Nov-2008	10	17-Apr-2009	07-May-2009	CA	WAES0903USA04897	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dyspnoea

Symptom Text: Information has been received from a physician concerning a 12 year old female with no medical history or drug allergies who was vaccinated with the first and the second (lot # 661764/0650X) dose of GARDASIL on 03-SEP-2008 and 17-NOV-2008 respectively. Concomitant therapy included MENACTRA, Hep A (manufacturer unknown) and DTAP. The patient experienced an acute episode of shortness of breath 10 days after vaccination of her second dose of GARDASIL. The patient had no lab diagnostics studies performed. Subsequently, the patient recovered from acute episode of shortness of breath on 27-NOV-2008. The patient sought medical attention via office visit. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345366-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	08-May-2009	NY	WAES0903USA04899	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT HIV test false positive

Symptom Text: Information has been received from a physician concerning a female who was vaccinated with GARDASIL (unspecified number of doses) may have 1-2 false HIV positive. The patient was seen in the office. At the time of reporting, the outcome was unknown. Additional information has been requested.

Other Meds: Unknown

Lab Data: diagnostic laboratory, 1-2 HIV false positive

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345367-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	26-Jan-2009	16-Mar-2009	49	17-Apr-2009	08-May-2009	MO	WAES0903USA04903	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site reaction, Pain, Pyrexia, Viral infection

Symptom Text: Information has been received from a physician concerning a female patient who on approximately 26-JAN-2009 ("two months ago") was vaccinated with the first dose of GARDASIL. Subsequently the patient experienced injection site reaction. Last week the patient was vaccinated with the second dose of GARDASIL. The patient experienced viral syndrome with a fever and body aches since the second dose of vaccine was given. At the time of reporting, the patient's viral syndrome with a fever and body aches persisted. The patient sought medical attention via visiting office. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345368-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	20-Mar-2009	24-Mar-2009	4	17-Apr-2009	07-May-2009	--	WAES0903USA04909	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Left arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site necrosis, Injection site pain, Injection site pruritus, Injection site swelling

Symptom Text: Information has been received from a physician concerning a 25 year old female who was received a first dose of GARDASIL (lot # not reported) in her left arm on Friday, 20-MAR-2009. It was unknown whether the injection has been administered subcutaneously instead of intramuscularly. The patient's relevant medical history, concomitant medications, and relevant past drug history were unknown. On 24-MAR-2009, the patient noted the onset of itching and swelling (the size of a quarter) at the injection site. This progressed in size (doubling) by the time she was seen on 26-MAR-2009. On 26-MAR-2009, the site was reported as tender and also started o become necrotic. At the tine of the report, the patient's outcome was unknown. The patient was being referred to her primary care physician for further evaluation. It was reported that the physician was considering this patient related issue as an emergency. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345369-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	29-Jan-2009	Unknown		17-Apr-2009	07-May-2009	MD	WAES0903USA04915	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Fatigue

Symptom Text: Information has been received from a medical assistant, for GARDASIL, a Pregnancy Registry product, concerning a 26 year old female with pain in shoulder and reflux and a history of abnormal PAP in June 2008 who was vaccinated with the first and second dose of GARDASIL on 29-JAN-2009 and 26-MAR-2009 respectively. Concomitant therapy included NAPROXEN and ranitidine. The patient was pregnant after the second dose of GARDASIL. After the patient was given the dose, the patient was given a pregnancy test because she was reporting symptoms of "being tired and missed her monthly cycle". The patient sought medical attention- spoke to her physician. Additional information has been requested.

Other Meds: NAPROXEN; ranitidine

Lab Data: beta-human chorionic, 3/26/09, pregnant

History: Papanicolaou smear abnormal

Prex Illness: Pregnancy NOS (LMP= unknown); Shoulder pain; Gastroesophageal reflux

Prex Vax Illns:

Vaers Id: **345370-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	04-Dec-2008	15-Jan-2009	42	17-Apr-2009	07-May-2009	--	WAES0903USA04528	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0947X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Gastrooesophageal reflux disease

Symptom Text: Information has been received from a nurse practitioner for the pregnancy registry of GARDASIL, concerning a 26 year old female patient with no pertinent medical history and no known drug allergies who on 4-DEC-2008 was vaccinated with the first dose of GARDASIL (lot # 0947X) 0.5ml intramuscularly. On 3-FEB-2009 patient received second dose of GARDASIL (lot # 1702X) 0.5 ml intramuscularly. Patient is now pregnant, last menstrual period: 15-JAN-2009; estimated delivery date: 22-OCT-2009; estimated conception date: 29-JAN-2009. Concomitant medications during this pregnancy include ZANTAC PRN for GERD. Patient has had two previous pregnancies, both which ended due to elective termination 6 to 7 weeks from LMP. Patient sought medical attention via an office visit. On 23-FEB-2008 patient had OB labs done. No adverse effect was reported. Additional information has been requested.

Other Meds:

Lab Data: diagnostic laboratory, 2/23/09

History:

Prex Illness: Pregnancy NOS (LMP= 1/15/2009)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345371-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	07-May-2009	VA	WAES0903USA04536	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chills, Pyrexia

Symptom Text: Information has been received from a physician concerning a female who on an unspecified date was vaccinated with first 0.5ml dose of GARDASIL (route and lot number not provided). The physician reported that the patient experienced chills and fever after vaccination. The patient sought unspecified medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345372-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	16-Dec-2008	19-Jan-2009	34	17-Apr-2009	07-May-2009	NC	WAES0903USA04922	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Gastroenteritis viral

Symptom Text: Information has been received from a 24 year old female, for the Pregnancy Registry for GARDASIL who on 16-DEC-2008 was vaccinated with a first dose of GARDASIL. On approximately 2-FEB-2009 was vaccinated with a second dose of GARDASIL intramuscularly o.5 ml and had a pregnancy test and found out that she was "about 2 weeks pregnant" at the time of the vaccination (The patient was 9 weeks and 3 days pregnant at the time of reporting, so the last menstrual date was estimated as on 19-JAN-2009 and the estimated delivery date was 25-OCT-2009). An ultrasound was done and "everything looked normal". On 16-FEB-2009, (also reported "about 2 weeks ago"), the patient was really sick and couldn't eat or keep anything down. She went to emergency room but was not admitted. This was diagnosed as "stomach virus". The patient recovered from stomach virus after 4 days. Additional information has been requested.

Other Meds: Unknown

Lab Data: ultrasound, everything looked normal

History:

Prex Illness: Pregnancy NOS (LMP= 1/19/2009)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345373-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	01-Aug-2008	Unknown		17-Apr-2009	07-May-2009	DE	WAES0903USA04544	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Fatigue, Vaccine positive rechallenge

Symptom Text: Information has been received from a 25 year old female patient with penicillin allergy who on August 2008, was vaccinated with the first dose of GARDASIL (lot # not provided). In October 2008 the patient was vaccinated with the second dose of GARDASIL (lot # not provided). On February 2009 patient was vaccinated with the third dose of GARDASIL (lot # not provided). There was no concomitant medication. After the second and first dose the patient experienced fatigue and dizziness. Patient sought unspecified medical attention and had blood work done. Additional information has been requested.

Other Meds: None

Lab Data: hematology

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345374-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	19-Jan-2009	19-Jan-2009	0	17-Apr-2009	07-May-2009	--	WAES0903USA04924	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Fatigue, Inappropriate schedule of drug administration

Symptom Text: Information has been received from a registered nurse concerning a 27 year old female patient with no pertinent medical history and no know drug allergies/reactions who on 19-JAN-2009 was vaccinated with the first 0.5 ml IM dose of GARDASIL (lot # 660616/0570X). There was no concomitant medication. On 20-JAN-2009 the patient experienced joint pain on her left arm where the vaccine was administered. The next day the pain spread to all joints along with fatigue. No lab diagnostics were performed. One week after the vaccination the patient recovered. The patient sought medical attention via seeing a physician. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345375-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	19-Feb-2009	Unknown		17-Apr-2009	07-May-2009	--	WAES0903USA04933	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site pain

Symptom Text: Information has been received from a consumer concerning her daughter who was vaccinated with a third dose of GARDASIL (lot # not reported) 5 weeks ago, on approximately 19-FEB-2009. It was reported that the patient still had pain off and on at the injection site. At the time of the report, the patient's outcome was unknown. Additional information is not expected.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345376-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	16-Mar-2009	16-Mar-2009	0	17-Apr-2009	07-May-2009	--	WAES0903USA04982	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Claustrophobia, Dyspnoea, Fatigue, Flushing, Headache, Injection site pain

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female patient with a history of mononucleosis at age of 15 who on 16-MAR-2009 was vaccinated with her first dose of GARDASIL (lot # unknown). The patient experienced soreness at the injection site the day the vaccine was administered on 16-MAR-2009. The patient was experiencing difficulty breathing, hear rate of 90-100, flushed face, weakness, fatigue, "air hunger" or claustrophobic feeling and severe headache on 25-MAR-2009 9 days after her vaccination. The patient had visited the physician's office for medial attention. The only medication the patient was on was ZOVIA (manufacturer unspecified) for the completion problems and painful menstrual cycles. The patient never had any heart rate problems or headache before. At the time of reporting the patient's difficulty breathing and heart rate of 9--100 and flushed face and weakness and fatigue and "air hunger" and claustrophobic feeling and soreness at the injection site and severe headache persisted. Additional information has been requested

Other Meds: ZOVIA

Lab Data: Unknown

History: Infectious mononucleosis

Prex Illness: Pain menstrual

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345377-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	17-Dec-2008	17-Dec-2008	0	17-Apr-2009	07-May-2009	FL	WAES0903USA05175	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MMR	MERCK & CO. INC.	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Information has been received from a medical assistant concerning her 13 year old daughter with no previous medical history reported who on 17-DEC-2008 was vaccinated with a first dose of GARDASIL and concomitantly at the same time with a dose of MMR . On 17-DEC-2008, the patient fainted after receiving her first and only dose of GARDASIL. The patient did not have any breakfast prior to vaccination. On 17-DEC-2008, the patient recovered within 10 minutes. The patient sought medial attention, the physician saw the patient. Additional information has been requested.

Other Meds:

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **345378-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	09-Mar-2009	09-Mar-2009	0	17-Apr-2009	07-May-2009	SD	WAES0903USA05202	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Contusion, Eye pain, Eye swelling

Symptom Text: Information has been received from a registered nurse concerning a 12 year old female patient with no drug allergies or medial history who on 9-MAR-2009 was vaccinated with her first and only dose of GARDASIL (lot # 661841/0653X) IM. Concomitant therapy included DIFFERIN. On 9-MAR-2009 the patient;s both eyes were swollen, bruised and sore after receiving the vaccine. The patient had called the office for medical attention. The outcome of the patient's adverse events was not reported. Additional information has been requested.

Other Meds: DIFFERIN

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345379-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	13-Mar-2009	13-Mar-2009	0	17-Apr-2009	07-May-2009	VA	WAES0903USA05288	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Pyrexia

Symptom Text: Information has been received from a physician concerning a 20 year old female with egg allergy who on approximately 13-MAR-2009, two weeks ago, was vaccinated with a dose of GARDASIL. The physician was not sure if this was the first or second dose of GARDASIL, as the patient was vaccinated in another office. The patient had experienced fevers of 101F since she was given the GARDASIL vaccine. The patient was not recovered at the time of this report. It was reported that the patient came to the physician's office for evaluation if the fevers. Additional information has been requested.

Other Meds: Unknown

Lab Data: body temp, 3/??/09, 101F

History:

Prex Illness: Egg allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345380-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
25.0	F	24-Mar-2009	24-Mar-2009	0	17-Apr-2009	07-May-2009	--	WAES0903USA04553	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Injection site erythema, Injection site pruritus

Symptom Text: Information has been received from a nurse concerning a 25 year old female with penicillin allergy who on 30-SEP-2008 was vaccinated with her first dose of GARDASIL and her second dose of the vaccine was on 11-DEC-2008 and her third dose of GARDASIL on 24-MAR-2009 (0.5 ml IM, 661846/1312X). The same day of the 3rd vaccination, the patient called the office back because she developed redness and itching from the elbow to the shoulder in the injection arm. She also developed lightheadedness. No additional information was available. Additional information has been requested.

Other Meds: Unknown

Lab Data: None

History:

Prex Illness: Penicillin allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345381-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	20-Mar-2009	Unknown		17-Apr-2009	07-May-2009	OR	WAES0903USA05321	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site pruritus, Injection site swelling, Pain in extremity

Symptom Text: Information has been received from a physician concerning a female patient who is also the receptionist in the office and on 20-MAR-2009 was vaccinated with GARDASIL (lot # was not available). Subsequently, the patient developed a red, swollen and itchy injection site. The physician added that the patient's arm became bigger and it continued to swell and now her arm hurts and the symptoms had been very persistent and progressing. The physician didn't specify if the patient received the first, second or third of GARDASIL. Physician added that the patient was given BENADRYL but the symptoms hadn't resolved yet. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345382-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	24-Mar-2009		17-Apr-2009	07-May-2009	VA	WAES0903USA04559	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abnormal behaviour, Presyncope, Unresponsive to stimuli

Symptom Text: Information has been received from a physician concerning a female patient with no pertinent medical history and no known drug allergies/reactions who was vaccinated with the first 0.5 ml IM dose of GARDASIL. Subsequently the patient experienced vasovagal reaction in the waiting room. The patient recovered and was sent home. On 24-MAR-2009 the patient was vaccinated with the second 0.5 ml IM dose of GARDASIL. There was no concomitant medication. On 24-MAR-2009 after receiving the vaccine the patient experienced not responding to their questions and acting strange. The patient was not conversing for about 2 minutes, but she did not pass out, The physician clarified that the patient did not have a seizure. The patient was observed at the office. No lab diagnostic studies were performed. On 24-MAR-2009 the patient recovered and was sent home. The patient would not get the third dose of GARDASIL. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **345383-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	07-May-2009	--	WAES0903USA05328	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Inappropriate schedule of drug administration, Malaise

Symptom Text: Information has been received from a consumer concerning her daughter who was vaccinated with the second dose of GARDASIL two weeks after the first dose and third dose another two weeks after the second dose. The reporter stated that her daughter has been feeling ill. The patient's adverse event did not improve at the time of this report. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345384-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
Unknown	F	Unknown	Unknown		17-Apr-2009	07-May-2009	PA	WAES0903USA04582	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Human papilloma virus test positive

Symptom Text: Information has been received from a physician concerning a female who in February 2009, was vaccinated with the third dose of GARDASIL. Subsequently, 3 weeks after the 3rd dose administration, the patient had a Pap test. The Pap test was positive for high risk HPV. No other information provided. The patient called office for medical attention. Additional information has been requested.

Other Meds: Unknown

Lab Data: Pap test, positive for high risk HPV

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345385-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	05-Jun-2008	Unknown		17-Apr-2009	07-May-2009	--	WAES0903USA04594	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1487U	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Arthralgia, Fatigue, Infectious mononucleosis, Pallor, Rash

Symptom Text: Information has been received from a physician assistant concerning a 16 year old female with penicillin allergy and sulfonamide allergy who on 05-JUN-2008 was vaccinated with a first dose of GARDASIL (lot number 659657/1487U). On 05-AUG-2008 the patient was vaccinated with a second dose of GARDASIL (lot number 659657/1487U) (injection site and route not reported). There was no concomitant medication. The patient developed a rash around her stomach lasting one week after the first vaccination. The rash came and went since the first vaccination. The patient also developed extreme fatigue, joint pain and was pale. The patient was tested positive for a variety of medical conditions. The patient had been tested for rheumatoid arthritis and mononucleosis but the results had not been received. The patient was prescribed prenatal vitamins, but she was not pregnant. The patient was seen in the physician's office. Laboratory test included pregnancy test, mononucleosis, AlC, blood cell count, MMA, thyroid and swallow study H. pylori Complete medical panel (results unspecified). The patient's mother refused the third dose due to the adverse events. At time of this report, the patient's events persisted. Follow-up information was received from the physician assistant concerning the 16 year old female. The Physician's assistant reported that it was determined on 27-MAR-2009 that the patient's mononucleosis and not the fact that she received two of three doses of GARDASIL resulted in the reported adverse events. Additional information is not expected.

Other Meds: None

Lab Data: Unknown

History: Infectious mononucleosis

Prex Illness: Penicillin allergy; Sulfonamide allergy

Prex Vax Illns:

Vaers Id: **345386-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
27.0	F	Unknown	24-Mar-2009		17-Apr-2009	07-May-2009	--	WAES0903USA04609	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Petechiae

Symptom Text: Information has been received from a Doctor of Pharmacy (Pharm. D.) student concerning a 27 year old female with no medical history or drug allergies who on an unspecified date was vaccinated intramuscularly with a 0.5 ml dose of GARDASIL. There was no concomitant medication. It was reported the patient developed a widespread petechial rash after administration of the vaccine. The reporter is unable to provide the dates of administration of GARDASIL or the date of onset of the rash. The patient sought medical attention. She was seen in a hospital emergency department on 24-MAR-2009 and was treated with BENADRYL and prednisone. The patient was released from the emergency department and did not require hospitalization. At the time of reporting the patient was not recovered. No further information is available.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345387-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	Unknown		17-Apr-2009	07-May-2009	SC	WAES0903USA04725	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Syncope

Symptom Text: Information has been received from a nurse concerning a 14 year old female who was vaccinated with all 3 doses of GARDASIL. That after the patient received her first or second dose of GARDASIL, she had fainted a "couple months ago". The patient felt dizzy and did not eat anything before her visit. The nurse did state that she did not faint when she received her third dose of GARDASIL. Not lot number was provided. Subsequently the patient recovered. The patient sought unspecified medical attention.

Other Meds: Unknown

Lab Data:

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345388-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
26.0	F	17-Mar-2009	21-Mar-2009	4	17-Apr-2009	07-May-2009	PA	WAES0903USA04851	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site mass, Injection site pain

Symptom Text: Information has been received from a 26 year old female who in December 2008 was vaccinated with a first dose of GARDASIL. On 17-MAR-2009 was vaccinated with a second dose of GARDASIL and when the nurse gave the injection she squeezed her arm and put the needle in. There was no concomitant medication. Then on Saturday 21-MAR-2009 the patient had a very large lump at the injection site that was the size of a half dollar and a little sore that day. As of 26-MAR-2009, the consumer stated the lump had gone down to the size of a pencil eraser and she had no pain. The consumer stated that she was unsure if she should get the third dose of the series. The patient sought medical attention by talking to the nurse. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 345389-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	25-Mar-2009	25-Mar-2009	0	17-Apr-2009	07-May-2009	--	WAES0903USA04853	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Muscle spasms

Symptom Text: Information has been received from a physician assistant concerning a 24 year old female with asthma and a history of urinary tract infection who on 25-MAR-2009 was vaccinated with the first dose of GARDASIL (lot# not provided) for cervical dysplasia. On 25-MAR-2009 the patient experienced muscle cramps in her calf and thigh about one hour after vaccination. The patient was a healthy personal trainer who worked out on a new piece of equipment 2 days ago. The patient was not admitted but referred to a neurologist for follow up. The patient's muscle cramps in her calf and thigh persisted. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Urinary tract infection

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **345404-1 (S)** **Related reports:** 345404-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	07-Mar-2009	11-Apr-2009	35	01-May-2009	05-May-2009	NY		12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	2	Left arm	Intramuscular	HPV4
							TDAP
							VARCEL
							VARCEL

Seriousness: ER VISIT, HOSPITALIZED, LIFE THREATENING, SERIOUS

MedDRA PT Convulsion

Symptom Text: My daughter was given all three doses of Gardasil on 8/28/08, then on 11/1/08, and the last on 3/7/09. On April 11, 2009 my daughter suffered with two seizures on this day and was hospitalized for five days. There is no history of seizures in my family. She was then put on Keppra. A week and a half later she suffered with three more seizures. Patient was again hospitalized. Keppra was then increased to 1500 mg twice a day. Now we are going to the neurologist to try to pinpoint the cause. I did research and found the side affects of Gardasil and one of them were seizures.

Other Meds: None

Lab Data: Cat, MRI, EEG, Blood work

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: **345404-2 (S)** **Related reports:** 345404-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	Unknown	11-Apr-2009		11-May-2009	12-May-2009	--	WAES0905USA00555	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Convulsion, Intensive care

Symptom Text: Information has been received from a consumer concerning her 14 year old daughter who was vaccinated with all three doses of GARDASIL (lot # not provided). On 11-APR-2009 the patient experienced seizures and was hospitalized from 11-APR-2009 to 15-APR-2009. The patient was readmitted from 23-APR-2009 to 25-APR-2009. The patient was readmitted again on 04-MAY-2009 and currently the patient was in ICU. The patient had sought unspecified medical attention. At the time of reporting, the patient's seizures persisted. Upon internal review, the patient's seizures was considered to be other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: electroencephalography; magnetic resonance; computed axial

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345407-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	07-Jan-2009	08-Jan-2009	1	01-May-2009	07-May-2009	ID		12-May-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARCEL	MERCK & CO. INC.	1330X	1	Left arm	Unknown	
TDAP	SANOFI PASTEUR	C3027AA	1	Right arm	Intramuscular	
HPV4	MERCK & CO. INC.	0572X	0	Right arm	Intramuscular	
FLUN	MEDIMMUNE VACCINES, INC.	50057UP	0	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Anorexia, Chills, Diarrhoea, Dizziness, Dyspepsia, Flatulence, Influenza like illness, Listless, Nausea, Pyrexia, Syncope, Vomiting, Weight decreased

Symptom Text: Vomiting, indegestion, lack of appetite, weightloss, dizziness, abdominal pain, fever, fainting, listlessness and nausea. This lasted from date of vaccine in January until end of March.She went to the Pediatrician three times, the Pediatric Gastroenteroligist, a Chiropractor and a surgeon. She underwent two blood tests, had a stool sample, an ultrasound and a Endosopy with no results found. She took several anti nausea vmiting medicines, took over the counter medications for her nausea and indigestion. 5/5/05 Records received DOS 1/7/09 to 3/7/09. Includes immunization records. FINAL DIAGNOSIS: Post vaccination: Flu-like symptoms, fever, chills, nausea and vomiting. Diarrhea. Later developed epigastric pain. Foul smelling flatus. LABS: MCV low, Abdominal Ultrasound WNL 5/11/09 Gastroenterology records received DOS 2/9/09 to 2/19/09. FINAL DIAGNOSIS: Abdominal pain, nausea, vomiting Post vaccination: Flu-like symptoms, fever, chills, nausea and vomiting which subsided, followed one week later with recurrence of nausea, and development of epigastric abdominal pain, diarrhea. Progressed to persistant vomiting, epigastric pain, and severe nausea. Frequent foul smelling flatus.

Other Meds: None

Lab Data: Ultrasound, Endoscopy, Blood tests and stool sample 5/5/05 Records received DOS 1/7/09 to 3/7/09. LABS: MCV low, Abdominal Ultrasound WNL 5/11/09 Gastroenterology records received DOS 2/9/09 to 2/19/09. LABS and DIAGNOSTICS: Endoscopy

History: Lactose intolerance, nocternal enuresis, hypothyroidism

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345420-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-Apr-2009	27-Apr-2009	0	01-May-2009	08-May-2009	GA		08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	2	Right arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB262AA	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness

Symptom Text: APPROXIMATELY 3-5 MINUTES AFTER RECEIVING THE VACCINE THE PATIENT SUDDENLY PASSED OUT - SHE HAD NO WARNING - SHE CAME BACK ARROUND IMMEDIATELY - FEELING A LITTLE DIZZY FOR A FEW MINUTES AND THEN FINE - THERE WAS NO TREATMENT OTHER THAN COLD COMPRESSES TO THE FACE.

Other Meds:

Lab Data:

History:

Prex Illness: DYSMENORRHEA

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345424-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Apr-2009	26-Apr-2009	2	02-May-2009	08-May-2009	KS		08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	UNKNOWN	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Lethargy, Pain, Pyrexia

Symptom Text: Fever, ache, lethartic onset 48 hours after vaccination with guardisil

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345429-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	20-Apr-2009	22-Apr-2009	2	02-May-2009	08-May-2009	FL		08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	TDAP	UNKNOWN MANUFACTURER	NULL		Unknown	Unknown	
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abdominal pain upper, Conjunctivitis infective, Dyspnoea, Lethargy, Neck pain, Oropharyngeal pain, Pain in extremity

Symptom Text: WITHIN A LITTLE OVER 24 HOURS. FIRST SIGNS, SEVERE SORE THROAT, NECK PAIN, ARM PAIN, STOMACH PAIN, A PINK EYE TYPE INFECTION. LETHARGIC. AT FIRST THOUGHT IT WAS THE SHOTS, THEN THOUGHT MAYBE THE FLU. NOW I GO BACK TO THE SHOTS! I DID NOT HAVE HER SEEN FOR TREATMENT. THIS LASTED A WEEK AND A HALF. HARD TIME BREATHING.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **345435-1 (D)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	Unknown	Unknown		01-May-2009	04-May-2009	--	WAES0904USA03499	04-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: DIED, SERIOUS

MedDRA PT Death

Symptom Text: Information has been received via the internet concerning a 21 year old female who was vaccinated with GARDASIL. The patient died 4 days after vaccination. The cause of death was unknown. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345440-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	24-Apr-2009	24-Apr-2009	0	01-May-2009	07-May-2009	NM		13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Immediate post-injection reaction, No reaction on previous exposure to drug, Presyncope

Symptom Text: On 4/24/09, Pt came in for #2 GARDASIL. Pt had no adverse reaction to #1 dose. Pt had a vasovagal episode immediately after vaccine given. Pt had appropriate recovery time after event.

Other Meds: None

Lab Data: None

History: Environmental allergies

Prex Illness: None

Prex Vax Illns:

Vaers Id: **345463-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	24-Apr-2009	24-Apr-2009	0	01-May-2009	07-May-2009	ND		07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash

Symptom Text: Broke out in a rash that evening. Rash is on the face, neck, both arms legs and abdomen. No temperature. Patient stated her Band Aid at home she had used may have had latex also used and old WYMOX pill and she scratched area of injection. No redness or swelling at site.

Other Meds:

Lab Data:

History: Phenergan; codeine

Prex Illness: sore throat

Prex Vax Illns:

Vaers Id: 345521-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	23-Dec-2008	01-Jan-2009	9	04-May-2009	05-May-2009	FR	WAES0904USA04385	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Acute disseminated encephalomyelitis, Agitation, Anxiety, Disinhibition, Disturbance in attention, Dysgraphia, Echolalia, Enuresis, Expressive language disorder, Hypersomnia, Obsessive-compulsive disorder, Regressive behaviour

Symptom Text: Information has been received from the Health Authority under the reference number PB20090202. A 14 year old female patient had received the first dose of GARDASIL (batch # and lot # not reported) on 08-OCT-2008, and the second dose (batch # and lot # not reported) on 23-DEC-2008. She had a medical history of adenoidectomy in 1995 and viral meningitis in Dec 2001. She was born at full term, eutrophic, with a normal psychomotor development. She had a healthy 9 year old brother and was the eldest. There was no particular family medical history. On 01-JAN-2009, the patient developed hypersomnia, characterized by nights of 14 to 16 hours of sleep plus naps. Appetite was normal, but she developed a secondary enuresis in the context of a behavioral regression. After 15 days, the patient went back to a normal rhythm between waking and sleeping, but enuresis persisted. Then the patient presented with behavioral disorders such as agitation, affective regression and some elements in favour of frontal syndrome: disinhibition, echolalia, gibberish with the addition of English words at the end of sentences, concentration troubles with the impossibility to read longer than 10 minutes, and a few obsessive-compulsive disorders such as anxiety at closing doors. Little by little the troubles progressively eased. MRI was performed on 29-JAN-2009 which revealed T1 hypersignals at the level of the central gray nucleus, predominant on the right, and this despite of the artifacts due to the dental appliance. Besides, head CT scan performed in the same time, with and without injection, showed hypodensity at the level of the right central nucleus correlation with MRI images. On 02-FEB-2009 the patient was taken to ambulatory care where her cerebrospinal fluid was explored. Results were a clear fluid, not hypertensive, 2 red blood cells, 0 white blood cells. The following serologies were performed: Lyme disease, A and B influenza, enteroviruses, varicella-zoster virus, HSV-1 and 2, HHV6 and CMV. All were negative in PCR. (Except for negat

Other Meds: Unknown

Lab Data: head computed axial tomography, 29Jan09, showed hypodensity at the level of the right central nucleus; magnetic resonance imaging, 29Jan09, T1 hypersignals at the level of the central gray nucleus, predominant on the right; magnetic resonan

History: Adenoidectomy; Meningitis viral

Prex Illness:

Prex Vax Illns:

Vaers Id: 345523-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	05-Oct-2007	07-Dec-2007	63	04-May-2009	05-May-2009	FR	WAES0904USA00436	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0251U	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Peripheral vascular disorder, Pyrexia, Rash, Similar reaction on previous exposure to drug

Symptom Text: Information has been received from a gynecologist concerning a female adolescent (exact age of onset not reported) who on an unspecified date, was vaccinated with the second dose of GARDASIL (Lot # not reported), intramuscularly into the upper arm. In the evening post vaccination the patient developed severe rash and high fever. The patient recovered within an unspecified time. A similar reaction had occurred after administration of first dose (Lot # not reported) (unspecified date of vaccination). Follow up information received on 24-APR-2009. This case was upgraded to serious due to hospitalization. The 17 year old patient was vaccinated with D2 of GARDASIL (Lot # 0278U; batch # NF56940) on 04-DEC-2007. Concomitant therapy included hormonal contraceptives. Three to four days p.v., the patient developed rash, fever of 41.3 C and peripheral circulatory disorder. The patient was hospitalized on an unspecified date. No information was given regarding the exams performed during hospitalization and the length of the stay. The exact duration of rash, fever and circulatory disorder was not reported, but complete recovery was after 2 weeks. After dose 1 administered 05-OCT-2007 (lot #0251U, batch NF43780), the patient developed similar symptoms (rash and fever). The patient was not hospitalized after dose 1 and recovered after 2 weeks. Other business partner numbers included E2009-02432. No further information is available. The case is closed.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: temperature measurement, 07?Dec07, 41.3 C

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345524-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Sep-2008	18-Nov-2008	75	04-May-2009	05-May-2009	FR	WAES0904USA03606	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Loss of consciousness, Tonic clonic movements

Symptom Text: Information has been received from a health authority (reference number ES-AGEMED-818821344) regarding a 14 year old female who on 04-SEP-2008 and 18-NOV-2008 was vaccinated with the first 0.5 ml dose and second dose (respectively) of GARDASIL intramuscularly. It was reported that after vaccine administration on the 18-NOV-2008 the patient presented with dizziness, probably because she has an aversion to needles, this also happened every time the patient had blood extraction. The patient recovered spontaneously. After vaccination the patient had experienced 2 episodes of loss of consciousness accompanied with tonic clonic movements, which lasted for a short period time, episodes occurred on the 18-DEC-2008 and on the 29-JAN-2009, both episodes took place during a neck massage. The case was being studied by neurologists. Case reported as serious by the HA with other medically important condition as criteria. Other business partner numbers include E200903460. No further information is available. Case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345525-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	07-Aug-2008	12-Feb-2009	189	04-May-2009	05-May-2009	FR	WAES0904USA04276	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Hodgkins disease stage II, Lymphadenopathy

Symptom Text: Information has been received from the Health Authority (reference # ES-AGEMED-008183336) concerning a 16 year old female patient with acaridae allergy who on 07-AUG-2008 was vaccinated with the second dose of GARDASIL (Batch # not reported) by intramuscular route (site of administration not reported). It was reported that a few days after the administration of the second dose of GARDASIL, August 2008, exact date not reported, the patient presented with swollen cervical lymph nodes ipsilateral to vaccine administration site. Ear, nose, throat exploration, a 15 day treatment with VARIDASE was prescribed (start and stop dates not reported), the patient did not improve, an ECO-PAF was performed with normal results, although, it was observed that other lymph nodes had grown in size in the neck and mediastinum. Biopsy results came out positive for a stage II Hodgkin lymphoma. On 12-FEB-2009 the patient was diagnosed with supradiaphragmatic stage II Hodgkin's disease. Hodgkin's disease NOS stage II supradiaphragmatic presentation and lymph nodes cervical swollen were coded in the Health Authority's report as adverse reaction. The patient had not recovered at the time of the report. The reporter determined that Hodgkin's disease NOS stage II supradiaphragmatic presentation was an other important medical event. Other business partner numbers include: E2009-03531. No further information is available.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 25Jan08, biochemistry results normal; diagnostic laboratory test, 19Mar08, biochemistry results normal; lymphatic structure biopsy, ??Aug08, abnormal; ultrasound, ??Aug08, echography, normal; complete blood cell

History:

Prex Illness: Acaridae allergy

Prex Vax Illns:

Vaers Id: 345526-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	04-Dec-2008	Unknown		04-May-2009	05-May-2009	FR	WAES0904USA04283	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Ageusia, Fall, Hypotonia, Loss of consciousness, Muscular weakness, Nystagmus, Paraesthesia, Reaction to previous exposure to any vaccine, Sensation of heaviness, Sensory loss, Vertigo, Vision blurred

Symptom Text: Information has been received from the a health professional regarding her daughter, a 14 year old female who was administered on the 04-DEC-2008 the second dose of GARDASIL (Batch #, route and site of administration not reported). After receiving the second dose of GARDASIL, dates have not been reported, the patient presented with loss of consciousness (even while seated), blurry vision, vertigo, nystagmus, weakness of legs, loss of muscular tone, loss of posture (the patient while walking would lean to the left side losing control of her posture). Two months later after vaccine administration the patient had to be hospital admitted (admission date has not been reported) due to symptoms. No information has been reported concerning medications used to treat events, performed tests or test results. The patient was discharged from hospital on March 2009, exact date not reported, the patient has improved. She has not suffered vertigo, dizziness or nystagmus for the last month. The patient sometimes felt heaviness in her legs and has not recovered her muscle tone completely. Four months after the administration of the second dose of GARDASIL the patient had lost sense of taste, causing a difficulty detecting salty taste. Also the patient had lost sensitivity to temperature, it was noticed that the patient showered with very hot water, not being able to detect the high temperature of the water. This had also improved lately. It was also reported that after receiving the first dose of the vaccine on 19-SEP-2008 the patient experienced an injection site inflammation and fever (reaching 40 degrees C). Ibuprofen was used to treat adverse events. The patient was taken to the emergency room due to high fever where she was diagnosed with an otitis which was treated with AUGMENTIN. The patient had refused to have the third dose of vaccine. Other business partner numbers include: E2009-03555. This is one of several cases from the same source. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345527-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	26-Dec-2008	01-Mar-2009	65	04-May-2009	05-May-2009	FR	WAES0904USA04309	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Complex partial seizures, Vaccine positive rechallenge

Symptom Text: Initial information received on the 24-APR-2009 from the Health Authority (reference number ES-AGEMED-618726347) regarding a 21 year old female who was administered on the 26-FEB-2009 the second dose of a GARDASIL (lot number not reported) by intramuscular route (site of administration not reported). Two or three days after vaccination and during 48 to 72 hours, the patient had 6 episodes of complex partial epileptic crisis of the temporal lobe. The patient did not require hospital attention; she attended an external medical consultation. Exploration is normal; EEG and MRI results are pending. The patient was vaccinated with the first dose of GARDASIL on 26-DEC-2008, it was reported that she had the same adverse events. From the 05-JAN-2009 to the 10-JAN-2009 she presented 3 or 4 episodes of complex partial epileptic crisis of the temporal lobe that lasted for a few minutes. It has been reported that according to the patient, the episodes after the second dose were more critical. Case reported as serious by the Health Authority with other medically important condition as criteria. Other business partner numbers include: E2009-03598. Case is closed.

Other Meds: Unknown

Lab Data: electroencephalography, 01?Mar09, waiting for results; magnetic resonance imaging, 01?Mar09, waiting for results; physical examination, 01?Mar09, normal

History: Complex partial seizures

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345528-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	01-Mar-2008	01-Mar-2008	0	04-May-2009	05-May-2009	--	WAES0904USA04339	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a TV news report and the patient's father concerning his 16 year old daughter who in March 2008, was vaccinated with GARDASIL. The patient's father reported that in March 2008 just after the vaccination, he received a phone call in which he was informed that his daughter had a seizure and was on her way to the ER. The patient's father stated that although the doctors were not connecting seizures with the vaccine, he thought it was too much of a coincidence that the vaccination was involved at the same time, closely related with the only seizure his daughter has had in her life. The patient's father felt that the GARDASIL had absolutely something to do with the seizure. It as reported that the patient survived and is healthy today. Upon internal review, seizure was considered an important medical event. This is one of two reports received from the same source. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345529-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	01-Jul-2008	01-Nov-2008	123	04-May-2009	05-May-2009	FR	WAES0904USA04383	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Anogenital warts, Smear cervix abnormal

Symptom Text: This case was initially reported to agency by a health care professional on 24-APR-2009 (no: 80737). This case concerns a 23 year old female patient. Details of the patient's medical history and concomitant medication have not been reported. In June 2008, the patient received the first dose of GARDASIL batch number, route and site not reported. In July 2008, the patient received the second dose of GARDASIL batch number, route and site not reported. In November 2008, five months after the first dose and four months after the second dose of GARDASIL, the patient underwent a cervical smear test which showed changes suggestive of a wart infection. The patient was referred to a clinic but had no clinical signs of genital warts. Human papilloma virus testing was not carried out. The patient subsequently received the third dose of GARDASIL, batch number, route and site not reported in December 2008. It was not known if the patient had recovered. The adverse events were reported as other important medical events. Additional information has been requested. Other business partner numbers include E2009-03643.

Other Meds: Unknown

Lab Data: cervical smear, ??Nov08, changes suggestive of a wart infection

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345537-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	25-Mar-2009	25-Mar-2009	0	04-May-2009	05-May-2009	FR	WAES0904USA04279	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Vertigo

Symptom Text: Initial information received on 21-APR-2009 from the Health Authorities (reference number ES-AGEMED-118914444) regarding a 15 year old female who was administered, on 25-MAR-2009 a dose of GARDASIL (lot # and batch # not reported, routed of administration unknown, site not reported). On the same day of vaccine administration, 25-MAR-2009 the patient presented with vertigo. The patient recovered on 29-MAR-2009. The adverse event lasted for 5 days. It had been reported that the patient was hospitalized during 4 days (admission and discharge dates had not been reported. Other business partner numbers include E2009-03548. No further information is available. Case is closed.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345538-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	03-Feb-2009	16-Feb-2009	13	04-May-2009	05-May-2009	FR	WAES0904USA04288	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Rash maculo-papular

Symptom Text: Information has been received from a health authority (H.A. ref # ES-AGEMED-120887341) concerning a 14 year old female who on 03-FEB-2009 was vaccinated with a dose of GARDASIL by intramuscular route (batch # not reported). 14 days after vaccination on 16-FEB-2009 the patient presented with a slightly squamous maculo-papular exanthema. The patient had not yet recovered. The health authority considered maculo-papular exanthema to be an other important medical event. Other business partner numbers included: E2009-03594. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345539-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	01-Mar-2009	20-Apr-2009	50	04-May-2009	05-May-2009	FR	WAES0904USA04307	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Facial palsy

Symptom Text: Information has been received from a health care professional concerning a 13 year old female patient with no medical history, who in March 2009, was vaccinated with the first dose of GARDASIL (Batch # not reported). On 20-APR-2009 the patient experienced a bilateral facial palsy without radiculopathy. At time of reporting the outcome was not specified. There was hospitalization (unspecified date) and several exams were conducted on 21-APR-2009 and 22-APR-2009 without known results. Other business partner numbers include: E2009-03614. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: 345540-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Mar-2009	19-Mar-2009	0	04-May-2009	05-May-2009	--	WAES0903USA03976	05-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1311X	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a registered nurse, for the GARDASIL a Pregnancy Registry, concerning a 17 year old female patient with a history of pelvic inflammatory disease who on 19-Mar-2009 was vaccinated with a dose of GARDASIL (lot# not specified). It was reported that 2 weeks ago the patient was being treated for pelvic inflammatory disease, and that time was given an urine hCG test which was negative. On 19-Mar-2009 the patient was given vaccines (not specified) and afterward was also given another urine hCG pregnancy test which was positive. LMP was not provided. The nurse indicated that the patient has an office visit on 23-Mar-2009 for counseling. The patient will not receive prenatal care there since this is a pediatric office. The nurse will provide whatever health care professional contact information for the patient's prenatal care that she obtains. Follow up information has been received from a health professional and a registered nurse concerning a 17 year old female with oligomenorrhoea and a history of pelvic inflammatory disease who on 19-Mar-2009 was vaccinated with third dose of GARDASIL (dose and route not reported, lot number 661531 / 1311X). The registered nurse reported that the patient's mother had called the clinic on 26-Mar-2009 to report that her daughter had an appointment on 30-Mar-2009. In a subsequent phone call to the clinic on 22-Apr-2009, the mother reported that the pregnancy had been electively terminated. Upon internal review, pregnancy had been electively terminated was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Urine beta-human, 03/19/09, positive

History: Pelvic inflammatory disease

Prex Illness: Pregnancy NOS (LMP = Unknown); Oligomenorrhoea

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345552-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	17-Apr-2009	17-Apr-2009	0	04-May-2009	08-May-2009	IL		08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651X	2	Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2733AA	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Loss of consciousness, Tonic clonic movements, Urinary incontinence

Symptom Text: Child received 2 vaccines, MENACTRA and GARDASIL # #3, in opposite deltoids. Within 5 seconds after receiving the 2nd shot child had a seizure which lasted about 10-15 seconds. Seizure included loss of consciousness, tonic clonic movements of arms and urinating on self.

Other Meds:

Lab Data: None done

History:

Prex Illness: Headache- likely tension

Prex Vax Illns:

Vaers Id: **345563-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	19-Dec-2008	19-Dec-2008	0	08-Apr-2009	06-May-2009	IN	WAES0812USA04509	06-May-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
VARZOS	MERCK & CO. INC.	0159X	0	Unknown	Subcutaneously	
MNQ	SANOFI PASTEUR	U2733AA	0	Unknown	Intramuscular	
HPV4	MERCK & CO. INC.	0575X	0	Unknown	Intramuscular	
HEP	GLAXOSMITHKLINE BIOLOGICALS	AHBUB5E2AA	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Wrong drug administered

Symptom Text: Information has been received from a physician concerning a 15 year old female patient, who on an unspecified date, was vaccinated with ZOSTAVAX (Oka/Merck). The physician reported that the patient received ZOSTAVAX (Oka/Merck) instead of VARIVAX (Oka/Merck0 (MSD). The outcome is unknown. Follow-up information from her physician indicated that she was a 15 year old female patient, with no known drug reactions/allergies, who on 19-DEC-2008 at 18:30, the patient was accidentally vaccinated with the first dose of ZOSTAVAX (Oka/Merck) (Lot # 659760/0159X), subcutaneously, instead of VARIVAX (Oka/Merck). Concomitant therapy included the first dose of GARDASIL (Lot # 661530/0575X), intramuscularly, the first dose of MENACTRA (Lot # U2733AA), intramuscularly and the first dose of ENGERIX B (Lot # AHBUB5E2AA), intramuscularly. There were no illnesses at the time of vaccination. Additional information has been requested.

Other Meds:

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **345607-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.3	F	01-May-2009	02-May-2009	1	04-May-2009	08-May-2009	CA		08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	0653X	0	Left arm	Unknown	
	HPV4	MERCK & CO. INC.	AHAVB330CA	1	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness, Tremor

Symptom Text: Tremors in R hand started 12-24 hours after injections. Dizziness - resolved.

Other Meds:

Lab Data:

History: EBV-Mono 1/18/09

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345611-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.2	F	Unknown	Unknown		04-May-2009	08-May-2009	WI		08-May-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB334DA	1	Left arm	Unknown	
HPV4	MERCK & CO. INC.	0575X		Right arm	Unknown	
VARCEL	MERCK & CO. INC.	0338Y	1	Left arm	Unknown	
TDAP	SANOFI PASTEUR	NULL		Left arm	Unknown	
MNQ	SANOFI PASTEUR	U2911AA	0	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Head injury, Syncope

Symptom Text: Teen had syncopal episode after taking 2 steps when she got off the exam table - 11 feet and hit head against door frame. BP was low and remained low for about 10 minutes.

Other Meds: Albuterol prn -

Lab Data: - BP 102/60 lying; 80/70 sitting.

History: asthma

Prex Illness: none

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345615-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
28.0	F	17-Apr-2009	Unknown		04-May-2009	08-May-2009	MD		08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0243U	2	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy

Symptom Text: Pt. presented to GARDASIL clinic 7-22-08 to begin series. Completed series 4-17-09 after reporting LMP 3-26-09. Presented to health department for + pregnancy test 5-4-09.

Other Meds: None

Lab Data: None

History: None

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345646-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.3	F	17-Apr-2009	17-Apr-2009	0	04-May-2009	07-May-2009	CA		07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Left arm	Unknown	
	FLU	SANOFI PASTEUR	U2898AA		Right arm	Unknown	
	MNQ	SANOFI PASTEUR	U2844AA		Right arm	Unknown	
	TDAP	SANOFI PASTEUR	C2766AA	5	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Eye swelling, Ocular hyperaemia, Oropharyngeal pain, Pyrexia, Rhinorrhoea, Sneezing, Swelling face, Swollen tongue

Symptom Text: Fever on 4-17-09, 7 PM. On 4-18-09 upon awakening had eyes swollen shut, face incl tongue puffy and red, eyes were also red. Facial swelling/redness resolved on 4-19-09 mid-day. Parent measured highest temp as 100.8. Seen in clinic 4-21-08, T 102, sneezing, nasal discharge, sore throat.

Other Meds: MOTRIN on 4-17-09; 4-19-09; 4-20-09; 4-21-09

Lab Data: Quick viral strep (-); U/A dipstick; SC, 1015; ph 6; Tr leuk; Tr protein; Small blood

History: Blisters on soles of feet 2' running (mild)

Prex Illness: None. T 98.3

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345680-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	29-Apr-2009	30-Apr-2009	1	05-May-2009	11-May-2009	MN		11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0630X	1	Left arm	Unknown	
	MNQ	SANOFI PASTEUR	U2815AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	UF47113A	5	Right arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1312X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site inflammation, Local reaction

Symptom Text: 4cm localized inflammation to left upper extremity - no streaking noted. No fever - began morning after varicella SC injection.

Other Meds:

Lab Data:

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 345686-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	29-Apr-2009	29-Apr-2009	0	05-May-2009	11-May-2009	MI		11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0651K	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Cold sweat, Cyanosis, Depressed level of consciousness, Heart rate normal, Nasopharyngitis, Pallor, Paraesthesia, Respiratory arrest, Respiratory rate, Syncope

Symptom Text: Patient fainted, difficult to arouse (12 sec) utilized ammonia to arouse. Patient stopped breathing during fainting spell. Patient cold, pale and clammy fingertips blue with c/o tingling in fingertips then legs. Blood pressure 92/58, pulse 60. RR16. 911 called. Patient transported to nearest ER.

Other Meds: None

Lab Data:

History: None Known

Prex Illness: None

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345695-1** **Related reports:** 345695-2

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	03-Nov-2008	12-Feb-2009	101	05-May-2009	06-May-2009	FR	WAES0904USA04376	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0253U	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Epilepsy, Loss of consciousness, Muscle spasms

Symptom Text: Information has been received from a health authority (reference no. PEI2009008417) concerning an 18 year old female with a medical history of chronic headaches due to sinusitis that did not improve despite surgery and medication (onset: approx. SEP-2008) and pollen allergy who was vaccinated with the first dose of GARDASIL on 10-DEC-2007(batch# NF58540, LOT# 0253U), the second dose on 21-APR-2008(batch# NF58540, LOT# 0253U), the third dose on 03-NOV-2008(batch# NF58540, LOT# 0253U). On 12-FEB-2009 the patient developed recurrent attacks of unconsciousness with muscle spasms of approximately 30 minutes - similar to epileptic seizures. Despite anticonvulsive treatment with lamotrigine the patient experienced further seizures. The patient had not recovered at the time of reporting. Epilepsy was determined to be an other important medical event. File closed.

Other Meds: Unknown

Lab Data: Unknown

History: Surgery

Prex Illness: Sinusitis; Pollen allergy; Chronic headaches; Hypersensitivity

Prex Vax Illns:

Vaers Id: **345695-2** **Related reports:** 345695-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	21-Apr-2008	01-Sep-2008	133	05-May-2009	06-May-2009	FR	WAES0904USA04612	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0253U	1	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Headache, No reaction on previous exposure to drug, Sinusitis, Surgery

Symptom Text: Information has been received from a health authority under HA reference no. PEI2009008417. This case is linked with serious case E2009-03559 (MSD WAES 0904USA04367) (same patient, same vaccine, but different reactions after the second dose). It was reported that a 17 year old (also reported as 18 year old) female with history of pollen allergy who on 10-DEC-2007 was vaccinated with the first dose of GARDASIL (lot # 0253U and batch # NF58540) that was well tolerated. On 21-APR-2008 the patient was vaccinated with the second dose of GARDASIL (lot # 0253U and batch # NF58540) IM. Since approximately September 2008, the patient experienced chronic headache. The headache was attributed to a sinusitis. Despite sinusitis was treated by surgery and medication (not otherwise specified) headache did not improve. Despite ongoing events the patient was vaccinated with a third dose of GARDASIL (lot # 0253U and batch # NF58540) IM on 03-NOV-2008. The patient has not recovered at the time of reporting. The agency considered sinusitis and chronic headaches to be other important medical events. Other business partner number included E200903721. File closed.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Hypersensitivity; Pollen allergy

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345696-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	23-Apr-2009	23-Apr-2009	0	05-May-2009	06-May-2009	TX	WAES0904USA03962	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Fatigue, Gaze palsy, Immediate post-injection reaction, Pallor, Stress, Tonic clonic movements

Symptom Text: Information has been received from a physician concerning a 22 year old female who on 23-APR-2009 was vaccinated with the second dose of GARDASIL. The patient received the first vaccination on 13-FEB-2009 (lot # reported as "660825/0423X"). After receiving the second dose on 23-APR-2009 the patient's face turned white, eyes rolled back in her head and she had a seizure. The physician reported that after the patient had a seizure she was sent to her primary care physician for further evaluation. The physician reported that the patient's primary care physician wanted the patient to go and have test done but the patient wanted the patient to go and have test done but the patient refused. The physician reported that the patient was still feeling tired and she was under a lot of stress but she was recovering. Follow-up information was received from a physician. The physician stated that the patient had a seizure that lasted 4-5 min with tonic, clonic posturing. The physician stated that the patient was "completely out". The patient "perked-up and came to with no postictal confusion". The physician stated that the patient had no history of seizures. The seizure occurred immediately after the patient received GARDASIL. The physician stated that he was not sure if the patient had the seizure due to GARDASIL or a drop in blood pressure. The physician did not know if the seizure was due to a neurological disorder. The physician stated that he thought the patient's Primary Care was another physician. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345697-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
19.0	F	05-Feb-2009	05-Feb-2009	0	05-May-2009	06-May-2009	--	WAES0903USA05524	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0570X	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion spontaneous, Drug exposure during pregnancy, Haemorrhage, Nausea

Symptom Text: Information has been received from a registered nurse concerning a 19 year old female with no medical history and no known drug allergies who on 05-FEB-2009 was intramuscularly vaccinated with a 0.5 ml dose of GARDASIL (lot #660616/0570X). Concomitant therapy included vitamins (unspecified) (FLINTSTONES MULTIVITAMIN). The patient was pregnant while received GARDASIL. Her LMP was 25-JAN-2009. No adverse effect was reported. Lab diagnostic studies included prenatal screen. The patient had an office visit for medical attention. Follow up information was received from the registered nurse who reported that the 19 year old patient was a smoker with HPV infection. She had one previous pregnancy and pre-term delivery at 35.4 weeks by caesarean section in 2008. The patient was vaccinated with the first dose of GARDASIL on 05-FEB-2009. Concomitant therapy included vitamins (unspecified) (FLINTSTONES MULTIVITAMIN) for prenatal use. The patient experienced nausea during her pregnancy and was prescribed ZOFRAN 8mg every 12 hrs on 23-MAR-2009 for treatment. Her pregnancy was confirmed by sonogram at the first OB appointment on 26-MAR-2009. She was advised to quit smoking. There was no illness during the pregnancy. The patient was seen on 03-APR-2009 with known spotting. The patient also experienced heavy bleeding. She experienced spontaneous abortion complete in an emergency room while on vacation on 04-APR-2009, that was 8.2 weeks from her LMP. The patient was seen in the reporter's office on 08-APR-2009 and confirmed spontaneous abortion and by ultrasound. Upon internal review, spontaneous abortion was determined to be an other important medical event. Additional information is not expected.

Other Meds: FLINTSTONES MULTIVITAMIN

Lab Data: ultrasound, 03/26/09, 7 weeks OB; ultrasound, 04/08/09, confirmed SAB

History: Caesarean section; Early onset of delivery

Prex Illness: Pregnancy NOS (LMP = 1/25/2009); Smoker; Papilloma viral infection

Prex Vax Illns:

Vaers Id: **345698-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	22-Aug-2007	24-Mar-2008	215	05-May-2009	06-May-2009	--	WAES0805USA06266	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0186U	0	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Blood pressure decreased, Caesarean section, Drug exposure during pregnancy

Symptom Text: Initial information and follow up has been received from a nurse and consumer for the Pregnancy Registry for GARDASIL concerning a 17 year old female who was born three months premature was vaccinated on 22-AUG-2007 intramuscularly with her first dose of GARDASIL (lot# 655618/0186U). on 25-APR-2008 the patient was vaccinated intramuscularly with her second dose of GARDASIL (lot# 659655/1486U) and was pregnant. Concomitant therapy on 25-APR-2008 included HepB (duration and dose not reported). The patient's LMP was estimated to be 24-MAR-2008. She had a positive urine pregnancy test. The patient sought medical attention on an unspecified date in the physician's office. Subsequently the patient experienced no symptoms. The patient has had no previous pregnancies. Follow-up information was received from the registered nurse. On 13-JAN-2009 the patient, with no significant past medical history and no concurrent medical condition, gave birth to a live, normal female baby with birth weight 6 lb 5 oz, length 19.2 inch, head circumference 13 and passed Apgar score and all testing. The baby was delivered by c-section due to mother's blood pressure dropping. There was no other complication. There were no congenital anomalies and other complications or abnormalities. Upon internal review, delivered by c-section due to mother's blood pressure dropping was determined to be an other important medical event. Additional information is not expected.

Other Meds: Unknown

Lab Data: urine beta-human, positive

History: Premature baby

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345699-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	01-Apr-2009	01-Apr-2009	0	05-May-2009	06-May-2009	FR	WAES0904USA04375	06-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0153X		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Erythema, Erythema multiforme, Rash papular

Symptom Text: Information has been received from a health authority (case n. 97801) (local case n. IT172/09) concerning a 12 year old female who was vaccinated on 01-APR-2009 with one dose of GARDASIL. On the same the patient presented with erythema and papule on the elbows, lower limbs and then over the entire body. She was admitted to the hospital and diagnosed with erythema multiforme or polymorph. She was treated with oxatomide, cetirizine hydrochloride and desoximetasone. She was discharged on 06-APR-2009. At the time of reporting the patient had not yet recovered. The case is closed. Other business partner numbers include E2009-03589.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345708-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	30-Jul-2008	26-Aug-2008	27	05-May-2009	11-May-2009	NC		12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	MNQ	SANOFI PASTEUR	U2657AA	0	Left leg	Unknown	
	HPV4	MERCK & CO. INC.	0571X	0	Right arm	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Back pain, Cholecystectomy, Headache, Musculoskeletal pain, Pain, Ulcer

Symptom Text: Parents concerned that vaccine (s) have caused chronic pain. Has had ulcers and cholecystectomy (abnormal gallbladder scan), but persists with abdominal, back and should pain, headaches.

Other Meds: Albuterol; Enalapril; Zyrtec

Lab Data: CMP; CBC; TSH; CRP; ANA; RA normal.

History: was s/p surgery for endometriosis

Prex Illness: had been having some chest pain

Prex Vax Illns:

Vaers Id: **345720-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-Apr-2009	01-May-2009	9	05-May-2009	12-May-2009	GA		12-May-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB258AA	0	Right leg	Intramuscular	
HPV4	MERCK & CO. INC.	0070X	0	Left leg	Intramuscular	
VARCEL	MERCK & CO. INC.	1193X	1	Left leg	Subcutaneously	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Urticaria

Symptom Text: Hives occured 9 days after administration of HPV, HepA and Varicella vaccines

Other Meds: minocin

Lab Data: visual diagnosis

History: acne vulgaris

Prex Illness: acne vulgaris

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345730-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
43.0	M	06-Mar-2009	18-Mar-2009	12	05-May-2009	08-May-2009	NY		08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0074Y	1	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Chest pain, Dyspnoea, Pulmonary embolism

Symptom Text: Patient states that he developed diffculty breathing and chest pain on 3/18/09 and went to the Emergency room where he was admitted for a pulmonary embolism. He spent approximately 10 days at the hospital and was given heparin inthe hospital and was released on coumadin. He will probably remain on coumadin for at least 6 months maybe longer depending on his hematologist. Patient states that he had a DVT in 2008 that occurred while on a plane.

Other Meds: Protonix

Lab Data:

History: GERD, Phlebitis

Prex Illness: None

Prex Vax Illns:

Vaers Id: **345750-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
10.9	F	01-May-2009	02-May-2009	1	05-May-2009	11-May-2009	PA		12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Left arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2867AA	0	Right arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site induration, Injection site pain, Injection site swelling, Rash papular

Symptom Text: Received TYLENOL at home. Pt. received MANECTRA on R deltoid on 5/1/09. About 30 hours later on 5/2/09; mother noticed redness, induration pain and swelling about 4" below the injection site. When seen in the office on 5/4/09; there was an area of erythema with heat point of tenderness around a 2 mm papule which was about 4" below the injection site. Mild induration still present. Erythema spread all around that papule.

Other Meds:

Lab Data: None

History:

Prex Illness: None

Prex Vax Illns: Per mother; maybe at age 4 y/o, similar reaction occurred. No documentation available.~Vaccine not specified (no brand name)~UN~0~Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345755-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-Apr-2009	Unknown		05-May-2009	12-May-2009	AR		12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0042Y	1	Right arm	Unknown	
	HPV4	MERCK & CO. INC.	0651X	0	Unknown	Unknown	
	MNQ	SANOFI PASTEUR	U2877AA	0	Right arm	Unknown	
	TDAP	SANOFI PASTEUR	AC52B029AA	5	Right arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral

Symptom Text: 3 1/2 cm x 5 cm swelling and redness to RPUA.

Other Meds:

Lab Data:

History: Demerol

Prex Illness:

Prex Vax Illns:

Vaers Id: **345757-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.5	F	05-May-2009	05-May-2009	0	05-May-2009	12-May-2009	CO		12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Fall, Loss of consciousness

Symptom Text: Immunization administered - child sitting in chair with mom at side. Approx. 10 min. passed and then finger stick hgb. done. Child uncomfortable with this procedure. Approx. 5 min. passed - child decided to go to bathroom. Upon entering bathroom child felt against wall and passed out. Dr. at side immediately - LOC for only seconds. Elevated gest B/P 100/58 - popsicle given. Released with mom after 20 min. observation.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **345789-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	28-Apr-2009	28-Apr-2009	0	06-May-2009	07-May-2009	--	WAES0904USA04459	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	0	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Asthenia, Convulsion, Dyskinesia, Foaming at mouth, Gaze palsy, Musculoskeletal stiffness, Pallor, Tongue paralysis

Symptom Text: Information has been received from a nurse concerning a her great-niece 13 year old female with no known allergies or medical history reported, who on 28-APR-2009 was vaccinated with her first dose of GARDASIL (dose, route of administration and lot number not reported). There was no concomitant medication. The nurse reported, the patient two seizures soon after receiving her first dose of the vaccine. The first seizure was described as violent jerking, stiffness, frothing at the mouth, tongue deviated to the right and eyes rolled back lasting five minutes. The patient experienced a second seizure within the hour as she was being escorted from the office. The patient was transported home by her mother and was recovering, although still "weak and pale". The patient sought unspecified medical attention. Upon internal review, seizure was determined to be an other important medical event. Additional information has been requested.

Other Meds: None

Lab Data: None

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 345790-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	Unknown	Unknown		06-May-2009	07-May-2009	--	WAES0904USA04521	07-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Unknown	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Arthralgia, Myofascitis, Pain, Skin lesion

Symptom Text: Information has been received from a physician who reported that a patient's mother told him that her 24 year old daughter, on an unspecified date was vaccinated with the third dose of GARDASIL (Lot not reported) and "shortly after vaccination" the patient complained of sore body and pain in joints and she was diagnosed with macrophagic myofascitis. It was reported that the patient could not get out of bed. She also developed skin lesions. The patient's muscle biopsy showed that the muscle contain aluminum. The physician also reported that she is no longer his patient. Additional information has been received from the physician, who stated that he "run into the patient's mother and she told him that her daughter was diagnosed with macrophagic myofascitis" at another medical center. The patient's mother stated that aluminum hydroxide was found in the patient's muscle. The physician also stated that the patient did not receive GARDASIL in his office. The physician felt that Macrophagic myofascitis and skin lesions were considered to be disabling. No additional information is expected.

Other Meds: Unknown

Lab Data: muscular biopsy, muscle contain aluminum

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345795-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-May-2009	06-May-2009	0	06-May-2009	12-May-2009	IL		13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2621AA	0	Left arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2632AA	0	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Dizziness, Dyskinesia, Dyspnoea, Feeling cold, Hypoacusis, Lethargy, Muscle twitching, Mydriasis, Nausea, Obstructive airways disorder, Pupil fixed, Tachycardia, Unresponsive to stimuli, Visual impairment

Symptom Text: CLIENT C/O BEING COLD, DIZZY, THEN MOUTH, ARMS, AND HANDS STARTING TWITCHING, ALONG WITH BIG TOE. AMBULANCE CALLED. EYES GLAZED OVER AND DILATED AND FIXXED. THEN UNRESPONSIVE. AMBULANCE FROM FAYETTE COUNTY HOSPITAL IN VANDALIA, IL CALLED AND CLIENT TAKEN TO ER. 5/8/09 ED records received DOS 5/5/09. FINAL DIAGNOSIS: Drug reaction Nauseated, dizzy, twitching. 'Things got dark', could not hear people. Jerky movements, lethargic. Impaired airway. Shortness of breath, tachycardia. Condition improved while in ED and discharged.

Other Meds: LEXAPRO, RESIPRODRO

Lab Data: 5/8/09 ED records received DOS 5/5/09 LABS & DIAGNOSTICS - None reported.

History: CYSTIC FIBROSIS, DEPRESSION AND ASTHMA

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345798-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	06-May-2009	06-May-2009	0	06-May-2009	12-May-2009	OK		12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1446U	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Loss of consciousness, Posturing, Syncope

Symptom Text: Approximately 2 minutes after receiving 3rd HPV immunization, client fainted. Client was unconscious approximately 10 seconds, for 3-5 of those seconds, client noted to have posturing like movements. Client's hands were curving into fists at her chest, pointing toes down and head bobbing up and down. After only 3-5 seconds of that type of movement, client regained consciousness suddenly and was alert. When asked if she was okay, she smiled and stated "I'm okay". Whole episode lasted approximately 10 seconds.

Other Meds: Client had been taking Yaz for the last year.

Lab Data:

History: None, denied a history of seizures, mom stated client passed out 2 other times, once when having blood drawn and once when she had an oral surgery.

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345802-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
24.0	F	05-May-2009	06-May-2009	1	06-May-2009	12-May-2009	IL		12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0652X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Joint stiffness, Oedema peripheral

Symptom Text: ~ 24 hours after gardasil #1, patient reports left index and middle finger is mildly swollen and difficult to bend. Vaccine was given in the same left arm.

Other Meds:

Lab Data: no testing done, advise NSAIDs/ice/rest prn. At this time, patient understood instructions and did not feel finger pain/swelling was increasing

History: none noted

Prex Illness: none noted

Prex Vax Illns:

Vaers Id: **345822-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	04-May-2009	04-May-2009	0	06-May-2009	12-May-2009	MI		12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	00744	2	Left arm	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Head injury, Loss of consciousness, Suture insertion

Symptom Text: Immediately after receiving GARDASIL injection, pt passed out with her head on a desk. She quickly regained consciousness & required sutures.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: **345844-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	27-Apr-2009	28-Apr-2009	1	06-May-2009	13-May-2009	IL		13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0387U	0	Left arm	Intramuscular	
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	AHAVB334DA	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Blister, Erythema

Symptom Text: 4" diameter erythema 1-2mm vesicle in center - has burst

Other Meds:

Lab Data:

History: Jan 06 head injury with complete loss of memory - continues to have amnesia for all events prior to this

Prex Illness:

Prex Vax Illns:

Vaers Id: **345845-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	28-Apr-2009	Unknown		06-May-2009	12-May-2009	WI		12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	VARCEL	MERCK & CO. INC.	0190Y	1	Right arm	Subcutaneously	
	HPV4	MERCK & CO. INC.	0558X	2	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Injection site erythema, Injection site swelling

Symptom Text: Swelling in right arm post receiving VARICELLA vaccine. Swelling & reddness began 4/29/09. Tx'd with XYZAL 5 mg daily. Was already on MINOCYCLINE for another DX.

Other Meds: MINOCYCLINE; SINGULAIR; ZOLOFT

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vaers Id: 345848-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	22-Apr-2009	22-Apr-2009	0	07-May-2009	08-May-2009	TX	WAES0904USA03995	11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1312X	2	Left arm	Intramuscular	

Seriousness: ER VISIT, PERMANENT DISABILITY, SERIOUS

MedDRA PT Abdominal pain, Abdominal pain upper, Abdominal tenderness, Arthralgia, Burning sensation, Chills, Cough, Dizziness, Feeling hot, Headache, Hiccups, Hypoaesthesia, Hypokinesia, Immediate post-injection reaction, Inflammation, Injection site anaesthesia, Injection site erythema, Injection site swelling, Malaise, Nausea, Oedema peripheral, Pain, Paraesthesia, Pyrexia, Sensory disturbance, Systemic inflammatory response syndrome, Tremor

Symptom Text: Information has been received from a physician and a nurse concerning her 13 year old daughter with asthma and no known allergies who on 06-AUG-2008 was vaccinated with the first dose of GARDASIL (lot no. 660620/0571X). Second dose of GARDASIL (lot no. 659184/0843X) was given on 07-OCT-2008 and on 22-APR-2009 was given third dose of GARDASIL 0.5 ml, IM into the left arm (lot no. 661846/1312X). The patient did not have any other vaccines administered that day. The nurse was reporting that her daughter was having ongoing symptoms after getting the third dose of GARDASIL. There was immediate burning and pain during vaccination followed by a tingling and numbness within five minutes (also reported as 10 minutes) to the vaccinated arm (left). The injection site was red, raised, erythemous, warm to touch and the size of a ping pong ball. The nurse reported that, that night the patient's left arm felt numb from the fingers to the shoulder. The swelling at the injection site was the size of a golf ball. There was intense pain with the application of ice to the injection site. She was given ALEVE for pain. The next morning (on 23-APR-2009) she did not feel good. Both hands were puffy. On 23-APR-2009, around 10:00, she was shaking (chills), can't move having joint pain throughout, abdominal tenderness. and fever. She saw her pediatrician around 11:30 for the fever (100.6F), numbness, nausea and abdominal discomfort. The patient was prescribed ZANTAC and ANSAID or TYLENOL. At 19:00 the same day, the patient went to the emergency room (ER). She had a temperature of 103F. All labs came back negative. Lab test performed included C reactive protein ("RCP" for appendicitis), kidney profile, abdominal pelvis exam, contrast CT scan and Liver Function Test (LFT). She was given IV morphine (no relief) IV TORADOL (positive relief) and IV ZOFRAN. The nurse reported that the patient was diagnosed with acute inflammatory response to GARDASIL. Last evening the patient had a temperature of 101.6F, horrible abdominal pain (right sided from

Other Meds: ADVAIR; PATANASE

Lab Data: diagnostic laboratory, 04/24/09, kidney profile normal; diagnostic laboratory, 04/24/09, liver function test normal; diagnostic procedure, 04/24/09, pelvic examination normal; computed axial, 04/24/09, normal; diagnostic laboratory, 04/24/0

History:

Prex Illness: Asthma

Prex Vax Illns:

Vaers Id: **345849-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		07-May-2009	08-May-2009	--	WAES0905USA00040	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion

Symptom Text: Information has been received from a consumer concerning her friend's 15 year old daughter who was vaccinated with two doses of GARDASIL. After getting two doses of GARDASIL the patient experienced seizures. Upon internal review, seizures was determined to be an other important medical event. No further information was available.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345850-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
23.0	F	08-Feb-2008	Unknown		07-May-2009	08-May-2009	HI	WAES0802USA03044	08-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Ectopic pregnancy

Symptom Text: Information has been received from a pharmacist concerning a 23 year old female who on 08-FEB-2008 was vaccinated with her second dose of GARDASIL. The pharmacist reported on 12-FEB-2008, that the patient subsequently learned she was pregnant. The patient did not seek medical attention. No adverse reactions were reported. Follow-up information was received from a staff in the office and the registered pharmacist. The staff in the office reported that the patient had a tubal pregnancy in approximately February 2008 and "it had nothing to do with the GARDASIL". The registered pharmacist reported that she had received a request for the office for the third dose of GARDASIL for the patient in April 2008. The request note said that the patient was not pregnant at that time. The registered pharmacist had no any more information about the pregnancy. Upon internal review, tubal pregnancy was determined to be an other important medical event. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345865-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	Unknown	01-Oct-2008		07-May-2009	13-May-2009	NY		13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0279X	2	Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abdominal pain, Dizziness, Migraine

Symptom Text: Daily severe migraine headache unresponsive to prescription meds. Onset 10/08. Abdominal pain and some dizziness. Treated by pediatrician and neurologist.

Other Meds: None

Lab Data: Brain MRI, abdominal scan, and sinus scan. All clear.

History: None

Prex Illness: None

Prex Vax Illns:

Vaers Id: 345872-1

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	28-Apr-2009	28-Apr-2009	0	07-May-2009	13-May-2009	TX		13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1968U	0	Right arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Arthralgia, Back pain, Blister, Gait disturbance, Genital lesion, Pyrexia

Symptom Text: Patients calls the day after immunization was given c/o fever low back and B/L hip pain. States "difficult to walk" due to pain. Symptoms occurred (onset) at about 3 hours post immunization. Also notes 2 blisters on labia-never had before.

Other Meds:

Lab Data: Advised her to see physician. On flu about 5 hours later, pt. states she called a pharmacy hotline & was told this was normal. Improved with TYLENOL.

History: Allergy- BENADRYL

Prex Illness: None Apparent

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345877-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	05-May-2009	05-May-2009	0	07-May-2009	13-May-2009	NC		13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	GLAXOSMITHKLINE BIOLOGICALS	NULL		Unknown	Unknown	
	TDAP	SANOFI PASTEUR	C27688A	5	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Erythema, Induration, Oedema peripheral, Skin warm

Symptom Text: Left upper arm red, warm to touch, swollen, indurated

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345879-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	23-Apr-2009	23-Apr-2009	0	07-May-2009	13-May-2009	PA		13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0067	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Convulsion, Depressed level of consciousness, Loss of consciousness

Symptom Text: Mother of patient states patient received vaccine and then "slumped over in chair". Mother left room to get addional help. When mother returned to room, patient was lying on floor. Mother was told by nurse that she "had a seizure". Patient was "slow to respond and did not recognize" mom for 10 minutes post event.

Other Meds: Haldol, Depo-Provera Shot

Lab Data: None.

History: No Known Allergies

Prex Illness: None

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345894-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	06-May-2009	06-May-2009	0	07-May-2009	13-May-2009	CA		13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0653X	0	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2816AA	0	Left arm	Intramuscular	
	VARCEL	MERCK & CO. INC.	1757X	1	Left arm	Subcutaneously	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Syncope

Symptom Text: Pt had syncopal episode 15 min after administration of vaccines.

Other Meds:

Lab Data: Blood Glucose-98; Vital signs stable

History:

Prex Illness: none

Prex Vax Illns:

Vaers Id: **345940-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	10-Feb-2009	20-Feb-2009	10	08-May-2009	11-May-2009	FR	WAES0903USA04763	11-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1400U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Dizziness, Nausea, Orthostatic intolerance, Syncope

Symptom Text: Information has been received from a physician and a health authority through SPMSD (HA reference number PEI 2009005756) concerning a 15 year old female who on 10-FEB-2009 was vaccinated intramuscularly into deltoid muscle with first dose of GARDASIL (dose not reported) (Batch number NH38400, lot number 1400U). On 20-FEB-2009 the patient developed dizziness and recurrent syncopes. She was repeatedly hospitalized. All investigations (unspecified "internal, neurological") were normal. The patient recovered after two weeks. Follow up information has been received from a health authority (HA reference number PEI 2009005756). The hospital report was sent. The patient had additionally developed nausea. It was reported that all routine laboratories showed normal results. Schellong test, blood pressure (over 24 hours), echocardiography, MRI, (neurocranium) and ENT examination showed normal results, except EEG which showed intermittent retardation (bilateral posterior, with accentuation right). Orthostatic dysregulation was suspected as a possible cause for the syncope. A relation to the vaccine was considered to be possible. The physician's expected a "soon recovery" of the patient and did not recommend any further diagnostics. Other business partner numbers included: E2009-02496. No further information is available. Case is closed.

Other Meds: Unknown

Lab Data: electroencephalography, intermittent retardation (bilateral posterior, with accentuation right); diagnostic laboratory test, SCHELLONG test, normal results; electrocardiogram, normal results; ears, nose, and throat examination, normal resul

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **345948-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	04-May-2009	05-May-2009	1	08-May-2009	13-May-2009	MD		13-May-2009

VAX Detail:

Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
MMR	MERCK & CO. INC.	MSD1249X		Left arm	Subcutaneously	
MNQ	SANOFI PASTEUR	AVBU2733AA	0	Right arm	Intramuscular	
HEPA	GLAXOSMITHKLINE BIOLOGICALS	SKBAHAVB334 CA	0	Right arm	Intramuscular	
IPV	SANOFI PASTEUR	AVBB04752		Left arm	Subcutaneously	
HPV4	MERCK & CO. INC.	MSD0243U		Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Chest discomfort, Dizziness, Headache

Symptom Text: Pt & Foster Mother walked into Center. Pt received immunizations 05/04/09. Pt now c/o of dizziness, headache & chest discomfort. Follow-up phone call later in day-Foster Mother reports pt. is feeling better.

Other Meds: Denies

Lab Data: BP-90/60 P-90 R-20 T-98.6

History: Denies

Prex Illness: Denies

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345954-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	07-May-2009	07-May-2009	0	08-May-2009	13-May-2009	TX		13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HEPA	MERCK & CO. INC.	15844	1	Right arm	Intramuscular	
	MNQ	SANOFI PASTEUR	U2821AA	2	Right arm	Intramuscular	
	TDAP	SANOFI PASTEUR	C2768BA	0	Left arm	Intramuscular	
	HPV4	MERCK & CO. INC.	1129X	0	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Erythema, Oedema peripheral

Symptom Text: reddness swelling upper arms

Other Meds:

Lab Data: none

History:

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **345997-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	21-Apr-2009	21-Apr-2009	0	08-May-2009	13-May-2009	NY		13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1129X	1	Left arm	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Dizziness

Symptom Text: c/o dizziness-instructed to lay down waited for 15 min and sat up slowly. No further problems.

Other Meds:

Lab Data:

History:

Prex Illness:

Prex Vax Illns: 12/23/2008~HPV (Gardasil)~1~15~Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **346049-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Dec-2008	03-Mar-2009	75	11-May-2009	12-May-2009	FR	WAES0905USA00620	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1050U	0	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Depressed level of consciousness, Epilepsy

Symptom Text: Information has been received from a Health Authority (reference # PEI2009008420) concerning a 14 year old female who on 18-DEC-2008 and 16-JAN-2009 was vaccinated intramuscularly with the first and second dose of GARDASIL (LOT# 1050U batch # NH32130, batch # reported as NH21130, respectively). On 03-MAR-2009 the patient experienced epileptic seizure with consciousness clouding, duration: 2 days. Under anticonvulsive treatment with ORFIRIL the symptoms stopped, but the patient has not recovered at the time of reporting. Other business partner numbers include: E2009-03558. Additional information is not available. The file is closed.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **346050-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	01-Dec-2007	01-Jun-2008	183	11-May-2009	12-May-2009	FR	WAES0905USA00435	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Loss of consciousness

Symptom Text: Information has been received from a Health Authority (reference # ES-AGEMED-514454343) concerning a 14 year old female who between December 2007 and June 2008 was vaccinated intramuscularly with GARDASIL (number of dose/doses not specified). It was reported that between January 2008 and December 2008 the patient presented with several episodes of loss of consciousness with similar characteristics which do not suggest convulsive crisis. Since January 2009 the patient has clearly improved, ECG is normal and neurological exploration is also normal. The patient required hospitalization (admission and discharge dates not reported). The health authority considered this report to be serious, it was an other important medical event. Other business partner numbers include: E2009-03761. Additional information is not available.

Other Meds: Unknown

Lab Data: electrocardiogram, ??Jan09, normal; neurological examination, ??Jan09, normal

History: Unknown

Prex Illness:

Prex Vax Illns:

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **346051-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
16.0	F	10-Mar-2009	10-Mar-2009	0	11-May-2009	12-May-2009	FR	WAES0905USA00434	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	2	Unknown	Intramuscular	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Back pain, Neck pain, Pain in extremity, Pyrexia, Renal pain, Tremor

Symptom Text: Information has been received from the Health Authorities regarding a 16 year old female with no reported medical history who on 10-MAR-2009 received the third 0.5 ml dose of GARDASIL (batch number not reported) by intramuscular route (site of administration not reported). It has been reported that on the 10-MAR-2009, the same day of vaccine administration, the patient presented with high fever, tremor, neck pain, renal fossa pain and pain in arm. The patient was treated in an emergency room and recovered within 4 hours, after medication. Tremor, lumbar pain, neck pain, fever and pain in arm were considered to be other important medical events. Case is closed. Other business partner numbers included E200903750. No further information is available.

Other Meds: Unknown

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: 346052-1 (S)

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
13.0	F	26-Sep-2008	Unknown		11-May-2009	12-May-2009	NC	WAES0905USA00372	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0843X	2	Unknown	Unknown	

Seriousness: PERMANENT DISABILITY, SERIOUS

MedDRA PT Activities of daily living impaired, Bedridden, Blood test normal, Chest X-ray normal, Chest pain, Computerised tomogram normal, Decreased activity, Electroencephalogram normal, Gastric disorder, Headache, Musculoskeletal stiffness, Mydriasis, Nausea, Pyrexia, Sleep study normal

Symptom Text: Initial and follow-up information has been received from a consumer concerning a 13 year old female with no pertinent medical history and no drug reactions/allergies who on 13-MAR-2008, 23-MAY-2008 and 26-SEP-2008 was vaccinated with the first, second and third dose of GARDASIL respectively (lot # 659182/1757U, 660391/0063X and 659184/0843X), injection. Concomitant therapy included ibuprofen and AMITRIPTYLIN. In September 2008, the mother stated her daughter experienced chest pain, fever, nausea, muscle stiffness, headaches, stomach problem, and when she was not really feeling well in her pupils became "dilated", while on GARDASIL. She did not go to school and was not active because she could not even get out of bed. The patient had had chest X-rays, EEG'S, CAT Scans, sleep studies, and blood work done which all came back negative. The consumer also reported that the patient was an avid dancer before getting GARDASIL and she could not even get out of bed, "I had taken her to specialist and other physicians and no one can figure out what is wrong". The patient's outcome was not recovered. On unspecified date, the patient sought unspecified medical attention. The nurse stated that the patient's mother consented to come to the office to sign the Consent for the Release of Medical Information concerning the patient, and she would call back when the patient's mother signed the Consent Form about if the patient was able to attend school. Upon internal review she doesn't go to school and isn't active because she can't even get out of bed was considered to be disabling. This is one of several reports concerning the same source. A lot check has been initiated. Additional information has been requested.

Other Meds: AMITRIPTYLIN mg; ibuprofen

Lab Data: Unknown

History: None

Prex Illness:

Prex Vax Illns:

Vaers Id: **346053-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	02-Oct-2008	01-Nov-2008	30	11-May-2009	12-May-2009	FL	WAES0905USA00360	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0650X	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a registered nurse, for the Pregnancy Registry for GARDASIL, concerning a 21 year old female with CECLOR allergy on 02-OCT-2008 and 01-DEC-2008 was vaccinated with her first (lot number 659184/0843X) and second (lot number 661764/0650X) dose of GARDASIL 0.5ml IM (site not reported) respectively. Subsequently the patient was determined to be pregnant and she established her prenatal care with a physician. The patient's last menstrual period was 01-NOV-2008. The patient's estimated date of delivery was 08-Aug-2009. Testing performed at 15 weeks gestation revealed Trisomy 18 and the patient underwent an elective termination in February 2009. The patient subsequently fully recovered. On 30-APR-2009 the patient was vaccinated with her third dose of GARDASIL 0.5ml IM (lot number 661846/1312X; site not reported). Additional information was received from the registered nurse. The nurse reported that the patient had seen different physicians for obstetrics and for the pregnancy. The patient was not on any other medications during the vaccines, "just the pill". The patient stopped the pill after the first dose and became pregnant after the second dose. A no Cul test revealed a 3.1cm which suggested a congenital anomaly. An amniocentesis was performed on 19-FEB-2009 which revealed Trisomy 18. Elective termination was performed at the end of February 2009. The patient fully recovered and came back in after the pregnancy and finished her third vaccination. Elective termination was considered to be an other important medical event and Trisomy 18 was considered to be a congenital anomaly. Additional information has been requested.

Other Meds: None

Lab Data: amniocentesis, 02/19/09, trisomy 18; diagnostic procedure, 3.1 cm, No Cul test: suggested a congenital anomaly

History:

Prex Illness: Pregnancy NOS (LMP = 11/1/2008); Allergic reaction to antibiotics

Prex Vax Illns:

Vaers Id: **346054-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
15.0	F	Unknown	Unknown		11-May-2009	12-May-2009	--	WAES0905USA00344	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Cyanosis, Dizziness, Haemorrhage, Headache

Symptom Text: Information has been received from a physician's wife concerning her daughter, an 15 year old female who was on unspecified dates vaccinated with two 0.5ml doses of GARDASIL (lot number not reported). Subsequently the patient experienced blue color around mouth, dizziness, headache and bleeding problems. The patient had sought unspecified medical attention. At time of reporting, the patient was not recovered. The patient's blue color around mouth, dizziness, headache and bleeding problems were considered to be immediately life-threatening. The patient's sister also experienced blue color around mouth, dizziness, headache and bleeding problems after vaccination with GARDASIL (MSD WAES 0905USA00188). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: Cyanosis; Dizziness; Headache; Haemorrhagic disorder~HPV (Gardasil)~2~11~Patient

Vaers Id: **346055-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
11.0	F	Unknown	Unknown		11-May-2009	12-May-2009	--	WAES0905USA00188	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Unknown	

Seriousness: LIFE THREATENING, SERIOUS

MedDRA PT Cyanosis, Dizziness, Haemorrhage, Headache

Symptom Text: Information has been received from a physician's wife concerning her daughter, an 11 year old female who was on unspecified dates vaccinated with two 0.5ml doses of GARDASIL (lot number not reported). Subsequently the patient experienced blue color around mouth, dizziness, headache and bleeding problems. The patient had sought unspecified medical attention. At time of reporting, the patient was not recovered. The patient's blue color around mouth, dizziness, headache and bleeding problems were considered to be immediately life-threatening. The patient's sister also experienced blue color around mouth, dizziness, headache and bleeding problems after vaccination with GARDASIL (MSD WAES0905USA00344). Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History: Unknown

Prex Illness:

Prex Vax Illns: Cyanosis; Dizziness; Headache; Haemorrhagic disorder~HPV (Gardasil)~2~15~Patient

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **346056-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
20.0	F	31-Jul-2008	31-Jul-2008	0	11-May-2009	12-May-2009	--	WAES0809USA03554	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0072X		Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Drug exposure during pregnancy, Foetal disorder

Symptom Text: Information has been received from a nurse practitioner through a pregnancy registry for GARDASIL, concerning a 20-year-old female, with prior history of pregnancy and delivery, who on 31-JUL-2008 received a dose of 0.5 ml GARDASIL (lot # 660557/0072X) via intramuscular route in her deltoid area. Concomitant medication included birth control pill YAZ. It was reported that the patient was pregnant now. She had urine pregnancy test; her last menstrual period was on 12-JUL-2008. Estimated delivery date was 18-APR-2009. The patient sought medical attention at the office. At the time of reporting, no adverse symptom was reported. Follow-up information has been received from a completed questionnaire. The patient had positive PPD skin test as concurrent condition and a history of 1 previous pregnancy with full term delivery. There was neither birth defect nor infant complications in the previous pregnancy. Ultrasounds for pregnancy were performed on 02-OCT-2008 and 11-DEC-2008 with results "12 inch /7 w" and 22" inch/ 17 w", respectively. The patient was on iron TID per day and prenatal vitamins once per day during her pregnancy. On 04-APR-2009, 39 weeks (reported as "2 weeks") from LMP, the patient delivered a normal female infant weighing 7 pounds 8 ounces, with 19.5 inch in length and Apgar score 9/9. The infant had sacral dimple. There were no complications, infections or illnesses during her pregnancy, labor/delivery. The infant had no complications or abnormalities. Upon internal review, sacral dimple was considered to be an event of congenital anomalies. Additional information is not expected.

Other Meds: YAZ

Lab Data: ultrasound, 10/02/08, 12"/ 7W.; ultrasound, 12/11/08, 22"/ 17W.

History:

Prex Illness: Pregnancy NOS (LMP = 7/12/2008); PPD skin test positive

Prex Vax Illns:

Vaers Id: **346057-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	18-Jun-2007	01-Aug-2007	44	11-May-2009	12-May-2009	FR	WAES0804AUS00133	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	0138U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Areflexia, Asthenia, Blood product transfusion, Chronic inflammatory demyelinating polyradiculoneuropathy, Febrile infection, Gait disturbance, Guillain-Barre syndrome, Hypoaesthesia, Muscular weakness, Mycoplasma infection, Peroneal nerve palsy, Sensory disturbance, Sensory loss

Symptom Text: Information was obtained on request by the Company from the agency via a Case Line Listing with further follow-up via a Public Case Details form concerning a 14 year old female who on 18-JUN-2007 was vaccinated with GARDASIL (Batch No. J0801, Expiry Date 07-AUG-2009, Lot No. 655742/0138U). On 01-AUG-2007 the patient experienced Guillain-Barre syndrome. The patient developed sensory impairment with weakness of the lower leg and feet. On 12-AUG-2007, the patient developed the weakness in toes, feet and ankles and had unsteady gait. This progressed while the patient was in hospital. On examination during admission, power was 3-4/5 on the toes, feet and ankles with absent ankle jerk. There was sensory loss to light touch and position. At the time of reporting on 11-SEP-2007, the patient's Guillain-Barre syndrome persisted. The agency considered the Guillain-Barre syndrome was related to therapy with GARDASIL. The original reporting source was not provided. Subsequently the patient's experienced was reported in an article. Information was received from the agency in an Expert Panel Report. The Expert Panel was an independent body commissioned by the agency to undertake an evaluation of the safety of GARDASIL. Further follow-up was also obtained upon request by the Company via a Public Case Detail Form from the agency. The patient's neurological symptoms began 6 weeks after the second dose of GARDASIL and consisted of numbness in her feet. Two weeks later, the patient developed a bilateral foot drop. This was diagnosed as Guillain-Barre Syndrome (GBS). It was subsequently reported by the Expert Panel that the diagnosis of Guillain-Barre Syndrome (GBS) had been changed since the time of reporting to Chronic Inflammatory Demyelinating Polyneuropathy (CIDP) on the basis of worsening condition and follow up nerve conduction studies. The patient was found to have experienced a febrile illness 6 weeks prior to the onset of neurological symptoms and had positive Mycoplasma serology with a rise in titre. Since Mycoplasma infec

Other Meds: Unknown

Lab Data: nerve conduction study; Mycoplasma PCR, positive Mycoplasma serology with a rise in titre

History: Unknown

Prex Illness:

Prex Vax Illns:

Vaers Id: **346058-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
18.0	F	01-Aug-2007	05-Mar-2008	217	11-May-2009	12-May-2009	PA	WAES0712USA08104	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL	1	Unknown	Intramuscular	

Seriousness: ER VISIT, NOT SERIOUS

MedDRA PT Abortion threatened, Caesarean section, Drug exposure during pregnancy, Placenta praevia

Symptom Text: Information has been received from a licensed practical nurse through a Pregnancy registry concerning an 18 year old female who in June 2007 and August 2007 was vaccinated intramuscularly with a 0.5mL first and second dose of GARDASIL. The nurse reported that the patient was possibly pregnant when she was vaccinated with the second dose of GARDASIL. On 24-NOV-2007, a pregnancy test was positive. Follow up information received from a licensed practical nurse revealed that patient received dose one and two of GARDASIL in June 2007 and August 2007. There was no third dose in their system so the patient never received it at this facility. She also reported that there was never a pregnancy test done at this facility until 07-APR-2008. On this date, the patient had a positive test at the office after having two positive tests at home. Her LMP was 05-MAR-2008. On 17-APR-2008, she was seen by OB/GYN group. It was noted at this visit that it was an unplanned pregnancy that occurred on oral contraceptives. On 28-APR-2008, she was seen for a threatened abortion. It was noted that at this visit patient was GRAVIDA 1 Para 0 (G1P0). An ultrasound was done that showed a viable fetus with an EDD of 02-DEC-2008. On 21-MAY-2008, a placenta previa was noted. On 12-NOV-2008, an ultrasound was done for growth and weight. A male baby weighing 6 pounds and 6 ounces was seen. On 10-DEC-2008, she delivered a healthy boy via C-section. She said it looked like the patient was induced but she did not have the exact reason for the C-section. Apgars were 8 and 9 and mom and baby did great. The licensed practical nurse indicated that , since no pregnancy test was done in their office prior to April 2008 and it was noted that she was G1P0 at the visit in April 2008 then the originally reported "possible" pregnancy must not have been a true pregnancy. She stated that if there was a pregnancy that had any problems then it would have been in their system. Upon internal review, threatened abortion and obstetric complication req

Other Meds: Unknown

Lab Data: Ultrasound, 04/28/08, Viable fetus with and EDD of 02-DEC-2008; Ultrasound, 11/12/08, Male baby weighing 6 pounds and 6 ounces was seen; Beta-human chorionic, 11/24/07, positive; Apgar score, 11/12/08, 8 and 9; Beta-human chorionic, 04/

History:

Prex Illness: Pregnancy NOS (LMP = 3/5/2008)

Prex Vax Illns:

Vaers Id: **346092-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
12.0	F	24-Mar-2009	24-Mar-2009	0	11-May-2009	12-May-2009	FR	B0572990A	12-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NH55600	1	Unknown	Intramuscular	
	HEPAB	GLAXOSMITHKLINE BIOLOGICALS	AHABB144AD	1	Left arm	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Conversion disorder, Crying, Dizziness, Headache, No reaction on previous exposure to drug, Syncope

Symptom Text: This case was reported by a regulatory authority (# 2009-01768) and described the occurrence of syncope in a 12-year-old female subject who was vaccinated with TWINRIX pediatric(GlaxoSmithKline), GARDASIL (non-GSK). The subject was healthy and had no concomitant medication. She was not using any drugs or alcohol. All the previous vaccinations were well tolerated. On 24 March 2009, the subject received 2nd dose of TWINRIX pediatric (intramuscular, unknown injection site), 2nd dose of GARDASIL (intramuscular, unknown injection site). On 24 March 2009, less than one day after vaccination with GARDASIL and TWINRIX pediatric, the subject experienced syncope for a few seconds. The patient recovered immediately after keeping her legs in elevated position and she left the doctor. 10 minutes later, the subject experienced headache, hysterical excitement, crying abnormal and dizziness. She came back to the doctor. The circulation was stable all the time. The subject was transferred to hospital and stayed at ER under observation for a short time. The symptoms were resolving and the patient was discharged. A physical examination was done without any findings and no further examinations were performed. On 31 March 2009, the subject went to her family doctor, with persisting headache. At the time of reporting, the events were resolved but the outcome of headache was still unspecified. The regulatory authority reported that the events were possibly related to vaccination with TWINRIX pediatric and GARDASIL, Only the event hysterical excitement was probably related to TWINRIX. Due to the temporal relationship the causality between the different symptoms and GARDASIL as well as TWINRIX is evaluated as possible. Besides the syncope could also be a vasovagal reaction to the injection. Finally, however, a psychogenic component cannot be completely excluded as cause as well.

Other Meds:

Lab Data: UNK

History:

Prex Illness: Unknown

Prex Vax Illns:

Vaers Id: **346148-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
21.0	F	08-Jan-2008	01-May-2008	114	12-May-2009	13-May-2009	MD	WAES0905USA00550	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1448U	1	Unknown	Unknown	

Seriousness: ER VISIT, HOSPITALIZED, SERIOUS

MedDRA PT Conjunctivitis infective, Convulsion, Presyncope, Sinusitis, Tongue biting

Symptom Text: Information has been received from a 21 year old female concerning herself with no medical history or drug allergy who experienced seizures the next day after receiving the second dose of GARDASIL. There was no concomitant therapy. Patient mentioned that she had seizures attacks for 4 consecutive days and then after that she was hospitalized for 5 days. Patient added that her physician told her that she had sinus infection and she was also prescribed KEPPRA for the seizures and she had been taking KEPPRA now for 20 months. The patient described her seizures, she reported that she would have seizures during her sleep because when she woke up, she would see bite marks on her tongue and her mouth. Patient noted that since she took KEPPRA, she would have occasional pre seizures symptoms but it didn't result to seizures attacks. At the time of the report the patient was not recovered. She added that her twin sister received the complete GARDASIL series and she did not have the AE. Follow-up information has been received from a registered nurse concerning the patient. The first GARDASIL dose was given in their office on 08-JAN-2008 (lot #659653/1448U). The second dose was given in their office on 29-MAY-2008 (lot #660389/1968U); no other vaccines were given at the same time as the GARDASIL doses. Concomitant medications included YASMIN for birth control and PYRIDIUM for a UTI. Patient had no medical history or drug allergies. Their records showed that the patient was admitted to the hospital on 09-JUN-2008 and was discharged on 13-JUN-2008. The patient was last seen in their office on 02-JAN-2009 for pink eye. The nurse did not know the name of the physician who was following the patient for her seizures, did not know what diagnostic tests were performed. Additional information has been requested.

Other Meds: YASMIN

Lab Data: Unknown

History:

Prex Illness: Contraception

Prex Vax Illns:

Vaers Id: **346149-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
17.0	F	19-Feb-2009	23-Mar-2009	32	12-May-2009	13-May-2009	FR	WAES0905USA00800	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1050U	0	Left arm	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Colitis ulcerative, Crohns disease, Erythema, Gastrointestinal inflammation, Intestinal haemorrhage

Symptom Text: Information has been received from a gynaecologist concerning a 17 year old female patient with a medical history of intestinal hemorrhage during a stay in 2008, who was vaccinated with a first dose of GARDASIL (lot 1050U; batch # NH32140, injection route not reported) into the left upper arm on 19-FEB-2009. Concomitant medication included unspecified hormonal contraceptive for systemic use. On 23-MAR-2009 the patient developed intestinal hemorrhage. A doctor's letter from 02-APR-2009 was provided. A colonscopy showed plane redness of the left intestinal flexure and of the rectum with small aphthae (biopsies of the suspect areas were taken) and Crohn's disease was suspected. The histological results showed an inflammation of the left intestinal flexure as well as the rectum. This result was consistent with the suspicion of ulcerative colitis. The physician assumed ulcerative colitis and treated the patient with PENTASA X-TREND. Under this therapy the symptoms improved. Final outcome not reported. Crohn's disease and ulcerative colitis were considered to be an other important medical event by the company. No further information is available. The case is closed.

Other Meds: hormonal contraceptives (unspecified)

Lab Data: colonoscopy, plane redness left intestinal flexure; diagnostic pathological examination, inflammation left intestinal flexure

History: Intestinal haemorrhage

Prex Illness:

Prex Vax Illns:

Vaers Id: **346150-1 (S)**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
14.0	F	27-May-2008	10-Jun-2008	14	12-May-2009	13-May-2009	FR	WAES0905USA00593	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	1114U	0	Unknown	Intramuscular	

Seriousness: HOSPITALIZED, SERIOUS

MedDRA PT Central nervous system inflammation, Hypoaesthesia, Joint range of motion decreased, Muscular weakness, Myelitis, Neuritis, Tendon disorder, Vaccine positive rechallenge, Viral infection

Symptom Text: Information has been received from a healthcare professional on 30-Apr-2009. It was reported by a gynaecologist that a 14-year physician concerning a 14 year old female who on 27-MAY-2008 was vaccinated with GARDASIL (lot #: 1114U, batch #: NH15190) into the deltoid muscle on 27-MAY-2008. A doctor's letter was provided. Two weeks p.v. the patient developed weakness on the right lower leg and the mobility of the knee joint was decreased. She experienced hypaesthesia from the knee downwards. The patient was hospitalized from 04-JUN-2008 until 17-JUN-2008. CSF puncture and cranial MRI on 06-JUN-2008 showed normal results. Electrophysiology on 05-JUN-2008 and 11-JUN-2008 showed a partial affection of the right lumbar plexus and a neurogenic and myogenic impairment with suspicion of inflammatory CNS process. Orthopedic examination on 06-JUN-2008 showed a distortion of semitendinosus tendon. CK was increased to 5840 u/l. The cause of the events could not be clarified. Under intensive physiotherapy the motoric and sensory deficits completely resolved, but the patient has not recovered. The physicians considered the symptoms most likely as viral myelitis without detected agent (plexus neuritis was assumed as differential diagnosis). Despite ongoing events the patient was vaccinated with the second dose of GARDASIL (lot #: 1695U, batch #: NH25730) into the deltoid muscle on 28-APR-2009. One day p.v., hypaesthesia of the right lower leg was seen. The patient has not recovered at the time of reporting. Neurological clarification was planned. Additional information has been requested. Other business partner numbers include E2009-03753.

Other Meds: Unknown

Lab Data: diagnostic laboratory test, 05Jun08, Electrophysiology showed a partial affection of the right lumbar plexus and a neurogenic and myogeni; cranial puncture, 06Jun08, CSF normal; orthopedic examination, 06Jun08, distortion of semitendinosus

History: Unknown

Prex Illness:

Prex Vax Illns:

FDA Freedom of Information Distribution

VAERS Line List Report

Vax Type: HPV4 Reported Date: 01-MAY-08 - 15-MAY-09 All comb. w/AND

Vaers Id: **346166-1**

Age	Gender	Vaccine Date	Onset Date	Days	Received Date	Status Date	State	Mfr Report Id	Last Edit Date
22.0	F	Unknown	Unknown		12-May-2009	13-May-2009	FR	WAES0905USA00436	13-May-2009

VAX Detail:	Type	Manufacturer	Lot	Prev Doses	Site	Route	Other Vaccine
	HPV4	MERCK & CO. INC.	NULL		Unknown	Unknown	

Seriousness: NO CONDITIONS, NOT SERIOUS

MedDRA PT Abortion induced, Drug exposure during pregnancy

Symptom Text: Information has been received from a nurse via agency as part of a business agreement (manufacturer control # 20090505JV1) concerning a 22 year old female who was vaccinated with GARDASIL (date and dose not specified) while unknowingly pregnancy. The patient was advised by general practitioner (GP) to have a termination. The pregnancy was terminated (date not specified). It was reported that the patient was partly recovered at the time of this report. The reporter stated that it was unknown if the elective termination of pregnancy was related to GARDASIL. Upon internal review, pregnancy termination was determined to be an other important event. Additional information has been requested.

Other Meds: Unknown

Lab Data: Unknown

History:

Prex Illness: Pregnancy NOS (LMP = Unknown)

Prex Vax Illns:

Total Non Serious	**5612**	**83%**
Total Serious Non Fatal	**1061**	**16%**
Total Death:	**50**	**1%**
Total All Reports:	**6723**	